STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Executive summary

EXECUTIVE SUMMARY

STUDY OBJECTIVES AND SCOPE

EurEau commissioned a study to assess the potential applicability and relevance of extended producer responsibility (EPR) in order to develop clear policy guidance to address emissions of micropollutants and microplastics from products.

The study defines micropollutants as persistent and biologically active substances that are found in water bodies in low concentrations and which can have detrimental effects on humans, the environment and drinking water resources. Secondary microplastics are defined as small plastic parts found in the (aquatic) environment with a diameter of less than 5mm that are formed and released via abrasion or weathering of larger plastic particles, products or debris. The five product categories assessed are pharmaceuticals (human medicinal products), pesticides (plant protection products, biocides (human hygiene/ antibacterial products), textiles (clothing) and tyres.

FROM ENVIRONMENTAL TO ECONOMIC IMPACTS

In addition to the implications for human health and the environment, the presence of micropollutants and microplastics in water bodies throughout Europe also has important economic impacts including the costs to water services both upstream and downstream, affecting drinking and waste water treatment. **Extra treatment to comply with current or future legislative requirements for drinking and waste water regarding micropollutants and microplastics will result in several billion euros per year of investment in advanced water treatment technologies and additional operational costs, unless effective source-control measures are taken**.

Assuming no further action is taken in regard to the current situation, water service providers would have to pass these substantial costs on to water customers and consumers, affecting access to and affordability of water services. These customers are not the root cause of these pollutants and as such should not be required to bear the full costs of their impacts.

MOST RELEVANT POLICY OPTIONS & FRAMEWORK FOR APPLICATION OF EPR

There is currently no overarching regulatory framework at EU level, which specifically targets the release of micropollutants and microplastics in the aquatic environment. Relevant provisions are laid out in existing cross-cutting legislation such as the Water Framework Directive 2000/60 and REACH Regulation and product-specific legislation e.g. Directive 2001/83 on human pharmaceutical products, Plant Protection Products Regulation 1107/2009, Biocide Products Regulation 528/2012, etc. Against this backdrop, the legislative assessment of implementation of EPR focused specifically on the most relevant provisions on the product categories assessed in respect to potential changes/ amendments required to cover drinking and waste water treatment costs and further contribute to addressing the occurrence of micropollutants and microplastics in the water cycle. The four policy options assessed include:

- **Option A**: Voluntary control-at-source & post-marketing measures (including EPR)
- **Option B**: Mandatory control-at-source measures
- **Option C**: Mandatory control-at-source & post-marketing measures (including EPR)
- **Option D**: Mandatory EPR measures

Control-at-source measures refer to measures applied upstream or early on during the product life-cycle e.g. product design, market authorisation and restrictions, requirements on manufacturing processes; whereas post-marketing measures include the application of EPR schemes as well as other actions implemented farther down the product life-cycle e.g. information and awareness raising campaigns, end-of-life management, etc.. The comparative analysis of the policy options included parameters such as the implementation approach (voluntary versus mandatory options), estimated timeframe for the implementation of specific measures, coverage of end-of-life/ treatment costs, life-cycle approach, stakeholder support and overall product coverage.

KEY FINDINGS

A key finding of the study confirms that control-at-source measures should be the starting point of mitigation measures. They are usually more effective due to the large number and diffuse nature of emission pathways into the environment. However, the release and presence of these substances continue to be a concerning issue at EU level. This indicates that control-at-source measures are not fully implemented and/or that they alone are not sufficient to effectively address the problem. **Products containing potentially hazardous substances continue to be placed on the market and humans and other living organisms continue to be exposed to their potentially harmful effects.** This demonstrates the urgency of immediate regulatory actions, which is supported by a solid existing knowledge base (including scientific findings) to justify corrective measures; and therefore applying the precautionary principle.

Of the four policy options assessed, Option C (mandatory control-at-source and post-marketing measures, including EPR) and Option D (mandatory EPR measures) are found to be the most effective options. Both options are based on mandatory approaches. It should be noted that the study did not conduct a cost-benefit analysis of these options. Of these two options, a key strength worth noting is that Option C addresses the entire product life-cycle and would be applicable to all products, whereas Option D focuses mainly on post-marketing/ end-of-life stages. As such, it is assumed that there would be a higher level of stakeholder acceptance for Option C compared to Option D since Option C would imply a wider scope and share of responsibility in terms of the potential actors across the supply chain concerned. Furthermore, option C would fully respond to the provisions of article 191.2 TFEU.

The study findings indicate that in addition to control-at-source measures, the existing legislative basis at EU level provides clear opportunities where EPR could be applied in order to more effectively contribute to avoiding and/or reducing micropollutants and microplastics emitted from products during their life-cycle. While EPR holds significant potential to ensure producers take on full physical and financial responsibility of their products, the study concludes that, similar to control-at-source measures, EPR as a stand-alone policy is not the magic solution to solving Europe's water pollution challenges. Instead, only a combination of both upstream and downstream measures would be able to adequately tackle the full extent and scope of the problem.

RECOMMENDATIONS

Some of the main opportunities identified where EPR could be applied in existing EU legislation to ensure producers are held financially and physically responsible for their products throughout their life-cycle, include:

- Defining legal and financial responsibility for the products placed on the market, and consequently a transparent system of traceability;
- Applying appropriate product/substance fees that reflect the full costs of treatment of these products;
- Promoting eco-design by providing incentives to producers to implement more efficient and sustainable product-design and manufacturing practices.

Furthermore, from a practical point of view, EPR is generally more acceptable to society compared to for example a tax imposed to finance downstream measures. EPR is more targeted in that it aims to use collected funds to finance pollution mitigation measures, leaving more flexibility to polluters to decide about the most effective ways to spend these funds. The following key messages and recommendations can be drawn from the study's findings:

- **Control-at-source is key:** Due to the diffuse nature of the occurrence of micropollutants and microplastics in the aquatic environment, measures should be implemented as **early on as possible** in the product life-cycle e.g. substance/product authorisations and restrictions before they can be placed on the market.
- **Develop a clear legislative framework for EPR:** While the polluter-pays principle is enshrined in the TFEU and stipulated in the Water Framework Directive (Recital 38 on use of economic instruments and Article 9 on recovery of costs for water services), these principles are not applied in practice when it comes to

micropollutants and microplastics in the aquatic environment. Therefore, there is a need for a clear regulatory framework based on a full life-cycle approach at EU level for the implementation of the polluter-pays principle through EPR. This should build on control-at-source measures and include mitigation measures that could be financed through funds collected under EPR.

- **Traceability and designation of the responsible producers:** The development of a fair and proportionate EPR scheme must address these two points in cooperation with the producers concerned. The experience of existing EU legislation such as waste directives and the Single Use Plastics Directive should be used.
- **Cost-benefit analysis:** An in-depth assessment should be conducted on all possible measures from product design to end-of-life, including mitigation measures that EPR funds could help finance. Other important parameters to evaluate include the impacts on energy consumption and CO_2 emissions, on contributions to the circular economy objectives, the internal market and society, etc.
- **Consideration of local and national specificities:** EPR schemes should be sufficiently flexible to accommodate regional peculiarities such as concentration of 'hotspots', specific local conditions e.g. economic and waste infrastructure systems, material and waste flows, etc.
- **Cross-sectoral stakeholder dialogue:** It is crucial to establish and maintain dialogue between all relevant stakeholders in order to exchange knowledge and best practices, coordinate research and innovation and ensure full application of EU legislation and functioning of the internal market.
- **Boost scientific research**: As scientific understanding of the potential effects of pollutants has increased, so has public and political concern on their potentially hazardous impacts. Public health and environmental concerns, increased scientific knowledge and awareness are important drivers that could further boost innovation, changes to the existing regulatory framework and consumer behaviour.

Stay up-to-date on policy evolutions: National, European and international policy developments should be monitored to avoid potential overlaps, inconsistencies and administrative burden. Likewise, it is essential that policy reflects the latest technological and innovative solutions to anticipate future challenges in regard to new potentially hazardous substances, but also innovative and cost-effective mitigation measures.

STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Module 1 – Relevance of EPR for products emitting pollutants to the aquatic environment

In Extenso
Innovation Croissance

Deloitte.

STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Module 1: Relevance of EPR for products emitting pollutants to the aquatic environment

FINAL REPORT

December 2019

EurEau

CONTENTS

Part I. Study objectives, methodology & scope

1. Objectives 6
2. Methodology 7
3. Scope 8

Part II. Impacts, sources & pathways

4. Impacts of micropollutants & microplastics in the aquatic environment 11
5. Emission sources and pathways 24

Part III. Relevance & applicability of extended producer responsibility

6. Existing measures to reduce micropollutants & microplastics emissions 40
7. Potential of extended producer responsibility 56

Annex. Supporting information

8. Overview of applicable EU Legislation 65
9. References 68

List of figures:

Figure 1: Impacts of micropollutants & microplastics in the aquatic environment 12
Figure 2: Entry pathways for pharmaceuticals (human and veterinary medicines).....28
Figure 3: Entry pathways for pesticides 30
Figure 4: Entry pathways for PFASs 32
Figure 5: Main entry pathway for silver as disinfectant (biocide).....34
Figure 6: Main entry pathway for preservatives (biocides) 35
Figure 7: Main entry pathways for microplastics (tyres and textiles) 38
Figure 8: Overview of advanced treatment technologies 48
Figure 9 : "Take Back Chemicals" economic model.....53
Figure 10: EPR schemes–product type, 2016 57
Figure 11: EPR by policy.....57

List of tables:

Table 1: Description of product categories assessed..... 9
Table 2: Costs of advanced water treatment technologies, Switzerland 15
Table 3: Cost of advanced water treatment technologies, Sweden 16
Table 4: Cost comparison – Netherlands and Germany for micropollutant removal (m^3/per WWTP effluent) 17
Table 5: Cost comparison – Netherlands and Switzerland for micropollutant removal 17
Table 6: Roles and responsibilities of key stakeholders 22
Table 7: Main entry pathways for micropollutants 25
Table 8: Examples of measures developed under the Netherlands' pharmaceutical chain approach 51
Table 9: List of potential EU legislations to be assessed 65

Abbreviations

BAF	Biologically activated filtration
BPR	Biocidal Products Regulation
CSO	Combined sewer overflows
DG ENV	DG Environment
DWD	Drinking Water Directive (Directive 98/83)
DWTP	Drinking water treatment plants
EC	European Commission
ECHA	European Chemicals Agency
EDC	Endocrine disrupting compound
EPR	Extended Producer Responsibility
EQSD	Environmental Quality Standards Directive
EurEau	European federation of national water services
GAC	Granulated activated carbon
IED	EU Industrial Emissions Directive 2010/75/EU
LCA	Life-cycle analysis
PAC	Powdered activated carbon
PCB	Polychlorinated biphenyl
PCP	Personal care products
PE	Population equivalent
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanoic sulfonate
PFASs	Perfluoroalkylated substances
POP	Persistent organic pollutant
PPP	Plant protection product
PP	Polluter pays principle
PRO	Producer Responsibility Organisation
TCS	Triclosan
TF	Tolylfluanid
VMP	Veterinary medicinal products
WFD	Water Framework Directive (Directive 2000/60)
WWF	World Wildlife Fund

Terms and definitions

Aquatic environment: aquatic environments include inland surface water, seas, and ground water, all of which contain diverse microbial populations and microorganisms.

Extended Producer Responsibility: a policy approach under which producers are given a significant financial and/or physical responsibility for the treatment or disposal of post-consumer products. The overarching aim of extended producer responsibility is to provide incentives to prevent wastes at the source, promote product design for the environment and support the achievement of public recycling and materials management goals.

Emerging substances: substances those that have only recently been analysed/ identified in the environment and therefore currently not entirely regulated, which are believed to cause adverse effects on ecosystems and humans.

Final products: A final product is a product that is ready for sale without significant further processing. For example, in the pharmaceutical industry, a finished product would take a final dosage form e.g. a tablet, capsule or solution that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients.

Intermediary products: An intermediate good or product is a product used to produce a final good or finished product. These goods are sold between industries for resale or the production of other goods. An intermediate product usually requires further processing before it is saleable to the ultimate consumer (or end consumer). This further processing might be done by the producer or by another processor. Thus, an intermediate product might be a final product for one company and an input for another company that will process it further.

Microplastics (secondary): Secondary microplastics are very small particles of plastic material (typically smaller than 5mm) that can be unintentionally formed through the wear and tear of larger pieces of plastic or the degradation of plastic waste in the environment. (ECHA 2018)

Micropollutants: Micropollutants encompass a wide variety of substances that are characterised as small, persistent and biologically active, found in aquatic environments in low concentrations (typically in the range of ng–µg/l) and can have detrimental effects on humans, the environment or drinking water supplies.

Product life-cycle: Refers to all the stages of a product's life from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, and end-of-life e.g. disposal, re-use or recycling.

Substance of concern: Any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is used in the manufacturing of product in sufficient concentration to present risks of such an effect.

Part I. Study objectives, methodology & scope

1. Objectives

The overall objective of this study is to analyse the feasibility of an effective extended producer responsibility (EPR) scheme on products that release micropollutants and microplastics into the aquatic environment during their life cycle.

The study is organised around four following modules and guiding questions:

- **Module 1**: Relevance of EPR
- **Module 2**: Applicability of EU legislation for EPR on products emitting pollutants to aquatic environments
- **Module 3:** Assessment of the arguments for and against EPR
- **Module 4:** Communication documents

1.1 Module 1 objectives and contents of report

The objective of module 1 is to analyse the **relevance and applicability** of extended producer responsibility for products that release micropollutants and microplastics into the aquatic environment. The module 1 report presents findings of our analysis on the:

- Potential impacts of the continued release and presence of micropollutants and microplastics in Europe's waterbodies (Part II, chapter 4);
- Emission sources & pathways of the products and associated substances assessed (Part II, chapter 5);
- Potential of EPR to address current challenges when existing measures (Part III, chapter 6), such as control-at-source are not sufficient (Part III, chapter 7); and
- Relevance of establishing accountability and responsibility for remedial actions and ensuring compliance (Part III, chapter 8).

Part I of the report summarises the objectives (chapter 1), methodology (chapter 2) and scope of the study (chapter 3). Part IV provides the list of relevant legislation that is assessed in Module 2.

2. Methodology

2.1 Literature review

A comprehensive review of recent and relevant literature allowed the research team to identify and collect necessary information for the analyses. The literature review included over 80 sources, covering a wide range of documents such as scientific articles, guidance and policy reports and stakeholder position papers. Priority sources were reviewed based on their relevance to the study and scientific robustness. In addition, several sources provided by EurEau, for example on costs, were also thoroughly reviewed. The list of references can be found in chapter 8.

2.2 Stakeholder consultation

The stakeholder consultation process included **stakeholder interviews** and a **stakeholder workshop**. **Targeted stakeholder interviews** were carried out to gather key feedback on different stakeholder perspectives – from industry, policy makers, consumer and environmental associations as well as from the drinking and waste water treatment section on the applicability of EPR for the products assessed.

The selection process for the stakeholders invited to participate in the study was based on several aspects, for example ensuring that a diverse range of representative stakeholders, coverage of both proponents and opponents of an EPR scheme, the level of stakeholder interest or role and their presence and participation in initiatives and events such as EU/international/industry working groups and conferences. Priority stakeholder contacts were identified following discussions and agreement with EurEau members.

The results of the stakeholder consultation are summarised in the Module 3 report, presenting the different stakeholder perspectives on the feasibility and applicability of an EPR approach on products that emit micropollutants and microplastics in the aquatic environment.

In addition, a **stakeholder workshop** was hosted by EurEau on 14 February 2019 with the participation of a small number of stakeholders, reflecting EU representatives, international organisations, associations, EurEau and the project team. The goal of the workshop was to further encourage and enhance multi-level and cross-sectoral dialogue on the topic of EPR and micropollutants and to collect useful information for the study.

3. Scope

For the purposes of this study, micropolluants are defined as persistent and biologically active substances found in water bodies in low concentrations and which can have detrimental effects on humans, the environment or drinking water supplies. Secondary microplastics are defined as small plastic parts found in the aquatic environment with a diameter of less than 5mm that are formed and released via abrasion or weathering of larger plastic particles, products or debris (ECHA 2018).

The approach employed for the selection of product categories assessed takes into account the representativeness of the manufacturing sectors concerned, while limiting the assessment to the most pertinent products/product categories with regards to the water treatment sector. In other words, substances with properties that have the potential to pollute water sources (drinking water), are technically difficult or costly to remove during drinking water/ wastewater treatment and which can cause detrimental environmental and health effects if left untreated in aquatic environments (see Table 1). Other criteria considered include:

- Anthropogenically produced substances (with the exception of silver, which is used as a biocide in sports wear) that are released directly or indirectly into the aquatic environment in a diffuse way (i.e. no precise discharge point); and
- Evidence that the substance has been detected in Europe's waterbodies at a certain frequency, concentration and occurrence.

The study assesses the following five product categories:

- **Pharmaceuticals**: Human medicinal products
- **Pesticides**: Plant protection products (agriculture)
- **Biocides**: Antibacterial products (human hygiene)
- **Textiles**: Clothing
- **Tyres:** Car tyres

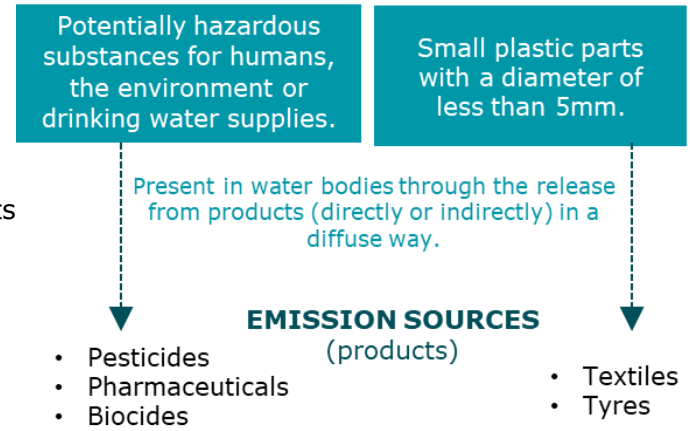
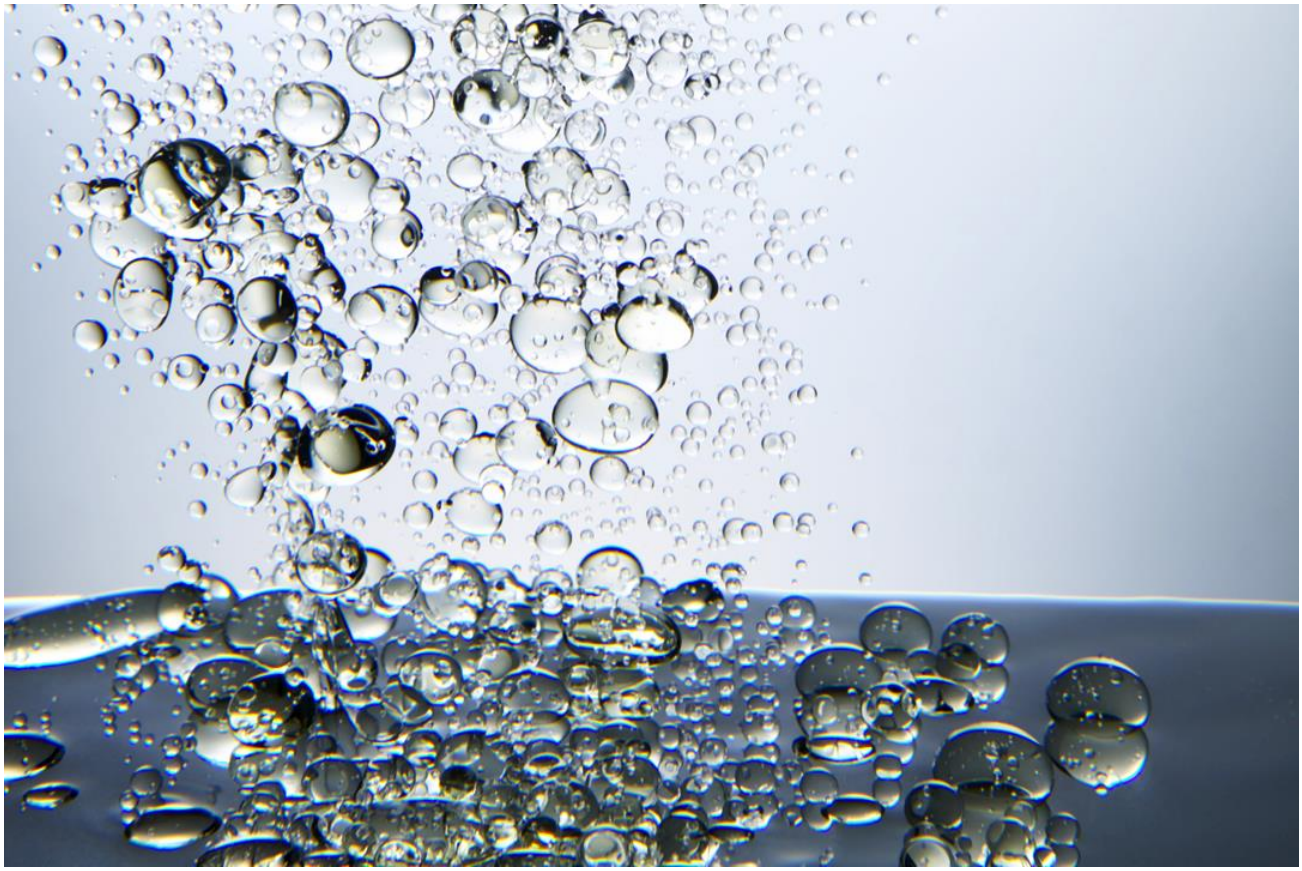


Table 1: Description of product categories assessed

Product group	Description
Emission of micropollutants	
Pharmaceuticals[1]**:** Human medicinal products	Pharmaceuticals refers to medicinal products for human use, which emit potentially hazardous substances e.g. ethinylestradiol, estrone, diclofenac, paracetamol, etc. into the aquatic environment via the consumption phase and incorrect disposal. Macrolide antibiotics are of particular concern, as conventional wastewater treatment plants (WWTPs) cannot fully remove these compounds without the application of more advanced treatments steps (EC, 2016a).
Pesticides[1]: Plant protection products	Pesticides refer to plant protection products used in the agricultural sector, that are intended to protect plants and also their products after harvesting. Plant protection products are considered as pesticides (including herbicides and insecticides). Plant protection products consists of one or more active substances called co-formulates, which can pose potentially hazardous risks to human health and the environment if they are not used or disposed of properly.
Biocides: Products such as antibacterial and disinfectants (human hygiene and cleaning purposes)	Biocidal products refers to products used in a non-agricultural context (to distinguish from the use of biocides for plant protection, which is covered by pesticides) to serve as antibacterial purposes. For example, the use of silver as a biocide in sportswear (socks, jumpers, jerseys, etc.). Silver is a biocide used to "reduce odours" in sportswear; however, is not easily degradable and represents potentially hazardous risks to aquatic organisms and human health.
Emission of secondary microplastics	
Textiles: Clothing **Tyres:** Car tyres	Secondary microplastic particles are released from textile products and tyres into the aquatic environment during use/service life e.g. washing of clothing and carpets and tyre abrasion.

[1] Several of the substances used in pharmaceutical and pesticide products are on the Watch List of substances to be monitored in EU surface waters: https://ec.europa.eu/jrc/en/science-update/updated-surface-water-watch-list-adopted-commission



Part II. Impacts, sources & pathways

4. Impacts of micropollutants & microplastics in the aquatic environment

Amongst the challenges which need to be addressed to improve the quality of the aquatic environment in Europe, tackling microplastics and chemical pollutants in waterbodies has been an increasingly concerning issue in recent years.

Micropollutants refer to persistent and biologically active substances that are of great concern because of the potential adverse effects they can have on organisms (on both humans and other living organisms) at low concentrations. Micropollutants are ubiquitous and are found almost everywhere on earth, particularly in water bodies, but also in soils and even in food destined for human consumption. Micropollutants originate from products manufactured from industries such as pharmaceutics, personal care products, pesticides and industrial chemicals and released by industry, households, or agriculture into the environment and spread throughout the water cycle.

There are many pathways for how micropollutants end up in the aquatic environment. One of them, waste water treatment operations, can only partially remove micropollutants, therefore they are usually not completely eliminated once they enter water bodies. Consequently, micropollutants are ingested by aquatic organisms or humans via contaminated water or food, and transported to different tissues within the organism. Depending on the properties of the micropollutants and the biology of the target species, they may bio accumulate, metabolize or cause adverse effects (Burkhardt, 2011). These effects may translate into alterations on a higher biological level such as disruption of the hormone system, followed by impacts on reproduction, etc.

There is no standardised definition on microplastics at EU or international level. As such, there are no standardised testing, sampling or other analytical methods in order to compare results and data on their affects, quantity, concentration, etc. **Microplastics** found in the environment can either be:

- **Unintentionally formed** through the wear and tear of larger pieces of plastic (secondary microplastics) such as car tyre abrasion from road transport, washing of synthetic textiles; through the degradation of plastic waste / fragmentation of plastic litter in the environment; or unintentionally released through production processes e.g. from spills, leakages or poor storage for example during manufacturing plastic pellets (Eunomia, 2018).
- **Intentionally added** to products or deliberately manufactured for a specific purpose (primary microplastics): Examples include exfoliating beads in facial or body scrubs (ECHA, 2018) or industrial abrasives (Swedish EPA, 2017). It should be noted intentionally added microplastics are not evaluated in this study.

Most currently used drinking water treatment technologies cannot completely remove all micropollutants found in drinking water resources, with removal efficiencies varying widely depending on the type of substance and treatment technology concerned. Certain types of waste water treatment with at least secondary treatment can remove a very high share of

microplastics (up to 99% in some cases). However, a significant part of the removed particles end up in sewage sludge, which can potentially affect recycling options.

Findings from two recent reports on microplastics in Norwegian drinking water (Norsk Vann, 2018) and in Danish drinking water (Aarhus University 2018) suggests that the there is no significant concentration of microplastics in certain drinking water resources.

Concern over substances that can resist wastewater treatment and may contaminate water resources, particularly those for drinking water production, has increased in recent years. However, at present, knowledge on many new **emerging substances** is patchy with respect to their effects on humans, animals, and their fate in the environment.

Water pollution in the form of micropollutants with potentially adverse effects will not diminish over time due to certain demographic changes (an aging society consumes more medicine) and economic trends (industrial agriculture still uses large quantities of plant protection products), etc. Therefore, necessary measures should be taken as soon as possible if we are to avoid future damage and costly remedial measures (UBA, 2018). Similar concerns exist regarding microplastics, although more research is needed to determine the extent of their impact on human health and the environment (soil, water, living organisms).

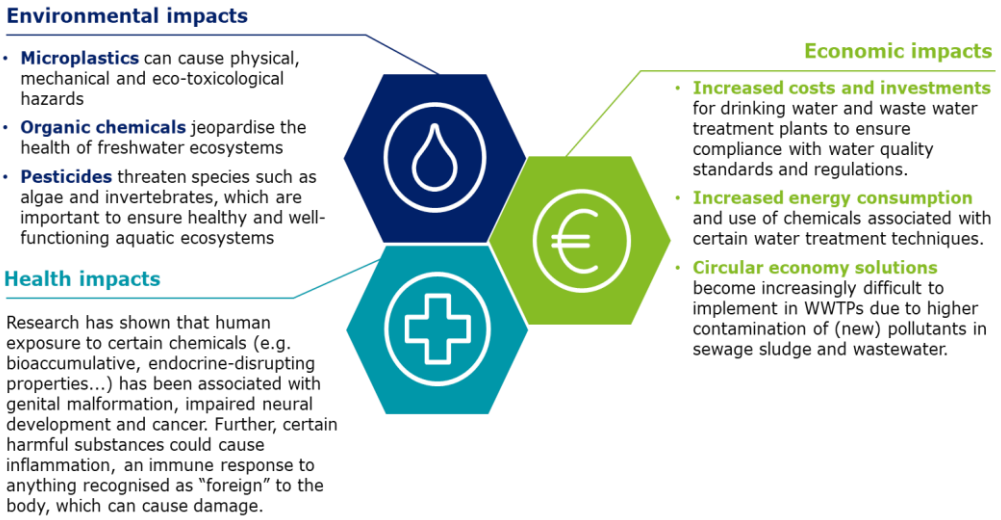
"**Emerging substances** are those that have only recently been analysed/ identified in the environment and which are believed to cause adverse effects on ecosystems and humans. However, remain insufficiently regulated or entirely unregulated."

- Murray, 2010

4.1 Environmental and health impacts

The potential impacts of these micropollutants in Europe's aquatic environments on human health and infrastructure, natural habitats and biodiversity are broad, can be quite significant and in many cases unknown. Further, much of the burden in terms ensuring effective treatment of these pollutants falls upon wastewater service providers, drinking water suppliers, environmental protection authorities, regulatory bodies and ultimately tax payers. Figure 1 summarises some of the potential environmental, health and economic impacts of micropollutants and microplastics present in waterbodies.

Figure 1: Impacts of micropollutants & microplastics in the aquatic environment



Of particular concern are the hazardous properties and potential adverse effects of micropollutants and microplastics. For example,

- **Persistent, bioaccumulative and toxic** (PBT): PBTs are a class of compounds that have high resistance to degradation from abiotic and biotic factors, high mobility in the environment and high toxicity.
- **Persistent, mobile and toxic** (PMT): PMTs compounds are highly soluble and therefore difficult to remove in drinking water treatment plants.
- **Endocrine-active or as endocrine-disrupting compounds** (EDC): EDCs are mostly man-made, found in various materials such as pesticides, metals, additives or contaminants in food, and personal care products. EDCs are associated with altered reproductive function in males and females; increased incidence of breast cancer, abnormal growth patterns and neurodevelopmental delays in children, as well as changes in immune function.
- **Persistent organic pollutant** (POP): chemical substances that persist in the environment, bioaccumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. This group of priority pollutants consists of pesticides (such as DDT), industrial chemicals (such as polychlorinated biphenyls, PCBs) and unintentional by-products of industrial processes (such as dioxins and furans).
- **Bioaccumulation:** uptake of a chemical by an organism through a combination of water, food, sediment and air, as occurs in the natural aquatic environment.

Microplastics in particular, can persist for long periods in the aquatic environment if not properly disposed of or recycled. Microplastics have been found in wastewater, sewage sludge, freshwater and in the terrestrial environment, and in species of fish and shellfish consumed as food (ECHA, 2018). As reflected in a recent note published by the ECHA (European Chemicals Agency), the concern associated with microplastics is the potential environmental and human health risks posed by their presence in the environment. Microplastics are readily available for ingestion due to their very small (typically microscopic) size and are also very resistant to normal environmental degradation i.e. high resistance towards physical and chemical effects and a low degradability. A recent report from the Danish Environmental Protection Agency indicates that the most abundant microplastic particles in wastewater, sludge and soil samples tested were polyamide/nylon, most likely originating from textiles, clothing and carpets (DEPA 2016).

According to a pan-European study carried out in 2018 by the European Environmental Agency, the majority of Europe's rivers, lakes and estuaries are highly polluted with chemicals and other pollutants – only 38 % of the water bodies evaluated met chemical pollution standards (EEA 2018). The improved performance of metrology and monitoring technologies have led to the identification of new pollutants in waterbodies. This trend reflects the increasing number and types of products that are being put on the market. For example, it is estimated that approximately 100 000 organic chemicals are in regular use in Europe, with 1 000 new ones entering the market each year.

4.2 Economic impacts

In addition to the environmental and health impacts associated with the release and presence of micropollutants and microplastics in water bodies throughout Europe, important economic impacts include the costs of water services both upstream and downstream, effecting **drinking water and waste water treatment**. A discussion on some of the technical limitations of advanced water treatment technologies is provided in section 6.2.1.

4.2.1 Costs of advanced wastewater treatment

Municipal wastewater treatment plants represent a major entry pathway of micropollutants and microplastics to waters, as they are the collection point of urban wastewater and, in the case of combined sewers, of road run-offs. Conventional waste water treatment plants (WWTPs) in the EU were established to comply with the requirements of the Urban Waste Water Directive (UWWTD), which aims to protect the environment from the adverse effects of urban waste water discharges. Accordingly, traditional WWTPs using conventional biological and mechanical processes are not specifically designed to eliminate micropollutants and microplastics – specifically newer and more complex water pollutants that stem from chemicals, products and materials with increasingly new properties and pathways of synthesis (Klaus et al. 2019) – which due to their persistence in the environment, many are able to pass through wastewater biological treatment processes. Although recent innovations in chemicals and materials may promise advantages such as increased efficiency of new products put on the market, the current situation represents both **technical and economic difficulties** for the drinking and waste water sector.

In order to comply with requirements such as those on urban waste water discharges, many WWTPs in the EU must invest in advanced water treatment technologies, which implies increased costs. The additional costs borne by WWTPs to treat waste water is usually being passed on the final consumer, leading to increased water bills. The cost of wastewater treatment depends on several factors such as the condition of the WWTP, its size, the technology that is installed and the quantity and types of pollutants that need to be treated in order to reach the desired water quality. Implementing advanced wastewater treatment is particularly problematic for smaller WWTPs due to the investments costs (including increased energy consumption) and infrastructure required. In most cases, economies of scale and cost effectiveness can be achieved for larger installations as they have more resources to ensure follow-up, process optimisation, and operation and maintenance of the facility. In addition, costs and energy demand per cubic meter are generally lower for larger facilities, and are also likely to decrease as technologies develop and prices drop with increasing market demand. However, if investment requirements come at the wrong moment of the investment cycle, larger treatment plants may also face significant difficulties.

Information on advanced treatment costs are presented in the following paragraphs for Switzerland, Germany, the Netherlands and Sweden. Although some data is available in existing literature, it should be noted that **cost data varies widely depending on the different parameters considered** (e.g. location of the WWTP, local conditions, capacity of the WWTP, measured in population equivalent size, water recharge rate, etc.) as well as differences between Dutch, Swiss, Swedish and German cost and wastewater treatment structures. For example, the design capacity of a WWTP in population equivalents (p.e.) is

not calculated in the same way nor are important cost variables such as capital costs, electricity and labour.

Switzerland is one of the first countries to start implementing a national policy to reduce micropollutants in the effluents of municipal sewage treatment plants (STPs). According to a report commissioned by the Swiss Federal Institute of Aquatic Science and Technology, the Institute of Biogeochemistry and Pollutant Dynamics and the Federal Office for the Environment, the average cost for wastewater treatment including nutrient removal in Switzerland is around 0.61 €/m^3 (0.7 CHF/m^3) wastewater (Eggen 2014). Table 2 summarises the overall investment and capital costs of different types of advanced treatment technologies in Switzerland (Poyroy[2] 2016).

Table 2: Costs of advanced water treatment technologies, Switzerland[3]

Estimated costs	**Advanced water treatment technology** p.e. (population equivalent) = 100 000	
	Ozonation + new filtration	Power activated carbon + new filtration
Total investment sum	10 million € (11.3 million CHF)	10.8 million € (12.3 million CHF)
Capital costs (€/p.e./year)	6.4	6.7
Operating costs (€/p.e./year)	3.2	4.7

Under the Swiss national policy, the total investment costs to upgrade 100 WWTPs (out of approximately 650 WWTPs and covering approximately 50 % of national annual wastewater) are estimated at 1.2 billion CHF (1 billion €), or 130 million CHF (114 million €) per year, over a period of implementation of 25 years (2016-2040)[4]. The planned upgrades to WWTPs are expected to increase the annual costs of urban drainage and wastewater treatment by 6%. Treatment costs are expected to increase by 10−20% for WWTPs serving > 80 000 persons and by 20−50% for WWTPs serving between 8 000 and 80 000 persons (Eggen 2014). **Compared to Germany**, the costs of upgrading 230 large municipal treatment plants (size category 5, covering approximately 50 % of the nationwide annual amount of wastewater) over a period of 25 years are estimated at 10.4 to 10.9 billion €, which would equate to 415 to 435 million € in annual costs for the elimination of micropollutants, including post-treatment (UBA 2018). An earlier report published by the German Environment Agency estimated that the specific costs of advanced waste water treatment in municipal sewage treatment plants range from 0.124 €/m^3 for size class 3 to 0.051 €/m^3 for sewage treatment plants larger than 1 million population equivalents (size class 5). The annual total costs of around 1.3 billion euros

[2] Poyroy is one of the main consulting and engineering companies that has overseen many of the WWTPs upgrades in Switzerland.
[3] Poyroy (2016)
[4] www.water2020.eu/sites/default/files/keynote_adriano_joss_eawag_switzerland.pdf

(net) are expected when upgrading all the German sewage treatment plants in the size classes 3 to 5 (3 013 in total) to integrate targeted micropollutant removal (UBA 2014).

In Sweden, a government-commissioned report (which based its calculations on the Baresel et al (2017) study) estimates that the advanced waste water treatment costs for facilities larger than 100 000 population equivalents (p.e.) is less than 1 SEK/m^3 (0.09 €/m^3). For smaller facilities (2 000–20 000 p.e.), the costs of advanced treatment technologies are about 5 SEK/m^3 (0.5 €/m^3) (SEPA, 2017). The report breaks down the estimated costs by technology as summarised in Table 3:

Table 3: Cost of advanced water treatment technologies, Sweden[5]

	Ultrafiltration	**GAC**[6]	**PAC**[7]	**BAF**[8]	**Ozonation**
Installation CAPEX (M €)					
2 000 p.e.	9.7–12.4 M€	3.5 M€	0.13 M€	3.5 M€	1.2–4.4 M€
20 000 p.e.	15–22 M€	6.6 M€	0.22 M€	6.6 M€	3–7.9 M€
100 000 p.e.	44 – 66 M€	15.4 M€	0.7 M€	15.4 M€	9.3 – 17.6 M€
Annual capital expenditure CAPEX (M€/year)					
2 000 p.e.	0.7–0.9 M€	0.26 M€	0.008 M€	0.26 M€	0.08–0.35 M€
20 000 p.e.	1.4–1.7 M€	0.44 M€	0.01 M€	0.6 M€	0.26–0.6 M€
100 000 p.e.	3.2–4.8 M€	1 M€	0.05 M€	1.4 M€	0.7-1.3 M€
Operating expenditure OPEX (M€/year)					
2 000 p.e.	0.35–0.4 M€	0.6 M€	0.30 M€	0.6 M€	0.17 M€
20 000 p.e.	0.7–1.4 M€	1.4 M€	1.8 M€	0.79 M€	0.35 M€
100 000 p.e.	3–5.2 M€	6.8 M€	7.5 M€	3.5 M€	1.3 M€
Total cost (€/m^3)					
2 000 p.e.	3–3.9 €	0.88–1.05 €	0.97 €	0.88–1.05 €	0.48–0.8 €
20 000 p.e.	0.6–0.97 €	0.6–0.88 €	0.50 €	0.4–0.7 €	0.20–0.30 €
100 000 p.e.	0.44–0.66 €	0.44–0.6 €	0.50 €	0.30–0.52 €	0.16–0.18 €
Operational electricity consumption (kWh/m^3)					
	0.1–0.5	<0.01	0.01–0.05	<0.01	0.1–0.3

[5] Treatment costs per cubic metre of treated effluent (SEK/m^3) are calculated by dividing the total Annual investment costs and operation costs by the total annual effluent treated by the WWTP. The dimensioning flow used for all facilities is 150 m^3/ (p.e. / year).
[6] Granular activated carbon
[7] Powdered activated carbon
[8] Biologically active filtration

The Swedish study estimates the total costs of upgrading all WWTPs in Sweden (greater than 2 000 p.e.) between 46 million € (41 million kronor) and 2.3 billion € (2.1 billion kronor) per year. This corresponds to approximately 62 - 540 € (55-480 kronor) per household per year (SEPA, 2017).

Another study commissioned by STOWA (Dutch Foundation for Applied Water Research, compared the costs of different advanced water treatment techniques in the Netherlands, Germany and Switzerland (Mulder, 2015). When taking into account the differences in calculation methods (e.g. population equivalents, treated amount of effluent, use of already existing processes, cost structures, etc.), key findings from the report indicate that the calculated costs are similar across the three countries (Table 4 and Table 5).

Table 4: Cost comparison – Netherlands and Germany for micropollutant removal (m^3/per WWTP effluent)[9]

Equivalent		Netherlands	Germany
Capacity p.e. – NL (150g TOD)[10]	Capacity p.e. – DE (60g BOD)[11]		
20 000	14 000	0.22 – 0.26 € ± 0.05 €	0.21 € ± 0.08 €
100 000	70 000	0.18 – 0.20 € ± 0.05 €	0.19 € ± 0.08 €
300 000	210 000	0.16 – 0.18 € ± 0.05 €	0.14 € ± 0.08 €

Table 5: Cost comparison – Netherlands and Switzerland for micropollutant removal[12]

Treated capacity: > 80%	Total costs	Costs per Swiss p.e. (120g COD)[13]	Costs per Dutch p.e (150g TOD)[10]
4 500 000 p.e. CH	66.5 M€	14.30 €	12.40 €
13 500 000 p.e. NL	150 -190 M€	12.80 – 16.20 €	11.10 – 14.10 €

Other cost figures identified through the literature review that can provide additional insights on the overall cost implications of advanced water treatment technologies indicate the following figures:

- Traditional wastewater treatment = 0.17 €/m^3, with 47% of residues left after treatment

[9]Mulder (2015). The cost calculations in the Mulder (2015) study are based on the study: UBA (2015). Measures to reduce micropollutants entering aquatic environment [Masnahmen zurVerminderung des Eintrages von Mikroschadstoffen in die Gewasser, Umweltbundesamt Dessau-Roslau, and Januari 2015].
[10] TOD= total oxygen demand / 1 p.e in the Netherlands = 150g TOD
[11] BOD= biochemical oxygen demand / 1 p.e. in Germany = 60g BOD
[12] Mulder (2015). Estimations provided: removal per m^3 incoming wastewater, based on removal of indicator substances of the BAFU, 2012 study (Diclofenac, Carbamazepine, Sulfamethoxazole, Benzotriazole, Mecoprop). Cost calculations based on the study: BG Ingenieure und Berater AG (BAFU), 2012. Planning and Financing for the elimination of micropollutants in waste water.
[13] COD= chemical oxygen demand/ 1 p.e. in Switzerland = 120g COD

- Reverse osmosis = 0.48 €/m^3, with 4 % of residues left after treatment
- Powered activated carbon = 0.65 €/m^3, with 3% of residues left after treatment
- Ultraviolet (UV) irradiation = 0.35 €/m^3, with 13% of residues left after treatment
- Ozone: 0.23 €/m^3, with 2% of residues left after treatment[14]

The above figures should however be considered with caution and could be misleading, due to potentially vested interests of the source for these figures. The data listed above is provided by Primozone, a Norwegian based company specialised in ozone technology.

4.2.1 Costs for drinking water treatment

The presence of micropollutants and microplastics in the aquatic environment not only affects the costs for wastewater treatment, but also those of drinking water operations. Drinking water can be produced from both groundwater and surface water sources depending on the geographic context. Similar to wastewater treatment technologies, conventional drinking water treatment processes (e.g. sand filtration, flocculation etc.), which were primarily developed for the removal of pathogens and nutrients, have proven inefficient in the removal of many micropollutants. Advanced treatment processes such as nanofiltration and reverse osmosis membrane can more efficiently decrease the levels of micropollutants in raw water sources, however complete removal is not always achieved and the effectiveness of treatments generally decreases with usage and time (Tröger 2018). Their practical use in full-scale drinking water treatment plants (DWTP) can be problematic in the case of high micropollutant concentrations in the retentate, which can eventually lead to human exposure and bioaccumulation of hazardous compounds, particularly in the case of perfluoroalkyl substances (PFASs).

Furthermore, much of the drinking water produced from groundwater or spring water only require minimal treatment making it a natural product containing many valuable minerals. Drinking water produced through reverse osmosis would require re-mineralisation turning it into an artificial product. In addition, advanced drinking water treatment processes may require additional costs in terms of investments for upgrades to DWTP, operations and training. Figures on drinking water costs associated with micropollutants resulting from the agriculture sector are summarised below (EurEau, 2016):

- **Austria:** In Austria, a relatively small portion of the country's water resources (approximately 7%) is treated because of the generally high quality of drinking water resources (ground water, spring water). In cases where drinking water sources must be treated due to, for example, elevated nitrate levels caused by agricultural activities, cost estimates from a regional water supplier (supplying 6% of the Austrian population) indicate investment costs of almost 14 million € (over a 16 year period from 1998 – 2014) for establishing treatment plants (membrane filters in combination with activated carbon). Operating costs were estimated at approximately 0.40 €/m^3. Costs for the construction of new wells, regional drinking water pipes and mobile membrane filters were not included in these figures.

[14] Micropollutants "Cost of treating water micropollutants". Accessible at: http://micropollutants.com/Portals/0/Downloads/Cost-of-treatment-water-micropollutants.pdfs

- **Denmark:** In Denmark, drinking water treatment costs associated with the presence of micropollutants in water sources are difficult to estimate because of national and regional specificities. There are only a small amount of the Danish drinking water suppliers that have extended water treatment. The number is rising though, due to increasing problems with emerging substances, primarily metabolites from pesticides and biocides. Water prices are set to reflect a variety of parameters such as infiltration rates to aquifers and the percentage of the catchment areas which are subject to certain measures. Further, some costs are covered through public and government funds e.g. taxes for planning costs. Nonetheless, significant efforts are made by the national government to regulate groundwater sources (and therefore the use of fertilisers and pesticides) due to the fact that about 2/3 of the area in Denmark is farmland. Measures to reduce nitrate leaching to groundwater can vary from a few thousand Euro to 20 000 € per hectare (lump sum); and costs for protecting groundwater against pesticide pollution can range from 2 000 € to 10 000 € (lump sum) depending on the crop system and proximity to abstraction areas. Other important costs include rising drinking production costs, protection of groundwater sources, administrative expenses required for planning, monitoring and enforcement activities and public awareness raising campaigns on groundwater protection issues.
- **Germany:** In Germany, costs related to nitrate elimination when treating raw water for drinking water purposes vary between 0.10 €/m³ and 0.50 €/m³.

4.2.2 Reduced sludge quality and circular economy options

Sludge refers to the residual, semi-solid material that is produced as a by-product during treatment of industrial or municipal wastewater. EU policy has placed priority on the use of sludge on land – for agricultural for example – to utilise the resource value of organic matter and nutrients, and to avoid the use of incineration if possible, which would promote the transition to a circular economy. However, the use of sludge on land must abide by **strict quality standards**, due to the possible presence of heavy metals and pathogens, which is highly dependent on factors such as the nature of the catchment of sewage treatment works (i.e. presence of industries, hospitals, abattoirs, combined drainage etc.) and the type of advanced treatment technique applied. The content of different pharmaceutical residues and other hazardous substances in the sludge resulting from advanced treatment impacts the quality of the sludge that is produced (SEPA, 2017). Other considerations for sludge use includes potential problems of odour, litter (screenings) and bulk (high water content).

Despite the considerable advances in control and treatment technologies, albeit with increased costs, sludge quality remains one of the principal constraints on sludge use particularly as quality standards continue to be tightened.[15] Sludge managers are therefore faced with the challenge of finding cost-effective and innovative solutions whilst responding to ever-growing environmental, regulatory and public pressures. Sludge production will continue to increase as new sewage treatment works are built and effluent and

[15] European Commission, DG ENV (n.d.). Workshop on sludge papers, Session 3: Technology and Innovative options related to sludge management. Accessible at: http://ec.europa.eu/environment/archives/waste/sludge/pdf/workshoppart4.pdf

environmental quality standards are tightened to reduce nutrient emissions. In the case that future quality standards for sludge and its application are made too stringent, the agricultural outlet may no longer be a viable option for the water utility sector, resulting in sludge being disposed of by other means that offer the utilities greater operational and financial security, but which may be less sustainable in the long-term[16].

4.2.3 External costs & benefits of avoiding the release of pollutants in the environment

Chemicals undoubtedly play an important role in today's society, to support human health, agricultural production, manufacturing, construction, and many other industrial sectors. Nevertheless, the expanding use of chemicals poses risks to the environment and human health. As such, the costs of additional treatment should be weighed against the benefit of removing micropollutants and microplastics from wastewater or drinking water resources. In order to evaluate the trade-offs between the benefits brought by the production and application of chemicals and the costs associated with the negative impacts that result from their unsustainable use and presence in the environment, robust information would be needed on the price involved in the production and use of chemicals, of current levels and effects of chemicals once they are placed on the market, society's willingness to accept the risks and a clear knowledge of the major entry routes of micropollutants and microplastics to water bodies. Further, micropollutants often occur in the environment not as single compounds, but in mixtures with many other chemicals. Whereas individual substances may be present in concentrations too low to cause effects, additive or synergistic effects due to the presence of other substances can cause detrimental impacts on organisms (Institute of Water Policy 2011). The relatively limited number of studies and information on these aspects hinder a more robust evaluation of the benefits associated with the reduction of these substances in drinking water or wastewater through updating treatment plants with new and often costly advanced treatment technology (Baltic Sea Centre, 2018).

The costs of advanced water treatment as discussed in the previous section have been evaluated by several studies, however, less information is available regarding the benefits of removing known and unknown substances from our water sources. This is a key challenge of environmental policy in terms of being able to evaluate the monetary quantification of its nonmarket values (costs and benefits). Nonmarket values have been estimated in some studies by measuring **peoples' willingness to pay** for the protection of for instance water resources or the estimated socioeconomic value of these resources. The only study identified by the research team that attempts to quantify the potential benefits is the study carried by Logar et al., 2015 and study published by DG Environment on the Economic Value of Water (Ecorys 2018). Although, these surveys indicate that economic benefits exceed the costs of additional treatment, the actual value of this precaution is very difficult to estimate (Baltic Sea Centre, 2018).

[16] European Commission, DG ENV (n.d.). Workshop on sludge papers, Session 3: Technology and Innovative options related to sludge management. Accessible at: http://ec.europa.eu/environment/archives/waste/sludge/pdf/workshoppart4.pdf

As one of the few countries that have implemented a nation-wide policy on reducing micropollutants in waste water treatment plants, experience from the Switzerland case can provide some insights on the costs and benefits. A recent study published by the Swiss Federal Institute of Aquatic Science and Technology, estimated the benefits of reducing micropollutants loads from wastewater. The results of the study show that despite high uncertainty surrounding the impacts of micropollutants, Swiss households are willing to pay a substantial amount of money on top of their current water bill for their reduction (Logar 2015). Findings of the study indicate that the estimated annual cost for upgrading 123 sewage treatment plants (STPs)[17] is CHF 133 million (€ 117 million) or CHF 86 (€ 76) per household. The average willingness to pay per household for reducing the potential environmental risk of micropollutants is CHF 100 (€ 73) annually, which generates a total annual economic value of CHF 155 million (€ 137 million). Based on the figures of the report's cost-benefit analysis, the benefits (€ 137 million), calculated based on willingness to pay, outweigh the costs (€ 117 million), thereby justifying the investment decision from an economic point of view and supports the implementation of the national policy in ongoing political discussions (Logar, 2015).

The DG Environment study estimated the indirect use value of water, which the study defines as the benefits of water to people's wellbeing that are not included in market prices. Under a hypothetical scenario of reduced access to water, the use of alternative strategies or technologies would increase the costs of water by 15 to 55% (Ecorys, 2018).The above findings should however be considered carefully as the methods used to measure the potential benefits via people's willingness to pay, is based on stated preference surveys. A major criticism of stated preference methods is their **hypothetical nature and potential overestimation** of stated preference values compared to real market payments (Logar, 2015). The Avoided Cost methodology used in the DG Environment study to calculate indirect use value is subject to high uncertainties due to significant data gaps, scope constraints and the definition of the alternative situation (Ecorys, 2018). In addition, it is important to highlight the significance of national and local specificities and associated public perspective. In Switzerland, for example, many of the receiving waters are also drinking water sources (SEPA, 2017), which is a factor that could affect general public perception of water quality. Further, the cost estimates in the study are based on several assumptions and scenarios and not on real cost data. Certain elements of the report could be utilised as a basis for future assessments and calculation models, however careful attention must be made in terms of extrapolating the findings in the context of other countries due to national specificities such as different development stages and awareness levels.

Other indications that could provide some insight on the potential price of inaction include cases of drinking water reservoir contamination, increasing water scarcity and increased policy priority on protecting water resources and their safe reuse. Further, there are many examples of the substantial costs (financial, but also health and environmental) and the technical difficulties of the remedial actions needed to clean-up polluted areas.

[17] These costs comprise investment and operating costs, including the increased energy consumption required by the implementation of new technologies.

Finally, another factor that merits consideration is the potential impact on other economic sectors such as product manufacturers and the advanced water treatment solution sector. For example, measures to reduce or prevent the release of certain substances into the aquatic environment could drive certain manufacturers to use alternative substances (see section 6.2.1) or adopt different production practices. In cases where producers are faced with higher costs for the use of alternative (and less toxic) substances and materials, these additional costs could be potentially passed on to the consumer in the final purchase price of the product. Concerning the water treatment solutions sector, potential impacts could include new market and research opportunities for more cost-effective treatment technologies. As such, the potential impacts on other sectors is another aspect that needs to be further investigated in order to obtain further information on the potential external costs and benefits of avoiding the release of pollutants in the environment.

4.3 Key stakeholders

Table 6 summarises the key stakeholders concerned in regards to their relevance to EPR and products that release micropollutants / microplastics into the aquatic environment during their life-cycle. Please refer to the study Module 3 report for in-depth overview of the main feedback received during the dedicated stakeholder consultation.

Table 6: Roles and responsibilities of key stakeholders

Stakeholder group	Role and potential impacts
Manufacturers (including suppliers and distributors or retailers)	- Key emission sources/ manufacturers of products from which micropollutants / microplastics are released into the aquatic environment - Compliance with existing national and European legislations related to limits of use of certain substances, disposal requirements, etc. - Responsible for placing products put on the market
European Institutions: • EMA • EC • ECHA • Etc.	- Approval for products placed on the market - Regulations on substance concentrations and use in different applications, monitoring and reporting obligations - Scientific and technical assessments
National/ local MS authorities: • National environmental, public health, transport and urban planning agencies	- Responsible for implementation of relevant MS and EU level legislation - Surveillance of national waterbodies to ensure water quality standards
Consumers or end-users: • Hospitals, pharmacists, patients • Households (habitants) • Businesses • Agriculture	- Entry pathways of micropollutants into water bodies (product disposal) - Purchase and consumption of products (use-phase) that emit micropollutants into the aquatic environment - Use and release of substances through agricultural activities (farming, breeding, application of pesticides)
Waste management and drinking water sector:	- Compliance with existing national and European legislations related to water quality standards

Stakeholder group	Role and potential impacts
• Drinking water producers • Wastewater treatment operators • Municipal waste management sector	- Responsible for collection, treatment and proper discharge of different waste streams (microplastics from single use plastic products, unused pharmaceuticals, unused potentially hazardous substances)

5. Emission sources and pathways

A detailed overview of the different **emission sources** and **entry pathways** of micropollutants and microplastics found in the aquatic environment is particularly important when considering extended producer responsibility principles, as it can trace back dangerous substances to the associated product that was placed on the market.

5.1 Overview of emission sources & entry pathways

Emission sources refers to the product (final and/ or intermediate) that is placed on the market (by manufacturers, importers, retailers or distributors), which ultimately releases micropollutants and microplastics to the aquatic environment during one or more life cycle stages. In general, micropollutants and microplastics are released into the aquatic environment from two types of sources: point sources or diffuse sources. Point source pollution comes from a specific source, such as wastewater discharged from industrial sites (effluents). Point source pollution is usually easy to identify. This study focuses specifically on micropollutants and microplastics that enter the waterways through **nonpoint or diffuse sources**, meaning that the substances come from many different sources (e.g. a wide range of products placed on the European market), released (entry pathways) from different entry points and locations e.g. via households, businesses and industry, etc. and consequently transported throughout the water cycle e.g. through wastewater, run-off, melting snow and rainwater. Nonpoint source pollution is difficult to pinpoint, and therefore control and monitor because of the difficulty of tracing it back to the original source of pollution.

Although the concentration of pollutants from diffuse sources may be lower than the concentration from a point source, the total amount of a pollutant delivered from nonpoint sources may be higher because the pollutants come from many places. It also varies over time in terms of the flow and the types of pollutants. The water catchment area where the micropollutant is most frequently detected presents the highest risk in terms of contamination and the possible adverse health and environmental impacts.

"Approximately 10 to 33 % of prescribed medicines are **not consumed**. Due to a lack of safe and secure disposal options, 30% of consumers dispose of unused medicines through the household trash or toilet."
- Bicket, 2017

Entry pathways describe how substances are released (e.g. during use phase, processing phase, etc.) and where it finds itself in the aquatic environment (e.g. surface waters, groundwater, etc.). The entry pathways of micropollutants and microplastics found in waterbodies vary greatly and depend on factors such as how the substance is used or where they are produced or applied. Table 7 summarises the different entry pathways for the micropollutants and microplastics released by the product categories assessed. The following section provides specific details of the most significant entry pathways as identified in existing literature.

Table 7: Main entry pathways for micropollutants

Entry pathways	Description
Urban wastewater treatment plants	Urban waste water generally constitutes domestic waste water from households, and wastewater from offices and public facilities including hospitals and retirement homes. Therefore, urban wastewater treatment plants receive a cocktail of substances stemming from pharmaceuticals, personal care products, household chemicals and microfibers from textiles. It can also treat run-off rain water in the case of combined sewer systems (explained below). As these plants are not designed to treat micropollutants and microplastics, they represent a major entry pathway of these substances in the aquatic environment. Further details on substance removal efficiencies are provided in section 6.2.1
Industrial wastewater plants	This entry pathway refers to plants' effluent containing substances that are mainly emitted in industrial effluents from manufacturing processes. These industrial processes emit micropollutants both during the manufacturing of substances and/ or the substance's use as a component for the manufacturing of the final product.
Combined sewer overflows	Combined sewer systems which collect rainwater runoff and domestic sewage in the same pipe, can receive higher than normal flows during heavy rain or snow storms. Thus, these sewers are designed to overflow occasionally and discharge excess wastewater directly to waterbodies. These overflows, also known as combined sewer overflows (CSO), contain numerous untreated substances including micropollutants and microplastics emitted from the wear and tear of tyres from road run-offs.
Agriculture	Agricultural areas constitute another important diffuse source for potentially harmful substances emitted from the use of and/or disposal of veterinary pharmaceuticals and pesticides. Such substances are emitted into the water cycle via run-off through the application of pesticides and in some cases via the absorption of pesticide products by plants. Other entry pathways from agriculture include the spreading of manure or contaminated sludge on agricultural fields causing leaching to surface waters and groundwater.
Waste (landfill)	Waste from landfill areas can potentially leach out and emit micropollutants directly into the water cycle (particularly groundwater sources). These may include in particular chemical wastes from the manufacturing processes, expired or unused pharmaceutical products and products containing PFAS.

5.2 In-depth overview of emission sources and pathways of selected product categories

Pharmaceuticals

The study focuses specifically on herbicides and insecticides (in particular neonicotinoid insecticides), several of which are included in the current EU watch List of substances to be monitored in surface waters. Herbicides are generally more frequently detected and found in larger concentrations than fungicides and insecticides, reflecting differences Pharmaceuticals are the source of many major chemicals that are emitted into waterbodies. The impact of the presence of active pharmaceutical ingredients has been underestimated for many years – that is until the discovery of synthetic estrogens in sewage effluents as a cause of the feminisation of fish in the late 1990s. Studies have also uncovered high concentration of analgesics, antibiotics, and psychiatric drugs in the environment at levels, which research indicates is dangerous for wildlife, in particular the aquatic environment. Antibiotics and growth hormones used in medicines initially destined for human consumption are also used as veterinary medicines, increasing the emission sources of these substances in the environment. Moreover, wastewater treatment plants, representing a main pathway for their release into waterbodies, are not equipped to treat these substances.

In terms of pharmaceutical sales, the EU is second only to the United States, accounting for 25% of the world pharmaceutical sales for human purposes, and 31% for veterinary purposes. The sector represent approximately 3000 different ingredients in the EU, including antibiotics and macrolide antibiotics, hormones/ synthetic estrogens, analgesics (NSAIDs), antidepressants and many more, for human consumptions (therapeutic or diagnostic purposes) (Ternes, 2006).

Due to their adverse effects on aquatic organisms, the EU is focusing the watch list on substances linked to pharmaceuticals through the Water Framework Directive (2000/60). In particular, the updated watch list[18] includes the sex hormones 17-beta-estradiol (E2) and estrone (E1), the contraceptive hormone 17-alpha-ethinylestradiol (EE2), and macrolide antibiotics (erythromycin, clarithromycin and azithromycin) and other antibiotics (amoxicillin and ciprofloxacin). The Directive also requires the European Commission (hereafter the "Commission") to quickly come forward, with proposals for a strategy for dealing with pharmaceuticals. Control-at-source measures must have priority and covers actions such as the phasing out of particularly harmful substances for which alternatives exist, eco-design, ban of over-the-counter sales etc.). As this may not be sufficient, other measures down the supply chain (doctors, hospitals, pharmacies, WWTP) may need to be considered. For those cases, EPR could be an effective way to limit the release of these products in the aquatic environment.

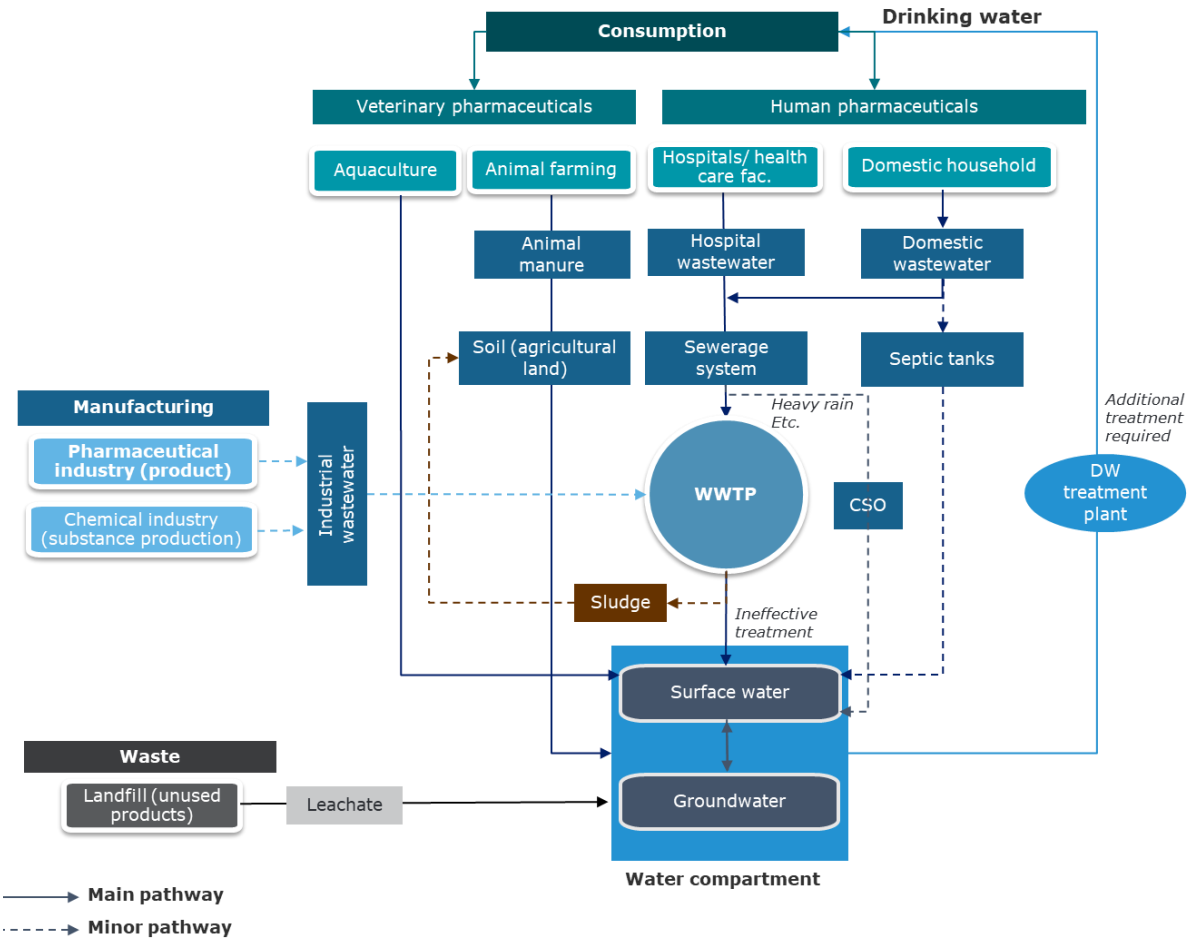
In Europe and the United States, the consumption phase of pharmaceuticals is considered to be the most significant contributor to the emissions of medicinal products into the

[18] An updated surface water Watch List was adopted by the Commission in July 2018

environment, notably through excretions (between 30% and 90% of an orally administered dose is generally excreted as an active substance in the urine of animals and humans) and incorrect disposal of unused medicines e.g. via sewer systems through sinks and toilets (EC, 2016b). The main entry pathways include (see Figure 2):

- **Domestic households** are the main entry pathway of harmful substances from pharmaceuticals in the aquatic environment, through excretion and incorrect disposal of the expired medicines and their leftovers. These substances are emitted in the sewerage system and, depending on the substance, ineffectively treated by urban WWTPs.
- **Hospitals** are also considered as one of the main emission source of pharmaceuticals related-substances into the water cycle. Most hospitals are, in fact, not specifically equipped with waste water treatment infrastructure to immediately treat their effluent after discharge. As such, a large amount of chemicals resulted from healthcare services (hospitals, long-term care facilities and other medical facilities) are discharged directly into the urban wastewater system.
- **Combined sewer systems**, which are generally designed to overflow in case of heavy rain for example, is also an entry pathway of numerous untreated pollutants into waterbodies including pharmaceuticals. The significance of CSO as a pathway for micropollutants will vary from one location to another depending on wet weather conditions.
- **Unused or expired medicinal products**, if disposed in landfilling areas, could lead to the release of substances in waterbodies. In fact, once discarded in municipal solid waste, pharmaceuticals within a landfill may undergo degradation, adsorption, or enter the leachate and eventually exit the landfill (Metzger, 2004). In case of no collection of the effluent, this may be a source for contamination of surface water or groundwater (Kalyva, 2017).
- **Veterinary use of pharmaceuticals,** e.g. for animal farming (in particular, large intensive animal farms) and aquaculture, is also a major emission source of pharmaceuticals in the aquatic environment. In such case, significant amounts of micropollutants can be emitted through excreted animal faeces; up to 75% in animal faeces according to some studies (BIO 2013). Harmful substances stemming from veterinary pharmaceuticals are released into the water cycle depending on their application. For example, when applied in animal husbandry (agricultural activities involving the breeding and raising of livestock animals on land), they are released into the soil environment, where over time, residues from these veterinary drugs accumulate in the soil or drain into groundwater or surface water (UBA 2014) or through the spreading of contaminated manure on land. Veterinary pharmaceuticals used in aquaculture (cultivation of freshwater and saltwater populations- fish, crustaceans, algae, etc. - under controlled conditions) directly enter surface waters.
- **Industrial chemical residues** from medicines manufacturing processes could also enter the water cycle through direct discharge (in industrial wastewater) or indirect discharge (in case of leakage). In Europe, this entry pathway is minor compared to the others.

Figure 2: Entry pathways for pharmaceuticals (human and veterinary medicines)



Pesticides

The study focuses specifically on herbicides and insecticides (in particular neonicotinoid insecticides), several of which are included in the current EU watch List of substances to be monitored in surface waters. Herbicides are generally more frequently detected and found in larger concentrations than fungicides and insecticides, reflecting differences in mobility in the environment (Sandin, 2017). In the case of neonicotinoids, their use has been prohibited in the EU on May 2018. However two of these substances, including thiacloprid (candidate for substitution) and Acetaprimid, can be used with some restriction.

Generally speaking, pesticides refer to any chemicals that is intended to kill or control pests. This includes herbicides (weeds), insecticides (insects), fungicides (fungi), and nematocides (nematodes), rodenticides (vertebrate poisons) amongst others. Pesticide products are mainly used for agricultural purposes – as a plant protection product (PPP), one of the few activities where chemicals are intentionally released into the environment. Other uses for pesticides (non-professional uses for home gardening purposes, for instance) have also been identified and can be a major source of emission depending on the product.

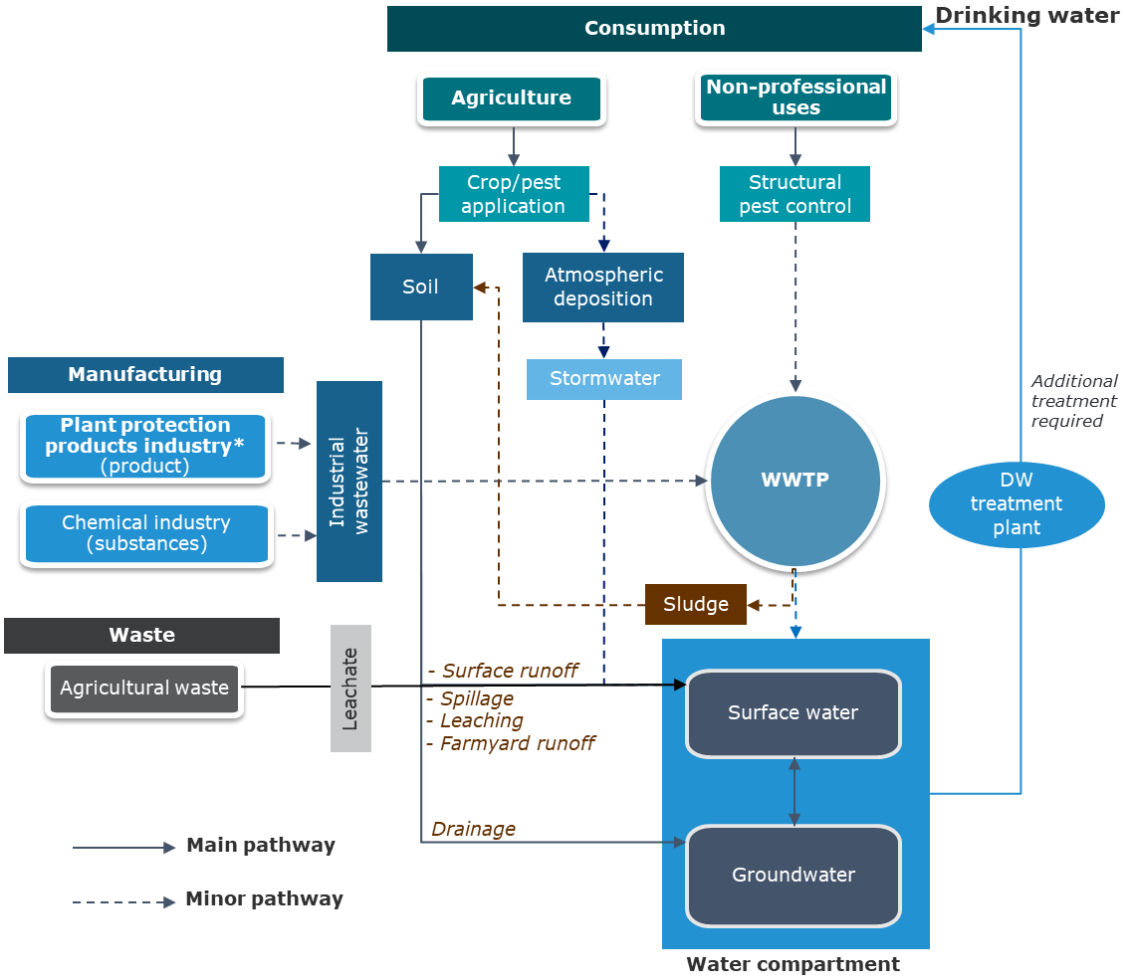
In terms of use, pesticide use in the EU has not decreased despite much of the recent debate on the sustainability of agricultural activities. In 2016, almost 400 000 tonnes of pesticides were sold in Europe, with the vast majority used in the agricultural sector (Eurostat, 2018).

Regarding the impacts, although terrestrial impacts by pesticides do occur, the principal pathway that causes harmful ecological impacts is that of water contaminated by pesticide runoff. The impact on water quality is associated with different factors including the chemical, microbial or photochemical degradation of the active ingredient in pesticide formulation. The Netherlands National Institute of Public Health and Environmental Protection (RIVM, 1992) concluded that *"groundwater is threatened by pesticides in all European states. It has been calculated that on 65% of all agricultural land the EU standard for the sum of pesticides (0.5 mg/l) will be exceeded..."* Pesticides are also degraded into toxic metabolites biologically active, which can be detected in water sources and wastewater effluents at higher concentrations (Gavrilescu, 2015). These products are thus a serious issue to drinking water services, as they are directly released in water in general.

Pesticides can reach waterbodies along several pathways, originating mainly from point sources such as farmyard runoff or wastewater treatment plants, and also from surface runoff and leaching to field drains or to groundwater, or as diffuse losses due to spray drift and atmospheric deposition. Generally the largest concentrations of these substances occur during rainfall-induced high-flow conditions (Neumann, 2002; Petersen, 2012).

- Pesticides could be mainly emitted to the natural environment from farmyards runoff due to improper waste disposal or accidental spills, and also wastewater treatment plants. Some studies have showed that these point sources account for 20-80% of total pesticide loads to surface waters (Holvoet, 2007). It has been assumed in most cases that wastewater treatment plants are minor entry pathways of pesticides into the water cycle. Those reaching wastewater treatment plants originate from industrial discharges (manufacturing processes), and urban activities using these substances e.g. in households gardens. Munz (2017) however found elevated concentrations downstream of WWTPs.
- These substances can also be transported with wind during spreading on crop and deposited, depending on meteorological conditions, on surface water through rainwater. However, the contribution from atmospheric deposition to pollution loads in surface waters is generally small compared with other entry routes (Sandin, 2017).
- Regarding surface runoff which is another main entry pathway of pesticides in waters, it occurs in case of infiltration-excess. In fact pesticides could be transported, dissolved in the aqueous phase, or adsorbed to eroded soil particles entrained in the flow. Infiltration-excess runoff then occurs when the rainfall intensity exceeds the local infiltration capacity and depression storage capacity of the soil. This can increase leaching of pesticides to groundwater (Sandin, 2017).
- Lastly, pesticides could be transported through drainage from fields to surface and groundwater. Drainage generally depends on soil clay content and can also occur in lighter-textured loamy soils (Sandin, 2017). Other transport sources include gardeners, imported plants and greenhouses.

Figure 3: Entry pathways for pesticides



PFASs (perfluoroalkylated substances)

Perfluoroalkylated substances (PFASs) are a family of more than 3 000 manmade fluorinated organic chemicals that have been widely used in various industrial and consumer applications since the 1950s, from chromium metal plating to various fire-fighting foams and for surface treatment of textiles, carpets and papers (OECD, 2015). The release of PFASs in the environment can occur during the manufacturing, the use and disposal of products containing these substances. Certain PFASs are persistent, bioaccumulative and toxic (CDC, 2018). Due to this risk to human health and the environment, PFOS are regulated as a persistent organic pollutant under Regulation 850/2004 (POP Regulation), and PFOA, its salts and PFOA-related substances were added to the list of restricted substances in Annex XVII to the REACH Regulation on June 2017. Perfluorohexane-1-sulphonic acid and its salts (PFHxS) was also added to the REACH candidate list of substances of very high concern as a 'very persistent and very bioaccumulative substance'.

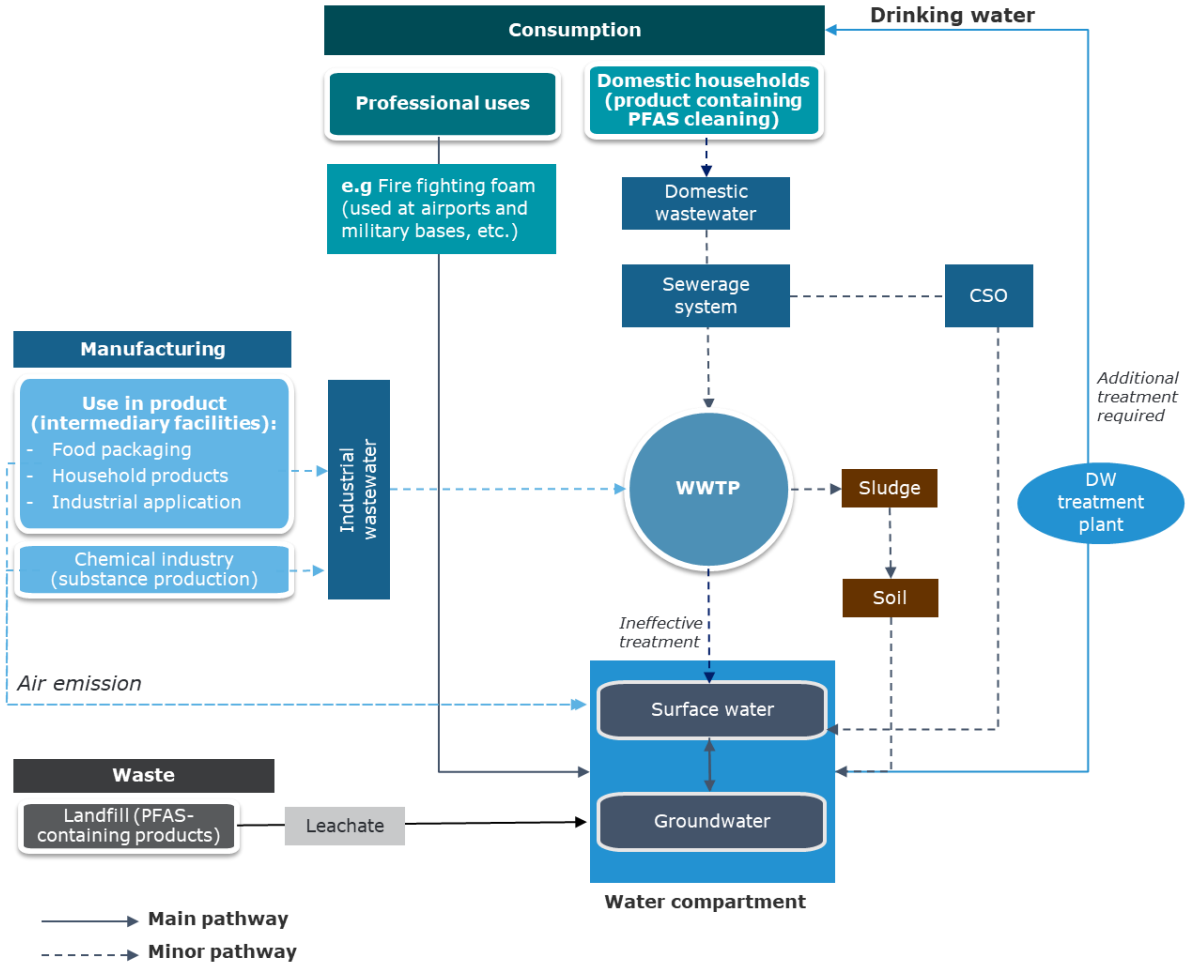
In terms of market sales, the production of PFOA and its salts has been declining for the last three years. However, in 2016, PFOS and its derivatives were still being produced in Germany, Italy, and China[19] (ITRC, 2017). The inclusion of these substances to the annexes of the REACH regulation has notably led to the decrease of their use in Europe. However, they are being replaced by short-chain PFAS, which are assumed to be less bioaccumulative but are more mobile comparing to long-chain PFAS and difficult to remove by wastewater treatment and drinking water treatment plants (Brendel, 2018).

PFAS are found in groundwater primarily as a consequence of contamination of soil by fire-fighting foams. However, they can also result from industrial point pollution, and stem from domestic household products during washing/clearing and end up in drinking water supplies (ITRC, 2017).

- Firefighting foams containing a mixture of PFAS, and used as fire suppression at military installations and civilian airports, as well as at petroleum refineries and chemical manufacturing plants, are a major entry pathway of PFAS into the aquatic environment. They enter in the water compartment through atmospheric deposition, surface runoff (and thus surface waters) and infiltrate to groundwater (Liu, 2016).
- PFAS can also be released from manufacturing facilities through air emission and dispersion, spills, and disposal of manufacturing wastes and wastewater. Several manufacturing sectors were identified to potentially release these substances including, textiles & leather, paper products, metal plating and etching, wire manufacturing, etc. (Liu, 2016).
- PFAS, in particular PFOA and PFOS, can be found in WWTP effluents, originating from consumers and industrial discharges (through the use of PFAS-containing materials), and also CSO depending on weather conditions. Conventional sewage treatment methods do not efficiently remove PFAS (Gallen, 2018).
- Disposal of waste generated during primary PFAS manufacturing (substance production) and secondary manufacturing using PFAS (use in product) can be sources of PFAS environmental contamination. Leachate from municipal solid waste landfills, has been shown to be another source of PFAS release (Benskin, 2012).

[19] In accordance to the Stockholm Convention on POPs, a grant from Global Environment Facility (GEF) was approved in 2017 to support the reduction of PFOS in China as well (ITRC, 2017).

Figure 4: Entry pathways for PFASs



Biocides

According to the Biocidal Products Regulation (BPR) *"a 'biocidal product' is defined as any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances – or – generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product"*. Biocides are classified into 22 biocidal product-types, grouped in four main areas:

- Disinfectants composed of five product-types including those intended to be incorporated in textiles such as silver;
- Preservatives used to prevent microbial and algal development and divided into 8 product-types such as wood preservatives; and
- Pest control products (7 product-types) and other biocidal products (two product-types).

As mentioned above, three relevant product categories and associated substances will be analysed to characterize the impacts of biocidal products used for non-agricultural

purposes:

- **Silver** used as an antibacterial to "reduce odours" in sportswear
- **Triclosan** used as a preservative in cosmetics
- **Tolylfluanid** used as a wood preservation agent

The use of biocidal products has been growing in recent years, this is reflected in the increasing sales of antimicrobial hand-wash, cleaning products and even in sports sock textiles. However, at least 30% of biocides are endocrine disruptive, persistent, or carcinogenic, according to the Pesticide Action Network (PAN). They can also pose a risk for the environment (toxic to water organisms) (Balmer, 2004).

Biocides enter water systems via various routes, for example as preservative residues washed off building facades with rainwater, from consumer products during cleaning, or as disinfectants residues from clothes treatment and washing.

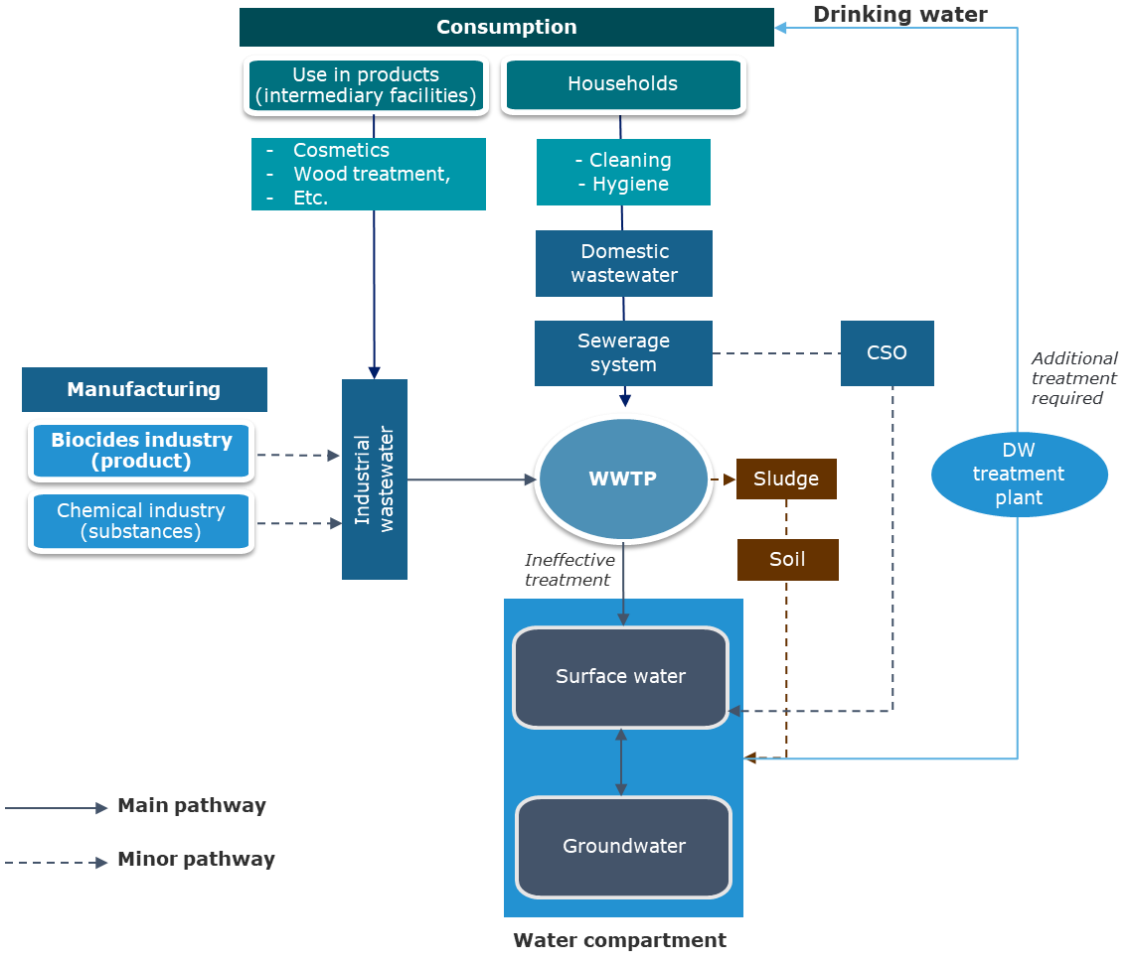
Biocides as disinfectants : silver

For many years silver has been known to be effective against a broad range of microorganisms. Today, silver ions are used to control bacterial growth in a variety of medical applications, and nonmedical purposes, such as anti-odour in sportswear. But some studies showed the emission of this metal in the water cycle and its adverse effects on the aquatic organisms due to its biocidal action. In fact, when washing sportswear a certain amount of silver leaches out, a significant part also stems from industrial activities (manufacturing and use in product). According to the Swedish Water & Wastewater Association (Svenskt Vatten), about 31–90 % of silver leach from the silver-treated clothing after ten washes, 10% is emitted in the receiving waterbodies and 90% of the silver is successfully separated by the treatment plants but contaminates sewage sludge which is generally used for agricultural purposes (Svenskt Vatten, 2018).

Silver has been shown to be highly toxic to the aquatic environment. At the laboratory level, silver ions have shown a low biodegradability (depending on physicochemical conditions) and were extremely toxic to aquatic plants and animals (WHO, 2002). Besides, the spread of silver in the environment may be contributing to the rise in antimicrobial resistance.

There are several different entry pathways for disinfectants to the environment because of its wide-range of use and presence in many different types of products. As such, Figure 5 mapping out the entry pathways for silver illustrates only one example of how disinfectants enter the environment.

Figure 5: Main entry pathway for silver as disinfectant (biocide)



Biocides as preservatives : tolylfluanid (wood preservative) and triclosan (cosmetics preservative)

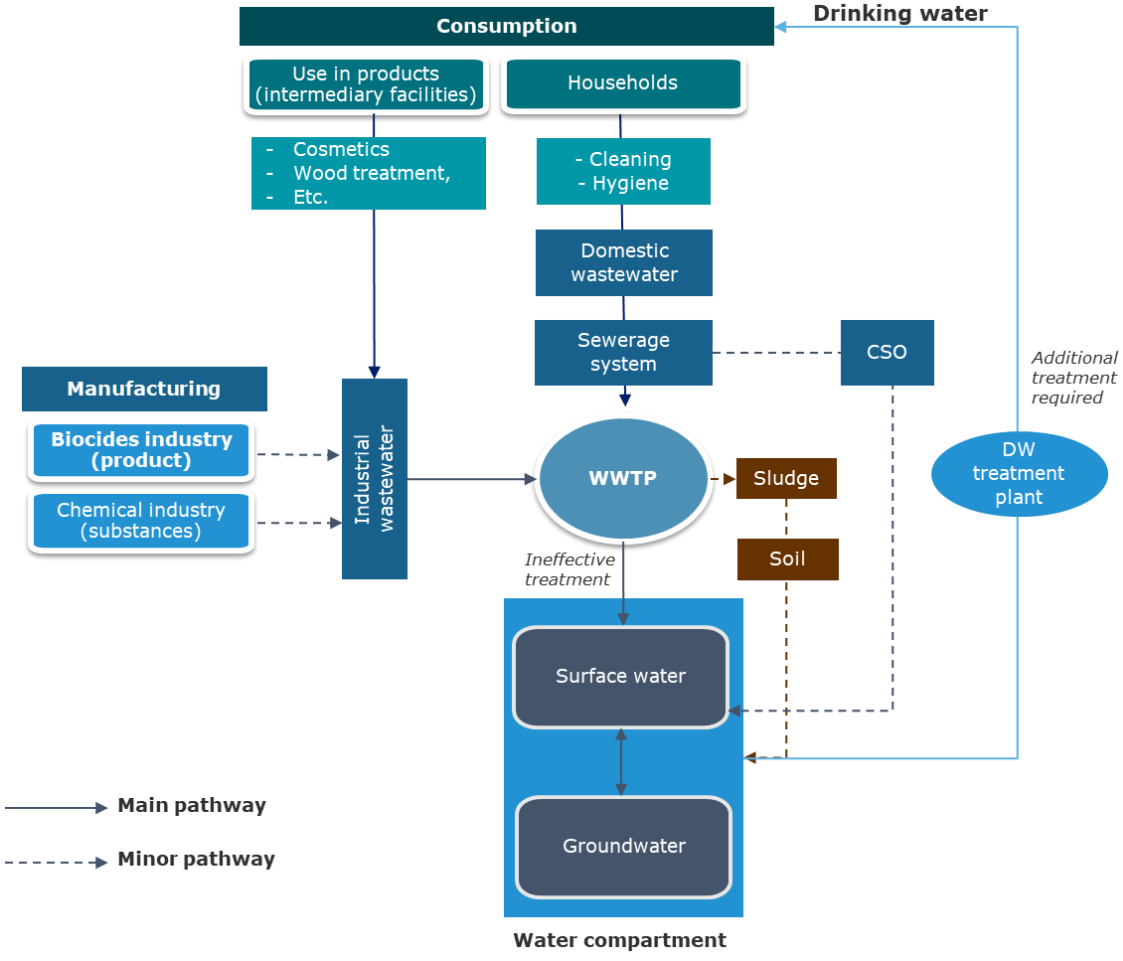
Tolylfluanid (TF) is a member of the phenylsulfamide family of fungicides. It was banned from use as an active agent in pesticides, but still approved for use as a wood preservative. Although tolyfluanid has been defined as non-bioaccumulative (ECHA, 2016), it is highly hydrophobic, strongly suggesting the capacity to concentrate in lipid-rich tissues. Besides some studies have shown that exposure to TF may promote the development of metabolic disease in humans (Endocrine Society, 2014).
Tolylfluanid is of concern from the view of drinking water production due to a transformation product (N, N-dimethylsulfamide) that can be converted to carcinogenic N-nitrosodimethylamine (NDMA) during ozonation of raw water for drinking water production. Moreover, the high mobility and persistency of N, N-dimethylsulfamide in water makes it a potential precursor of NDMA for a very long time (Committee on Biocidal Products 2009). TF can be emitted in waterways though manufacturing discharge, during product application and also from the use phase in particular treated-wood cleaning.

Triclosan (TCS) is a broad range antimicrobial agent used in many personal care products such as soaps, deodorants, toothpastes, etc. This substance has been reported in various environmental compartments including surface water and sewage water in many European

countries such as Germany, and Switzerland. Once in the sewer system, they are transported to wastewater treatment facilities. Triclosan has been shown to undergo complete biodegradation in an activated-sludge treatment system (Ciba Specialty Chemicals, 2001). However, TCS may be biotransformed to a more slowly degradable methoxy-triclosan (TCS-OMe; 5-chloro-2- [2, 4-dichloro-phenoxy]-anisole) intermediate in wastewater treatment systems (Ciba Specialty Chemicals, 2001). TCS and its biotransformation by-products have been reported to have a low removal in the aquatic environment.

Regarding the entry pathways, this substance is mainly emitted in the sewage system from consumer uses (from cosmetics). A minor quantity is also expected to stem from the manufacturing process (producers) and intermediary facilities using the substance in their products.

Figure 6: Main entry pathway for preservatives (biocides)



Secondary microplastics emissions from textiles and tyres

Plastic use has increased exponentially since synthetic organic polymers were developed in the mid-20th century. Over 300 million tons are currently produced yearly to manufacture objects in plastic: 29 % in China, 19 % in Europe, 18% in North America, and 34 % in the rest of the world. The long-term average annual growth rate has been roughly 4% (PlasticsEurope, 2018). In addition to that, there are the plastics for other uses that are not accounted in these statistics such as synthetic fibres for textiles (37.2 million tons produced worldwide) or synthetic rubber for tyres (6.4 million tons produced worldwide) (IUCN 2017). A large number of these plastics ends up in the aquatic environment through different pathways. For example, Jambeck (2015) reported that between 4.8 and 12.7 Mtons of plastic are released globally into the oceans every year because of mismanaged waste, which can lead to microplastics (Eriksen, 2014); (Sebille, 2015).

There are two types of microplastics: primary and secondary microplastics. The distinction is based on whether the particles were originally manufactured to be that size or whether they have resulted from the breakdown of larger items. According to the Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP, 2016):

- **The primary sources** of microplastics are manufactured microplastics that are designed for particular applications. These primary particles may be released from point sources such as plastic processing plants (production pellets or powders for injection moulding) or from more diffuse and regular source points such as populated places along rivers and coastlines (microbeads, industrial abrasives). As these microplastics are currently undergoing a regulatory review (REACH restriction proposed), the study focusses on secondary sources of microplastics, as described below.
- **The secondary sources** are microplastics created by fragmentation and degradation of macroplastics. For example, they can originate from the erosion of tyres when driving or stem from the abrasion of synthetic textiles during washing. There are also pre-production pellets, which are the second source of microplastics in Europe. Their release (estimated to 16 888 – 167 431 tonnes per year according to Eunomia), is not intended during normal operation but can occur in case of spills (e.g. when loading material from trucks) or during storage (Eunomia, 2018). Biobeads, which are used by WWTP to filter chemical and organic contaminants have been identified as another source of microplastics. Rough estimates based on UK data indicates that approximately 1 200—5 000 tonnes/ year is released into the environment (not including one-off spills).

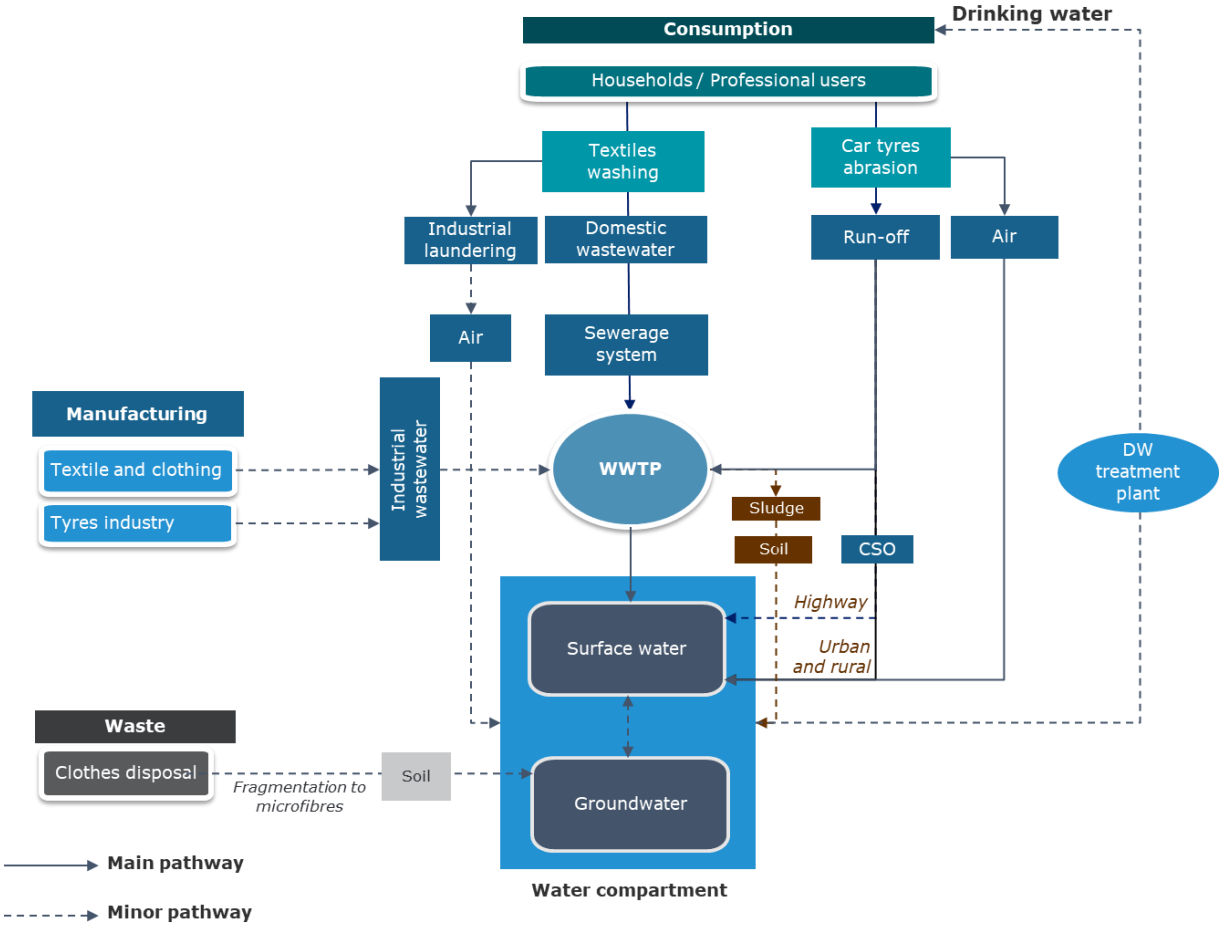
Regarding the impacts, the concern is focused not only on the effect of microplastics as such but also on additives and chemical contaminants absorbed by microplastics that may be released and affect negatively environmental health. Even though it has been assumed that microplastics have almost infiltrated all of the marine habitats and many species of wildlife, much of the impact evidence has been demonstrated in laboratory studies typically at high concentrations and there are only limited studies from nature (Rainieri, 2018). Hence, there is a clear need for further research regarding the impacts related to microplastic debris. Furthermore, a few studies also highlight the importance of microplastics as a potential transport route for other contaminants in the aquatic environment. For example, in the case where microplastics take up or absorb other substances in areas of high concentration, and then release (desorb) them as they move throughout the water cycle.

Several studies have suggested that wear and tear from car tyres and synthetic fibres from clothes are an important source of microplastics in the environment. An IUCN report showed that between 15 and 31% of the estimated 9.5 m tonnes of plastic released into the oceans each year could be microplastics, almost two-thirds of which come from the washing of synthetic textiles and the abrasion of tyres while driving (IUCN, 2017). Another study from Eunomia showed that automotive tyres and washing of clothing are the largest source of microplastics entering the aquatic environment (Eunomia, 2018). In fact, 503 586 tonnes of microplastics are generated from the wear of automotive tyres in Europe every year, and microfibres released from the washing of synthetic clothing in Europe have been estimated between 18 000 to 47 000 tonnes per year. These two sectors are therefore key sources of microplastic emissions into the aquatic environment. While wastewater treatment plants are not specifically equipped for microplastics treatment, a modern treatment plant with secondary treatment removes the large majority of them.

Eunomia's study also showed that the main entry pathways of car tyres are urban and rural roads drains, representing 80% of tyre wear emissions in Europe (highways account for 20%). Another major entry pathway of microplastics stemming from car tyres, is rubber particle dust (mainly <80 µm) which can end in surface waters (GESAM, 2016). In fact, a significant part of the dust is transported into the air as particulate matter, the rest lands directly on the road or adjoining land and from there a proportion enter surface waters or drains. For example, annual emission estimates of tyre rubber dust for Norway, Sweden and Germany are 4 500, 10 000 and 110 000 tonnes respectively (NEA, 2014). WWTPs are concerned by microplastics stemming from car tyres, as these pollutants may enter the sewer system through urban run-off. There is no evidence of drinking water pollution (from groundwater) by microplastics.

Regarding microfibers from synthetic clothing, the main entry pathway is domestic wash. Commercial laundering which is a minor entry pathway of microfibers accounts for 14% of the total washed domestically. It has been assumed that about 0, 9 g of fibres is released per wash in Europe. Browne (2011) also found that an estimated 1 900 synthetic microfibres were rinsed out of a single piece of clothing. Industrial laundering facilities have also been reported to likely expel microfibers to the atmosphere in unknown quantities, which can end up into surfaces water. They can originate from disposal, where clothes can undergo fragmentation processes and migrate from soil to the aquatic environment.

Figure 7: Main entry pathways for microplastics (tyres and textiles)



Part III. Relevance & applicability of extended producer responsibility

6. Existing measures to reduce micropollutants & microplastics emissions

Several policy measures and technical solutions are employed at EU, MS and international levels to reduce and/or avoid the release of harmful substances and microplastics to the aquatic environment, which are, however, not always sufficient.

6.1 Regulatory measures – control-at-source & quality standards

The two main policy approaches used at EU level to control and address the release of harmful substances into the aquatic environment include control and source measures and quality standards.

Control-at-source: Control-at-source measures consist of actions taken as far upstream as possible by implementing measures to reduce or even phase out substances and products that emit these micropollutants. Referring back to the EU Treaty, this approach must be the guiding principle when controlling the release of pollutants to the (aquatic) environment. The most sustainable and preferred solution is therefore to prevent pollutants – including microplastics - from entering the water cycle. Control at source approach involves the implementation of two types of actions including, legislative measures that regulate the placing on the market and the use of certain hazardous substances, and voluntary industrial initiatives (best practices) reducing micropollutant emissions.

Generally, regulatory measures are the starting point to promote control-at-source measures. It defines a framework and guides the chemical users to implement a pollutants release prevention strategy. The EU has implemented a stringent authorisation of chemicals through a number of product and substance-related regulations. These policies include environmental criteria in the authorisation procedures and a more controlled use of potentially harmful products. Source control also includes implementing best environmental practices (at industrial level) and disposal requirements, which also contribute to avoiding and reducing pollutants loads in the natural environment. Those practices are generally implemented to be compliant to the regulatory measures but can also be voluntary initiatives.

Quality standards: Quality standards refer to standards that set requirements, specifications, guidelines, or characteristics that must be complied with to achieve or maintain specific environmental quality objectives in the long term. For example, environmental quality standards that lay down the maximum allowable concentration of a substance in air, soil or water. At EU level, environmental quality standards in the context of water pollution are established under the Environmental Quality Standards Directive (EQSD), which covers a list of 45 priority substances. These priority substances have defined Environmental Quality Standards (EQS), i.e. concentration thresholds that should not be exceeded in the aquatic environment. The main provisions and requirements of the EQSD are described in the next section.

Limitations of control at source measures & quality standards

Despite existing regulatory measures and source control initiatives to reduce micropollutants and microplastics emissions into the waterbodies, the release and presence of these substances continue to be an issue at EU level.

"There has been a **dichotomy** in the pollution control approach at European level. **Each approach has potential flaws**. Source controls alone can allow a cumulative concentration of pollution sources, which is severely detrimental to the environment. Quality standards can underestimate the effect of a particular substance on the ecosystem due to the limitations in scientific knowledge on dose-response relationships and the mechanics of transport within the environment."

In the EU, good chemical status for surface waters (rivers, lakes and transitional and coastal waters) is defined by limits set by environmental quality standards (EQS) on the concentration of certain pollutants, known as priority substances. In a recent report, the European Environment Agency (EEA) concluded that only 38% of European surface waters are in good chemical status, while 46 % have not achieved good chemical status and for 16 % with their status unknown (EEA 2018). In most Member States, a few priority substances account for poor chemical status, the most common being mercury. If mercury and other ubiquitous priority substances were omitted, only 3 % of surface water bodies would fail to achieve good chemical status. Improvements for individual substances show that Member States are making progress in tackling the sources of contamination.

Generally speaking, the introduction of control mechanisms takes several years and is not adequate or feasible in all situations: for example, in the case of requirements on the safe and sound disposal of pharmaceuticals from households, it is very difficult to implement realistic control mechanisms. Controlling every household and its respective pharmaceutical disposal habits on a regular basis would not be economically feasible for governments. Information campaigns on optimal usage, storage and disposal of chemicals may lead to behavioural changes. However, product-related regulations alone, or even coupled with changes in consumer behaviour, are unlikely to be sufficient to lower the release of the many thousands of chemicals that are used in different ways and can enter the water cycle over a variety of pathways.

There are also inconsistencies across certain policies, whereby potentially hazardous substances are not adequately addressed. For example, the sustainable use of pesticides directive aims at reducing the risks and impacts of pesticide use and promoting the use of Integrated Pest Management through the use of alternative approaches to pesticides. The directive actively contributes to the reduction of substances stemming from agricultural pesticides, however, does not cover biocide-based products, many of which are composed of similar active ingredients and properties.

Another limitation in current EU policies is the need to fully integrate a complete life cycle approach for products. Even though some stringent procedures, including binding tests on the ecotoxicological impacts, are being applied in the context of products/substances approval, in most cases regulation does not require producers to perform a full life cycle assessment (LCA) of such products, which prevents the possibility of a full assessment of the potential impacts of the substance or product in question. In the case of human medicinal products for example an Environmental risk Assessment (ERA) is required under the Directive on medicinal products for human use (Directive 2001/83) in order to obtain marketing authorisation. The ERA is based on the use of the product and the physio-

chemical, ecotoxicological, and fate properties of its active substance. However, the results of the ERA does not constitute a criterion for refusal of a marketing authorisation (EMA, 2018). Instead, based on the outcome of the ERA, specific arrangements to limit the impact of the pharmaceutical on the environment should be considered e.g. product labelling, instructions for safe disposal and storage in patient leaflets, etc. This is not the case for veterinary pharmaceuticals, where a risk to the environment does lead to refusal of a marketing authorisation.

Further, other factors such as the high costs and time needed to monitor micropollutants, the insufficient enforcement and control of hazardous substances contained in imported products, along with global treaties that complicate compliance further exacerbate the problem of "free-riders".

Finally, a particularity of chemicals regulation is the issue of time. Regulation of chemicals is usually implemented on a case by case basis and takes several years. In many cases, regulation is enacted as a reactive measure, once there are demonstrated adverse impacts in the environment. In other words, the potential risks due to combination effects and effects of unknown degradation products are not currently considered in existing legislation at EU level.

The main limitation concerning quality standards is the general lack of data on concentrations of contaminants and the knowledge gap at European level of their ecotoxicological effects to demonstrate the significant risk to or via the aquatic environment, either individually or in combination with other substances. In addition, information on the sources and emissions of many pollutants remains incomplete and uncertain, limiting the scope for identifying and targeting appropriate measures. Other elements such as eutrophication, overfishing and climate related changes, combined with the lack of data mentioned previously make it difficult to assess for example the real-life status of different water bodies[20]. In the example of the EQSD, the number of priority substances (45) may not be sufficient to accurately evaluate the chemical status of different water bodies. The majority of assessments are based on only a few indicator substances, however more than a thousand chemicals have been identified in European waters, and are rarely monitored, despite their known or suspected adverse ecological effects.[21] Finally, it should be noted that apart from source control and quality standards, end-of-pipe requirements have been set. For example, the DWD sets parametric values for pesticide concentrations in DW.

6.1.1 EU policy context

This section provides a brief description of some the relevant legislation for the product categories assessed (Table 9). A more in-depth assessment of the applicability of these legislations in the context of a potential EPR scheme is provided in Module 2.

[20] Baltic Eye, Advanced wastewater treatment, 10/19/2018. Accessible at: https://balticeye.org/en/pollutants/policy-brief-advanced-wastewater-treatment/ 5/6
[21] Baltic Eye, Advanced wastewater treatment, 10/19/2018. Accessible at: https://balticeye.org/en/pollutants/policy-brief-advanced-wastewater-treatment/ 5/6

The increasing demand of citizens to have a better water quality in Europe has highly contributed to the establishment of measures in order to prevent and reduce water pollution and incite states and industries to integrate water resources management in the national and business strategies. This is achieved by a combination of precautionary measures at the source and during product use that include stringent regulatory measures and best practices at industrial level, the establishment of environmental quality objectives and the implementation of the best available technologies for reducing downstream emissions.

At EU level, the **EU Water Framework Directive (WFD)** serves as the legislative basis for water management in Europe, establishing water quality standards through **environmental quality standards (EQS)** for **priority substances** to ensure minimum water quality throughout Europe. This is laid out under the **European Quality Standards Directive** (EQSD). The WFD is currently under-going a "fitness check", with the aim of assessing whether the current regulatory framework is "fit for purpose" in regards to its effectiveness, efficiency, coherence, relevance and EU added value in meeting current and future challenges. Aspects such as the potential for regulatory simplification and burden reduction, assessment of costs and benefits, impacts on business and elements of the legislation or implementation that could be improved will be covered.[22] The review phase is expected to be complete by the end of 2019.

Two major water-related directives set end-of-pipe requirements. The **Urban Waste Water Treatment Directive** (UWWTD) aims to protect the environment from the adverse effects of urban waste water discharges from households and sets requirements on the collection, treatment (see also section 4.2.1 and the Module 2 report). The UWWTD is currently under-going a review and evaluation. The **Drinking Water Directive** (Directive 98/83) addresses the quality of water intended for human consumption and the protection of human health. The Directive establishes the essential quality standards at EU level, covering a total of 48 microbiological, chemical and indicator parameters that must be monitored and tested regularly. On 1 February 2018, the Commission adopted a proposal for a revised drinking water directive to improve the quality of drinking water and provide greater access and information to citizens. Some of the key elements of the proposal include:

- Updates to existing safety standards in line with latest recommendations of the World Health Organisation (WHO) to ensure safe drinking water is safe in the long-term;
- Better assist authorities in addressing water supply risks and engage with polluters;
- Additional requirements regarding materials in contact with drinking water;
- Providing consumers with more transparent information on the efficiency and effectiveness of water suppliers; and
- Contributing to the transition to a circular economy by considering drinking water in a resource-efficient and sustainable manner, reduce energy use and unnecessary water loss.[23]

[22] EC website on Fitness Check of the Water Framework Directive, accessible at: http://ec.europa.eu/environment/water/fitness_check_of_the_eu_water_legislation/index_en.htm
[23] EC website on the "Review of the drinking water directive". Accessible at: http://ec.europa.eu/environment/water/water-drink/review_en.html

EU chemicals legislation, particularly Regulation 1907/2006 concerning the **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)** is a core piece of legislation to address the protection of human health and the environment from the risks that can be posed by chemicals. REACH places the burden of proof on companies by requiring that companies identify and manage the risks linked to the substances they manufacture and market in the EU. Proof that the substance can be safely used and that risk management measures are communicated to the users are important elements of the regulation. REACH also restricts the use of certain substances based on risk assessment findings and promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

Other European legislation that are applicable when considering water pollution targets and water quality concern specific areas such as industrial activity, for example in the context of agriculture (i.e. the Nitrates Directive regulating the use of fertilisers and serving to reduce nutrient loads from agriculture) or specific products/ substances (e.g. Ecodesign Directive, Biocide Products regulation, Sustainable Use of Pesticides Regulation, etc.).

Finally, EU waste legislation, notably, the **Waste Framework Directive** (Directive 2008/98) and the accompanying **EU Circular Economy package** also cover important principles such as **polluter pays and extended producer responsibility**, notably rules to harmonise EPR systems to ensure consistent implementation across the EU. The EU Circular Economy package proposes to strengthen measures introduced under the EU's eco-design working plan to improve the recyclability, reparability, durability, and reuse potential of end-of-life products. In particular, Article 8 of the new Directive on the reduction of the impact of certain plastic products on the environment[24] (or the Directive on Single-Use Plastics) specifically calls for the application of EPR schemes for single-use plastic products. EPR schemes should be established to ensure that costs for the collection, transport, treatment, including litter clean up and awareness raising measures are covered by producers. Further analysis of the applicability of the provisions of the Directive is carried out in Module 2.

6.2 Non-regulatory measures

Given the number of micropollutants and microplastics, as well as the diversity of their use and pathways, effectively reducing their discharge to the aquatic environment requires a combination of complementary measures. Therefore, in addition to the control at source regulatory measures as described previously, there are several measures applied at industrial level and end-of-pipe solutions downstream to ensure the compliance to the quality standards.

Existing technical solutions that aim to avoid or reduce the release of micropollutants and microplastics into the aquatic environment include the use of alternative, less toxic substances and materials and end-of-pipe solutions (i.e. requirement of advanced water treatment, quality of effluent, etc.). These options have varying levels of effectiveness,

[24] Link to text of the Directive: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A52018PC0340

depending on the sector or product concerned, or the type of substance targeted and technology used in the case of end-of-pipe solutions.

6.2.1 Use of alternative substances

The use of substitutes that are less harmful for human health and the environment can be a sustainable option in terms of reducing or avoiding the release of their more toxic counterparts. It can also have a significant positive impact on the implementation of a circular economy and drive research and innovation. Different substitution options include for example switching to a less hazardous chemical, using an alternative technique or creating a different product design. According to ECHA and several stakeholders interviewed in the context of this study, companies in the EU are increasingly substituting hazardous chemicals and manufacturing processes with safer chemicals and greener technologies[25]. However, the use of alternative substances and other substitution options are not always straightforward.

Box 1: Best practice – reducing microplastic emissions from textiles

An example of best practice to reduce or avoid the release of microfibres from textiles is based on a combination of ecodesign principles, consumer information and end-of-pipe treatment. This practice, which is seeing increased uptake across the textile industry, incorporates the use of more **natural textiles** such as wool and cotton, which can shed little to no microplastic particles (depending on the overall textile composition of the garment) during wash compared to synthetic based or low-quality textiles. Natural fibres are biodegradable and do not accumulate in the environment compared to synthetic materials, in particular nylon and polyester. Moreover, wool is easy-to-recycle and easier to maintain, as it requires less frequent washings, less detergents or conditioners and at lower temperatures.

Despite the benefits of natural fibres, it is important to note that certain chemicals used to dye and treat cotton or wool can increase the eco-toxicity of natural fibres. Other solutions that are being considered include the development of **improved filters** in washing machines to reduce the amount the microfibers entering laundry effluent and **educating consumers** (households and businesses) about how to change their consumption patterns to extend the life of garment and reduce washing frequency.

Substitutes should not only respond to client demands or legal requirements but also maintain technical performance, improve the environmental footprint of products or manufacturing processes and reduce the overall risks to human health and the environment. As such, finding suitable alternatives and testing them can be a lengthy and expensive process. For example, methods that work in one sector or company may not work for all, implying that several alternative solutions may need to be tested before the best option is identified. Wider effects such as energy and resource use, waste, recycling or social impact should also be considered. Another important element to consider in substitution is the impact on the final price of the product – producers may find suitable substitution options that reduce the potential risks caused by the substances used, but at a higher price. Such costs have so far been unquantifiable and most likely vary from one

[25] ECHA website on « Substitution to safer chemicals ». Accessible at: https://echa.europa.eu/substitution-to-safer-chemicals

substance to another. Nonetheless, there are cases where substitution has improved production efficiency, increased competitive advantage and saved overall costs[25].

6.2.1 End-of-pipe solutions

In the context of water services, end-of-pipe solutions refers to water treatment processes that aim to improve the quality of water through the removal or reduction of contaminants in order to be used for its desired end-use. End uses can include drinking, industrial water supply, irrigation, water recreation, river flow maintenance, including being safely returned to the environment. End-of-pipe solutions are therefore opposite to control-at-source measures and usually constitute the last step (and oftentimes additional treatment steps) for drinking and waste water plants to achieve relevant quality standards e.g. Drinking Water Directive, Urban Waste Water Directive.

In the case of drinking water, treatment involves the removal of contaminants from raw water sources to produce water that is pure enough for human consumption without any short term or long term risk of any adverse health effect. Substances that are removed during the process of drinking water treatment include suspended solids, bacteria, algae, viruses, fungi, and minerals such as iron and manganese. The processes involved in removing substances include physical processes e.g. settling and filtration, chemical processes e.g. disinfection and coagulation and biological processes e.g. slow sand filtration. For wastewater, treatment refers to the processes that remove contaminants from wastewater or sewage, producing both liquid effluent suitable for disposal to the natural environment and sludge.

As described previously in section 4.2, conventional drinking and wastewater treatment plants are not specifically designed to treat new and persistent substances. The **additional treatment steps** required to tackle micropollutants and microplastics in drinking water production and wastewater often entail the use of **advanced treatments**. Advanced treatment can be loosely categorised under four different methods: physical, oxidative, biological and adsorptive (Figure 8). However, the use and operation of advanced treatment technologies entail high costs and can result in increased energy and chemical consumption, representing significant investments for drinking and waste water treatment plants. In addition to high costs of advanced water treatment technologies, there are also important **technical limitations** that merit consideration:

- **Increased energy demand and costs:** According to the Swedish Environment Protection Agency, the advanced treatment technologies and technology combinations assessed in their study will result in increased energy use and therefore emissions during energy production. This is particularly the case for ozonation and ultrafiltration (UF) technologies (SEPA, 2017). The additional electricity consumption for operating these technologies is estimated to be between 0.01 and 0.55 kWh/m^3 depending on the technology. In the example of Switzerland presented above, additional treatment processes will result in increased energy consumption of between 5 and 30 %, which will increase total national consumption of electricity is by 0.1 % (Eggen, 2014).
- **Use of harmful chemicals**: Some treatment technologies such as oxidative treatments require chemicals that can cause negative environmental impact during production and use and a risk of forming new potentially toxic contaminants (SEPA, 2017).

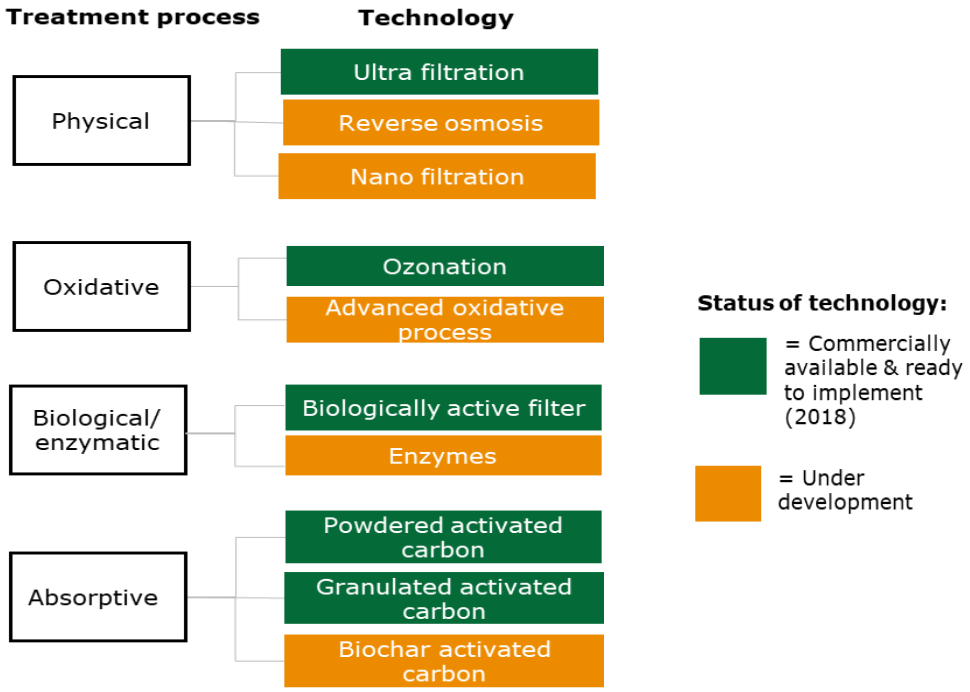
- **Need for increased training and skills**: additional competence requirements (and associated labour costs) may be needed in order to operate and monitor certain advanced treatment technologies, particularly for smaller treatment plants.
- **Generation of by-products/ transformation products with potentially adverse effects**: Some advanced water treatment processes can generate by-products such as bromate, from parent compounds (transformation products) of often-unknown chemical structure, fate and toxicity. For example, several studies have shown that wastewater treatment by ozone in particular may result in a selection of antibiotic resistance genes (ARGs) in effluent (Klaus, 2019, Lüddeke, 2015; Moreira, 2016; Alexandera, 2016; Czekalski, 2016). This makes it extremely challenging to use such treated effluents for drinking water purposes or for (waste) water reuse e.g. irrigation of agricultural land as such compounds can reach groundwater and contaminate clean water resources. To be noted that ozonation and powdered activated carbon treatment are systematically used for drinking water treatment.
- **Higher space requirements and sludge production** for treatment technologies such as powder activated carbon (Poyroy, 2016), which usually require multiple tanks and pumping systems.
- **Reduced sludge quality and circular economy options** (see section 4.2.2)
- **CSO:** Combined sewer overflows contain untreated or partially treated human and industrial waste, toxic materials, and debris as well as storm water and can represent an importance source of micropollutant emissions in wastewater (see chapter 5). During periods of particularly heavy rainfall or snowmelt (referred to as wet weather conditions), CSO can further effect the efficiency of WWTPs as the wastewater volume in a combined sewer system can exceed the capacity of WWTPs. Increased flows at wastewater treatment facilities create operational challenges, potentially affecting treatment efficiency, reliability, and control of treatment units at these facilities.[26]
- **Varying removal efficiencies:** the efficiency rates of different advanced water treatment technologies vary greatly depending on the technology, the way in which the technique is implemented and the substance targeted. For example, according to Mulder (2015), depending on the substance and treatment technology used, the rate of removal can vary anywhere between 30-50% to more than 80%. The SEPA (2017) study found that none of the advanced treatment technologies studied (Figure 9) applied individually can achieve a complete removal (>90%) of certain pharmaceutical residues and contaminants. The study concludes that only a combination of different technologies that use various treatment mechanisms can ensure an almost complete removal of pharmaceutical substances from wastewater. Regarding microplastics in particular, some studies show that removal by conventional primary and secondary wastewater treatment technologies are relatively effective – up to 99% removal rate (IVL, 2014), however due to the large volumes of wastewater processed daily, a large WWTP could still release approximately 900 000 to 3 600 million microplastics per day to aquatic environments (Horton, 2017).

Figure 8 provides an overview of existing advanced water treatment technologies and Box 2 summarises removal efficiency rates identified through various literature sources. It

[26] US EPA website on CSO: www.epa.gov/npdes/combined-sewer-overflows-csos

should be noted the varying removal efficiencies from published literature reflect the wide variety of definitions, calculation/ modelling methodologies, assumptions and approximations that different authors adopt and make, highlighting the importance of referring to original sources to avoid misinterpretations.

Figure 8: Overview of advanced treatment technologies[27]



Box 2: Examples of removal efficiencies by technology and substance

During **powdered activated carbon** (PAC) treatment processes, powdered activated carbon is added to an anaerobic or aerobic treatment system, which adsorbs recalcitrant compounds that are not readily biodegradable, thereby reducing the chemical oxygen demand of the wastewater and removing toxins. According to Besnault (2014), PAC had the following elimination efficiency rates:

- > 85% for urea-based pesticides and triazine
- Partial removal efficiency that decreases with time for polycyclic aromatic hydrocarbons (PAHs)

[27] Figure adapted from the SEPA, 2017 study

- 30 to 70% for alkyphenol (a compound used in the manufacturing of a variety of products from detergents and fuel additives to fire retardants and pesticides.
- > 99% for beta blockers
- > 73% for antibiotics

Ozonation (O_3) is an oxidative treatment in which different substances are oxidized with ozone. The ozonation process eliminates a range of organic and inorganic matter, bacteria and substances. The elimination efficiency rates are (Besnault 2014):

- > 55% for urea-based pesticides and triazine
- > 67% for aminomethylphosphonic acid (main metabolite of glyphosate)
- > 90% for polycyclic aromatic hydrocarbons
- 70 to 90% for alkyphenol (a compound used in)
- > 98% for beta blockers
- > 72% for antibiotics

In the city of Cracow, Poland, a project was launched to assess the effectiveness of existing waste water treatment technology relating to new contaminants. Some substances have been measured: Salicylic acid, aspirin, ibuprofen, caffeine, bisphenol A, diclofenac, carbamazepine, naproxen, ketoprofen, paracetamol, triclosan, bezafibrate, trifluoroacetic acid, propranolol, metoprolol. The range of concentration of these substances in waste water is [0.25 – 12.8] µg/ L while the range of concentration in treated waste water is [0.31 – 2.9] µg/ L. The highest concentration is for carbamazepine and diclofenac. In this case, removal of these substances from waste water is the most problematic.

Despite the considerable technological advances observed in water treatment solutions, which are more effective at treating newer or more persistent water pollutants compared to conventional treatment, they also come with important limitations that must be taken into account when considering potential reduction and mitigation measures. Stand-alone advanced treatment techniques are not able to completely remove substances found in effluents. Further, the diversity of already existing chemicals, the usage of old and new chemicals, the potential effects when certain substances are mixed together, as well as their anticipated increase presents a significant challenge as technologies may not be developed as quickly as needed to address them (Kümmerer, 2019).

End of pipe solutions by way of advanced water treatment technologies do not constitute a viable long-term solution to addressing increasing demographic and environmental pressures that can jeopardise access to sufficient quantity and adequate quality of water resources. The key challenges to consider therefore include not only ensuring that regulations are in place, but also that they are able to keep up with technological evolutions that result in the use of new substances and consequently new pollutants. In addition to regulatory factors, it is also essential that all actors, but in particular manufacturers, bear responsibility to ensure effective end-of-life management of products that release pollutants into the aquatic environment.

6.3 National level and industry-led initiatives

Examples of national, international and sector specific initiatives can provide additional insights on how the micropollutants and microplastics challenge is being addressed and whether there are lessons learned and best practices that can be considered in the application of a potential EPR scheme at EU level.

6.3.1 National legislation

Several EU Member States have initiated policies at national level to further address the release and presence of micropollutants and microplastics.

Germany: As part of the on-going work to establish the Trace Substance Strategy of the Federal Government, a multi-stakeholder dialogue was held including industry, environmental non-governmental organisations, drinking water suppliers, operators of waste water treatment plants, public authorities and Federal State representatives, etc. The purpose of the strategy is to prevent and reduce inputs of trace substances to the aquatic environment from biocides, human and veterinary pharmaceuticals, plant protection products, industrial chemicals, detergents and personal care products. A key result of the multi-stakeholder dialogue was the elaboration of 14 source-related, user-related and end-of-pipe related recommendations covering issues such as producer responsibility, communication of potential hazards, sector-specific agreements on imported products and closing knowledge gaps. The proposed recommendations are to be further concretised in a follow-on phase (UBA, 2017).

France: France aims to reduce at source, the transfer of micropollutants to aquatic environments through the government launched the "National plan against micropollutants 2016-2021" (Ministère de la Transition écologique et solidaire, 2016). The strategy consists of a comprehensive program to protect and preserve water quality and biodiversity through the achievement of 3 main objectives: (1) reduce as of now micropollutants emissions that end up in aquatic environments, whose relevance is known, (2) consolidate knowledge to adapt the fight against water pollution and preserve biodiversity, (3) Identify the priority pollutants where reduction actions are most needed. Furthermore, approximately 13 pilot projects have been launched over a four-year period (2014 - 2018) covering topics such as the emissions of hazardous substances from pharmaceutical residues and cosmetics, hospital waste discharges, integrated micropollutant management in communal sanitation networks, and storm water management solutions.

The Netherlands: In early 2016, a small team led by the Ministry of Infrastructure and Water Management as well as representatives from regional water authorities, drinking water companies, the Ministry of Health and the Ministry of Agriculture, started work on a "pharmaceutical chain approach". The pharmaceutical chain approach is a multi-stakeholder programme based on the following objectives:

1. Form a small project team with each stakeholder represented;
2. Detailed mapping of the entire pharmaceutical chain and the stakeholders concerned;
3. Agree on the 'rules of the game' (prerequisites for action);
4. Explore possible actions; and
5. Choose promising measures for the establishment of an implementation plan.[28]

By the end of 2016, a set of 17 possible measures to reduce or mitigate the impacts of pharmaceutical residues in water had been identified for further investigation. Each of the measures evaluated and proposed target one of three intervention steps of the

[28]Based on an excerpt from a case study for a paper prepared for the OECD workshop on Contaminants of Emerging Concern in 2018. Accessible at: https://zoek.officielebekendmakingen.nl/blg-834486.pdf

pharmaceutical chain. These steps for intervention are clustered as 'development and authorisation', 'prescription and use', and 'waste and sewage treatment'. Table 8 below lists some of the relevant measures that were developed.

A key challenge that was highlighted from this exercise is the capacity to take measures to the next level of implementation as well as retain the attention, energy and enthusiasm that all stakeholders have expressed so far. Currently, the measures are being further developed, notably through an assessment of the overall costs and benefits and effectiveness of individual measures.

Table 8: Examples of measures developed under the Netherlands' pharmaceutical chain approach[28]

Intervention point	Possible measure	Sector responsible
Environmental impacts	Identify pharmaceuticals that have negative environmental effects	Water authorities, drinking water sector
Development/ authorisation	• Development of 'green medicines' that have less environmental impact • Access to (environmental) data on active ingredients	Pharmaceutical companies, research institutions, authorising agencies, international authorities
Waste & sewage treatment	• Development of improved treatment of sewage at STP's, including overview of existing innovative treatment and overview of costs • Identify STP's with highest impact on aquatic ecology and drinking water sources	Water authorities, research institutions
Cross cutting issues	• Learn from the best practices abroad • Put issue on international agenda (e.g. river basin commissions of Rhine and Meuse, European Commission, etc.)	Ministry of Water Management

Switzerland: In 2016, following the precautionary principle, the Swiss government was one of the first to impose national legal requirements for reducing micropollutants in effluents from WWTPs, through an amendment of the Waters Protection Act to establish the new Water Protection Ordinance (WPO). The WPO requires certain municipal sewage treatment plants to take the necessary steps (upgrades) to eliminate at a minimum 80% of selected trace substances. WWTPs targeted for the upgrades include those that serve:

- ≥ 80 000 connected residents (for load reduction)
- ≥ 24 000 connected residents in the catchment area of lakes (for drinking water protection)
- ≥ 8 000 connected residents that discharge into a watercourse containing more than 10 % waste water
- ≥ 8 000 connected residents, if the removal is required due to special hydrogeological conditions

Approximately 100 out of 650 WWTPs are concerned by the new legislation in Switzerland. Upgrades to WWTPs are funded through a waste water charge, which is based on the following (see also section 4.2.1):

- 75% of the investment provided through the national budget:
    - Municipalities pay 9 CHF (7.9 €)/person/year into the fund
    - Municipalities with upgraded WWTPs are exempted
    - Only direct costs for upgrading for micropollutant removal covered (nutrient removal not covered)
    - Financing starts in 2016 and ends in 2040

- 25% of the investment + operation costs covered by the municipalities[29]

6.3.2 Research & funding initiatives

In addition to national measures at MS level, there are several examples of research projects (e.g. EU level research projects: COHIBA[30], RiSKWa[31], OgRe[32]) and funds dedicated to micropollution of waters and the necessity of reduction measures:

- **Sweden:** The Agency for Marine and Water Management received 32 million kronor (3 million €) in funding over a 4-year period (2014–2018), which was awarded to eight projects that promote advanced wastewater treatment with the aim to reduce discharges of pharmaceutical residues and other micropollutants that cannot be removed in the treatment plants' current processes (SEPA, 2017)
- **Denmark:** Denmark funds the Bonus CleanWater research project, which focuses on reducing the input of micropollutants and microplastic into the Baltic Sea by exploring, developing and comparing new eco-technological approaches[33].
- **German:** The German Environment Agency (Umweltbundesamt, UBA) has commissioned a number of research projects at the national level. A number of German federal states such as North Rhine Westphalia and Baden-Württemberg, are also working on solutions, through for example the establishment of competence centres (UBA, 2018).

6.3.3 Industry-led initiatives

To achieve corporate social responsibility objectives and anticipate environmental, demographic, regulatory and economic pressures, many companies have launched and/ or participate in industry-based voluntary initiatives that cover topics such as the sustainable use of substances, circular economy principles including cleaner production practices, etc. to reduce the environmental impacts of their activities. Among the numerous voluntary industry initiatives that exist, a few non-exhaustive examples include:

- **The Raw Water Database on Plant Protection Products (RWD PPP)**: is a joint initiative established in 2012 by the German Technical and Scientific Association for Gas and Water (DVGW), Industrieverband Agrar (IVA), the German Association of Energy and Water Industries (BDEW) and the German Association of Drinking Water Utilities (VKU). Several major pesticides producers including Bayer, BASF, and Monsanto are participants of the programme. The objectives of the collaboration are:
    - To promote the preventive protection of water in the further development and use of plant protection products for sustainable agricultural practices.

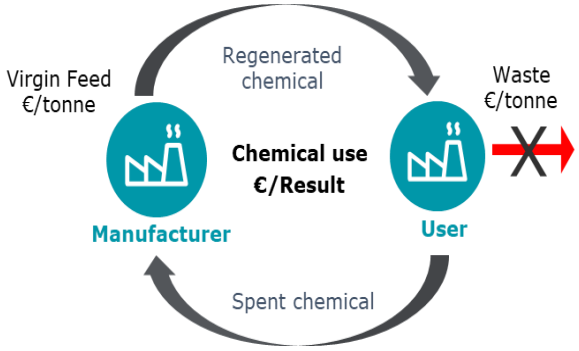
[29]Joss, Adriano (Eawag), Keynote presentation on "Micropollutants: the Swiss strategy". Accessible at: www.water2020.eu/sites/default/files/keynote_adriano_joss_eawag_switzerland.pdf
[30] www.helcom.fi/helcom-at-work/projects/completed-projects/cohiba
[31]www.researchgate.net/publication/257885065_SchussenAktivplus_Reduction_of_micropollutants_and_of_potentially_pathogenic_bacteria_for_further_water_quality_improvement_of_the_river_Schussen_a_tributary_of_Lake_Constance_Germany
[32] www.kompetenz-wasser.de/en/project/ogre-relevanz-organischer-spurenstoffe-im-regenwasserabfluss-berlins
[33] http://envs.au.dk/en/current/news/artikel/bonus-cleanwater-innovative-research-on-water-technology-to-remove-micropollutants-and-microplastic/

- To encourage the mutual exchange of information and discussion of the problems faced by both sides and develop options for joint actions oriented towards water protection for the use of plant protection products.

The RWD PPP is the first ever national systematic compilation and analysis of PPP raw water data. Data on pesticides (active substances, metabolites) is systematically collected and monitored to identify potential 'hot spots' of contaminated drinking water resources. In the case of contaminated sites, possible solutions are discussed amongst all stakeholders (including the respective pesticides producer, water utility, farmers and water authorities) to ensure that the water resource can be used again for drinking water production purposes. The involvement of the pesticides industry ranges from financing, monitoring of specific water catchment areas, feasibility studies and recommendations for the use of alternative pesticides to farmers. Despite the active participation of the different stakeholder groups involved, certain limitations of the initiative include the time and resource consuming process of collecting, monitoring and assessing data and the need for the involvement of all actors concerned in order to resolve individual contamination cases.

- **Take Back Chemicals:** is a business model based on circular economy principles that was launched by the chemicals industry. The Take Back Chemicals business model aims at closing material cycles for chemical related industries by increasing the value and therefore efficiency of specific chemical substances. To do this, the model is based on a « chemicals leasing » system where the supplier of a particular material or substance is paid for the service delivered rather than the amount of substance used, and the type of payment changes from a traditional volume-driven pricing (€/tonne chemical supplied) to a results-driven, measurable metric pricing system (e.g. €/tonne treated product) (Figure 9). The supplier retains ownership of the material it supplies, and takes it back after use. The ultimate result is that the material is 'leased' to the customer. The model aims to incentivise both suppliers and users (manufacturers) to continuously increase the efficiency of chemical substances use. A study was carried out on the feasibility and applicability of the Take Back Chemicals model in the Netherlands and Belgium in several sectors including textiles, salts, plastics and pharmaceuticals[34].

Figure 9: "Take Back Chemicals" economic model[34]



[34] Adapted from the report: Take Back Chemicals, 2017, Business Incentives of Chemical leasing, Case-based learnings for the Netherlands, White Paper, and 1 March 2017.

- **Global Organic Textile Standard (GOTS)**[35]: GOTS is an international textile processing standard for organic fibres established in 2006. The objective of the standard is to establish globally-recognised requirements that ensure the organic status of textiles, covering the processing, manufacturing, packaging, labelling, trading and distribution of all textiles made from at least 70% certified organic natural fibres.
- **Zero discharge of hazardous chemicals (ZDHC) Programme**[36]: The ZDHC Programme was launched in 2011 by six textile brands to promote best practices in the discharge of hazardous chemicals across the textile and footwear product life cycle. The fundamental principles of the programme include: transparency, fact-based decision making and integrated approaches to chemicals management. Currently, the programme involves the collaboration of 27 signatory brands, 77 value chain affiliates, and 18 associates that are working together on the following areas: Manufacturing Restricted Substances List (MRSL) & Conformity Guidance, Wastewater Quality, Audit Protocol, Research, Data and Disclosure, and Training. In particular, the MRSL includes a list of chemical substances (e.g. alkylphenol, chlorobenzenes and chlorotoluenes, , dyes, flame retardants, halogenated solvents, organotin compounds, polycyclic aromatic hydrocarbons, perfluorinated and polyfluorinated chemicals, phthalates, etc.) banned from intentional use in facilities that process textile materials in apparel and footwear. The ZDHC MRSL establishes acceptable concentration limits for substances in chemical formulations used within manufacturing facilities that are designed to eliminate the possibility of intentional use of listed substances[37].
- **The Tire Industry Project (TIP)**: The Tire Industry Project was established in 2005 under the umbrella of the World Business Council for Sustainable Development (WBCSD). It represents the primary global forum for the tire industry on sustainability issues. This voluntary initiative is currently comprised of 11 major tyre manufacturing companies, accounting for approximately 65% of the world's tire manufacturing capacity.[38] TIP aims to proactively identify and address the potential human health and environmental impacts associated with the life cycle impacts of tires in order to proactively contribute to a more sustainable future. The European Tyre & Rubber Manufacturers' Association (ETRMA) is currently carrying out a study on the fate and possible effects of tire and road wear particles generated during tire use. The research project is based on the work produced by the TIP, which according to ERTM is "supported by an independent scientific advisory board, which has validated its approach and protocol".[39] ETRMA intends to use the results of the study as part of a larger European Commission investigation into options for reducing releases in the aquatic environment of microplastics.

[35] www.global-standard.org
[36] www.roadmaptozero.com
[37] ZDHC, 2015. Joint Roadmap Update. Available at: www.roadmaptozero.com/fileadmin/layout/media/downloads/en/JointRoadmapUpdate_FINAL.pdf
[38] WBCSD website on the Tire Industry Project, Accessible at: www.wbcsd.org/Sector-Projects/Tire-Industry-Project
[39] www.rubbernews.com/article/20170410/NEWS/170419993/etrma-to-study-environmental-impact-of-tire-particles

Despite the many voluntary initiatives launched by industry, the **voluntary nature** of these collaborations may not be sufficient to tackle the still very present problem of micropollutants and microplastics in the aquatic environment, particularly in terms of engaging the participation of major industries (and polluters) and addressing the problem of free-riders. Further, according to a recent OECD report, due to public budget constraints and a lack of environmental regulations on diffuse pollution, other measures such as subsidy-based programmes can have limited impact (OECD, 2017).

7. Potential of extended producer responsibility

Extended producer responsibility presents significant opportunities to address the serious challenges of micropollutants and microplastics emitted into the aquatic environment.

Increasing demand and the acceleration of the renewal of post-consumer products is resulting in a significant increase in post-consumer waste, posing serious risks and concerns regarding their end-of-life. The burden and risk that remain at the end of a product's life suggest a need for policy measures to help align the experiences of different actors throughout a product's lifecycle with the social and environmental costs that they incur.

Among the possible policy approaches, extended producer responsibility (EPR) gained momentum in the 1990s and has since been applied in various sectors throughout the world. The Organisation for Economic Co-operation and Development (OECD) defines extended producer responsibility as a 'policy approach under which producers are given a significant responsibility – financial and/or physical – for the treatment or disposal of post-consumer products. Assigning such responsibility could in principle provide incentives to prevent wastes at the source, promote product design for the environment and support the achievement of public recycling and materials management goals.'[40]

EPR is therefore an approach that recognises the producers' distinct responsibility for the products they place on the market, which extends beyond the production and consumption stage to its end-of-life stage. For example, through EPR policies, the producer takes on the costs of ensuring safe end-of-life waste disposal. In this way, EPR can be expected to help relieve the public of some of the costs of waste disposal, and supports the consideration of social and environmental impacts that a product may incur.

The principles of EPR can be widely interpreted depending on the value chain of the product and the type of waste generated (especially when it is not imposed by existing legislation e.g. the End of life vehicles Directive, Batteries Directive, Waste Electrical and Electronic Equipment Directive, Packaging and Packaging waste Directive). In general, EPR is when producers are given a significant responsibility – financial and/or physical, organisational – for the treatment or disposal of post-consumer products (e.g. waste). An important aspect of EPR is to **provide incentives for producers** to take into account environmental considerations along the products' life-cycle by improving product design, using alternative substances, etc. In other words, internalising costs to drive and incentivise greener design. Figure 11 summarises some of the principle policy instruments used to implement EPR.

[40] OECD website on EPR: www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm

There are numerous EPR schemes implemented in the EU and globally covering a wide range of products from end-of-life vehicles, used oils, used tyres, graphic paper and textile, medicines, fluorinated refrigerant fluids to agricultural films, mobile homes and furniture, etc.

According to the most recent EPR guidance published by the OECD in 2016 (updating the 2001 EPR Guidance report), small consumer electronic equipment accounts for more than one-third of EPR systems, followed by packaging and tyres (each 17%), end-of life vehicles, lead-acid batteries and a range of other products (Figure 10).

"About 400 EPR systems currently in operation. Nearly three-quarters were established since 2001. Legislation has been a major driver, and most EPRs appear to be mandatory rather than voluntary."

- OECD, 2016

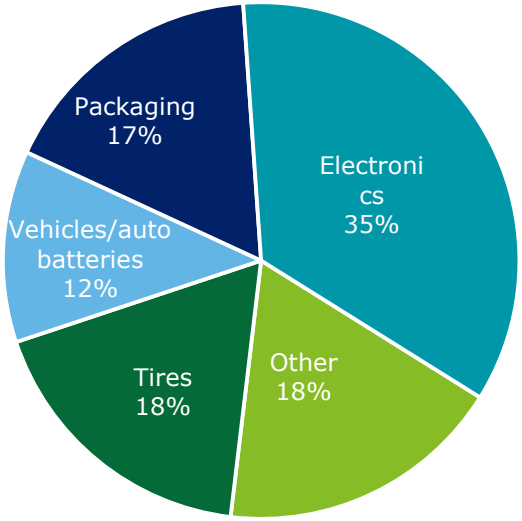


Figure 10: EPR schemes–product type, 2016[41]

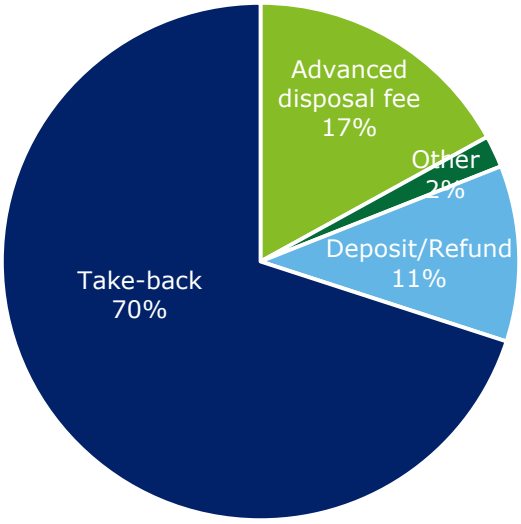


Figure 11: EPR by policy[41]

The recently adopted Directive on Single Use Plastics covers a range of products under Part E, Article 8 on extended producer responsibility[42]:

- **Food containers** i.e. receptacles such as boxes, with or without a cover, used to contain food that is intended for immediate consumption from the receptacle either on-the-spot or take-away without any further preparation, such as food containers used for fast food, except beverage containers, plates and packets and wrappers containing food
- **Packets and wrappers** made from flexible material containing food that is intended for immediate consumption from the packet or wrapper without any further preparation

[41] OECD, 2016, Improving EPR programs worldwide: the new OECD guidelines.
[42] https://eur-lex.europa.eu/resource.html?uri=cellar:fc5c74e0-6255-11e8-ab9c-01aa75ed71a1.0002.02/DOC_1&format=PDF

- **Beverage containers** i.e. receptacles used to contain liquid such as beverage bottles including their caps and lids
- **Cups for beverages,** including their caps and lids
- **Tobacco products with filters** and filters marketed for use in combination with tobacco products
- **Wet wipes** i.e. pre-wetted personal care, domestic and industrial wipes
- **Balloons,** except balloons for industrial or other professional uses and applications, that are not distributed to consumers
- **Lightweight plastic carrier bags** as defined in Article 3(1c) of Directive 94/62

In addition to the wide variety of products that are covered by existing EPR schemes, EPR can also be applied using different approaches and policy instruments. They can be voluntary or mandatory, with the possibility of individual or collective organisation schemes. Regarding financial instruments in particular, different types of financial mechanisms can be used for cost recovery, including for example advance disposal fees (ADF), take-back requirements, product taxes and charges, etc. (Figure 11).

7.1 The potential of EPR to address the challenges posed by micropollutants and microplastics

As demonstrated in the previous chapter, there are many limitations and loopholes in the existing regulatory and voluntary measures to reduce or avoid the emission of micropollutants and microplastics into the aquatic environment. Products containing potentially hazardous substances continue to be placed on the marketed and humans and other living organisms will continue to be exposed to their potentially harmful effects. Further action is therefore needed to ensure that all key players are actively involved towards a common goal; as such the principles of EPR can serve as the basis for a potential solution to the problem.

7.1.1 Contributions to meeting EU environmental and human health objectives

A particularity of the current situation in Europe of micropollutants and microplastics is the **cross-sectoral** scope and the **transboundary nature of substances** and water bodies. Chemicals cross national borders via the import and export of products, as well as transported throughout the environment through moving air and water masses. As such, **application of EPR at the EU-level** would be more effective compared to the national-level in terms of being able to fully address the scale of the micropollution problem. This reflects the principles of subsidiarity and proportionality as enshrined in Article 5(3) of the Treaty on European Union (TEU) and Protocol (No 2), which seeks to safeguard the ability of the Member States to take decisions and action and authorises intervention by the Union **when the objectives of an action cannot be sufficiently achieved by the Member States, but can be better achieved at Union level**, 'by reason of the scale and effects of the proposed action'. The Commission for example, demonstrates the subsidiarity principle to justify EU action for each of its legislative proposals through impact assessments. Some of the principle questions used in the Commission's impact assessment guidelines to assess subsidiarity (and proportionality) include:

- Why can the objective not be sufficiently achieved by Member States?

- Why would EU-level action better achieve the objective?
- Does the issue being addressed have transnational aspects which cannot be dealt with satisfactorily by action by Member States?
- Would action at Community level produce clear benefits compared with action at the level of Member States by reason of its scale and by reason of its effectiveness?

Based on the responses to the questions above, it appears clear that the environmental, economic and human health implications of the micropollution and microplastics problem in Europe would clearly call for action at EU level. In existing legislations such as the UWWTD, for example, this aspect is clearly reflected in the text of the directive, "*Whereas pollution due to insufficient treatment of waste water in one Member State often influences other Member States' waters; whereas in accordance with Article 130r, action at Community level is necessary*."

In addition, application of EPR at EU level would also contribute to addressing the issue of **free riders** – a challenge that existing voluntary and national measures face in terms of ensuring that all relevant actors are involved and collectively responsible for the efforts needed to address the micropollution problem. As it stands, certain industries have no incentive to improve product design or find alternative substances and users are not necessarily aware of the environmental impact their behaviours have ("licence to pollute").

Due to the cross-sectoral and transnational nature of micropollutant emissions, there are limits to the extent that voluntary initiatives or even national legislations can address the geographic and economic scale of the situation. Further, an EPR scheme at EU level would enable increased transparency, harmonisation and coherence of practices across Europe, which could ultimately contribute to creating a fairer and even playing field within the Single Market.

7.1.2 EPR as a financial mechanism to incentivise best practices

A key component of EPR is ensuring the financial responsibility of product manufacturers for the remedial actions along the supply chain, which could addresses pollutants stemming from different phases of the product's life cycle. EPR provides incentives to producers to implement more efficient and sustainable product-design and manufacturing practices that have less environmental and human health impacts. This is a fundamental element of closed-loop economies and the transition towards a circular economy, which EPR encourages through the use of more environmentally-friendly materials and products that can be recovered and re-introduced in the economy.

"**Plastic waste prevention should be the first priority**. We must start by limiting the use of plastic products and by setting compulsory eco-product design criteria. We need less and better plastics. We must remove existing subsidies on fossil fuels and barriers to a single market for secondary raw materials. Both make virgin plastics cheaper than recycled or bio-based plastics and obstruct the development of a circular economy for plastics."

- André Van de Nadort
Mayor of Weststellingwerf, Netherlands

An important element of the EU's Water Framework Directive is Article 9(1), which introduces the principle of **cost recovery** for water services in accordance with the **polluter pays principle (PPP)**. Article 9 of the WFD establishes that:

- Water prices must allow for the (adequate) cost recovery of water services, including environmental and resource costs;
- The main water uses (households, industry and agriculture) must adequately contribute to the recovery of costs of water services, proportionally to their contributions to the pressures imposed on aquatic ecosystems in line with the PPP;
- Water pricing policies must 'provide adequate incentives for users to use water resources efficiently and thereby contribute to environmental objectives.

However, the application of the above principles into real water pricing policies applied in EU Member States remains unclear and the WFD does not stipulate the use of a particular approach for assessing financial, environmental and resource costs (EEA, 2013). The approaches and calculation methods for internalising external (environmental and resource) costs, including the lifetime of investments, discount rates and costing methods, which have a direct impact on the assessment of financial cost recovery rate into water pricing remain a subject of debate (Entec, 2010).

It is therefore necessary to determine how current pricing and other financial mechanisms are applied in EU MS in relation to the meeting of environmental objectives and the requirements of the WFD regarding cost recovery, the PPP and incentives. In particular, how such costs are calculated and recovered and whether they reflect the real costs related to the investments, maintenance, infrastructure and upgrades needed to ensure a minimum level of water quality. In some cases, consumers and the water services sector are currently bearing the increased water treatment costs associated with the presence of micropollutants and microplastics in the aquatic environment – rather than industry or agriculture. In this context, EPR could provide the basis for setting an appropriate financing mechanism for water pricing in accordance with the polluter pays principle by ensuring that producers are also held financially accountable and responsible – to promote more efficient and fair water resource management.

Measures within an ERP scheme can cover a wide range of costs; for example, the costs for additional treatment of drinking or waste water, awareness raising measures, product labelling, remedial and restoration of contaminated water resources, monitoring of water resources, etc. Most importantly, extended producer responsibility schemes should take into account the full cost coverage of the end of life of products, which would hold producers accountable for costs such as separate collection, sorting and treatment operations, waste disposal, litter cleaning and transport of waste. A targeted and effective use of financing instruments within an EPR approach could provide incentives that could have both short-term effects (such as substitution of micropollutants or relevant products with already available alternatives) and medium to long-term effects (such as research and development of new environmentally friendly approaches or substitutes). For example, an EPR approach that incorporates an incentive system that applies a flat wastewater charge for discharging micropollutants but which offers the possibility of exemption and/ or reduction if certain efficiencies or targets are reached or which offers the opportunity to offset potential investment costs. By holding producers responsible for the full costs caused

by their products, companies will be incentivised to design products that can be more easily recycled or prepared for reuse or less costly to treat at its end-of-life.

As such, an EPR scheme can contribute towards the reduction and shift of financial and physical responsibility for treating difficult-to-treat drinking or waste water from local authorities and public utility services (and citizens' in regards to their water bills) to producers. With this in mind, however, one of the most important aspects to consider when evaluating the re-distribution of financial burden, is on the one hand, the **polluter-pays principle** and, on the other hand, **a fair and just distribution of costs between producers, the water sector and citizens**. This is because the decision of who shall bear the costs not only determines who has to contribute to a measure and how much, but also has significant effects that could lead directly and indirectly to further reduction of pollution. In all cases, cost recovery as stipulated by Article 9(1) of the WFD – whether it is established within an EPR scheme or not – should not result in a situation where industry is not held financially responsible and only citizens, public authorities and the water sector bear the costs.

7.2 Applicability of EPR approach on products releasing micropollutants and microplastics

Notwithstanding the significant opportunities that EPR could offer, several aspects should be considered to ensure its **effective and feasible application**. In addition to the need for a **clear legislative framework** at EU level (see Module 2 report), it is important to emphasise that the overall feasibility and effectiveness of an EPR scheme can greatly differ depending on its scope, level of implementation (voluntary versus mandatory) and governance (including financial and operating mechanisms). Some of the major challenges to overcome for an effective EPR approach on products that release micropollutants and microplastics are described in the following paragraphs.

7.2.1 Lack of a sufficient knowledge base

Extended producer responsibility is an important tool in waste legislation because it focuses on the end-of-use treatment of consumer products, with the aim of increasing the amount and degree of product recovery and to minimize the environmental impact of waste materials. This is an essential component in any EPR scheme in terms of the scope and coverage of the products (and waste streams) targeted. It is necessary to be able to link the generated waste directly to the product produced or consumed in order to establish an appropriate cost recovery and operating system. However, this is not always straight-forward as:

- The amount of waste delivered is sufficiently linked to the amount of product supplied, i.e. there are few leaks/additions from upstream to downstream; and
- A given product can be linked to a given (homogeneous) waste stream, i.e. amounts can be tracked from upstream to downstream.

For the purposes of this study, under a potential EPR scheme, we assume that the waste streams targeted are the micropollutants and microplastics released in the aquatic environment through different pathways including the sewer network and that the products responsible for their release are those evaluated (pharmaceuticals, pesticides, antibacterial products containing biocides, flame resistant products containing PFASs, textiles and

tyres). One of the key obstacles, which has been reflected in literature, existing legislation as well as in stakeholder feedback, is the general lack of knowledge and data on where, why and in which products chemicals are used and on which pathways they are released to the aquatic cycle. This issue prevents an accurate **traceability** of certain hazardous substances back to a specific sector; and going further to a specific producer. Several factors make it difficult to ensure a more robust traceability of such substances:

Although we have a generally good understanding of the main products groups responsible for the presence of micropollutants and microplastics in inland waters, their effects on complex aquatic ecosystems is currently poorly understood. They usually occur in low concentrations, in changing mixtures and are a part of multiple other stressors (e.g. changes in UV or light intensities, temperature, pH, predators, etc.) present in the aquatic environment that can effect organisms in natural ecosystems. This makes it difficult to pinpoint all the potentially hazardous substances (of which there are potentially thousands to consider) present in the aquatic environment that should be targeted.

Furthermore, the diffuse nature of how micropollutants and microplastics end up in the aquatic environment means there are multiple emission sources and entry pathways through which they are discharged and released. Likewise, the level of concentration and characteristics of micropollutants and microplastics vary across different water bodies in EU due to factors such as location of the WWTPs, proximity of urban areas and industrial and agricultural sites, etc. Finally, at EU level, a harmonised and comprehensive list on the production numbers, use, emissions, toxicological properties, and environmental effects of micropollutants and microplastics is lacking.

Due to the absence of sufficient understanding and consensus on which substances should be regulated and at what concentrations, many potentially harmful substances found in wastewater effluents are not regulated by current legislation. The above points are often used as arguments, brought forth by certain stakeholder groups to oppose changes in regulations that would establish stricter control and monitoring measures. In this context, the EPR principles can be used as a driver for further research and monitoring activities that are needed in order to establish a consensual knowledge base concerning the traceability of waste streams and products. In this case, major industrial sectors could contribute for example to a collective dedicated fund that could be used to pay for EU wide data collection, monitoring and assessment related to targeted substances and the actors involved. An example of this is seen in the current initiative carried out in Germany on the RWD PPP mentioned in the previous chapter.

7.2.2 Stakeholder acceptance and willingness

Ensuring an adequate level of stakeholder support and willingness is essential in any functional EPR scheme, particularly for the establishment of an effective financing mechanism, which would require the collaboration/ financial contributions from producers. The lack of a general consensus means that many producers are either not aware, do not recognise their role and responsibility and consequently unlikely to accept a mandatory EPR scheme. Therefore, a key obstacle to overcome is raising the awareness of producers so that they are informed and clearly understand the importance of their engagement. One way to do this is to focus stakeholder discussions and information exchanges on concrete impacts and data highlighted in this report and in an increasing number of studies and

initiatives on how the presence of micropollutants effect drinking water and wastewater treatment requirements and costs as well as potential effects on human health and the environment.

7.2.3 Governance and operations

In order to enforce a level playing field, environmental standards and targets and maximum transparency, governance mechanisms (planning, decision making, monitoring and reviewing) involving relevant stakeholders (manufacturers, retailers, recyclers, experts etc.) as well as strong government involvement are key factors for a well-functioning EPR scheme. As such, it is important that operational aspects such as the composition and functions of the governing body, the waste collection and treatment system, reporting and monitoring, the cost recovery scheme and a clear legislative framework in the case of a mandatory EU level scheme are defined. Finally, Member State (national markets, employment, existing initiatives, etc.) and sector specificities (potential impacts on competition for certain industries, import of products into the EU, compliance with international trade, etc. are also important factors to consider. Recent developments such as the revision of the Waste Framework Directive and the Directive on Single-Use Plastics explicitly call for the application of extended producer responsibility, providing important insights and direction for its extension to the product categories assessed in this study.

Annex. Supporting information

8. Overview of applicable EU Legislation

Table 9: List of potential EU legislations to be assessed

Product category	Overview of relevant requirements
ALL PRODUCT CATEGORIES	
EU Treaty Art. 191.2	Art. 191.2: Environmental policies shall be based on the precautionary principle and on the principles that preventive action should be taken…environmental damage should as a priority be rectified at source and that the polluter should pay.
Groundwater Directive (GWD) 2006/118	Specifications for good groundwater chemical status; reversal of significant and sustained upward trends in concentrations of pollutants; environmental quality standards (EQS) for pesticides and parameters for threshold values. Measures for achieving/maintaining good water status and for preventing or limiting the input of pollutants
Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	For all substances > 10 tons/produced/year, REACH requires a chemical safety assessment (CSA) wherein producers have to provide toxicological and ecotoxicological data (Annex VII to X). The suppliers have to identify all the final uses of the substances (along the substance's life cycle), exposure scenarios and characterise the risks: • No urban water cycle risk assessment included in this assessment. • Some restriction only for SVHCs • No fees for these substances treatment in wastewater • Polymers are not covered by the REACH regulation
Directive 2000/60 (Water Framework Directive)	Recovery of costs for water services: Article 9.1 establishes water pricing based on the contribution of different water uses and taking into account the polluter pays principle. This could serve as a potential driver to integrate the cost recovery for all activities emitting micropollutants in water bodies. Priority substances: Article 16 on strategies against pollution of water established a list of priority substances, which was later replaced by the Directive on Environmental Quality Standard (EQSD) also known as the Priority Substances Directive. The EQSD, however, which set environmental quality standards (EQS) for the substances in surface waters does not cover the scope of all micropollutants (e.g. stemming from certain medicinal products and microplastics
Waste legislation: • EU Circular Economy package • Waste Framework Directive 2008/98	EU Circular Economy package includes numerous measures addressing product recycling and reuse, including rules to harmonize EPR systems to ensure consistent implementation between EU MS, consolidating and building upon experience gained over the last two decades. This package proposes to strengthen measures introduced under the EU's eco-design working plan covering reparability, durability, and recyclability and review of the EU Waste Framework Directive to address implementation of EPR as well as waste collection and recycling targets
PHARMACEUTICALS	
Directive 2001/83 on medicinal products for human use	The authorisation of human medicinal products requires testing for potential impacts on the environment. If a risk to the environment is identified, denial of authorisation is not possible; authorisation can be subjected to conditions for the protection of the environment.

Product category	Overview of relevant requirements
Regulation 726/2004 on authorisation and supervision of medicinal products	
PESTICIDES	
Directive 2009/128 on the sustainable use of pesticides	Aims to achieve a sustainable use of pesticides in the EU by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management (IPM) and of alternative approaches or techniques, such as non-chemical alternatives to pesticides. EU countries have drawn up National Action Plans to implement the range of actions set out in the Directive.
Regulation 1107/2009 concerning the placing of plant protection products (PPP) on the market	PPPs contain at least one approved active substance; these may include micro-organisms, pheromones and botanical extracts. Before any PPP can be placed on the market or used, it must be authorised in the EU country concerned. Regulation 1107/2009 lays down the rules and procedures for authorisation of PPPs.
BIOCIDES	
Regulation 528/2012 on biocidal products	Regulation concerning the making available on the market and use of biocidal products. The Annex II of this regulation contains some requirements for active substances and a list of experimentations which have to be performed before use in a biocidal products. These test include a biodegradation test in freshwater and toxicity to aquatic organisms.
TEXTILES	
REACH: substances used in articles produced in textile industry	For textiles produced in Europe, substances incorporated in the textiles, need to be registered. For imported (outside of the EU) textiles, importers need to notify ECHA if the textiles they import contain SVHC (substances of very high concern) in concentration above 0,1% (w/w) if the total annual volume in all products imported is greater than 1 tonne. Consumers also have the possibility to ask retailers if products contain SVHC in a concentration above 0,1%
EU Eco-label, (Commission Decision 2009/567)	Criteria have been developed for textiles: bed mattresses, textile floor coverings and footwear
Waste Framework Directive 2008/98	The Waste Framework Directive specifically refers to textiles. Besides defining the waste hierarchy i.e. prevention, preparation for reuse, recycling, energy recovery and disposal, the directive also calls for end of waste specific criteria for textiles to be developed.
Regulation 1007/2011 on textile fibre names and related marking of the fibre composition of textilles	Development of a label for fibre release from washing of clothing to be included under the Regulation for labelling and marking of the fibre composition of textile products.
TYRES	

Product category	Overview of relevant requirements
Regulation 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters (the Tyre Labelling Regulation - TLR),	Proposals for updating and improving the EU regulation for the labelling of tyres were published by the Commission in May 2018 within the broader package of measures on Low Carbon Mobility. Aimed at giving consumers more information on fuel efficiency, safety and noise when they buy tyres, the changes aim to ensure that labels provide accurate, relevant and comparable information on those aspects. • Inclusion of tyre tread abrasion rates • Development of a standard measure of tyre tread abrasion
Regulation 661/2009 concerning type-approval requirements for the general safety of motor vehicles	Amendment of the regulation to restrict the worst performing tyres (in respect of tyre tread abrasion) from the market (once a standard measure of tyre tread abrasion has been developed)

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STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Module 2 – Applicability of EU legislation for implementation of EPR

In Extenso
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Module 2: Applicability of EU legislation for implementation of EPR

FINAL REPORT

December 2019

EurEau

CONTENTS

Part I. Objectives, scope & methodology

1. Objectives and scope 8
2. Methodology 12

Part II. Assessment of horizontal EU legislation

3. Water Framework Directive 2000/60 17
4. REACH Regulation 661/2009 21
5. Urban waste water treatment Directive 91/271 29

Part III. Assessment of product-specific EU legislation

6. Pharmaceuticals 32
7. Pesticides 43
8. Biocides 54
9. Textiles 59
10. Tyres 67

Part IV. Analysis of options for the way forward

11. Policy options & comparative analysis 77
12. Analysis of policy options 81
13. Key findings of legislative assessment 87
14. Recommendations for the way forward 92

Annex 95

List of figures:

Figure 1: Study scope 9
Figure 2: Applicable EU legislation to address substance emissions 11
Figure 3: Pros and Cons of different financing tools used for EPR 12
Figure 4: Policy tools on diffuse water pollution 13
Figure 5: EPR implementation: overview of challenges and solutions.....13
Figure 6: Full life-cycle approach to reduce emission of water pollutants.....15
Figure 7: Structure of ECHA guidance document on CSA 23
Figure 8: Applicable EU legislation across the life-cycle of pharmaceutical products.....33
Figure 9: Applicable EU legislation across the life-cycle of pesticide products.....44
Figure 10: Applicable EU legislation across the life-cycle of biocidal products 54
Figure 11: Applicable EU legislation across the life-cycle of textile products 59
Figure 12: Applicable EU legislation across the life-cycle of tyres 67
Figure 13: Approach for analysis of options.....78
Figure 14: Scoring approach 78

List of boxes:

Box 1: Blueprint to Safeguard Europe's Water Resources.....18
Box 2: Key components of CSA under REACH Regulation 661/2009 22
Box 3: Application of the REACH Regulation 661/2009 on PFASs 24
Box 4: Possible application of EPR principles on PFASs 28
Box 5: Recent updates to EU regulatory framework on pharmaceuticals 35
Box 6: Main components of the ERA for human pharmaceuticals (Directive 2001/83)....36
Box 7: Components of the evaluation for pesticides products, Regulation 1107/2009 46
Box 8: REFIT evaluation of the EU pesticide legislation, ...47
Box 9: Market authorisation requirements for biocidal products (Regulation 528/2012) .55
Box 10: The BPR and the use of silver as a biocide in textiles (sportswear) 56
Box 11: Review of Tyre Labelling Regulation 1222/2009.....69
Box 12: Tyre and Road Wear Particle Platform 69
Box 13: Ecodesign Directive 2009/125 – Relevant provisions & possible amendments...96
Box 14: Industrial Emissions Directive 2010/75 – Relevant provisions & possible amendments.....97
Box 15: Waste Framework Directive 2008/98 – Relevant provisions and possible amendments.....98
Box 16: Strategic Approach to Pharmaceuticals in the Environment 102

List of tables:

Table 1: Summary of most relevant EU legislation assessed.....10
Table 2: Criteria and framework for assessment of policy options 14
Table 3: Key provisions of EQS Directive 2008/105 and Groundwater Directive 2006/118 17
Table 4: Summary of relevant provisions of REACH Regulation 661/2009 21
Table 5: Summary of relevant product-specific provisions under REACH 24
Table 6: Possible amendments to the REACH Regulation 661/2009 26
Table 7: Summary of most relevant provisions on pharmaceutical products 33
Table 8: Potential legislative changes & EPR opportunities for pharmaceuticals.....39
Table 9: Potential obstacles and success factors 41

Table 10: Summary of most relevant provisions on pesticide products 44
Table 11: Potential legislative changes & EPR opportunities for pesticides 49
Table 12: Potential obstacles and success factors 52
Table 13: Summary of most relevant provisions on biocidal products 55
Table 14: Potential legislative changes & EPR opportunities for biocides 57
Table 15: Summary of most relevant provisions on textile products 61
Table 16: Potential legislative changes & EPR opportunities for textiles 64
Table 17: Summary of most relevant provisions on tyres.....68
Table 18: Potential legislative changes & EPR opportunities for tyres.....72
Table 19: Specific measures included in policy options 77
Table 20: Comparison of regulatory clarity of potential legal basis for EPR 81
Table 21: Comparative analysis of overall effectiveness of options 83
Table 22: SWOT analysis of policy options assessed.....85
Table 23: Priority substances (Environmental Quality Standards Directive 2008/105)..100
Table 24: List of substances on the surface water Watch List 100
Table 25: PBT assessment criteria for pharmaceuticals.....101
Table 26: Assessment of regulatory clarity of legal basis of EPR 103
Table 27: Estimated timeframe for implementation of specific measures based on EU legislative review process 104

Abbreviations

API	Active pharmaceutical ingredients
BAT	Best available techniques
BPR	Biocidal Products Regulation (Regulation 528/2012)
CMR	Carcinogens, mutagens and reprotoxic substances
CSA	Chemical safety assessment
ECHA	European Chemical Agency
ELT	End of life tyres
EMA	European Medicines Agency
EPR	Extended Producer Responsibility
EQSD	Environmental Quality Standards Directive (Directive 2008/105)
EQS	Environmental Quality Standards
ERA	Environmental Risk Assessment
IED	Industrial Emissions Directive (Directive 2010/75)
IPM	Integrated Pest Management
JRC	European Commission Joint Research Centre
MBI	Market-based instruments
MPD	Medicinal Products Directive (Directive 2004/27)
NAPs	National Action Plans
NSAID	Nonsteroidal anti-inflammatory drug
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, bioaccumulative and toxic substances
PRO	Producer responsibility organisation
SDS	Safety data sheet
SVHC	Substances of Very High Concern
SWL	Surface water Watch List
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (Regulation 1907/2006)
TLR	Tyre Labelling Regulation (Regulation 1222/2009)
TFEU	Treaty on the Functioning of the European Union
TRWP	Tyre and road wear particles
TWP	Tyre wear particles
UWWTD	Urban Waste Water Treatment Directive (Directive 91/27)
vPvB	Very persistent and very bioaccumulative substances
WFD	Water Framework Directive (Directive 2000/60)

Terms and definitions

Active pharmaceutical ingredients: Refers to the biologically active component or active ingredient of a pharmaceutical product. Medicinal products are usually composed of two core components: the active pharmaceutical ingredient, which is the primary ingredient or substance responsible for the activity of a medicine and all other ingredients, commonly referred to as excipients. Excipients are chemically inactive ingredients e.g. lactose or mineral oil. In the case of a pharmaceutical product such as a pill or capsule intended to treat headaches, acetaminophen is the active ingredient, while the liquid in the gel-capsule is the excipient.

Communication: A policy document with no mandatory authority or no legal effect. The Commission takes the initiative of publishing a Communication when it wishes to set out its own thinking on a topical issue.

Decision: A decision is binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable.

Directives: Are binding on the Member States to which they are addressed in respect of the result to be achieved, however, allows national authorities to decide on the specific form and methods used to fulfil various requirements. As such, directives should, as far as possible, be general in nature and cover the objectives, periods of validity and essential requirements, while technicalities and details are usually left to Member States to determine. Subsequent 'daughter' directives can then adopted with specific rules for individual products, sectors etc.

Economic instruments: Refers to economic or market-based tools that affect the cost or price in the market; in order words, aims to serve as economic signals or incentives. Examples of market-based instruments include taxes, charges, fees, fines, penalties, liability and compensation schemes, subsidies and incentives, deposit-refund systems, labelling schemes and tradable permit schemes.

Education and information: Refers to policy instruments such as information and publicity campaigns, training, guidelines, disclosure requirements, the introduction of standardised testing or rating systems that aim to contribute to meeting EU objectives by ensuring that citizens, consumers and producers are better informed.

Placement on the market: Refers to making a product available for the first time on the Community market with a view to its distribution or use within the Community, whether for reward or free of charge and irrespective of the selling technique.

Polluter-pays principle: The polluter-pays principle is set out under Article 191(2) under the EU Treaty and is very generally defined as the practice under which the polluter should pay for environmental damage. Several types of policy instruments can be used to implement the polluter-pays principle, notably command and control measures e.g. licensing procedures, prohibitions, emission limit values, market-based instruments e.g. subsidies, certificates, tax alleviations and voluntary approaches or 'soft law' e.g. voluntary agreements, labelling, etc.

Precautionary principle: The Precautionary principle is laid out under EU Treaty Article 191.2, which allows regulatory action to be taken even if a risk has not been established with full certainty. For example, the precautionary principle is applied to manage risk in cases of scientific uncertainty.

Proportionality principle: Action at Union level should not go beyond what is necessary to achieve a certain objective. Proportionality is about matching the policy intervention to the size and nature of the identified problem and its EU (subsidiarity) dimension in particular.

Regulations: Directly applicable in all Member States and binding in their entirety. Regulations are used most commonly where it is important to achieve a uniform implementation of a policy intervention such as in the internal market or the governance of mergers

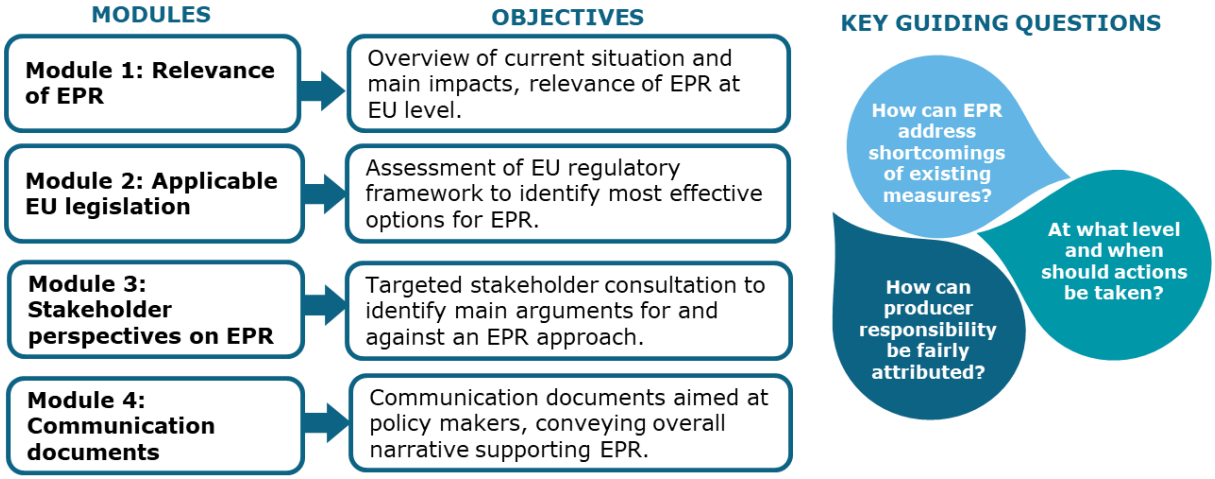
Part I. Objectives, scope & methodology

1. Objectives and scope

1.1 Study objectives

The overall objective of the study is to analyse the feasibility of applying an extended producer responsibility (EPR) scheme on products that release micropollutants and microplastics into the aquatic environment during their life cycle.

The study aims to identify the most effective approach – both in terms of practical feasibility and legislative applicability – for applying an EPR scheme to products releasing micropollutants and microplastics into the aquatic environment. Results of the study present the main advantages and disadvantages of a potential EPR approach, applicability of an EU regulatory framework and options for the way forward, with the overall aim of enhancing on-going and future stakeholder discussions. The study is organised around the four following modules, specific objectives and guiding questions:



1.2 Module 2 objectives and report contents

The objective of Module 2 is to assess relevant EU legislation with a view to determining the most effective way to implement EPR schemes for products emitting pollutants into the aquatic environment. The Module 2 report is structured as follows:

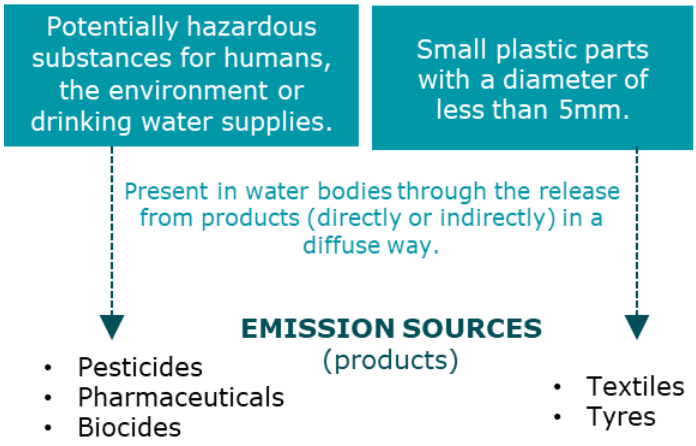
- Part I summarises the objectives, scope and methodology
- Part II evaluates applicable cross-cutting EU legislation
  Part III evaluates applicable product-specific EU legislation
- Part IV assesses the possible options for the way forward
- Annex provides supporting technical information and list of references

1.3 Scope

The study covers potentially hazardous **micropollutants and secondary microplastics** that are **released diffusely** into the aquatic environment by products during their life-cycle (Figure 1). The study focuses specifically on nonpoint or diffuse emission sources (as opposed to point or non-diffuse emission sources) i.e. substances that do not have a precise discharge point and are released from different emissions sources and entry pathways. The study defines micropollutants and secondary microplastics as follows:

- **Micropolluants** are small, persistent and biologically active substances that are found in water bodies in low concentrations and which can have detrimental effects on humans, the environment or drinking water supplies.
- **Secondary microplastics** are small plastic parts found in the aquatic environment with a diameter of less than 5mm that are formed and released via abrasion or weathering of larger plastic particles, products or debris (ECHA, 2018).

Figure 1: Study scope



The study assesses the following product categories:

- **Pharmaceuticals**: Human medicinal products
- **Pesticides**: Plant protection products (agriculture)
- **Biocides**: Antibacterial products (human hygiene)
- **Textiles**: Clothing
- **Tyres**: Car tyres

1.3.1 Product categories assessed

The approach for the selection of product categories considered the following factors:

(1) Evidence that the substance has been detected in Europe's waterbodies at a certain frequency, concentration and occurrence;
(2) Representativeness of the key manufacturing/ product sectors concerned;
(3) Relevance of the product/product category with regards to the water industry and protection of human health and the environment i.e. substances which are technically difficult or costly to remove during drinking water/ waste water treatment; and
(4) Substances that can potentially pollute water sources (drinking water) and characterised by properties that can cause detrimental environmental and health effects if left untreated in aquatic environments.

1.3.2 EU legislation and policy options assessed

In order to tackle the full scale of the micropolluants and microplastics problem in Europe, which is characterised by the diverse range of product categories concerned and different life-cycle stages, it is necessary to investigate regulatory options at EU level that cover both horizontal and product-specific approaches (Figure 2):

- **Horizontal legislation**: Applies to several or all products, substances and/ or life-cycle stages (substance approval, marketing authorisation, manufacturing, consumption, monitoring, and end-of-life).
- **Product-specific legislation**: Lays out provisions specific to particular substances/ product groups.

EU legislation assessed for each product category was selected based on possible legislative changes that could further contribute to reducing the release of potentially hazardous substances (at source) as well as potential areas where EPR could be applied to cover water

treatment costs (see Table 1 and Figure 2).

Based on the findings of the legislative assessment, four policy options were identified and analysed in further detail in regard to the extent that they contribute to meeting the following objectives:

- (1) Reducing and/ or avoiding the release of micropollutants and microplastics at source from the product categories assessed into the aquatic environment; and/or
- (2) Financing the costs of additional treatment (both drinking water and waste water treatment costs) and related mitigation measures by water operators, or other mitigation measures in the downstream supply chain.

In light of the above, the four policy options assessed include:

- Option A: Voluntary control-at-source & post-marketing measures (including EPR)
- Option B: Mandatory control-at-source measures
- Option C: Mandatory control-at-source & post-marketing measures (including EPR)
- Option D: Mandatory EPR measures

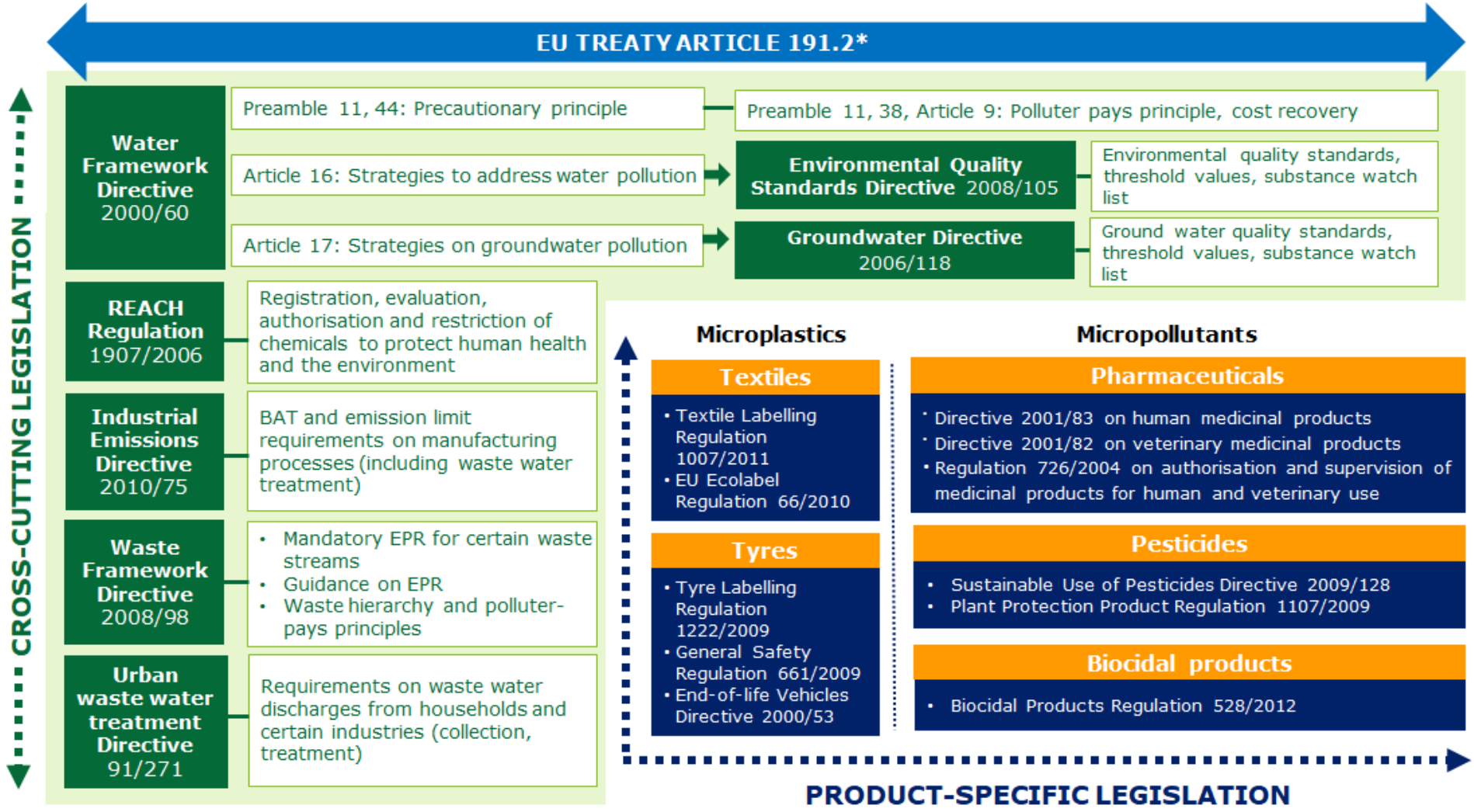
Table 1: Summary of most relevant EU legislation assessed

ALL PRODUCT GROUPS	

• REACH Regulation 1907/2006 (REACH)
• Water Framework Directive 2000/60 (WFD):
  ○ Environmental Quality Standards Directive 2008/105 (EQSD)
  ○ Groundwater Directive 2006/118
• Drinking Water Directive 98/83
	• Ecodesign Directive 2009/125
	• Industrial Emissions Directive 2010/75 (IED)
	• Urban Waste Water Treatment Directive 91/271 (UWWTD)
	• Waste Framework Directive 2008/98

PHARMACEUTICALS	
• Directive 2001/83 on medicinal products for human use and Directive 2001/82 on veterinary medicinal products	• Regulation 726/2004 on authorisation and supervision of medicinal products for human and veterinary use
PESTICIDES	
• Plant Protection Products Regulation 1107/2009 (PPP Regulation)	• Sustainable Use of Pesticides Directive 2009/128
BIOCIDES	
• Biocidal Products Regulation 528/2012 (BPR)	
TEXTILES	
• Textile Labelling Regulation 1007/2011	
TYRES	
• End-of-life Vehicles Directive 2000/53 • Tyre Labelling Regulation 1222/2009	• General Safety Tyres Regulation 661/2009

Figure 2: Applicable EU legislation to address substance emissions



**In accordance with EU Treaty Article 191(2), EU environmental policy should be based on four main principles: Precautionary principle, Prevention principle, Rectification at source principle and Polluter pays principle.*

2. Methodology

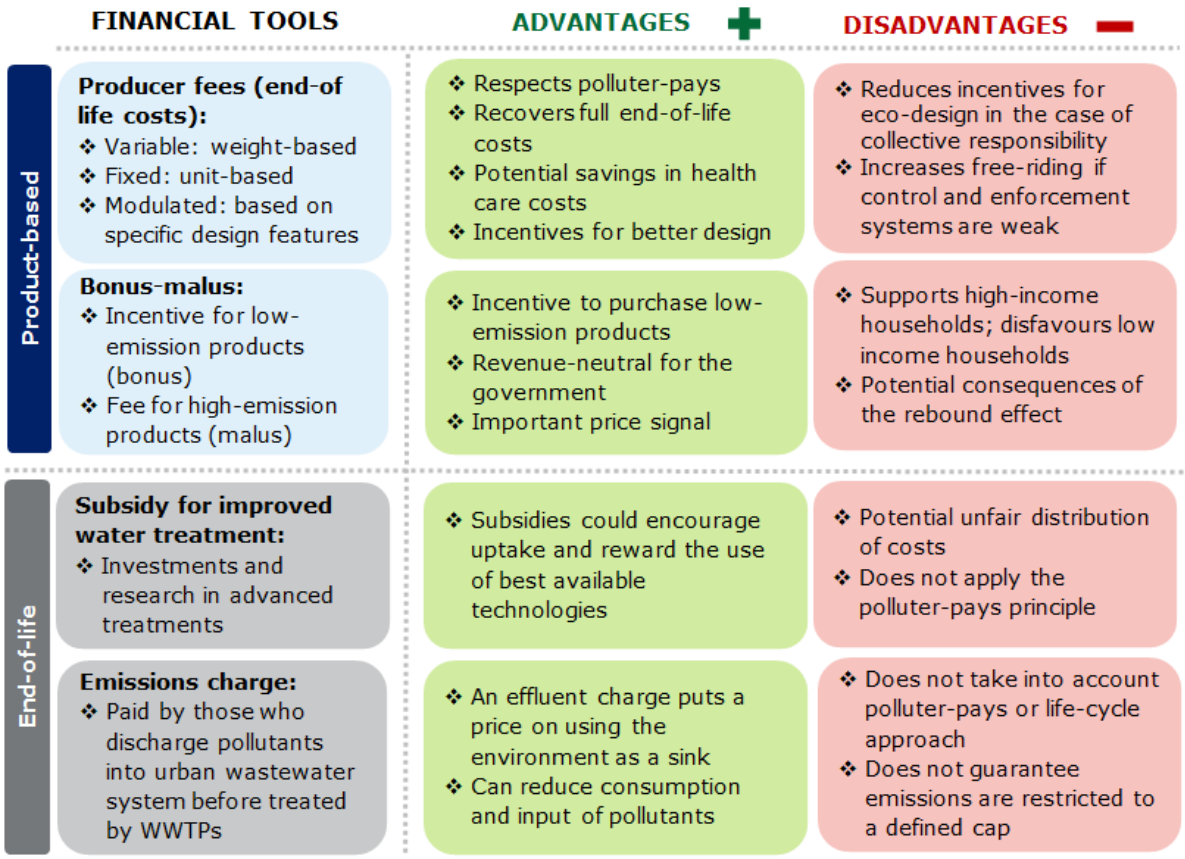
The key components of the methodology used for the assessment of applicable EU legislation for the selected product categories are described in the following chapter.

2.1 Assessment of EU legislation

The legislative assessments carried out for each of the five product groups focuses on:

- The most relevant legislative provisions in the context of addressing micropollutants and microplastics emissions and the implementation of EPR
- Possible amendments in existing legislation and areas where EPR could be applied in regards to ensuring that additional treatment costs are covered by producers and complementary measures to reduce/ prevent micropolluants and microplastics emissions (Figure 3 and Figure 4)
- Identification of the most relevant regulatory basis for the EPR scheme including potential obstacles and success factors

Figure 3: Pros and Cons of different financing tools used for EPR[1]



[1] See Module 1 report for specific case study examples of EPR schemes that apply some of these financial tools.

Figure 4: Policy tools on diffuse water pollution

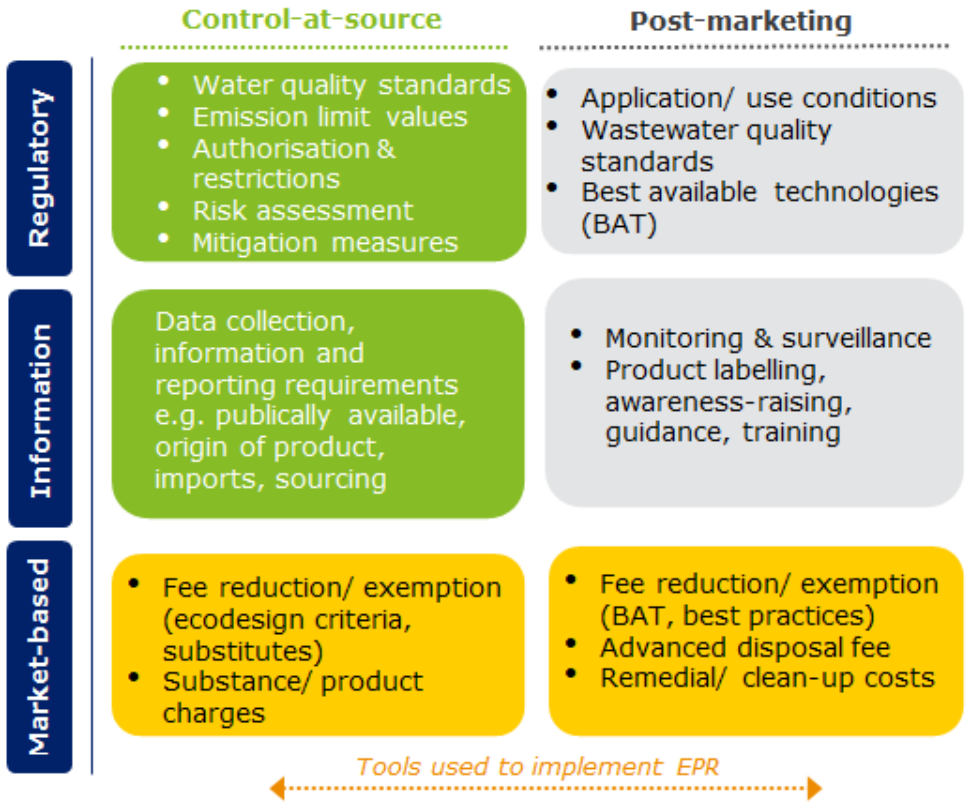
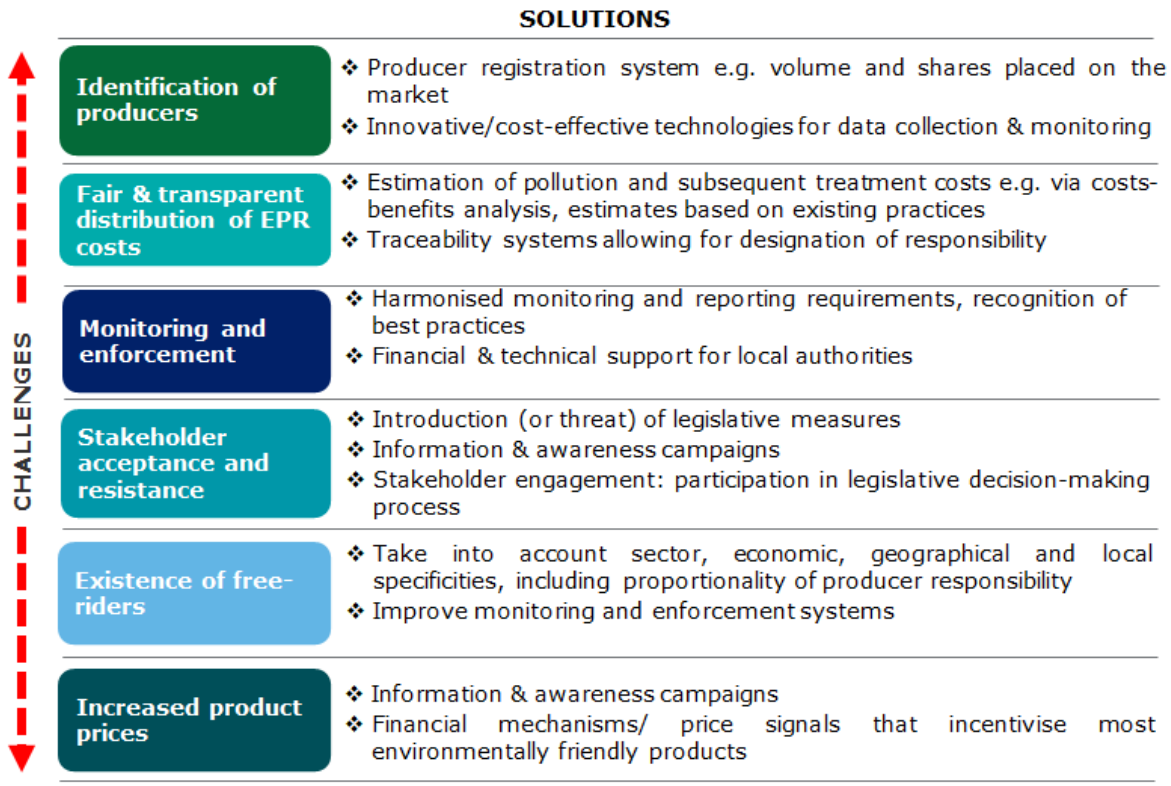


Figure 5: EPR implementation: overview of challenges and solutions



2.2 Assessment of policy options

The **aim** of the assessment of overall effectiveness of the policy options (and associated specific measures) is to determine the extent that they contribute to meeting the following two key objectives: (1) Reducing and/or avoiding the release of micropollutants and (2) microplastics and covering the costs of additional treatment.

The final selection of options assessed are based on an analytical framework, which was developed to account for several assessment criteria. A simplified numeric scoring system (1 = lowest 2 = medium 3 = highest) was developed with the aim of comparing the overall effectiveness of the different options. The scoring system incorporates a **weighted average** of the individual parameters assessed. It should be noted that the weighting of the different assessment parameters was based on expert judgement of the project team, which were established with the overall aim of reflecting the key priorities and most relevant parameters for the water sector.

Finally, SWOT (strengths, weaknesses, opportunities, threats) analyses was also carried out to provide further insights on the overall feasibility of each of the options.

The comparative analysis of the legislation assessed was carried at two levels – for (1) Regulatory clarity and (2) Overall effectiveness. The two parameters assessed include the following assessment criteria and associated weighting for the final assessment of the options as summarised in the following table (see section 11.2).

Table 2: Criteria and framework for assessment of policy options

Regulatory clarity:

- Identification and designation of producer responsibility (financial and physical)
- Financing mechanism in applying EPR/ polluter-pays principles
- Coherence and synergies with other EU legislation

Overall effectiveness:

- Implementation approach
- Timeframe
- EOL/ treatment costs
- Life-cycle approach
- Stakeholder support
- Product coverage

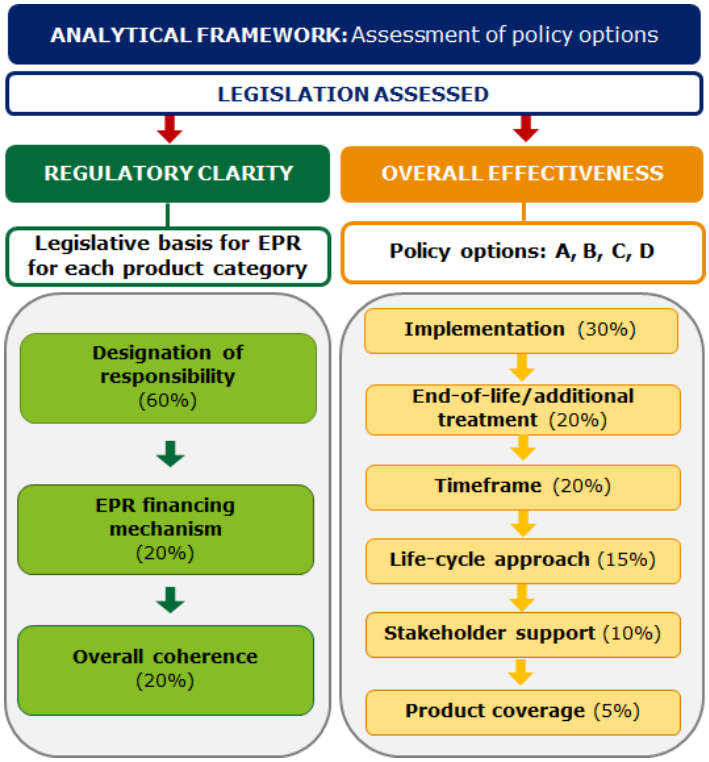
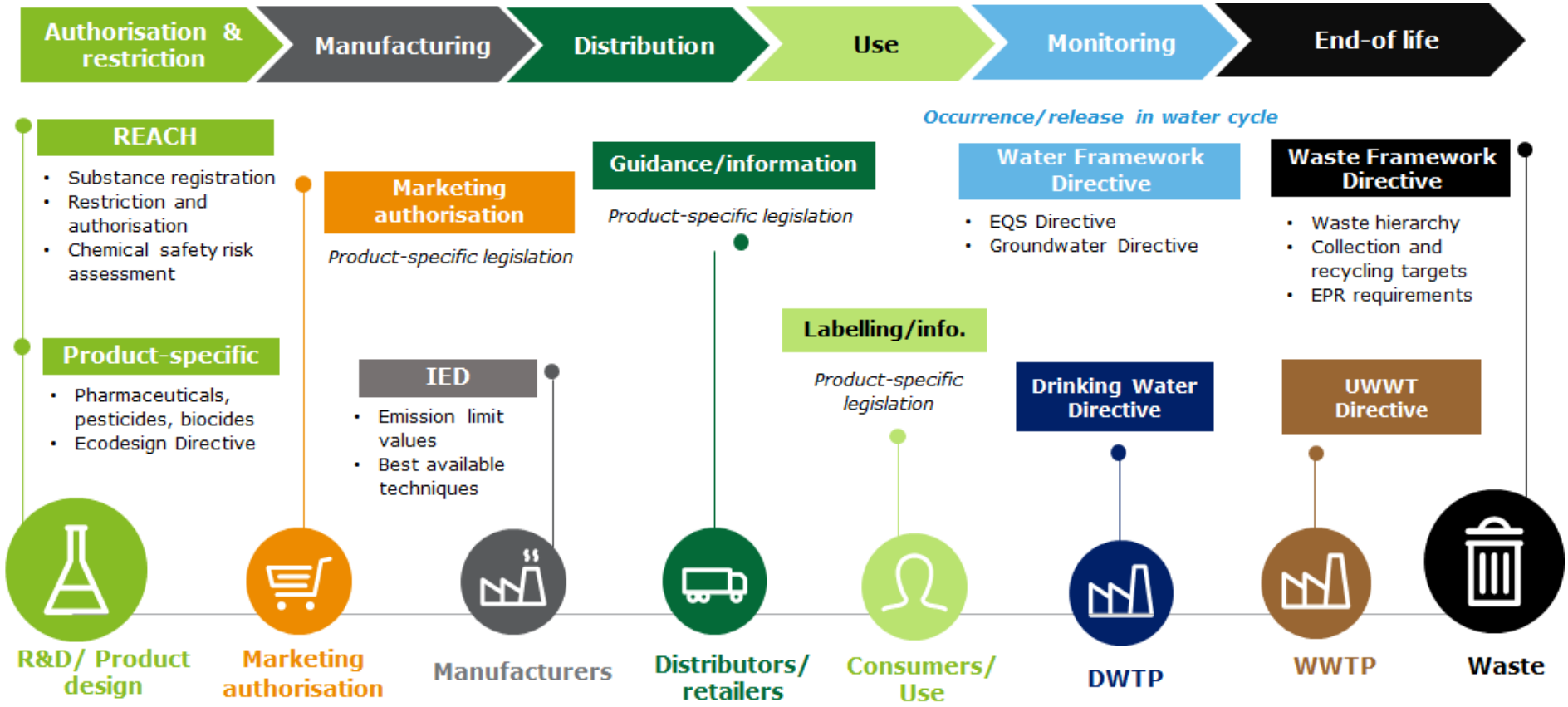


Figure 6: Full life-cycle approach to reduce emission of water pollutants



Part II. Assessment of horizontal EU legislation

Part II evaluates the applicability of three relevant cross-cutting EU legislation: Water Framework Directive 2000/60; REACH Regulation 661/2009 and Urban waste water treatment Directive 91/271. The Annex provides an overview of relevant provisions in other applicable cross-cutting EU legislation: Ecodesign Directive 2009/125, Industrial Emissions Directive 2010/75 and Waste Framework Directive 2008/98.

3. Water Framework Directive 2000/60

3.1 Key relevant provisions

The EU Water Framework Directive 2000/60 (WFD) entered into force on December 2000 and is a major component of the EU's 'Blueprint to safeguard Europe's waters' (see Box 1). The WFD is the most comprehensive and important legal basis for water policy in the EU. The objective of the WFD is to protect water resources (quality and quantity). It sets environmental objectives to ensure that all EU water bodies achieve good status. For groundwater it covers chemical and quantitative status. To achieve its goals, the WFD is accompanied by two 'daughter' Directives – the Groundwater Directive 2006/118 and the Environmental Quality Standards Directive 2008/105 – which lays out the following specific provisions:

- **Environmental Quality Standards Directive 2008/105** (EQSD) (also referred to as the Priority Substances Directive): Established in accordance with Article 16 'Strategies against pollution of water' of the Water Framework Directive, sets environmental quality standards (EQSs) concerning the presence in surface water of certain substances or groups of substances identified as priority pollutants because of the significant risk they pose to or via the aquatic environment. Priority substances are used to determine chemical status of surface waters.
- **Groundwater Directive 2006/118** (GWD)**:** Established in accordance to Article 17 'Strategies against pollution of groundwater' of the Water Framework Directive, aims to prevent and combat groundwater pollution in the EU and sets the procedures for assessing the quality (chemical) and quantitative status of groundwater as well as for the identification and reversal of significant and sustained upwards trends.

It should be noted that the WFD is currently under-going a "fitness check", with the aim of assessing whether the current regulatory framework is "fit for purpose" in regard to its effectiveness, efficiency, coherence, relevance and EU added value in meeting current and future challenges. Aspects such as the potential for regulatory simplification and burden reduction, assessment of costs and benefits, impacts on business and elements of the legislation or implementation that could be improved will be covered.[2] The review phase is expected to be complete by the end of 2019.

The provisions laid out by the WFD are potentially applicable to all hazardous substances present in the aquatic environment; many of which are emitted from pharmaceutical, pesticide and biocidal products, among others. Table 3 summarises how key provisions of the WFD apply to some of the product groups assessed.

Table 3: Key provisions of EQS Directive 2008/105 and Groundwater Directive 2006/118

Key provisions		Link to specific product groups
EQS Directive 2008/105	The EQSD sets **Environmental Quality Standards** (EQS) for priority substances. Several of these priority substances are classed as hazardous. The water standards defined under the	Several substances used in pharmaceuticals, plant protection and biocide products are currently identified as Priority Substances (Table 24). Further, the EQSD considers the contamination of water

[2] EC website on Fitness Check of the Water Framework Directive: http://ec.europa.eu/environment/water/fitness_check_of_the_eu_water_legislation/index_en.htm

Key provisions		Link to specific product groups
	EQSD include setting thresholds for average and maximum allowable concentration of the substance.	with pharmaceutical residues as an **emerging environmental concern** (Article 8c).
	Article 8b(1) of the EQSD establishes the **Surface water Watch List** to obtain high-quality EU-wide monitoring data on potential water pollutants for the purpose of determining the risk they pose and whether EQS should be set for them at EU level. This list should be updated every 2 years.	Several substances used in pharmaceuticals, pesticides and biocidal products are currently included in the surface water watch list (Table 24).
GWD Directive 2006/118	Similar to the EQSD, GWD establishes **groundwater quality standards** (GWQS) that must be met for pollutants of EU-wide concern (Annex I) as well as groundwater threshold values (Annex II).	Several substances used in plant protection and biocidal products are concerned by the requirements of the GWD, including GWQS.
	The **Groundwater Watch List (WL)** lists further substances for which threshold values should be set by EU MS if they are putting groundwater bodies at risk of failing their good status objective (Annex II).	To assess environment and health risks to groundwater, the persistence and mobility of the substance must be considered, which concerns in particular certain active substances used in pharmaceuticals, pesticides and biocide products.

Box 1: Blueprint to Safeguard Europe's Water Resources[3]

In 2012, the Commission published its Communication on 'A Blueprint to Safeguard Europe's Water Resources' (COM/2012/0673 final), outlining actions that concentrate on better implementation of current water legislation, integration of water policy objectives into other policies, and filling the gaps in particular as regards water quantity and efficiency. The Water Blueprint's time horizon runs in parallel to the EU's 2020 Strategy and the 2011 Resource Efficiency Roadmap, but also covers a longer time span up to 2050, to drive EU water policy over the long term. The Blueprint highlights the need for upstream measures and that they should be seen as preferable to downstream (cleaning up) solutions, the need for MS to improve implementation of the Water Framework Directive as well as legislation on nitrates, waste water treatment, industrial emissions, priority substances and plant protection products. Some of the Blueprint's proposed actions in the area of chemical status and pollution of EU waters include:

- Water Framework Directive 2000/60: Enforce reporting requirements.
- Urban Waste Water Treatment Directive 91/271: Improve compliance rates on waste water treatment through long-term investment planning.

Industrial Emissions Directive 2010/75: Ensure that industrial emissions permits include Emission Limit Values (ELVs), which are in line with Best Available Techniques (BAT) in relation to relevant water objectives.

According to the Commission website, the Commission will develop and regularly update a scoreboard to check progress on implementation of all aspects of the Blueprint and, if necessary, propose amendments to the WFD to facilitate the achievement of its objectives.[4]

[3] Communication on 'A Blueprint to Safeguard Europe's Water Resources': https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0673

[4] European Commission Memo, Brussels, 15 November 2012. Blueprint to Safeguard Europe's Water Resources:

3.2 Possible legislative changes and opportunities for EPR under the Water Framework Directive

The Water Framework Directive 2000/60 explicitly refers to the **polluter pays principle twice**, allowing for potential opportunities to use of EPR tools in order to apply the polluter-pays principle and achieve cost recovery objectives:

- **WFD, Recital 38 on the use of economic instruments:** MS may use market-based instruments (MBIs) as an appropriate part of a programme of measures. Principle of cost recovery of water services, including environmental/resource costs should be taken into account in accordance with the **polluter pays principle**.
- **WFD, Article 9: Recovery of costs for water services:** Member States shall take into account cost recovery of water services (including waste water treatment) the basis for water-pricing policies, that reflect an adequate contribution of different water uses (at least industry, households and agriculture) and in accordance in particular with the polluter pays principle.

Possible amendments to the Water Framework Directive and its related provisions, including areas where extended producer responsibility (EPR) principles could be applied to further address the release of micropollutants / microplastics include:

- **Identify possible areas for increased synergies:** Recital 12 and Article 11 of the WFD recognise the need to improve coordination, strengthen coherence and explore potential synergies with other pieces of legislation. There are several potential opportunities to further streamline the data and knowledge gathered in the context of other policies; for example by simplifying and harmonising reporting tools and establishing a centralised European register and database on elements such as environmental impacts of substances as well as relevant data on production volumes, consumption and end-of-life management. Environmental monitoring under the WFD provides essential information for other horizontal legislation, such as for substance evaluations under REACH Regulation and product-specific legislation (Plant Protection Products Regulation 1107/2009, Biocidal Product Regulation, etc.). However, as certain chemicals are persistent and can remain in the environment for a long time, information is needed on trends, frequency and occurrence to assess whether or not and how concentrations are changing.
- **Amendments to the Environmental Quality Standards Directive 2008/105:**
    - **Update chemical status assessment parameters:** To take into account the possible combined effects of chemical mixtures (mixture toxicity) (EEA, 2018b). The EQSD currently does not consider the combined effects of chemical mixtures. Subsequently, it is possible that while concentrations of priority substances could be slightly below their EQSs and meet good chemical status, the combination of substances e.g. neonicotinoid insecticides, antibiotics, etc. present could be harmful (EEA, 2018b).
    - **Surface water watch list:** Extend scope of monitoring by additional (active) substances to the Watch list, particularly in relation to combination with mixture effect predictions, to further improve and address the need for harmonised and high-quality EU-wide monitoring data on potential water pollutants and their risks to the environment. This measure could allow for more targeted monitoring and

http://europa.eu/rapid/press-release_MEMO-12-866_en.htm

reduction measures to be initiated and gain information about concentration levels of micropollutants to identify potential priority substances, for example active ingredients and substances used in pharmaceuticals, biocidal products and pesticides. Substances included in the watch list and the resulting monitoring data could be used as a basis for designating the substances to be covered by an eventual EPR scheme.

- **Amendments to the Groundwater Directive 2006/118:** Inclusion of additional potentially hazardous substances such as those used in pharmaceuticals, which are currently not included in the **Groundwater watch list**. Furthermore, the results of the environmental risk assessment (ERA) should be allowed to be considered during the review process of Annexes I and II. Similar to the surface water watch list, the substances monitored could contribute to identifying the priority substances to be addressed by EPR.

4. REACH Regulation 661/2009

4.1 Key relevant provisions

Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) came into force in June 2007, with the overall objective of protecting human health and the environment from the potential risks posed by chemicals. REACH has an impact on most industry sectors and companies across the EU due to the fact that the regulation is applicable to all chemical substances manufactured or imported into the EU in quantities of 1 tonne per year or more; including those used in industrial processes and to manufacture final products sold on the market e.g. cleaning products, paints, garments, furniture and electrical appliances. In other words, the REACH Regulation covers both individual substances, used in a preparation or in a manufactured article placed on the EU market. Key provisions of the REACH Regulation are summarised in Table 4.

Table 4: Summary of relevant provisions of REACH Regulation 661/2009

Requirements
Registration
Substances manufactured or imported over 1 tonne per year must be **registered** with the European Chemical Agency (ECHA) by manufacturers and importers, through a dossier containing information on the intrinsic properties and if relevant, the assessment of the risks presented by the substance during the manufacturing and intended use including risk management measures as part of the Chemical safety assessment (CSA) (Box 2)
Evaluation
A substance is evaluated by a designated MS competent authority for its environment/public health impact. The evaluation may conclude that the risks are sufficiently under control with existing measures, or lead to the proposal of EU-wide risk management measures e.g. restrictions, authorisation and identification of 'Substances of Very High Concern' (SVHC). The priority for evaluation is given to PBT, vPvB and CMR (Carcinogens, mutagens and reprotoxic) or equivalent level of concern (ELoC) as well as persistent, mobile and toxic (PMT) substances.
Authorisation & restriction

Requirements

REACH establishes and defines two distinct EU risk management approaches:

- **Authorisation**: Designed to ensure that SVHCs (substances of very high concern) are used safely while promoting substitution by suitable alternatives
- **Restriction**: Enables the EU to impose conditions on the manufacturing, placing on the market or use of substances

Authorisation and restriction requirements under REACH aim at ensuring that SVHCs are progressively replaced by less hazardous substances if alternatives exist, by constraining their placement on the market up to a tolerated cap. Substances meeting the SVHC criteria (identified by national Competent Authorities or ECHA) can be placed on one or both of two lists that are defined in Annex XIV of the REACH Regulation: the 'Candidate List' and the 'Authorisation List'. In particular, the 'Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020' (SVHC Roadmap 2020) aims to identify all relevant SVHCs in the Candidate List by 2020. The SVHC Roadmap 2020 foresees to cover the following groups of substances: Carcinogens, mutagens, reprotoxic (CMRs), sensitisers; persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) and endocrine disruptors (ED).

Communication in the supply chain

REACH requires manufacturers or importers to communicate information about the safe use of chemicals (risk management measures) across the supply chain in the format of Safety Data Sheets. However, an important distinction should be noted – companies established outside of the EU are not bound by the obligations of REACH, even if they export their products into the European Union. The responsibility for fulfilling the requirements of REACH lies in principle with the **importers established in the European Union**[5].

Substitution[6]

ECHA is currently carrying out several actions to promote the substitution of SVHCs as a measure towards the use of safer chemicals and products. In its Strategic Plan for 2019-2023, the agency identified several priority areas including: promoting best practice of increased substitution of hazardous substances, green chemistry and sustainability in the supply chain; promoting a mind-set and behavioural change within industry towards more sustainable and safer chemicals; collaborating with industry associations in raising awareness; and developing and providing tools for sustainability assessments of chemicals.

Box 2 provides an overview of the main components of the Chemical Safety Assessment (CSA) required as part of REACH registration requirements.

Box 2: Key components of CSA under REACH Regulation 661/2009

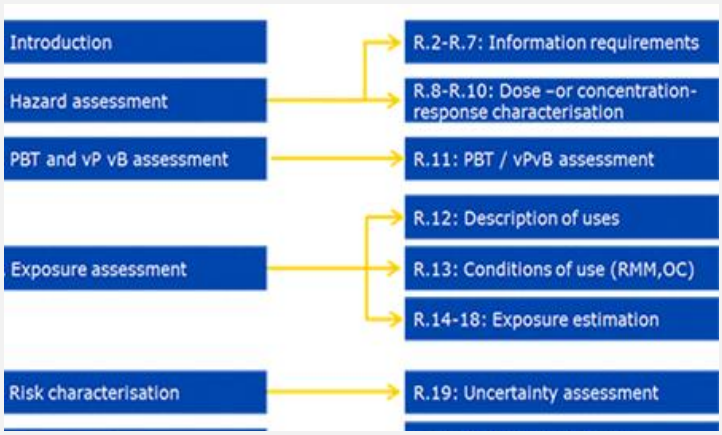
[5] ECHA website on the REACH regulation: https://echa.europa.eu/regulations/reach/understanding-reach
[6] ECHA (2018) Strategy to promote substitution to safer chemicals. Accessible at: https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf/bce91d57-9dfc-2a46-4afd-5998dbb88500

In accordance with the REACH Regulation 661/2009, a **Chemical Safety Assessment (CSA)** is mandatory for all substances that are manufactured or imported in volumes equal to or greater than 10 tonnes per year. The CSA is an essential component of the REACH registration process and also forms the basis for other REACH processes including substance evaluation, authorisation and restriction. The main objective of the CSA is to ensure that risks from exposure to the substance (exposure scenario) are identified and controlled. As part of the substance registration dossier, information from the CSA must be documented in the chemical safety report (CSR) (REACH, Annex I).

The principle components of the chemical safety report are illustrated in Figure 6, which is based on ECHA's guidance document on carrying out the CSA[7]:

- Human health hazard assessment
- Environmental hazard assessment
- PBT and vPvB assessment
- Exposure assessment
- Risk characterisation

Figure 7: Structure of ECHA guidance document on CSA



The scope of the chemical safety assessment considers the use of the substance on its own (including any major impurities and additives), in a preparation and in an article. Further, the CSA takes into account all relevant stages of the substance's life-cycle resulting from the manufacture and identified uses.

Based on the results of the chemical safety assessments and report, if the substance meets the criteria for classification as dangerous or PBT or vPvB, an exposure assessment (identification of all of the possible exposure scenarios or relevant uses and exposure estimation) and risk characterisation are required. Furthermore, all relevant and appropriate measures to control the risks related to all the intended uses should also be provided in the CSR in the form of safety data sheet (SDS). This information is particularly vital as it is passed down the supply chain, with the aim of ensuring that all potential risks situations and mitigation actions are accounted for. Lastly the CSR must also be updated regularly. For example, in cases where new properties of a substance are identified.

4.2 Product-specific provisions

The REACH Regulation 661/2009 applies to **all substances** with some exemptions, for example radioactive substances, substances under customs supervision, nonisolated intermediates and the transport of substances. Furthermore, substances used in certain products e.g. pharmaceuticals, biocidal products and plant protection products are also exempt from some REACH's requirements due to the existence of product-specific legislation that cover related requirements. Table 5 describes how some of the key relevant provisions of REACH apply to the product groups assessed.

[7] ECHA website on guidance on the CSA: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Table 5: Summary of relevant product-specific provisions under REACH

Product group	Product-specific provisions
Pharmaceuticals	All chemicals, including pharmaceutical starting materials and reagents, are subject to REACH requirements and must go through the registration process if they are produced or imported in quantities of more than 1t/y/company. Moreover, compliance with authorisation and restriction requirements is mandatory, even for volumes lower than 1t/y (if the substance is considered SVHC – substance of very high concern). However, active pharmaceutical ingredients (APIs) and excipients are exempt from registration, evaluation, and authorisation requirements under REACH if they are already registered with the European Medicines Agency (EMA) as an ingredient of a medicinal product for human or veterinary use (See chapter 6 on pharmaceuticals).
Plant protection products and biocides	Similar to substances used in pharmaceutical products, REACH's authorisation procedure and requirements do not apply to substances used in plant protection products (PPPs) and biocidal products as specific provisions apply for these substances/ product groups (see chapter 7 on pesticides and chapter 8 on biocidal products.)
Textiles	All textile articles incorporating chemical substances intended to be intentionally released (e.g. dyes, fragrance, etc.) must be registered for that specific use if present in those articles in quantities of over 1t/y/producer. The EU has initiated a transition period for the restriction of 33 chemicals used in the textile sector, which are classified as CMR (carcinogens, mutagens and reprotoxic). All textile suppliers in the EU must comply with the new restrictions by December 2020. However, there is no provision in REACH related to microplastics emissions from the use and manufacturing of synthetic textiles as they are not intended to be intentionally released from textile articles (intentionally added microplastics are currently being addressed under REACH).

Box 3: Application of the REACH Regulation 661/2009 on PFASs

PFOA, its salts and PFOA-related substances: Due to their high toxicity and wide use in consumer products, in June 2017, the Commission introduced Regulation 2017/1000 adding an extra entry in Annex XVII of REACH on the restriction on PFOA, its salts and PFOA-related substances. Limit values have been set for these substances and for products containing these substances e.g. textiles, paper, etc.

According to the regulation, PFOA, its salts and PFOA-related substances shall not be manufactured, placed on the market as substances on their own, used in another substance as a constituent, used in a mixture, or used in an article in a concentration equal to or above 25 ppb of PFOA including its salts or 1 000 ppb of one or a combination of PFOA-related substances. The restrictions will be applicable from **4 July 2020**. The following notable exemptions, however, are allowed:

- All articles placed on the market before **4 July 2020**;
- Concentrated fire-fighting foam mixtures (intended to be used, or used in the production of other fire-fighting foam mixtures) placed on the market before **4 July 2020**. This also applies for fire-fighting foam mixtures used for training purposes, provided that, emissions to the environment are minimised and effluents collected

are safely disposed of.
- Applications in photo-lithography processes for semi-conductors or etching processes for compound semiconductors, photographic coatings for films, paper or printing plates and for the production of implantable medical devices.

For certain articles that fall within the scope of the restriction, restrictions will not be applicable until a later date: **4 July 2022** for equipment used to manufacture semi-conductors and latex printing inks; **4 July 2023** for textiles used for the protection of workers, membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment and plasma nano-coatings; and **4 July 2032** for medical devices other than implantable medical devices. The restrictions do not cover PFOS and its derivatives, which are already widely restricted under Regulation 850/2004 on persistent organic pollutants (POPs Regulation) (as amended by Commission Regulation 757/2010).

PFHxS and its salts: Perfluorohexane-1-sulphonic acid and its salts (PFHxS) was also added to the REACH Candidate List of SHVCs as a 'very persistent and very bioaccumulative substance'.

PFCAs, salts and precursors: Concerning perfluorinated carboxylic acids (PFCAs) and salts and precursors including linear and branched chained C9-C14 substances, the restriction dossier is in preparation, with the aim of including these substances in Annex XVII, at the request of Germany and Sweden[8]. Once the restriction is adopted, these substances cannot be manufactured or placed on the market as substances on their own or in a mixture, or in an article or parts therein in a concentration equal or above 25 ppb (for the sum of C9-14 PFCAs and their salts) or 260 ppb (for the sum of C9-C14 PFCA related substances). The restriction aims to prevent a switch by industry using PFOA-based substances ('C8 chemistry') to longer chain PFCAs ('C9-14 chemistry') to fulfil the same role in the end products. The proposed restriction, however would not cover all relevant PFCA substances. In particular, proposed exemptions include (1) articles placed on the market before the restriction becomes effective; (2) C9-C14 PFCAs, their salts and related substances that occur as unintended by-products during the manufacturing of other fluorochemicals with a carbon chain equal to or shorter than eight carbon atoms; and (3) substance that is to be used, or is used as a transported isolated intermediate.

4.3 Possible legislative changes and opportunities for EPR under REACH

The introduction of the REACH Regulation 661/2009 has resulted in a notable reduction in the number of chemicals used on the European market as manufacturers must balance registration costs against possible revenues, while also taking into account requirements on substance authorisation and restrictions. The REACH regulation authorisation and restriction processes has allowed for the gradual phase out of many dangerous substances. And with the current trend of ever increasing new and emerging substances and their potential harmful impacts on human health and the environment, REACH will continue to play an important role in EU chemicals legislation. Despite the significant progress achieved under REACH to protect human health and the environment, facilitate communication throughout the supply chain and enable traceability, additional measures/criteria could be further explored to more adequately address diffuse micropollutant emissions. For example, REACH does not currently address specific aspects such as the mobility of chemical substances, which consequently does not allow for effective or sufficient control

[8] Public consultation on proposed restriction of the manufacturing, use, placing on the market and import of C9-C14 PFCAs, their salts and precursors Accessible at: https://echa.europa.eu/documents/10162/b6f777c3-aa56-9a46-f120-0f8c0b57dc2a

and monitoring of micropollutants released to the aquatic environment. Table 6 summarises the most relevant possible amendments to REACH that could further contribute to addressing the micropollutants and microplastics emissions.

Table 6: Possible amendments to the REACH Regulation 661/2009

Possible legislative changes	
Definition of SVHCs	Consider PMT substances as SVHCs: In accordance with REACH Art. 57, persistent, mobile and toxic (PMT) substances and/or metabolites originating from the degradation of a substance in the natural environment and fulfilling the PMT criteria, shall be considered as SVHC. In fact, PMT compounds are highly soluble and therefore difficult to remove in drinking water treatment plants. In June 2019, ECHA's Member State Committee agreed to list GenX chemicals as Substances of Very High Concern (SVHCs). This marks the first time that chemicals are identified as SVHCs in part based on their mobility in the environment. The committee agreed that the persistent, mobile and toxic (PMT) nature of GenX substances poses an equivalent level of concern (ELoC) as traditional categories used by REACH to define SVHCs – specifically CMR, PBT and vPvB[9].
Chemical Safety Assessment	Based on the results of the Environmental hazard assessment, an exposure assessment and risk characterisation steps shall be performed for substances meeting the criteria for classification as **PMT** as well as for PBT and vPvB. This would allow for their identification during registration and, consequently, these substances could be subject to additional authorisation steps and associated product/ disposal treatment fees, etc. Some key criteria to identify vPvM and PMT substances i.e. substances that can potentially disrupt the water cycle include their capacity to be transported and recirculated with the water cycle as well as the human exposure through drinking water. According to a study published by the UBA (Neumann, 2017), '*a substance fulfils the mobility criterion if: its water solubility is at environmental relevant pH 6-8 and 12 °C ≥150 µg/L and its log K_{OC}[10] at environmental relevant pH 6-8 and 12 °C is ≤ 4.5*'. Accordingly, water solubility and K_{OC} are key parameters to be monitored for PMT identification. KOC values are useful in predicting the mobility of organic soil contaminants i.e. higher KOC values correlate to less mobile organic chemicals while lower KOC values correlate to more mobile organic chemicals. These criteria could be added in the list of data that need to be provided for registration
List of authorised substances	The tolerable concentrations of authorised substances should be assessed based on the trends and results of research studies and monitoring activities on chemical emissions into the natural environment. As such, restriction conditions could be adapted accordingly.
Information provision	Distributors could be more involved in information requirements and processes: their responsibility should be extended, in particular they should be required to provide all the information needed for the safe use and disposal of substances to final consumers (as required for producers). In addition, information from manufacturers on metabolites release and their potential presence and impacts on the environment, should be mandatory and included in the safety data sheet. This information should also be communicated through labelling requirements in accordance with the Regulation 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP regulation).

[9] https://echa.europa.eu/-/msc-unanimously-agrees-that-hfpo-da-is-a-substance-of-very-high-concern

[10] K_{OC} is the equilibrium partition coefficient of a chemical between water and natural organic carbon. It is a very important input parameter for estimating environmental distribution and environmental exposure level of a chemical substance (K_{OC} measures the mobility of a substance in environmental compartments).

Further to the possible revisions of existing provisions of REACH as summarised above, there are also several areas for increased synergies with other relevant legislation that could further contribute to addressing micropollutants and microplastics the emissions:

- **EU water legislation** e.g. the Water Framework Directive 2000/60 (EQSD, GWD, UWWTD), Drinking Water Directive: Harmonisation and streamlining of data collection, databases, monitoring and reporting activities, are needed to constantly identify substances that can disrupt water cycle. These substances can then be banned or restricted under REACH. For example Article 44 on withdrawal or amendment of an authorisation of pesticides regulation (1107/2009) stipulates that a Member State (MS) shall review an authorisation at any time where, inter alia, it concludes that the approval criteria for active substances may not be achieved. The MS can also withdraw or amend the authorisation where the requirements referred to in Article 29 (requirements for the authorisation for placing on the market) are not or are no longer satisfied. Thus findings of PPP in water should lead to a re-assessment of substances and adjustment of the product authorisation process. This should be extended to all of the substances under REACH.
- **Industrial Emissions Directive 2010/75 (IED):** Operators of industrial installations manufacturing and or using chemical substances in their activities have obligations under both IED and REACH and are therefore key actors in making sure chemical substances are used safely and that their release to the environment is avoided or at least minimised. Downstream users/operators can benefit from the information generated under REACH and IED for cross-legislation compliance in many different situations. However, it is important to stress that the role that operators have under REACH will determine the amount of REACH information that they will have access to (IMPEL 2013). A harmonised database and information exchange between REACH and IED could be implemented.
- **Application of 'benign by design' or ecodesign:** The REACH regulation could further promote and support the use of ecodesign principles e.g. non-toxic chemicals and/or chemicals designed for fast and complete biodegradation in the environment into non-toxic degradation substances, etc. for new compounds or product development, through for example fast-track registration for "ecodesign chemicals and substances" in order to incentivise their development, use in products and placement on the market. Moreover, based on the assumption that these compounds / products have been specifically designed to be non-toxic and/or readily biodegraded in the environment, they would not need to be as extensively tested for effects in the environment, reducing costs, time and overall administrative burdens during the registration, approval and authorisation process.

Finally, in regard to potential opportunities for EPR, registration, monitoring and reporting data collected through the REACH Regulation could be used to help calculate EPR fees. Under a scenario where EPR is directly applied in the context of REACH, the following options could be considered in regard to EPR fees:

- A **product/substance fee** applied as part of the authorisation and restriction procedure on SVHCs, PMTs, etc., based on the volume placed on the market and the frequency of detection of the substance in water bodies in order to cover costs of additional treatment steps, mitigation measures, etc. at other life-cycle stages.
- Likewise, **modulated product/substance fees** could be another approach, whereby producers would be subject to a modulated product (substance) charge based on

environmental criteria e.g. severity of potentially hazardous properties of the active substance, frequency and occurrence in the natural environment, 'benign by design' or 'green chemistry' principles, recyclability/end-of-life treatment, biodegradability, etc. REACH currently allows registration fee reductions and exemptions for SMEs. Similar fee reductions or exemptions could be applied to 'green chemistry' based substances to promote the development and use of less hazardous alternative substances.

In addition to areas where EPR could be applied, other measures have been proposed as part of a review by several trade associations. For example, national and EU legislation should 'motivate' companies to actively look for alternatives to SVHCs by providing 'positive incentives', such as tax cuts for producers. Trade associations also suggest that a mechanism is established at EU level to allow for 'assurance of a minimum period of protection' for companies that invest in alternative processes or substances, including measures to boost investment in R&D initiatives for alternative solutions/ substitution development. For example, the implementation of a specific European programme (financed by producers) to support investments in new technologies, or upgrades, via Horizon 2020 or subsidies at national level for innovation projects to improve knowledge on chemicals. Box 4 provides an example of how EPR principles could be specifically applied in the case of PFASs.

Box 4: Possible application of EPR principles on PFASs

PFASs including PFOA, PFOS, PFHxS and PFCAs, are or are expected to be widely restricted under REACH and POP regulations. However, due to several exemptions and special conditions such as later application dates for certain articles and preparations, these regulations serve as an opportunity for some companies to 'empty their reserves' on the market to avoid financial losses. Further, as discussed previously in Box 3, short-chain PFAS (<C8), which are more mobile and persistent are not currently covered by existing regulations, allowing some manufacturers to switch from long to short chain PFASs (see Box 3). For these articles and preparations, a **modulated product fee** could be implemented depending on the volume of PFASs used in the product and placed on the market as well as **water cycle risk assessment** criteria, indicating high, medium and low level risks, based on criteria such as mobility, persistency, toxicity, water treatment complexity, etc. The concept of water cycle risk assessments could be incorporated into existing environmental and safety risk assessments (e.g. under the REACH Regulation 661/2009, pharmaceuticals, biocides and pesticides regulations). In the case of PFASs for example, fire-fighting foam mixtures present a high risk of emissions into the water cycle. Consequently, an emission charge could be added for the producers of these products (in a new article) in order to finance the costs of extra-treatment or other mitigation measures by drinking water and waste water treatment plants, or other actors. However, it should be noted that REACH provisions concerning PFAS have just been revised. To this end, solutions such as the integration of a water cycle risk assessment could therefore take time before being incorporated into legislation.

5. Urban waste water treatment Directive 91/271

5.1 General requirements and objectives of the UWWTD

In addition to the above provisions governing water and chemicals policy in the EU, the **Urban Waste Water Treatment Directive 91/271 (UWWTD)** is another important piece of "end-of-pipe" legislation, adopted in 1991, and aims to protect the environment from the adverse effects of urban waste water discharges from households and certain industrial sectors, setting requirements on the collection and treatment. The UWWTD is closely linked to the Water Framework Directive 2000/60 as its requirements are essential for the achievement of the WFD objectives. After more than 25 years of the UWWTD, significant improvements in the quality of European waters have been observed – particularly downstream of European urbanised zones. For example, according to most recent reported figures, approximately 95% of the EU's urban waste water is collected and over 85% is treated according to the Directive's requirements (EC, 2017). Despite the improvements to overall water quality since the Directive's existence, the review of its implementation reveals several challenges and areas where further progress is needed – notably in relation to **proper governance, adequate competences, significant investments and appropriate treatment level**. These challenges and other findings of the forthcoming evaluation will feed into the Commission's reflection on possible further action.

5.2 Key relevant provisions of the UWWTD

Similar to the Water Framework Directive 2000/60 and REACH Regulation 661/2009, the UWWTD regulates one of the many pathways through which micropollutants and microplastics are released into the aquatic environment. Relevant requirements of the UWWTD applicable to the product groups assessed include for example, Article 10, which requires MS to ensure that WWTPs are built to comply with treatment and discharge requirements and that they are designed, constructed, operated and maintained to ensure sufficient performance under all normal local climatic conditions. The basic elements for the implementation of the Directive include (1) the designation of receiving areas and (2) the delineation of the agglomeration. The size of an agglomeration and the sensitivity of water body (or receiving area), which receives waste water discharges define the treatment level requirements for the treatment plant(s) serving this agglomeration.

5.3 Possible legislative changes and opportunities for EPR under the UWWTD

The recent OECD report on the hazards and policy responses of pharmaceutical residues in freshwater states that, "*end-of-pipe measures should only be used in complementary to source-directed and use-orientated measures. An over-emphasis on upgrading waste water treatment plants infrastructure is not a sustainable, optimal use of limited resources*." (OECD, 2019). In order to ensure cost efficiency in regards to investments on WWTPs upgrades, the OECD also emphasizes the need for evaluation, prioritisation, and consideration of trade-offs, financing needs, cost-recovery mechanisms for capital, and operation and maintenance costs. This clearly indicates that as stand-alone solutions, mitigation measures applied at the very end of the product's life cycle is neither environmentally sustainable nor financially viable. Instead, end-of-life measures should

complement measures that address other life cycle stages and, in particular, at the source.

The UWWTD is currently undergoing review by the Commission and is expected to be completed in 2019. The scope of the evaluation examines implementation of the UWWTD covers its almost 25 years of existence. Some of the key areas of evaluation include (EC, 2017):

- **Effectiveness** in regard to the extent that polluter-pays is applied and pollutants released by urban areas are collected and treated
- **Efficiency** in relation to the costs and benefits e.g. investments, affordability of water services, administrative burden, etc.
- **Coherence** with other relevant legislation e.g. Water Framework Directive 2000/60, Sewage Sludge Directive 86/278, Bathing water Directive 76/160, etc.
- **Relevance** of current limit values, extent that emerging pollutants are covered, etc.

In addition to the above areas of review, other crucial aspects should also be considered in the evaluation of the Directive, particularly in the context of any additional requirements or amendments related to the treatment / removal of micropollutants and microplastics:

- Effective application of the polluter-pays principle and cost recovery based on a full life-cycle approach: ensuring that other life cycle stages further upstream are considered, including prioritisation of hotspots
- Complementary to other reduction measures, notably at control-at-source
- Waste water treatment requirements (within collecting systems or at waste water treatment plants) should be demonstrated to be effective in reducing/ efficiently removing micropollutants to levels, which are protective of the receiving environment without causing further harm by the introduction of additional treatment. Further, the energy requirements of treatment and carbon emissions must also be considered in regard to the benefits of additional treatment (see Module 1 report for in-depth analysis of costs and effectiveness of additional/advance treatment technologies).
- Requirements are proven to be effective to improve the quality of the environment and/or necessary to facilitate the use of water bodies for other purposes e.g. drinking water production, recreation, or use in agriculture
- A step-by-step approach to support R&D and innovation

The above points are essential to cover in the Directive's evaluation to ensure that any future possible revisions adequately address and propose actions that take into account the full-scale of the current issues related to adverse waste water discharges and environmental protection. In particular, as highlighted in the OECD report, ensuring cost recovery before setting new requirements is of upmost important when considering effective policy options for pollutants in freshwater.

In light of the above and in respect to opportunities for EPR, the UWWTD must first ensure the effective application of the polluter-pays principle first, before any new requirements are adopted to address reduction measures within waste water infrastructure. For example, in cases where additional treatment steps are needed for certain substances/ particles, the UWWTD could apply the principles of EPR in accordance with the polluter-pays principle through the use of market-based instruments e.g. financial charges, or subsidies and financial assistance, etc., with specific focus on (1) hotspots e.g. setting additional minimum waste water effluent quality standards and (2) covering the costs (by producers) of associated monitoring and reporting activities, collection systems and investments needed for upgrades in WWTPs. In all cases, financial mechanisms should be fair, proportionate and effective while covering investment, operational and maintenance costs as well as reduction/mitigation measures.

Part III. Assessment of product-specific EU legislation

Part III evaluates the potential of EU legislation at product-specific level to apply extended product responsibility on products that release micropolluants and microplastics from products into the aquatic environment.

6. Pharmaceuticals

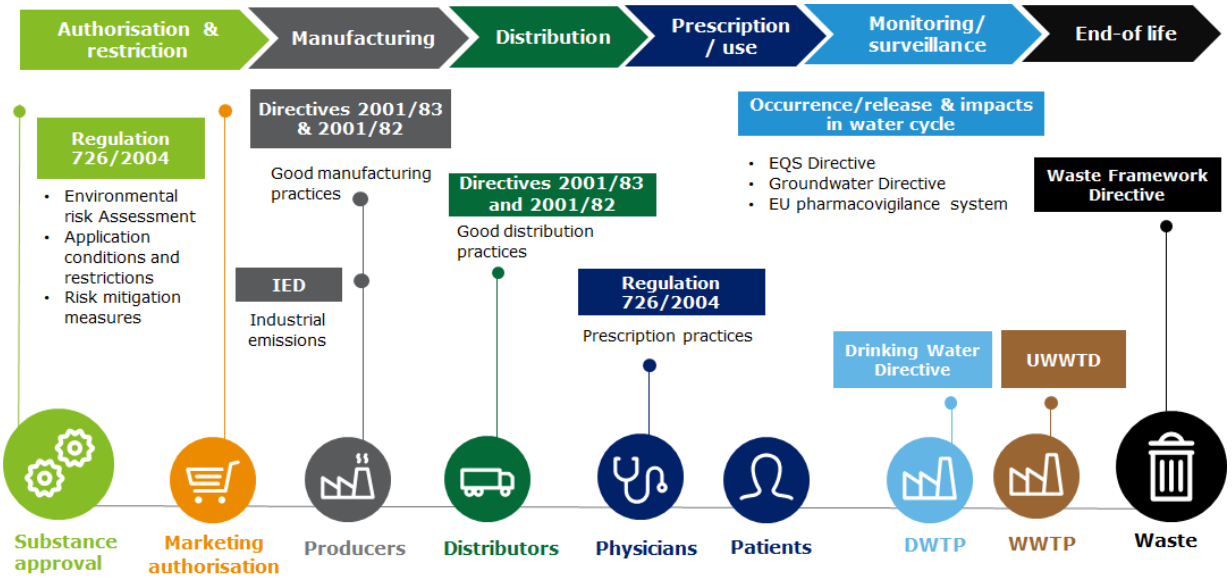
6.1 Overview of supply chain and relevant EU legislation

The pharmaceutical chain starts at the **research** and **development** phase involving research institutes and pharmaceutical companies, where research and review are carried out on new substances to determine whether a new medicine is ready for registration. At EU level, **marketing authorisation** must be obtained before pharmaceutical products can be registered and placed on the market. During the marketing authorisation process, the medicine is assessed for effectiveness and **safety for human use** by the authorising authority – either at EU level by the European Medicines Agency (EMA) or at national level by the relevant competent authority. Once marketing authorisation is approved, the medicine can be **produced, put on the market** and **distributed**. Once placed on the market, the safety of a medicinal product continues to be **monitored** throughout its entire lifespan through the EU system of pharmacovigilance for any adverse events on human health.

During the **use phase**, authorised medicines can be classified by level of control: prescription drugs (Rx), prescribed by order of a certified physician and over-the-counter (OTC) drugs, which are accessible without prescriptions in various points of sales depending on the country e.g. pharmacies, supermarkets, online retailers, etc. A recent study carried out by the BDEW (German Association of Energy and Water Industries) indicates that the use of human pharmaceutical products is expected to increase significantly – up to 70% by 2045 in Germany – due to current demographic trends and consumption i.e. younger generations are not only consuming more medications in terms of quantity but also in terms of potency e.g. strength and efficacy of active substances (BDEW, 2017). These findings are also reflected in the recent Commission Communication on 'Strategic Approach to Pharmaceuticals in the Environment' (See Box 16 in Annex).

In the EU, the largest source of pharmaceuticals discharge in the environment is the excretion of pharmaceuticals by humans and animals, estimated to be about 90% of total emissions (EC, 2019). At their **end-of-life**, human pharmaceutical residues are released into the urban waste water system through several channels, notably through households (via household garbage, toilets or collected through a dedicated collection scheme). As such, pharmaceutical substances are found in the aquatic environment, urban waste water, sewage sludge and manure. Emissions from manufacturing are another important source of emissions, along with emissions from the disposal of unused pharmaceuticals. Veterinary pharmaceutical residues are released in a more diffuse manner, mainly as a consequence of agricultural applications e.g. manure distribution, through excreted animal faeces and soil contamination from animal husbandry or directly released into waterbodies from use in aquaculture. Figure 8 provides an overview of the main EU legislation across the life-cycle of pharmaceutical products.

Figure 8: Applicable EU legislation across the life-cycle of pharmaceutical products



6.2 Key relevant provisions specific to pharmaceutical products

The most relevant EU legislation on pharmaceuticals (human use) for addressing micropollutants emissions and implementation of EPR is Regulation 726/2004 on the authorisation and supervision of medicinal products for human and veterinary use. It should be noted that for veterinary medicinal products, the recently adopted Regulation 2019/6 (entry into force in 2022) establishes a separate legal framework specific to veterinary products (Box 5). Regulation 726/2004 lays out the main provisions for marketing authorisation as well as requirements for the manufacturing and distribution of medicines in the EU. In particular, Regulation 726/2004 requires that companies submit an environmental risk assessment (ERA) as part of the market authorisation procedure (Box 6). The following table summarises the most relevant legislative provisions across the life-cycle of pharmaceutical products to address the emissions of micropollutants and potential application of EPR.

Table 7: Summary of most relevant provisions on pharmaceutical products

Life-cycle stage	Relevant provisions in existing EU legislation
Substance approval & marketing authorisation	**Regulation 726/2004** on the authorisation and supervision of medicinal products for human and veterinary use establishes the requirements and procedures that manufacturers must comply with in order to obtain marketing authorisation to place pharmaceuticals for human and veterinary use, respectively, on the market. Environmental Risk Assessment (ERA) is obligatory for any pharmaceutical company submitting a marketing authorisation application for a medicine, including generics. However, the ERA is only applicable to Human Medicinal Products (HMP) placed on the market after October 2005. Results of the ERA for HMP do not constitute a basis for refusal of marketing authorisation. If a risk to the environment is identified, authorisation can be subjected to certain conditions e.g. (non-binding) precautionary and risk mitigation measures. This is however, not the case for veterinary pharmaceuticals, where a risk to the environment identified in the ERA can result in the refusal of marketing authorisation. Some examples of key elements covered by the ERA to assess the potential impacts of medicinal products are provided in Box 6.
Manufacturing & distribution	**Directives 2001/83 and 2001/82:** As one of the conditions for obtaining and maintaining marketing authorisation, pharmaceutical manufacturers must comply with the principles and guidelines of good manufacturing practices (GMP). Some of the main principles of good manufacturing practices include ensuring that medicinal products are produced and monitored based on the requirements established for their intended use and that an effective quality management system is in place to cover aspects such as manufacturing operations, personnel, premises and equipment, documentation, quality control and assurance, contracting, complaints product recall and self-inspection.
	Directives 2001/83 and 2001/82: Similar to GMP guidance, good distribution practices (GDP) must also be respected in regards to ensuring adequate quality and control systems during distribution of medicinal products.
Monitoring	**Groundwater Directive 2006/118** (Article 17, WFD: Measures to prevent and control groundwater pollution, including criteria for assessing good groundwater chemical status): Although the Groundwater Directive does not explicitly refer to pharmaceuticals, the provisions of the directive considers substances that could potential pose environmental risks to aquatic ecosystems. Principle 20 and Article 6 of the GWD includes measures to be introduced by Member States on hormone-disruptive substances, CMR and PBT substances to prevent them from being introduced into bodies of water, which therefore also apply to pharmaceuticals. Furthermore, environmental quality norms have to date only been defined for nitrate, biocides, and pesticides, but not for pharmaceuticals. Similarly, Annex II, which establishes threshold values for pollutants in groundwater does not yet include pharmaceuticals.
	Environmental Quality Substances Directive 2013/39: • Recital 15: Adequate attention should be paid to assessment of the risks of environmental effects from medicinal products • Article 8(C): Strategic approach to the pollution of water by pharmaceutical substances.
	Regulation 726/2004: Established the **EU pharmacovigilance system** (under implementing Regulation 520/2012) to monitor potential risks and adverse side effects of pharmaceutical products on humans (does not cover effects on the environment).
Prescription & use	**Regulation 726/2004:** Certain active substances may be subject to specific conditions based on ERA results e.g. product information and labelling on requirements, identification of precautionary and risk mitigation measures.

Life-cycle stage	Relevant provisions in existing EU legislation
	Regulation 2019/6, Recital 47: Once in force in 2022, the Regulation will require prescriptions for antimicrobial veterinary medicinal products, which pose a potential risk to public or animal health, however, such an obligation does not currently exist for human medicinal products.
End-of-life	**Regulation 726/2004**: Member States are required to implement appropriate collection schemes for unused pharmaceutical products.
	Waste Framework Directive 2008/98, Articles 17-20, and Annex III: Establishes additional obligations and requires a stricter control regime for hazardous waste compared to non-hazardous waste. Requirements for hazardous waste include additional labelling, record keeping, monitoring and control obligations from the "cradle to the grave" i.e. from the waste production to final disposal or recovery. Mixing of hazardous waste is also prohibited to prevent risks for the environment and human health. Currently, the only pharmaceutical waste explicitly classified as hazardous are cytotoxic and cytostatic products (also referred to as cytotoxic chemotherapy and used to treat cancer).

Box 5: Recent updates to EU regulatory framework on pharmaceuticals

In September 2014, the Commission presented a proposal to amend Regulation 726/2004 on the authorisation and supervision of medicinal products for human and veterinary use, which resulted in the adoption of the new Regulation 2019/5 in January 2019. Requirements under Regulation 2019/05 applied from 28 January 2019. Member States have three years to ensure compliance with the obligations in this Regulation. Some of the notable changes include:

- **Scope of Regulation 726/2004**: The scope of the regulation is limited to the authorisation and supervision of medicinal products for human use only. Provisions specific to veterinary medicinal products are now exclusively governed by the new Regulation 2019/06, which repeals Directive 2001/82 on veterinary medicinal products and incorporates the provisions specific to veterinary products contained in Regulation 726/2004 (Articles 30 to 45). This thereby establishes a legal framework specific to veterinary products. The new provisions on veterinary medicinal products under Regulation 2019/05 will apply from **January 28, 2022**.
- **Delegated Acts:** Regulation 2019/05 gives the Commission the power to adopt further delegated acts that complement the 'core elements' now contained in Regulation 726/2004 on centralised procedures. Delegated acts are legally binding acts that enable the Commission to supplement or amend non-essential parts of EU legislative acts, for example, in order to define detailed measures. Concretely, this means that the Commission can now amend certain provisions through delegated acts, which would only require a Commission resolution (which the Parliament or the Council do not oppose), as opposed to amending a Regulation, which is more difficult and time-consuming, as it requires a co-decision procedure that involves the European Parliament and the Council and can take several years.
- **Definition of 'Antimicrobial':** Regulation 726/2004 requires the EMA to report periodically on the sale and use of antimicrobials as well as antimicrobial resistance and now includes an official legal definition of 'antimicrobial': *"Any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals."*
- **Temporary Measures**: In cases where manufacturers or importers can no longer fulfil obligations or when a MS or the Commission considers that a pharmacovigilance measure or sanction should be applied to a product, following consultation with the EMA, the Commission can now introduce necessary provisional measures within six

months.

- **Rules on financial penalties:** The Commission can now impose financial penalties on wider entities beyond the Marketing Authorisation Holder (MAH). In other words, financial penalties can be imposed on legal entities that are part of the same economic entity as the MAH; for example entities that exert a decisive influence over the MAH or who are involved in, or could have addressed, the non-compliance.

Box 6: Main components of the ERA for human pharmaceuticals (Directive 2001/83)

The ERA for pharmaceutical products as laid out Article 8(3) of Directive 2001/83 and Regulation 726/2004, is performed in a stepwise approach, divided by the two principal phases (see figure):

Phase I – Initial screening phase: Phase I aims to identify substances that require more in-depth evaluation (in Phase II). This is based on results of the following two main assessments:

- **Risk assessment** (estimation of exposure): Based on Predicted Environmental Concentration (PEC), which is considered to reflect the possibility of an effect occurring – in regards to ecotoxity and exposure of organisms to the active substance. It should be noted that the calculation of PEC is restricted to surface water only. The formula used to calculate PEC includes various default values, assumptions and parameters, such as:
  - The assumption that 1% of a population receive the active substance daily
  - The assumption that the sewage system is the main route of entry of the active substance into surface water and that there is no biodegradation or retention in the WWTP
  - Likelihood of an increase in environmental exposure
  - Whether the active substance is a naturally occurring substance or has a specific toxicity profile, etc.

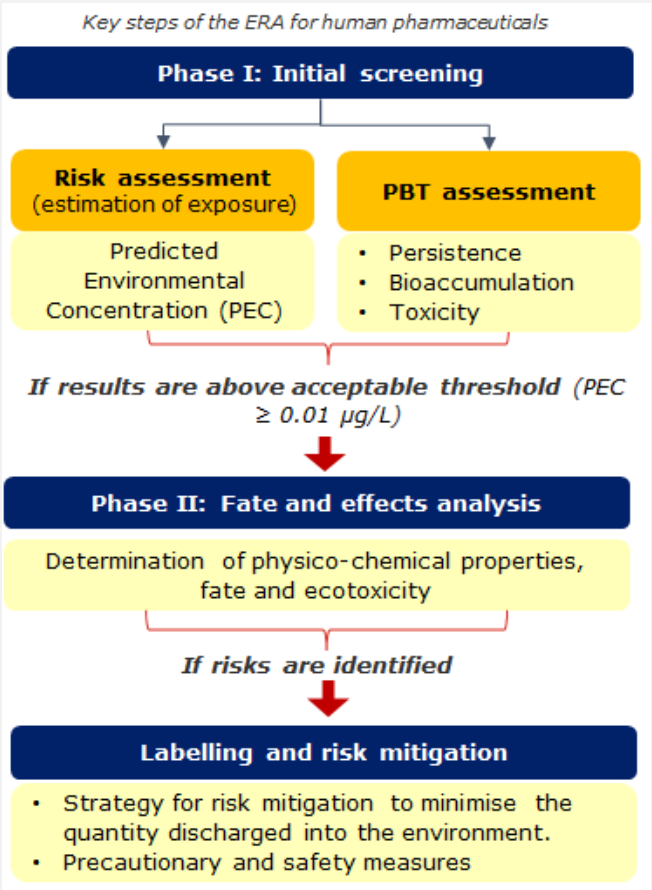
In the event that the initial risk assessment results reveal PEC ≥ 0.01 µg/L, additional testing must be carried out in Phase II. Some substances, however, (e.g. endocrine active substances, antiparasitics) must undergo a Phase II assessment regardless of PEC value due to their potential hazardous effects on organisms in the environment even at concentrations < 0.01 µg/L. For other substances with PEC < 0.01 µg/L, the risk assessment stops at Phase I as it assumed that the substance has limited use and/or limited environmental exposure and environmental effects

- **Persistent, bioaccumulative and toxic (PBT) assessment:** In Phase I, a PBT assessment must also be performed for all active ingredients regardless of whether or not the conditions for a Phase II risk assessment is met. The PBT assessment covers the intrinsic properties of a specific group of active substances. These include active substances that do not degrade well in the environment (persistent), accumulate in organisms (bioaccumulative) and are toxic. It should be noted that the ERA guidelines makes specific reference to the use of REACH guidance on PBT assessment to the fullest extent possible.

Phase II – Determination of physico-chemical properties, fate and ecotoxicity (fate and effects analysis): In Phase II, further tests are carried out on substances (only those identified under Phase I) to determine the fate of medicinal products in the environment and their potential effects on organisms. The EMA's Guidelines for ERA

proposes several testing methodologies – mainly those published by the Organisation for Economic Co-operation and Development (OECD). Some examples of the parameters applied to determine the physico-chemical, fate and ecotoxicity properties include:

- Physico-chemical e.g. water solubility
- Fate e.g. sorption to soil and sludge, biodegradability, etc. to evaluate environmental exposure, mobility and distribution in soil and water
- Ecotoxicity e.g. growth inhibition for algae, toxicity on fish, etc. based on chronic exposure and effects
- Risks for the functioning of WWTPs: potential effects of a substance on micro-organisms from activated sludge of WWTPs



In the event where the ERA identifies any specific potential environmental risks, adequate precautionary and safety measures should be considered to limit the risks as well as reduce the quantity discharged into the environment e.g. appropriate labelling on correct disposal, appropriate product storage, measures regarding appropriate use of the substance, etc. However, under no circumstances do the results of the ERA constitute a criterion for refusal of a marketing authorisation for human pharmaceuticals (as opposed to veterinary pharmaceuticals).

6.3 Possible legislative changes and opportunities for EPR

For pharmaceutical products, the **regulatory framework for the implementation of EPR** appears to be most relevant in the context of legislation that target the **marketing authorisation phase** (Regulation 726/2004 on authorisation of pharmaceutical products). Existing provisions in these legislations could be amended to incorporate EPR principles by requiring companies to adhere to the EPR scheme (payment of fees based on ERA results (Box 6) as an additional condition for obtaining marketing authorisation.

Possible opportunities for the application of EPR based on polluter pays identified for pharmaceutical products include:

- **A substance (product) fee** on active pharmaceutical ingredients: to be paid by manufacturers based on the quantity of the substance placed on the market and the estimated costs of drinking water and waste water treatment ; and
- **A dedicated EPR fund:** financed through the contributions by pharmaceutical producers based on an agreement between the pharmaceutical industry, EU and national governments and water treatment operators.

The above financing solutions were investigated in detail in recent studies commissioned by the BDEW on financing options based on the polluter-pays principle (BDEW, 2017). Preliminary findings indicate preference for the EPR fund due to lower administrative burdens compared to a product fee, however highlights a key drawback would be the voluntary nature of the financial tool due to the lack of a legally binding obligation. In order to provide incentives for producers, the calculation of product fees or financial contributions could be applied based on a **modulated fee approach.** The modulated fee approach could be based on several aspects such as the costs of treatment and the quantity of the active pharmaceutical ingredient placed on the market as well as environmental criteria, which could take into account for example:

- **Ecodesign** (benign by design or green chemistry) e.g. ease of recyclability/end-of-life treatment, biodegradability, use of less toxic alternative substances, etc.
- **Environmental impact** e.g. severity of potentially toxic properties of the active substance, frequency and occurrence in the natural environment, etc.

The modulated fee approach would, in practice, incentivise producers to use less harmful substances and alternatives e.g. via exemptions, reduced EPR fees, etc. The fees collected through a dedicated EPR scheme could be used to:

(1) Finance post-consumer water treatment of designated substances; and/ or
(2) Fund information and public awareness measures e.g. guidance on better prescribing practices, sustainable use of pharmaceuticals, etc.

To this end, Member States and health care professionals have a key role to play in terms of ensuring sustainable prescription practices and that relevant information on the potential environmental impacts of pharmaceuticals is communicated to patients. Similarly, the Commission plays a key role in bringing together relevant professionals and contributing to the funding of certain measures such as research and training programmes (EC, 2019). Moreover, pharmacies and other points of sales e.g. hospitals, supermarkets, online sellers, etc. also have an important role to play in regards to reducing overconsumption and the overall amount of product packaging used. For example, modulated EPR fees could be applied based on measures that aim to reduce product packaging and overconsumption e.g. provision of the prescribed amount of pills (unit of use) rather than pre-packaged, standardised or bulk units.

Regarding the designation and monitoring of potential substances (and producers), specific provisions on monitoring and knowledge gathered in the context of other legislation could be used in the context of the EPR scheme on micropollutants released from pharmaceuticals: substances from the Surface and Ground Water Watch Lists, Priority Substances identified under the EQSD, SVHC under REACH Regulation 661/2009, etc.

Based on the review of the existing legislative framework, Table 8 lists the possible changes in EU legislation that aim to reduce micropollutant emissions from pharmaceutical products and/ or finance their treatment. The table indicates whether the proposed measures target control-at-source actions (upstream measures) and/ or EPR-related (post-marketing or downstream measures).

Table 8: Potential legislative changes & EPR opportunities for pharmaceuticals

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Substance approval & marketing authorisation	**Regulation 726/2004 on authorisation of pharmaceutical products:** Revisions to the Environmental Risk Assessment. • Inclusion of additional risk assessment parameters e.g. impacts of metabolites and transformation/degradation products, risks related to antibiotic resistance, mixture toxicity assessments, extending testing scope to higher organisms, etc. • Require ERA for products placed on the market before 2006. Require ERA results as part of criteria for obtaining marketing authorisation for human medicines and that they are made publically available.	Authorisation and restrictions	–	Results of ERAs can serve as basis for identifying relevant substances/ producers and setting EPR fees.
	Regulation 726/2004: Amended to serve as the regulatory framework for the implementation of a dedicated EPR scheme for human pharmaceutical products[11]. • Establishment of EPR as an additional mandatory obligation for obtaining marketing authorisation. • Establishment of modulated EPR fees based on results of (updated) risk assessment and/or green chemistry criteria (benign by design). • Establishment of specific EPR requirements for unused medicines e.g. financing activities related to separate collection and treatment.	–	**EPR financing mechanism** (based on modulated fees)	**LEGAL BASIS FOR EPR**
Manufacturing & distribution	**Guidelines on GDP and GMP (Directives 2001/83 and 2001/82):** Revisions to existing requirements on good manufacturing and distribution practices to (1) include additional requirements related to environmental impacts and protection and (2) require that producers and/or distributors provide clear information on origin of product, sustainable use/ disposal practices, etc.	–	Information provision	–
Monitoring	**Water Framework Directive 2000/60:** Allow monitoring data to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees. • EQS Directive 2008/105: Inclusion of additional potentially hazardous active pharmaceutical ingredients in Surface water Watch List • Groundwater Directive 2006/118: (1) Inclusion of additional potentially hazardous active pharmaceutical ingredients in groundwater Watch List; and (2) allow ERA results for APIs to be taken into account during the review process of Annexes I and II.	–	Monitoring and reporting	• Data collected can serve as basis for setting EPR fees e.g. frequency, impacts, hotspots

[11] For veterinary pharmaceuticals, the most relevant regulatory basis for EPR would be Regulation 2019/6 (entry in force January 2022).

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
	REACH Regulation 661/2009: Revisions to the Chemical Safety Assessment. • Include additional toxicity e.g. mobility of chemical substances • Allow results of the CSA to be used in the context of a possible EPR scheme to designate priority substances/ products and set corresponding fees. • Inclusion of most relevant SVHC used in pharmaceutical products in candidate list.	–		• Monitoring activities financed through EPR
	Regulation 726/2004 on supervision of pharmaceutical products: Extend the scope of the EU pharmacovigilance system to incorporate environmental parameters. Monitoring and reporting requirements on environmental impacts and risks e.g. antimicrobial resistance, 'hotspot' locations, concentrations in soil and water, possible effects from the combined presence of pharmaceutical substances and other chemicals.	–	Monitoring and reporting	
Prescription & consumption	**Regulation 726/2004**: Launch targeted information and awareness campaigns to further on the safe and sound use and disposal of pharmaceutical products as well as the potential risks of pharmaceuticals in the environment and guidance on better prescribing practices.	–	Awareness raising	Mitigation measures to support (and financed by) EPR
	Directive 2001/83: Require prescriptions for human medicinal products identified as posing potential environmental risk or for which no ERA is available (products placed on market before 2006)[12]	–	Application (use) conditions	
End-of-life	**Waste Framework Directive 2008/98:** Update criteria laid out in Annex III of Directive 2008/98 specific to pharmaceutical waste that would allow for a more exhaustive approach to identifying and classifying potentially hazardous pharmaceutical waste.	–	EOL treatment requirements	–
	Complementary downstream (end-of-pipe) measures to support control-at-source measures and EPR: • Drinking Water Directive: Requirements on the installation of extra treatment technologies, if required, should comply with parametric values and ensure that quantities treated and associated costs are reported. • UWWTD: Review of the UWWTD should assess (1) the relevance and feasibility of additional treatment requirements (technology and coverage of costs by producers) in specific hotspots, where relevant, to treat pharmaceutical residues in line with official target values, (2) ensure that quantities treated and associated treatment costs are reported and (3) assess ways to reduce pharmaceuticals released through combined sewer overflows (CSOs).	–	• Monitoring and reporting • Drinking and waste water treatment requirements	Monitoring and reporting data can serve as basis for setting EPR fees e.g. substance and quantity treated, treatment costs, etc.

[12] Similar to the Veterinary Medicinal Products Directive, this requirement could also be supported by guidelines for identifying environmental risk thresholds triggering prescription-only administration of APIs of high relevance for the environment (EEB, 2018).

6.4 Potential obstacles and success factors

Some of the key potential obstacles and success factors to overcome them in the field of pharmaceuticals are summarised in Table 9.

Table 9: Potential obstacles and success factors

Obstacles	Success factors
Ethical and social aspects: The fact that any potential risks identified as a result of the ERA can lead to the refusal of marketing authorisation for veterinary medicines, but not for human medicines, reflects the tensions in priorities between the benefits of health care and risks to drinking water resources and ecosystems. In addition, the pharmaceutical industry often puts forwards ethical-based arguments such as additional (financial) charges on producers would unjustly and negatively impact the final purchasing price and investments in life-saving drugs and that such drugs do not have viable alternative substances. Such arguments, which are oftentimes not backed by scientific evidence can hinder much needed efforts, progress and regulatory measures in this area.	**Boost scientific research and build on public concern:** As scientific understanding of the potential effects of pollutants has increased, so has public and political concern on the release of potentially hazardous substances into the environment. Increasing concern and awareness could be a key driver for shifting ethical and social priorities and present important opportunities for the implementation of targeted information and awareness campaigns to ensure that consumers and other relevant stakeholders are provided with accurate and relevant information i.e. clear scientifically-backed information on priority substances and potential risks (which mostly do not concern 'life-saving drugs' often referred to by pharmaceutical companies), appropriate use and disposal of medicines, existence of alternative substances/ products, etc.
Stakeholder acceptance: Many pharmaceutical companies argue that there is a lack of sufficient scientific evidence to justify their role and responsibility in the problems and challenges that arise as a consequence of the release of micropollutants from their products into the aquatic environment. Their role as producer with extended responsibility is put in question (we are not the polluter) and problems in setting up a fair EPR scheme are emphasised. This has resulted in stakeholder resistance to taking further action and an overall lack of a general consensus.	**Encourage cross-sectoral stakeholder dialogue and increase awareness:** Multi-level stakeholder dialogue e.g. dedicated workshops, voluntary agreements, research initiatives, etc. play an important role in the process of scientific research and gathering support of important stakeholders. Furthermore, these venues also serve as good opportunities to further disseminate the most recent scientific research and findings.

Obstacles	Success factors
Remaining knowledge gaps: Several stakeholders claim that despite the amount of comprehensive and on-going new scientific evidence, more information is still needed to understand and evaluate certain pharmaceuticals in regards to their environmental concentrations and the resulting levels of risk (limited data on their environmental occurrence or on their ecotoxicology) and its consequences for human health and the environment.	**Role of policy:** Recent EU policy recognises the potentially significant environmental and health risks posed by pharmaceuticals in the environment (EU Strategic Approach for Pharmaceuticals in the environment). The available body of information is sufficient to justify corrective measures, thus applying the precautionary principle. In addition to the importance of prioritising this issue on the policy agenda, further actions to fill knowledge gaps include: • Fund research: The Strategic Approach to Pharmaceuticals identifies several knowledge gaps, which are being considered for research funding under the EU's next Multi-annual Financial Framework (2021-2027). • Ensure that pharmaceuticals put on the market in the past are subject to an environmental risk assessment as part of the authorisation process. • Expand the existing the EU pharmacovigilance system to monitor potential risks and adverse side effects of pharmaceutical products on the environment)

7. Pesticides

7.1 Overview of supply chain and relevant EU legislation

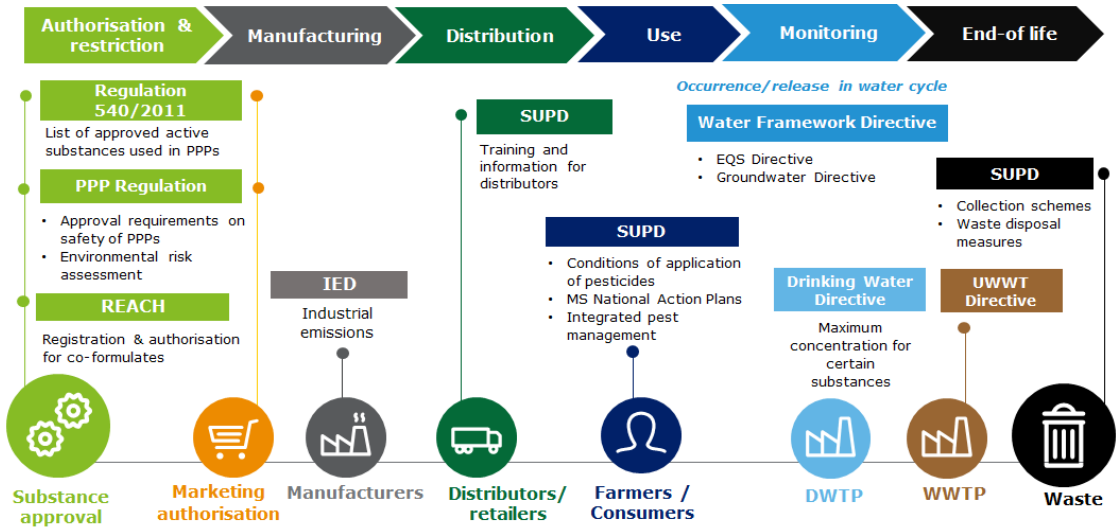
The pesticides supply chain begins at the **research and development** phase, involving both plant protection companies and the research community. Many plant protection products (PPPs) include **active substances**, which must be approved and registered at both national and EU levels before they can be **produced, distributed** and **placed on the market**. During the approval phase, active substances are thoroughly assessed for potential impact on human and animal health and the environment through risk assessments carried out by national institutions. During their **use phase**, PPPs can be accessed by distributers and end-users e.g. farmers, municipalities, etc. through a variety of outlets including farm cooperatives, specialised retailers such as garden centres, on-line retailers, etc.

According to the most recent EEA assessment report on the status and pressures of European waters (EEA, 2018a), nitrates were reported as the pollutant that most commonly caused poor chemical status by Member States (causing failure in 18 % of groundwater body areas). Pesticides were identified as another major source, causing failure in 6.5 % of groundwater bodies by area. A 2019 study assessed and screened water samples from 29 small waterways located in 10 different countries in the European Union. Among the 103 pesticides identified, 24 were banned in the EU (Casado, 2009). Herbicides were the main contributor to the total amount of pesticides found in the samples of this study. In addition to water or air quality monitoring, pesticide residues is monitored in food and feed, which is carried out at EU level by the European Food Safety Authority (EFSA). EFSA's latest annual report on pesticide residues in food concluded that in 2017, overall, 95.9% of the 88,247 samples analysed fell within the legal limits (EFSA, 2019). Although such assessments allow for the monitoring and identification of potentially high concentrations of pesticide residues (stemming from food products), the scope of the monitoring is limited (12 food products)[13] and it does not specifically cover the potential risks of pesticide residues in the environment is not specifically covered by the monitoring programme.

The EU's Seventh Environment Action Programme (7th EAP) lays out the objective that by 2020, the use of plant protection products should not have any harmful effects on human health and the environment. However, according to a report by the European Environment Agency (EEA), in 2018, the total reported sales of pesticides in the EU did not show a significant decrease between 2011 and 2016 and shares of different pesticide product groups remained relatively constant in 2015[14], indicating that this objective would most likely not be met. Therefore, trends in the overall evolution of pesticide sales do not point to a European-wide shift towards reduced consumption of PPPs and thereby the potential impact on the environment and human health. At their **end-of-life**, PPPs residues or their degradation products are released into the aquatic environment (surface water and groundwater) through soil run-off, collected and treated by drinking and waste water treatment plants. Figure 9 provides an overview of the main legislation at EU level across the life-cycle of pesticide products.

[13] EFSA monitors and assesses consumer exposure to pesticide residues by food commodity in 3-year cycles.
[14] www.eea.europa.eu/airs/2018/environment-and-health/pesticides-sales

Figure 9: Applicable EU legislation across the life-cycle of pesticide products



7.2 Key relevant provisions specific to pesticide products

The most relevant EU legislation on pesticide products in the context of addressing micropollutant emissions and potential application of EPR include Regulation 1107/2009[15] on the placing of plant protection products (PPP) on the market (Plant Protection Product Regulation) and to a lesser extent Directive 2009/128/EC on the sustainable use of pesticides (Sustainable Use of Pesticides Directive - SUPD). The PPP regulation is currently under-going a REFIT evaluation as part of the review of EU chemicals legislation (Box 5). The most relevant provisions of these legislations are summarised in Table 10. Box 7 provides an overview of the marketing authorisation procedure.

Table 10: Summary of most relevant provisions on pesticide products

Life-cycle stage	Relevant provisions in existing EU legislation
Substance approval & marketing authorisation	**Regulation 1107/2009 on placing of plant protection products on the market:** The PPP Regulation aims to ensure high level of protection of human and animal health and the environment and improve the functioning of the internal market and agricultural production. It is the main legislative instrument at EU level laying down the rules and procedures for the authorisation and placement of PPPs on the market (approval and marketing authorisation stages). The marketing authorisation requirements is based on a **two-step procedure**: (1) Active substances are approved at EU level based on risk management/assessment by the Commission, the European Food Safety Authority (EFSA) and national regulatory agencies. The Commission is required to establish a list of active substances with certain properties identified as 'candidates for substitution', with the aim of determining whether they can be replaced (substituted).[16] (2) Plant protection products are granted marketing authorisation at national level and is subject to several conditions, including evidence that the PPP does not have any (direct or indirect) harmful effects on humans or the environment e.g. pesticide exposure assessment for surface waters, existence of suitable and less harmful substitutes, etc.

[15] https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32011R0546&from=EN
[16] It takes approximately 2.5 to 3.5 years from the date of admissibility of the application to the publication of a Regulation

Life-cycle stage	Relevant provisions in existing EU legislation
	Regulation 540/2011 amending the Annex of Regulation 1107/2009: Provides a list of approved active substances for use in plant protection products. The exclusion criteria for the approval of active substances include carcinogens, mutagens and reprotoxic (CMR) substances, endocrine disruptors, PBT and vPvB substances.
	Regulations on conditions of approval of certain active substances found in pesticides (neonicotinoids): In May 2018, the Commission adopted these Regulations to completely ban the outdoor uses of the neonicotinoid insecticides: clothianidin, thiamethoxam and imidacloprid.[17]
Distribution & use	**Sustainable use of Pesticides Directive 2009/128:** The Sustainable use of Pesticides Directive (SUPD) aims to achieve more sustainable use of pesticides in the EU by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management (IPM), including alternative approaches or techniques, such as non-chemical alternatives to the use of pesticides. Key provisions therefore mainly address the distribution, use and management phase of PPPs: • Requirements to protect the aquatic environment and drinking water: encourages the use of pesticides that are not classified as dangerous for the aquatic environment, the most efficient and least environmentally harmful application techniques, use of mitigation measures which minimise the risk of off-site pollution, reduce as far as possible or eliminate applications that are in proximity to surface or groundwater sources or in areas with a high risk of run-off into surface water or sewage systems (Article 11, SUPD). • Training of distributors and users (farmers) on sustainable use of pesticides, including information and awareness raising • Quantitative objectives, targets, and timelines on measures to promote low-pesticide-input pest management and non-chemical methods, including both integrated pest management and organic farming in MS National Action Plans (NAPs).
Monitoring	**Groundwater Directive 2006/118**: Requires Member States to set quality standards or threshold values for maximum concentration of active substances used in PPPs detected in groundwater. Authorisation is only granted if plant protection products have no harmful effect on human health and the environment e.g. contamination of drinking water and groundwater.
	Drinking Water Directive 98/83 (as amended): Sets a maximum concentration of 0.1 µg/l for any single pesticide and the sum of the pesticides (relevant metabolites) must not exceed 0.5 µg/l for distributed tap water[18]. The Commission and Member States actively monitor several pesticides to encourage harmonised reporting, however, the limited number of pesticides monitored do not fully reflect all relevant pesticides and metabolites in a specific country. This makes it difficult to assess associated health and environmental risks.

approving a new active substance, however the time can vary greatly depending on the complexity and completeness of the dossier. Authorisations are typically granted for ten years: https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en

[17] Regulation No. 2018/783: bans the use of imidacloprid; Regulation No. 2018/784: bans the use of clothianidin; Regulation No. 2018/785: bans the use of thiamethoxam

[18] https://www.data.gouv.fr/fr/datasets/qualite-des-cours-deau-vis-a-vis-des-pesticides-sur-le-territoire-des-sage-bretons-respect-des-limites-reglementaires-sanitaires-fixees-pour-lalimentation-en-eau-potable/
https://www.generations-futures.fr/publications/residus-de-pesticides-lalimentation-leau-lair-reglementation/

Life-cycle stage	Relevant provisions in existing EU legislation
	Regulation 396/2005 on maximum residue levels (MRL) of pesticides in or on food and feed of plant and animal origin: Aims to protect consumers and animal health by setting limits and controls on the amount of pesticides used on food and animal feeding stuffs and facilitate trade by setting common standards. It should be noted however that the main objective of the Regulation is not intended to protect the environment, rather human health.
	Sustainable use of Pesticides Directive 2009/128: The SUPD requires MS to establish National Action Plans (NAPs) to implement the range of actions set out by the Directive. In particular, NAPs should include indicators to monitor the use of pesticides containing active substances of particular concern, especially if alternatives are available. In addition, the SUPD also includes provisions on the inspection and monitoring of spraying equipment and the establishment of an EU indicator for plant protection products.
End-of-life	**Sustainable use of Pesticides Directive 2009/128:** Article 13 of the Directive requires Member States to implement necessary measures to ensure that operations including handling of packaging and remnants of pesticides and disposal of tank mixtures remaining after application, by professional users (and where applicable by distributors) do not endanger human health or the environment. This means that Member States are required to implement appropriate collection schemes and waste disposal measures to minimise the risks posed by this waste stream. Finally, Member States are required to also take all necessary measures regarding pesticides authorised for non-professional users to avoid dangerous handling operations, including packaging disposal.

Box 7: Components of the evaluation for pesticides products, Regulation 1107/2009

In principle, active substances meeting the following exclusion criteria will not be approved:

- Mutagens substances categories 1A or 1B according to the CLP Regulation
- Carcinogens and reprotoxic substances categories 1A or 1B according to the CLP Regulation unless the exposure of humans to that active substance is negligible
- Endocrine disruptors unless the exposure of humans to that active substance is negligible
- Persistent organic pollutant (POP)
- Persistent, bioaccumulative and toxic (PBT) substances
- Very persistent and very bioaccumulative (vPvB) substances

However, there are exceptions to authorisation and approval requirements under the PPP. For example, for active substances that are considered necessary on the grounds of public health or of public interest and where no alternatives are available. In these situations, approval of an active substance is granted for a maximum of five years. The following criteria, based on the hazardous properties in combination with their use, are applied to identify active substances as candidates for substitution (if one of it is met):

- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use.
- It meets two of the criteria to be considered as PBT.
- It causes concerns for human or animal health and for the environment even with very restrictive risk management measures.
- It contains a significant proportion of non-active isomers or impurities.
- It is classified as carcinogen or toxic for reproduction category 1A or 1B and the exposure to humans is negligible.

Box 8: REFIT evaluation of the EU pesticide legislation[19,20]

In 2016, the Commission launched a REFIT evaluation of the EU pesticide legislation (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) to assess the extent that they meet the needs of citizens, businesses and public institutions. In particular, the PEST Committee (Special Committee set up by the European Parliament in 2018 to investigate the authorisation procedure for pesticides) published a report (adopted by the European Parliament on 16 January 2019) highlighting:

- The shortfalls of the current pesticide authorisation system and calls for substantial improvements in the process to ensure that pesticides used in agriculture and management of green/urban areas cause no adverse effects to humans, animals and the environment; and
- Sets recommendations that should be taken into account in the current REFIT process of the pesticide regulation.

In addition to the above EU legislation, it should be noted that several MS have also implemented more stringent requirements at national level for certain substances:

- Neonicotinoids: On the 27th of April 2018, the Member States adopted the Commission's proposal to ban the use of 3 neonicotinoids (imidacloprid, clothianidin, thiamethoxam) under the initiative of France. The use of these 3 molecules was partially restricted in 2013 by the Commission. This interdiction relied on the conclusion of the EFSA in February 2018 that stated the highly toxicity of neonicotinoids to honey bees, solitary bees and bumble bees. The same year in France, all neonicotinoids were banned (imidacloprid, clothianidin, thiamethoxam, thiacloprid et acetamiprid) as part of the biodiversity bill. The ban on the use of these substances has been effective since September 1st 2018, with a possibility of derogation until 2020. This measure has been completed by the agricultural and food law voted in November 2018, which extended the definition of neonicotinoids to other molecules (e.g. sulfoxaflor and flupyradifurone) that present a similar characteristics and functions.
- Glyphosate: In November 2017, after 18 months of intense debate, and despite strong pressure from EU citizens to ban glyphosate (cf. Ban glyphosate European Citizens' Initiative), the Commission approved the re-authorisation of glyphosate for an additional 5 years. France and Germany took the lead on this controversial subject by committing to a complete ban of glyphosate by 2022, the expected year of expiry of the approval for this substance. In 2019, a re-assessment process has been launched led by four countries: Hungary, Netherlands, Sweden and France.

7.3 Possible legislative changes and opportunities for EPR

The **Plant Protection Products Regulation 1107/2009** appears to be the most applicable legal basis for the implementation of an EPR scheme on pesticides. The PPP Regulation covers the marketing authorisation phase, therefore existing provisions could be amended to incorporate EPR and require companies to adhere to the EPR scheme (payment of fees based on risk assessment results or monitoring data) as an additional condition for obtaining marketing authorisation. **The Sustainable use of pesticides Directive 2009/128** also provides possible opportunities for applying EPR principles, for example by incentivising best practices in PPP application to reduce environmental and

[19] European Commission website on REFIT evaluation of EU pesticides legislation: https://ec.europa.eu/food/plant/pesticides/refit_en
[20] Pesticides Action Network – Europe. January 16, 2019 'European Parliament votes to improve the pesticide authorisation system' www.pan-europe.info/press-releases/2019/01/european-parliament-votes-improve-pesticide-authorisation-system

health risks e.g. EPR fee reductions, exemptions, subsidies, etc. Nonetheless, it should be noted that the national action plans required under the Sustainable use of pesticides Directive are often contain less ambitious targets and goals compared to the PPP Regulation 1107/2009.

In the context of PPPs, the financing mechanism for EPR could be established through an **EPR fund** to be financed by PPPs producers and farmers (end-users), where relevant or the application of a **dedicated EPR fee** on active substances to be paid by manufacturers based on:

- Quantity of the substance placed on the market
- Costs of treatment (and remediation)
- Green design/ecodesign criteria
- Local and regional conditions (in regard to hotspots i.e. localised areas with high concentrations of pollutants)

In the case of pesticides, holding manufacturers financially responsible for the costs of end-of-life treatment could lead to increased prices for pesticide products, which might be passed on to farmers. Although, this could be perceived as objectionable in the short-term, the overall objective would be to further encourage the uptake of best practices in product design as well as more sustainable farming practices. To address the transition period required for more sustainable eco-farming practices and systems, which may represent financial risks for producers and could require substantial investments for new equipment and facilities for farmers, dedicated EPR funds could be used to support the transitional period e.g. providing financing for investments needed to upgrade production and storage facilities, etc.

Regarding the designation of potential substances, substances from the Surface and Groundwater Watch Lists, Priority Substances identified under the Environmental Quality Standards Directive 2008/105 and substances identified as posing potential environmental risks based on the assessment results under the Plant Protection Product Regulation 1107/2009 could be used in the context of a potential EPR scheme. Table 11 identifies the possible legislative changes and opportunities for EPR to address the release of micropollutants from pesticide products.

Table 11: Potential legislative changes & EPR opportunities for pesticides

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Substance approval & marketing authorisation	**PPP Regulation 1107/2009:** Update requirements on substance approval and marketing authorisation: • Integrate additional parameters to be covered in the risk assessment e.g. long term toxicity, mobility of substances, potential harmful effects of metabolites. • Additional data and reporting requirements • Ensure that sales statistics concerning pesticides are publicly available per active substance and per Member State, and that pesticide statistics are further improved so as to provide full information for the environmental risk assessment as well as the comparative assessment plant protection products with substitution candidates.	Authorisation and restrictions	Monitoring and reporting	Results of risk assessment can serve as basis for identifying relevant substances/ producers and setting EPR fees.
	PPP REGULATION 1107/2009: Amended to serve as the regulatory framework for the implementation of a dedicated EPR scheme for PPPs. • EPR fees could be established (and modulated) based on results of the (updated) risk assessment e.g. level of risk for active substances and PPPs designed based on green chemistry criteria (benign by design). • Increase possible synergies with the Sustainable Use of Pesticides Directive and further incentivising best use practices e.g. for example by incorporating best use practices within framework for establishing EPR fees (and reductions).	–	**EPR financing mechanism** (based on modulated fees)	**LEGAL BASIS FOR EPR**
Monitoring	**Water Framework Directive 2000/60:** Allow monitoring data to be used within a possible EPR scheme to designate priority substances/products and set corresponding fees. Ensure that monitoring of substances cover both ground and surface water. • EQS Directive 2008/105: Inclusion of additional potentially hazardous active ingredients used in PPPs in Surface Watch List for surface water. • Groundwater Directive 2006/118: Inclusion of additional potentially hazardous active substances used in PPPs.	–	Monitoring and reporting	• Data collected can serve as basis for setting EPR fees • Monitoring activities financed through EPR
	REACH Regulation 661/2009: Additional monitoring and chemical safety requirements. • Update Chemical Safety Assessment to include additional toxicity properties and ensuring that environmental risks are assessed across the entire water cycle. • REACH Regulation 661/2009: Allow for the possibility of including possible SVHC relevant for plant protection products on candidate list.			

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Use	**Information provision requirements:** Ensure that producers provide guidance to end-users (farmers) on: • Safe and sound EOL management of PPPs • Sustainable use of PPPs put on the market (e.g. use of adequate equipment, guidance on best environmental practices and sustainable use).	–	Information provision	Mitigation measures to support (and financed by) EPR
	Sustainable use of pesticides Directive 2009/128: Increase synergies with Regulation 1107/2009 and further promote the objectives of the Directive by integrating key (additional) provisions within a dedicated EPR scheme. Including relevant provisions under Directive 2009/128 as part of a potential EPR scheme on pesticides (as described above under Regulation 1107/2009 as legal basis for EPR) would help to increase synergies as well as further support an EPR scheme. For example, application of EPR fee reductions, exemptions etc. based on uptake of best application (use) practices.	–	Application (use) conditions	Supporting mitigation measures for a dedicated EPR scheme.
End-of-life	**Waste Framework Directive 2008/98:** Although some substances found in PPP waste are currently included in Annex III of Directive 2008/98, classifying them as hazardous waste (and therefore subject to additional requirements and a stricter control regime), the criteria laid out in Annex III could be further assessed to allow for a more exhaustive approach to identifying and classifying potentially hazardous PPP waste.	–	EOL treatment requirements	–
	Sustainable use of Pesticides Directive 2009/128: Increase synergies with Regulation 1107/2009 and further promote the objectives of the Directive by integrating key (additional) provisions within a dedicated EPR scheme. • Integrate EPR recommendations laid out by the Waste Framework Directive 2008/98 e.g. financing of waste management and treatment costs. • Additional guidance to increase harmonised practices and performance of existing collection schemes.	–	• Information provision • EOL treatment requirements	Supporting mitigation measures for a dedicated EPR scheme.

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
	Complementary downstream (end-of-pipe) measures to support control-at-source and EPR: • Drinking water Directive 98/83: Requirements on additional water treatment, where relevant, should comply with parametric values and ensure that quantities treated and associated costs are reported. • Urban waste water Directive 91/271: Although WWTPs represent a minor pathway for PPPs, there may be specific hotspots for which additional treatment steps (technology and coverage of costs by producers) are needed to treat pesticide residues. As such, revisions to the UWWTD should assess the (1) relevance and feasibility of additional treatment requirements (technology and coverage of costs by producers) in such hotspots to treat PPP residues in line with official target values and (2) ensure that quantities treated and associated treatment costs are reported.	–	• Monitoring and reporting • Drinking and waste water treatment requirements	Monitoring and reporting data can serve as basis for setting EPR fees e.g. substance and quantity treated, treatment costs, etc.

7.4 Potential obstacles and success factors

Some of the key potential obstacles and success factors in the area of pesticides are summarised below in Table 4.

Table 12: Potential obstacles and success factors

Obstacles	Success factors
Impact on competition and internal market: Transferring treatment costs to manufacturers could lead to increased prices for pesticide products, which might be passed on to farmers and result in undesirable effects on competition and the market. Further, farmers may be reluctant to change their current e.g intensive farming practices.	**Incentivise best practices:** Application of EPR principles by incentivising producers and farmers to use less harmful substances PPPs, thereby encouraging best practices and ecodesign, which would contribute to promoting more sustainable farming practices. For example, reduction in the use of pesticides e.g. organic farming, soil health improvement practices, etc.
Stakeholder acceptance: Several actors from the pesticides industry such as farmer associations, claim that there is a lack of sufficient knowledge and data on the potential impacts of micropollutants released from PPPs in order to designate individual producer responsibility in a transparent and justified manner is difficult. The question of who is the polluter (producer or farmer) is also raised. This argument prevents wider stakeholder acceptance/ recognition of responsibility.	**Support scientific research, public concern and awareness:** The current available knowledge base on the sources of micropollutant emissions is very extensive, with perhaps the exception of certain transformation products generated in waste water and drinking water treatment plants. Thresholds for a wide range of potentially harmful pesticide substances are already established for example in the GWD. Increasing scientific research and public concern are important drivers for changing policies e.g. glyphosate and influencing the actions of producers. Supporting on-going and new research as well as addressing public concerns are therefore vital to ensure that consumers and other relevant stakeholders are provided with accurate and relevant information.

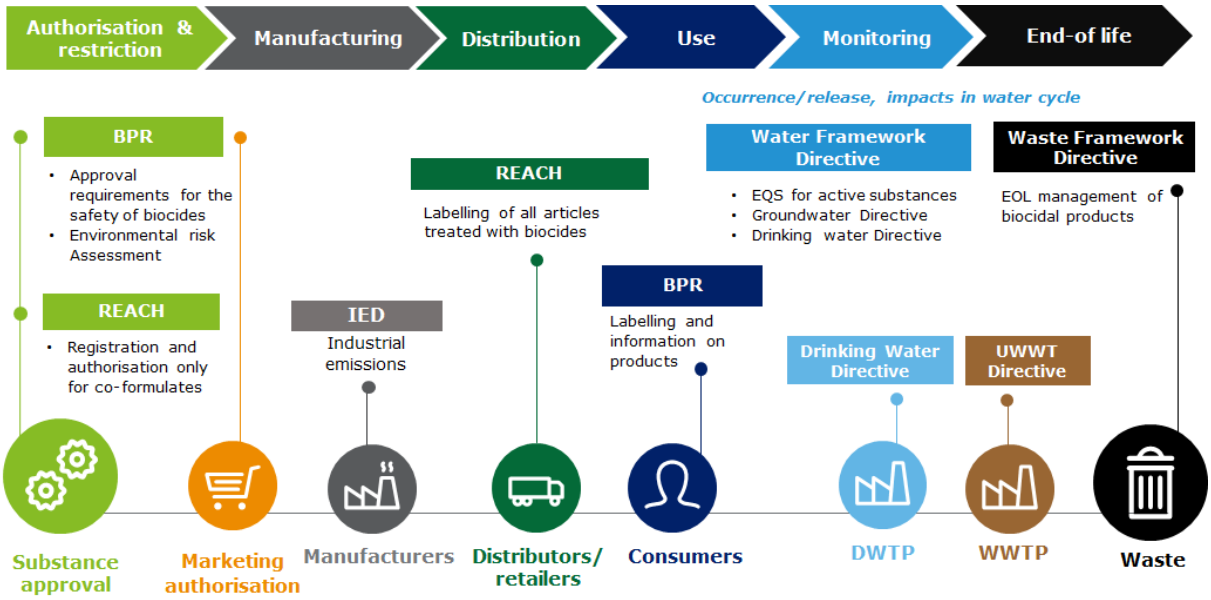
Obstacles	Success factors
Gaps in existing regulatory framework: Although there is a clear regulatory framework at EU level governing pesticides, current provisions do not specifically address micropollutants emissions, nor do they sufficiently encourage or require producers to accelerate the deployment of actions that would contribute to reducing/ avoiding the release of micropollutants from pesticide products into the aquatic environment. Despite good practice examples from some industry actors to implement their own initiatives to tackle pesticide residues, further legislative efforts involving all stakeholders are needed.	**Encourage cross-sectoral stakeholder dialogue, policy coherence and adapted legislation:** Multi-level stakeholder discussions and knowledge exchange play an important role in gathering data for scientific research and that the concerns of all stakeholders are adequately reflected in existing (and future) legislation. This would contribute to not only ensuring that the regulatory framework is adequate but also help to obtain stakeholder support. Examples of good cooperation between PPP producers, farmers and water suppliers as well as consumers should be extended and supported by public authorities. For example, according to a recent a Eurobarometer report, at least half of the EU citizens surveyed strongly support the consideration of environmental protection and tackling climate change within EU agricultural and rural policy objectives (Eurobarometer, 2018). In addition to cross-sectoral stakeholder cooperation, it is essential to increase the coherence and linkages between the PPP Regulation 1107/2009, SUPD and other relevant agricultural polices e.g. the EU's common agricultural policy (CAP).

8. Biocides

8.1 Overview of supply chain and relevant EU legislation

The biocides supply chain starts at the **research & development** phase, followed by the design phase, involving chemicals companies and the formulation of biocidal products and active substances. At the EU level, all active substances must be approved and in some cases renewed, before they can be registered and placed on the market. During the approval process, the active substance is thoroughly assessed regarding its impact on human and animal health as well as the environment. Once the active substance is approved, a **marketing authorisation** of the biocide must be applied for at the national level. A risk assessment is then made by a national institution and, once the biocide marketing authorisation is approved, it can be **produced** and **distributed** in the country. During **the use phase**, biocides are accessible to users via various distribution channels (specialised retailers, supermarkets, through online sales, etc.). Biocides can be applied on clothing surfaces and human skin for disinfectant and cosmetic purposes. The scope of this study concerns for example silver in sportswear, triclosan in cosmetic and tolylfluanid in wood preservation. Figure 10 provides an overview of the principal EU legislation across the life-cycle of biocidal products.

Figure 10: Applicable EU legislation across the life-cycle of biocidal products



8.2 Key relevant provisions specific to biocidal products

The most relevant EU legislation on biocidal products in the context of addressing the emissions of micropollutants and the potential application of EPR is Regulation 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation – BPR). Other legislation such as the Groundwater Directive 2006/118 and the Waste Framework Directive 2008/98 also include potentially relevant provisions. The following table summarises the most relevant provisions of these legislations.

Table 13: Summary of most relevant provisions on biocidal products

Life-cycle stage	Relevant provisions in existing EU legislation
Substance approval & marketing authorisation	**Biocidal Products Regulation 528/2012**: All biocidal products require an authorisation before they can be placed on the market in the EU (Box 9). Further, the active substances contained in that biocidal product must be previously approved. The BPR identifies substances of particular concern to public health and the environment, with the aim of ensuring that these substances are eventually phased-out and replaced by more suitable alternatives. The BPR also allows for a simplified authorisation procedure that aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. Further, companies can benefit from reduced registration fees when the active substance is not a candidate for substitution. Box 10 summarises some of the requirements under the BPR in regards to exclusions criteria, parameters used to assess the potential impacts of biocidal products, eligibility conditions for the simplified authorisation procedure and criteria for substances candidates for substitution.
Monitoring	**Groundwater Directive 2006/118** (Article 17 of Water Framework Directive): Similar to the PPP Directive, the placement on the market of biocidal products can only be authorised if the products have no harmful effect on human health, or groundwater and do not have undesirable effects on the environment, particularly on the contamination of water such as drinking and groundwater.
Use	**Biocidal Products Regulation 528/2012:** All treated articles placed on the market from 1 September 2013 onwards have to comply with the labelling and information requirements (Box 9 in Annex 2).
End-of-life	**Waste Framework Directive 2008/98:** Recital 25 of the Biocide Products Regulation stipulates that in order to avoid possible negative effects on the environment, the end-of-life management of biocidal products must be dealt with in accordance with the Waste Framework Directive.

Box 9: Market authorisation requirements for biocidal products (Regulation 528/2012)

As laid out under Regulation 528/2012, active substances meeting the following criteria cannot be placed on the market:

- Carcinogens, mutagens and reprotoxic (CMR) substances categories 1A or 1B according to the CLP Regulation
- Endocrine disruptors
- persistent, bioaccumulative and toxic (PBT) substances
- Very persistent and very bioaccumulative (vPvB) substances

There are however certain exceptions to authorisation requirements, notably for active substances that are considered necessary on the grounds of public health or of public interest and where no alternatives are available. In these situations, approval of an active substance is granted for a maximum of five years. Derogations also apply to biocidal products containing active substances in the Review Programme, which can be made available on the market pending the final decision on the approval of the active substance (and up to 3 years after). In addition, products containing new active substances that are still under assessment may be granted provisional market authorisation. This exemption applies to many active substances used in disinfectants and preservatives.
To be eligible for the simplified authorisation procedure a biocidal product must comply with all of the following conditions:

- All active substances contained in the biocidal product appear in Annex I of the BPR and comply with specified restrictions. Annex I lists all active substances identified as presenting

a low risk and toxicity under the REACH Regulation 661/2009 or the BPR, which includes substances such as food additives, pheromones, weak acids, alcohols and vegetable oils used in cosmetics and food.
- Does not contain any substance of concern, including nanomaterials.
- The biocidal product is sufficiently effective and does not require personal protective equipment in relation to intended use.

The following criteria, based on the hazardous properties in combination with intended use, are applied to identify active substances as **candidates for substitution**:

- Meets at least one of the exclusion criteria
- Classified as a respiratory sensitiser
- Toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use
- Meets two of the criteria to be considered as PBT
- Causes concerns for human or animal health and the environment even with very restrictive risk management measures
- Contains a significant proportion of non-active isomers or impurities.

The following information must appear on the labelling of a product treated by biocidal products:

- Statement that the treated article incorporates biocidal products;
- Biocidal property attributed to the treated article;
- In line with Article 24 of Regulation 1272/2008, the name of all active substances contained in the biocidal products; including any nanomaterials contained in the biocidal products;
- Any relevant instructions for use, including precautions to be taken.

Box 10: The BPR and the use of silver as a biocide in textiles (sportswear)

Silver is used in textile articles such as sportswear, for its antibacterial properties. However, an important challenge with the use of silver in sportswear is the leaching of silver from the sportswear during the washing and as a consequence the presence of silver ions in the aquatic and in the soil environment. Most of the silver has often leached from the sportswear after only 10 washes (Svenskt Vatten, 2018). The silver ions entering the waste water treatment plant can not at all be removed, they go either to the water environment or to the sludge. Unfortunately, many manufacturers or retailers of silver-treated textiles do not inform consumers on the potentially harmful effects of silver used in textile products. This has led to the examination of various silver-based substances in the context of the review programme of biocidal active substances as listed in Annex II to Regulation No 1062/2014. For some of these silver-based substances, ECHA has recently recommended non-approval based on lack of demonstration of efficacy and the potential risks to human health and to the environment arising from the use of silver in textiles.

8.3 Potential legislative changes and opportunities for EPR

For biocidal products, the Biocidal Products Regulation 528/2012 could serve as an applicable regulatory basis for the implementation of EPR. The BPR lays down the substance approval and marketing authorisation requirements for biocidal products, which could be amended to incorporate EPR by making adherence to the EPR scheme mandatory in order to obtain marketing authorisation. Similar to pharmaceuticals and pesticides, the application of EPR for biocidal products could be established through a dedicated EPR substance fee or contribution to an EPR fund. Finally, in regards to potential obstacles and success factors, the same factors identified for pesticides are also applicable to biocidal products (Table 12). An important aspect specific to biocides is the wide range of products and sectors covered by the BPR. Accordingly, aspects such as potential overlaps with other legislation e.g. Cosmetics Products Regulation 1223/2009, Detergents Regulation 648/2004, etc. and the need to involve all of the different actors concerned would need to be considered. Table 14 summarises some of the possible changes in existing EU legislation and opportunities for EPR to address the release of micropollutants from biocidal products.

Table 14: Potential legislative changes & EPR opportunities for biocides

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Substance approval & authorisation	**Biocidal Products Regulation 528/2012 (BPR):** Amendments to the procedure and requirements for substance approval and marketing authorisation, which integrate additional parameters covered by the environmental risk assessment e.g. long term toxicity, mobility of substances, potential harmful effects of metabolites.	Authorisation and restrictions	–	Data collected from ERA can serve as basis for setting EPR fees, identify relevant substances and producers, etc.
	BIOCIDAL PRODUCTS REGULATION 528/2012: Amended to serve as the regulatory framework for the implementation of a dedicated EPR scheme for relevant biocide products. • Adherence to EPR scheme as a mandatory obligation for obtaining marketing authorisation. • EPR fee could be based on results of the ERA e.g. level of risk for active substances used in biocidal products based on green chemistry criteria to incentivise the placing of biocides that pose a lower risk to environment and health on the market.	–	**EPR financing mechanism** (based on modulated fees)	**LEGAL BASIS FOR EPR**
Distribution & use	**Biocidal Products Regulation 528/2012:** Additional requirements on information provision: • Launch dedicated awareness campaign to provide information and guidance on the safe disposal, management and collection of end-of-life biocidal products. • Additional provisions on the product labelling regarding the sustainable use of biocidal products placed on the market. For example, ensuring the term 'biocide' or 'biocidal product' is indicated as well as the main active substance used.	–	• Product labelling • Awareness campaigns	Mitigation measures to support (and financed by) EPR
Monitoring	**Water Framework Directive 2000/60:** Allow monitoring data (for substances in both ground and surface water) to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees. • EQS Directive 2008/105: Inclusion of additional potentially hazardous active ingredients used in biocidal products in Watch List for surface water • Groundwater Directive 2006/118: Inclusion of additional potentially hazardous active ingredients used in biocidal products.	–	Monitoring and reporting	• Data collected can serve as basis for setting EPR fees • Monitoring activities financed through EPR
	REACH Regulation 661/2009: Revisions to SVHC list and CSA criteria • Inclusion of most relevant SVHC used in biocidal products in candidate list. • Update the Chemical Safety Assessment to include additional toxicity properties and ensuring that environmental risks are assessed across the entire water cycle.	–		

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
End-of-life	**Waste Framework Directive 2008/98**: Include a provision on biocides in Annex III regarding the properties of waste which render them hazardous including a general provision that allows for biocide substances to be added to the priority (hazardous) substances list, automatically classify them as hazardous waste.	–	EOL treatment requirements	–
	Complementary downstream (end-of-pipe) measures to support control-at-source and EPR measures: • Drinking water Directive 98/83: Requirements on the installation of extra treatment technologies, if required, to comply with parametric values and ensure that associated quantities treated and costs are reported. • Urban waste water treatment Directive 91/271: Review of the UWWTD should assess the (1) relevance and feasibility of additional treatment requirements (technology and coverage of costs by producers) in hot spots, where relevant, to treat residues stemming from biocidal products in line with official target values and (2) ensure that quantities treated and associated treatment costs are reported.	–	• Monitoring and reporting • Drinking and waste water treatment requirements	Monitoring and reporting data can serve as basis for setting EPR fees e.g. substance and quantity treated, treatment costs, etc.

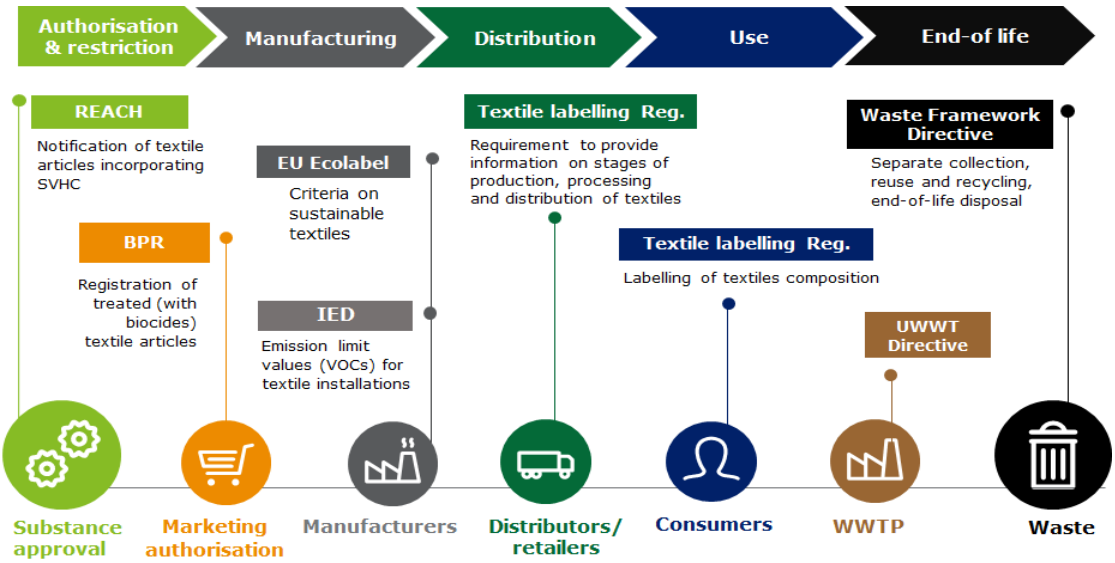
9. Textiles

9.1 Overview of supply chain and relevant EU legislation

The textile industry includes the production of textiles e.g. manufacturing of yarn, textiles and fabrics and clothing industry e.g. production of garments and apparel. Other types of textile products, such as household textiles and technical/industrial textiles (for instance, textiles for industrial filters, hygiene products, textiles for the car and medical industry) are also considered part of the textile industry. The production of textiles involves industrial processes for raw materials production to complement production and clothing manufacturing. **R&D** is the first step for the textiles and apparel industry, potentially allowing the development of new eco-friendly and sustainable raw materials and products, the improvement of existing manufacturing processes and the development of monitoring, control and testing instruments. The production of raw materials (spinning them into fibres, weaving fabrics and dyeing) require significant amounts of water and chemicals. While the EU remains a net importer of textiles and clothing, with annual imports over €80 billion, the EU is also one of the world's largest carpet producers (EC, 2019).

In regards to **consumption**, according to a European Parliament report, clothing accounts for between 2 % and 10 % of the environmental impact of EU consumption (EPRS, 2019). Further, the amount of clothes bought in the EU per person has **increased by 40 %** in just a few decades, driven by a fall in prices and the increased speed with which fashion is delivered to consumers (EPRS, 2019). During use, significant environmental impacts include water and energy consumption as well as the release of microplastics shed into the environment during washing, tumble drying and ironing. At their **end of life,** less than half of used clothes are collected for reuse or recycling, and only 1 % are recycled into new clothes due to the fact that technologies capable of recycling clothes into virgin fibres are only starting to emerge. Although systems for the collection, reuse and recycling of textiles are currently in place or being developed in a number of MS, collection rates are low (25%) with large differences between MS (EC, 2019). Figure 11 provides an overview of the principal legislation at EU level across the life-cycle of textiles.

Figure 11: Applicable EU legislation across the life-cycle of textile products



9.2 Key relevant provisions specific to textile products

The legislative assessment for textile products focuses on textiles at least partially composed of **synthetic fibres**, which are one of the main sources of secondary microplastics emissions in the natural environment. Natural fibres such as wool, cotton, hemp and jute, do not release microplastics and do therefore not fall within the scope of the assessment. The main issue related to textiles is the release of chemical substances e.g. dye and fragrance, as well as the release of microplastics during the use and manufacturing stages. Further, similar to biocidal products, textile products cover a wide range of different final products placed on the market e.g. synthetic yarns, bed-linens, industrial filters, carpets and clothing. As such, the industry is subject to a number of pieces of legislation and requirements throughout its supply chain.

There are currently no minimum criteria for the sustainable performance of textiles at EU level. Textiles production is covered by the REACH Regulation 661/2009 (see section 4.2) and the Industrial Emissions Directive 2010/75 (IED), which sets requirements for the chemicals used during textile production, as well as the reference document on best available techniques (BREF) on the textile industry (currently under review). Further, before they can be placed on the market, certain treated articles may also have to comply with the **Biocidal Products Regulation 528/2012**, which sets rules for the use of articles treated with, or intentionally incorporating biocidal products.

Once on the market, textile products must then comply with information and labelling criteria under Regulation 1007/2011 on Textile Fibre Names and related Labelling and Marking of the Fibre Composition of Textile Products (Textile Labelling Regulation). The **Textile Labelling Regulation** covers products at all stages of the supply chain and requires that textile products sold in the EU be labelled or marked to provide information about their fibre composition. However, the regulation does not include requirements to provide information on the producer or importer, the presence of substances potentially detrimental to human health e.g. microplastics emissions, nor guidelines on the sustainable use of textile products to reduce the release of microplastics. Similarly, textiles emitting microplastics are not in the scope of the REACH Regulation 661/2009, due to the fact that these articles are not designed to intentionally release microfibres. Finally, regarding their end-of-life, textile waste is currently governed under the **Waste Framework Directive 2008/98 and EU Circular Economy Package**. The EU circular economy package and accompanying revised Waste Framework requires Member States to set up separate collection schemes for textile waste produced by households by 2025. Further, it also requires the Commission to consider, by the end of 2024, whether targets for textile waste re-use and recycling and detailed criteria on the application of the end-of-waste status should be introduced.

The following table summarises the most relevant legislative provisions across the life-cycle of textile products to address the emissions of microplastics and potential application of EPR.

Table 15: Summary of most relevant provisions on textile products

Life-cycle stage	Relevant provisions in existing EU legislation
Substance approval	**REACH Regulation 661/2009:** Sets some requirements concerning the composition of textiles produced in Europe – notably, substances incorporated in textiles must be registered and importers are required to notify ECHA if textile products imported greater than 1 tonne, contain SVHC in concentrations above 0,1% (w/w) for products imported.
	Biocidal Products Regulation 528/2012: Restriction provisions under the BPR covers textile products that use biocidal finishes.
Manufacturing & distribution	**Industrial Emissions Directive 2010/75:** Includes thresholds and emission limit values (in particular VOCs emissions) for textile coating installations and activities, especially for pre-treatment (operations such as washing, bleaching, and mercerisation) or dyeing of textile fibres and textiles, tanning of hides and skins, and any activity using volatile organic compounds in an installation to clean garments. However, secondary microplastics emissions from industrial processes are not currently covered.
	Textiles Labelling Regulation 1007/2011: Harmonises the names of textile fibres and the indications appearing on labels, markings and documents which accompany textile products at the various stages of their production, processing and distribution: only the textile fibre names listed in Annex I to the Regulation shall be used on labels to describe the composition of a textile product. This regulation, however, does not integrate the labelling of textile articles that can unintentionally release fibres during the use phase.
	The EU Ecolabel Regulation 66/2010: Establishes some environmental criteria concerning textile fibres and chemicals used in manufacturing processes. These practices however, remain voluntary and the prevention of microplastics emissions during manufacturing and use phase e.g. ecodesign, use of natural fibres, are not specifically covered.
End-of-life	**The Waste Framework Directive 2008/98:** Establishes specific provisions in regards to end-of-life textile articles, including requirements on collection, reuse and recycling e.g. increasing preparing for re-use and recycling rates, enabling high-quality recycling and boost the uptake of quality secondary raw materials. In particular, the 2018 revision of the Waste Framework Directive introduced an obligation for separate collection of textiles by 2025. As part of the **European Strategy for Plastics in a Circular Economy**, the Commission is also investigating possible policy options for reducing the unintentional release of microplastics from certain products including textiles, with the aim of defining methods to assess microplastic losses as well as additional information requirements for product labelling (Annex I).

9.3 Potential legislative changes and EPR opportunities

Regarding the regulatory framework for the implementation of EPR on secondary microplastic emissions from textiles, the **Waste Framework Directive 2008/98** is found to serve as the most applicable legal basis. The Urban waste water treatment Directive 91/271 is another potential option, which is further discussed in the following chapter 12.

Although Member States are allowed to extend EPR to other waste streams (in addition to batteries, vehicles and electrical and electronic equipment), the application of the EPR to textile products is not common practice. To date, France is the only country implementing extended producer responsibility for end-of-use clothing, linen and shoes. However, recent policy developments could serve as an important driver to further extend the scope of existing requirements to take into account extended producer responsibility to address the costs of additional treatment steps related to the presence of microplastics in water bodies – especially since the obligation of fee modulation in case of collective fulfilment of the obligations by producers would also apply in case an EPR scheme for textiles is established (EC, 2019). For example, the recent revision of the Waste Framework Directive establishes obligations for separate collection of textiles by 2025, while one of the actions identified under the EU Plastics Strategy is to further examine possible policy options to address the unintentional release of microplastics from textiles.

In regards to the practical application of EPR, experience can be drawn from existing schemes. For example, the Eco TLC is a mandatory EPR scheme, accredited by the French Public Authorities, to manage the clothing and textiles sector's waste in France. It is currently the only mandatory EPR scheme that exists for end-of-life textile products. The scheme requires companies that introduce clothing, household linen, and footwear items on the French market to either set their own internal collecting and recycling programme or pay a contribution to Eco TLC. Experience and some of the elements of the EPR scheme could be a good basis for extending its scope in terms of technical (integrating microplastic emissions), geographic (EU wide) and legal basis (mandatory). Potential opportunities to apply EPR on microfibres released from textiles include:

- **Physical responsibility** of producers, in particular take-back and collection requirements, information requirements on product composition and sustainable use as well as the establishment of monitoring systems and information campaigns targeting consumers; and
- **Financial responsibility** placed on producers, applied through financing mechanisms that promote natural or low fibre-release garments and recycling and to cover the costs of treating microfibres in waste water or through microfilters in washing machines.

The funds collected by Eco TLC are used towards paying for waste treatment operations according to Eco TLC requirements, data collection and monitoring activities to analyse and develop reliable industry statistics, communication campaigns and guidance toolkits to all stakeholders involved in the programme. The scheme currently implements the following three approaches for calculating EPR contributions[21]:

- **Real costs:** Based on the volume placed on the market and size of each item.
- **Flat-rate contribution:** Based on the turnover of the company e.g. companies with a turnover of less than €750 000 or who put less than 5 000 items on the market per year are eligible for the flat-rate contribution. The flat-rate contribution is considered as the minimum contribution and is currently set at €45 per year.
- **Modulated fee:** Companies that implement ecodesign measures e.g. use of recycled fibres can benefit from a 25 to 75% reduction in the estimated real cost

Regarding the **modulated EPR fee** approach listed above, in order to adequately address the issue of microplastics emissions, additional ecodesign criteria e.g. biodegradability, use of natural fibres, etc. related to the release of microplastics would need to be established

[21] EcoTLC wesbite: www.ecotlc.fr/page-297-information-in-english.html

i.e. via the Ecodesign Directive 2009/125, which could be applied under the potential EPR scheme.

Complementary measures to support the EPR scheme include amendments to the **Textile Labelling Regulation 1007/2011** to require producer (importer) registration (similar to new proposals under the Tyre Labelling Regulation 1221/2009) to better identify producers, include product labelling information on microplastics emissions during wash and including appropriate instructions for sustainable use and safe disposal procedure (collection system for example). Labelling the recycled content of products could also serve as an incentive measure by educating consumers and providing them the opportunity to choose the type of products they want to buy and use.

Other supporting downstream "technical" measures include:

- A requirement that manufacturers / importers must first undergo initial washing of textiles and fibres under controlled conditions before they are sent to retailers, as a significant share of microplastics from textiles fibres are released during the first wash.
- Integration of filters designed to reduce the amount of microplastic loss in domestic washing machines and industrial washing sites, which could be applied within the context of ecodesign. A possible option for financing such filters could be a cross industry agreement between the clothing industry and the washing machine sector which would require clothing producers to help finance and develop filters for domestic washing machines. However, this last option would most likely be less effective due to the lack of a binding obligation. Furthermore, there would be a tangible risk that microfibres end up in sewers when filters are cleaned.

Finally, in addition to the establishment of a textile producer registry (manufacturers, importers), dedicated monitoring and data collection systems should also be implemented to provide sufficient information and control e.g reporting on treatment costs and quantities placed on the market, etc. For this, microfibres could be included in the list of substances to be monitored under the Water Framework Directive 2000/60 or included in future amendments under the Textile Labelling Regulation. Based on the review of existing EU legislation, Table 16 summarises possible changes in the regulatory framework and opportunities for EPR in regard to addressing secondary microplastics emissions from textiles.

Table 16: Potential legislative changes & EPR opportunities for textiles

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Marketing authorisation	**Ecodesign Directive 2009/125:** Extend the scope of the Directive to include textiles. • Establish material efficiency criteria on textiles e.g. minimum content of recycled material in new textile products; use of natural fibres from sustainable sources, biodegradability of fibres, the quantity of natural fibres used, resilience of products to abrasion during wash, etc. setting thresholds for microplastics emissions. • Add a requirement that manufacturers/importers undergo initial washing of synthetic textiles before they can be sent to retailers and placed on the market. • Introduce ecodesign requirements for the integration of microfibre filters in new washing machines before they can be placed on the market.	Authorisation and restrictions	–	Ecodesign/green chemistry criteria as a basis for establishing modulated EPR fees.
Production	**Industrial Emissions Directive 2010/75:** • Set limit values for microfibres emissions during manufacturing to encourage producers to use the best techniques available (BAT) e.g. filters for industrial use, reducing microplastics release in the aquatic environment. • Installation of post filtration at industrial level to ensure a pre-treatment of industrial effluents before discharge into the sewer system	Best available techniques (BAT)	–	–
Consumption	**Textile Labelling Regulation 1007/2011:** Amendments to the requirements on labelling for products placed on the market • Establishment of textile producers registry • Producers (manufacturers and importers) should be required to provide product labelling information on microplastics emissions (abrasion during laundry) • Appropriate instructions for sustainable use e.g. washing at low temperature, using liquid detergent instead of washing powder, using a softener and washing with a full load, used of specialised filters in washing machines, etc.	–	• Product labelling • Monitoring and reporting	Supporting mitigation measures under a dedicated EPR scheme.
	Waste Framework Directive 2008/98: Targeted information campaigns on best practices, notably in regard to consumption and appropriate end-of-life disposal.	–	Awareness campaign	Mitigation measures to support (and financed by) EPR.

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Monitoring	**Water Framework Directive 2000/60:** Allow monitoring data to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees. EQS Directive 2008/105: (1) Include additional parameters on monitoring and reporting requirements e.g. concentration of secondary microplastics emissions and (2) allow monitoring data to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees.	–	Monitoring and reporting	Data collected can serve as basis for setting EPR fees e.g. frequency, impacts, hotspots, etc.
	REACH Regulation 661/2009: Update the Chemical Safety Assessment to include additional toxicity properties that take account for secondary microplastics emissions and ensuring that environmental risks are assessed across the entire water cycle.			
End-of-life	**WASTE FRAMEWORK DIRECTIVE 2008/98:** Extend scope of requirements on textile waste to integrate specific EPR provisions related to microfibre release: • EPR could be applied to textile producers based on the amount and the type of product that is placed on the market and associated treatment (and remediation costs). Modulated product fees could be used based on ecodesign criteria e.g. product design, biodegradability criteria, level of risk of microplastic emissions etc. • Dedicated EPR fees used to help cover additional treatment costs, establishment of a producer register and monitoring and data collection system to ensure sufficient control and enforcement, as well as funding of information and awareness campaigns.	–	**EPR financing mechanism** (based on modulated EPR fees)	**LEGAL BASIS FOR EPR**
	Complementary downstream (end-of-pipe) measures to support upstream (EPR) measures: Urban waste water treatment Directive 91/271: Review of the UWWTD to assess (1) the relevance and feasibility of additional treatment requirements (technology and coverage of costs by producers) in hotspots, where relevant, to treat microplastics stemming from textile products (2) ensure that associated quantities treated and costs are reported and (3) assess ways to reduce microfibre release through CSOs.	–	• Monitoring and reporting • Waste water treatment requirements	Monitoring and reporting data can serve as basis for setting EPR fees e.g. substance and quantity treated, treatment costs, etc.

9.4 Potential obstacles and success factors

Some of the key potential obstacles and success factors of EPR in the context of microfibers released from textiles are described below.

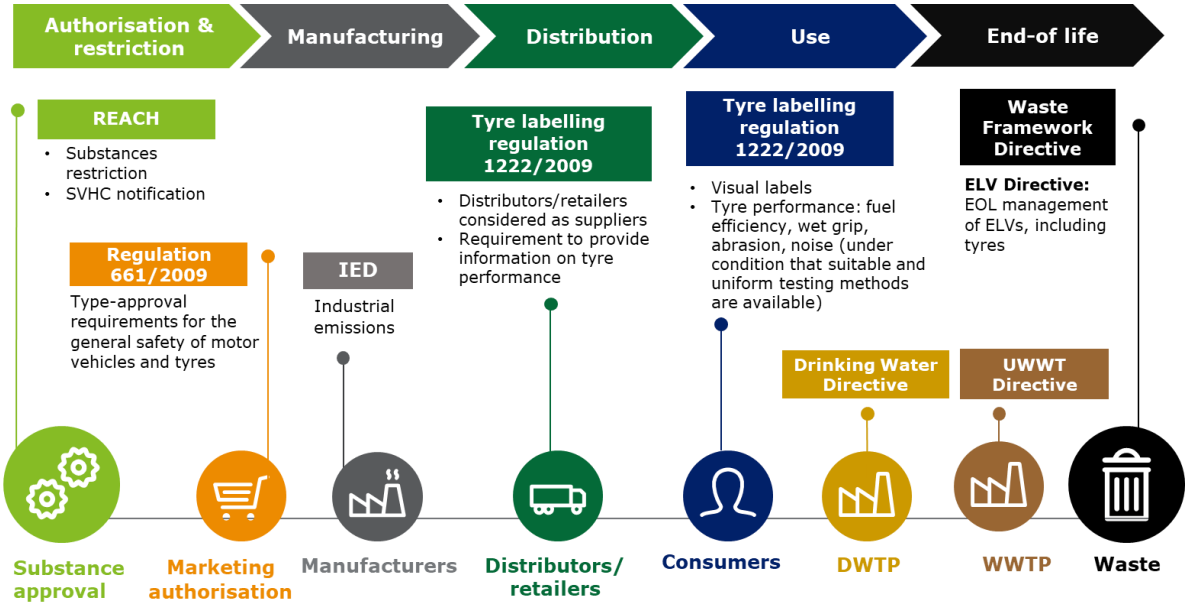
Obstacles	Success factors
Absence of sufficient regulatory framework: Currently, the release of microplastics from textiles are not regulated by existing EU legislation.	**Application of mitigation measures:** Current scientific research and public pressure point to the urgent need of addressing microplastic emissions. Mitigating measures such as initial washing by producers, the integration of microfibre filters in new washing machines and information provision to consumers are necessary actions to further reduce microplastic emissions and ensure that industry are held responsible. The funds collected from a dedicated EPR scheme could be used to further support scientific research, for example, the creation of an industry-led fund in partnership with other stakeholders such as water treatment operators and public authorities to finance research and investment in innovative solutions and technologies aimed at: reducing the environmental impact of textiles, fibre-to-fibre recycling, detection methods to quantify the release of microplastics, etc.
Role of consumers: A key challenge to address is the important role of consumers in partaking in existing collection schemes and other sustainable use and disposal practices. While an EPR scheme could encourage producers to use more sustainable raw materials, it could also lead to increases in final purchasing prices. This could in turn lead to purchasing behaviours that favour products that are cheaper and that result in more significant negative environmental impacts (non-compliant imported products for example).	**Information and awareness raising:** Consumer education and awareness is vital for an effective waste management system. Recent public concern about plastic pollution could be a key driver to further incentivise consumers to actively participate in the safe and sound use and disposal of textile products. Targeted information campaigns could help to increase consumer awareness and labelling on the importance of their actions as most households are not aware of the environmental consequences linked to microfibers loss from use and disposal.

10. Tyres

10.1 Overview of supply chain and relevant EU legislation

Tyres are subject to several EU regulations before they can be placed on the European market. Tyres must comply with product as well as information requirements e.g. product labelling, chemical composition, product safety, etc. Once tyre manufacturers obtain **authorisation** to place their products on the market, the **use phase** follows, during which, microplastics stemming from vehicle tyre wear are emitted onto road surfaces and end up into the aquatic environment and the soil. At their **end-of-life**, two types of end-of-life tyres (ELTs) can be distinguished: partly-worn tyres or end of life tyres. Certain end-of-life tyres (ELTs) comply with end of waste criteria enshrined in the EU Waste Framework Directive 2008/98. As such, a market or demand for ELT derived materials exists. They enter a waste management system based on product / material recycling, energy recovery or go to landfill. ELT derived materials are commonly used for specific purposes, meet related technical requirements as well as existing legislation and standards applicable to products. For example, ELTs can be resold as second-hand purchases or are re-usable after reprocessing, after which they can be reutilised for their original purpose. Figure 12 provides an overview of the principal legislation at EU level across the life-cycle of tyres.

Figure 12: Applicable EU legislation across the life-cycle of tyres



10.2 Key relevant provisions specific to tyres

The most relevant EU legislation on tyres in the context of addressing microplastics emissions and the implementation of EPR include provisions stemming from (1) REACH Regulation 661/2009 concerning restrictions on tyre chemical emissions, (2) Regulation 661/2009 on type-approval requirements for the general safety of motor vehicles and tyres (General Safety of Tyres Regulation 661/2009), (3) Tyre Labelling Regulation 1222/2009 and (4) Directive 2000/53 on end-of-life vehicles (ELV Directive). The following table summarises the most relevant legislative provisions across the life-cycle of tyres to address the emissions of microplastics and potential application of EPR.

Table 17: Summary of most relevant provisions on tyres

Life-cycle stage	Relevant provisions in existing EU legislation
Marketing authorisation	**REACH Regulation 661/2009** (Annex XVII) restricts the amount of PAHs[22] (POP and CMR) that can be emitted in the rubber production process. In addition, tyres which contain any substance on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information (substance declaration) to their customers to allow safe use of the article.
	General Safety of Tyres Regulation 661/2009 on type-approval requirements for the general safety of motor vehicles and tyres aims to harmonise at EU level the technical and environmental requirements e.g. sets minimum requirements on rolling resistance, tyre pressure monitoring systems, wet grip, rolling noise limits, CO_2 emissions, etc. from transport to ensure a high level of road safety and environmental protection throughout the EU. The Regulation lays out tyre performance standards by considering both **safety and environmental performance requirements** in the same legislative text.
Manufacturing & distribution	**Tyre Labelling Regulation 1222/2009** aims to ensure that safer, quieter and more fuel efficient tyres are placed on the EU market and encourages tyre manufactures to optimise those parameters. It defines a harmonised labelling (allowing consumers to make informed purchasing decisions) and testing regime throughout the EU. Under this regulation, it is necessary to measure the parameters of the tyre in accordance with UNECE Regulation 117 and then communicate these results in the form of a label on tyres (visible at the point of sale) and via technical promotion material. The Commission recently submitted a proposal for a new regulation on the labelling of tyres, which seeks to increase consumer awareness and improve market monitoring and enforcement across Member States[23]. These two aspects were identified as significant weaknesses of the current regulation. Box 11 summarises the most recent developments on the new proposal for the Tyre Labelling Regulation.
End-of-life	**End-of-life Vehicles Directive 2000/53** (ELV Directive) regulates the reuse, recycling and recovery of the ELVs and their components, which includes end-of-life tyres. Relevant provisions include requirements on producer registration, materials and components, free vehicle take-back and recovery and recycling targets. The ELV Directive is currently undergoing an evaluation by the Commission, which aims to review the feasibility of setting targets for specific materials contained in relevant waste streams and the problem of end-of-life vehicles that are not accounted for e.g. "vehicles of unknown whereabouts". This Strategy specifically refers to the automotive sector as a significant source of plastic waste that could be recycled and to its good potential for uptake of recycled content and includes under its actions the assessment of regulatory or economic incentives for the uptake, in particular in the context of the evaluation/review of the ELV Directive 2000/53.[24]

[22] Polycyclic aromatic hydrocarbons
[23] www.europarl.europa.eu/legislative-train/theme-resilient-energy-union-with-a-climate-change-policy/file-new-eu-rules-on-the-labelling-of-tyres
[24] Roadmap for Evaluation of the ELV Directive 2000/53: https://ec.europa.eu/info/law/better-regulation/initiative/1912/publication/307427/attachment/090166e5be276944_en

Box 11: Review of Tyre Labelling Regulation 1222/2009[25]

On 17 May 2018, the Commission adopted a new proposal on the labelling of tyres with respect to fuel efficiency, amending Regulation 2017/1369 and repealing Regulation 1222/2009. The objectives of the proposal were to clarify and extend the scope of the current regulatory framework, within the broader package of measures on Low Carbon Mobility. Following intense discussions with the Energy Working Party and European Parliament, the Council reached a provisional agreement on 13 November 2019 of the annexed text of the new proposal. Pending official procedural confirmation e.g. provisional agreement has been confirmed; final adoption by the co-legislators, some of the main changes to the regulatory framework to be expected include:

- Improve enforcement through the establishment of a dedicated tyre registration in a product database;
- Re-treaded tyres would be included within scope of the regulation and the new rules would apply to them, once a suitable testing method has been developed;
- Provisions on mileage and abrasion could be included in the new regulatory framework, once suitable testing methods are available.

Box 12: Tyre and Road Wear Particle Platform

The European Tyre and Rubber Manufacturers' Association (ETRMA) has launched in July 2018 the European Tyre and Road Wear Particles Platform (TRWP Platform), a multi-stakeholder initiative to tackle wear and tear from tyres issue. The Platform bring together members from European and National governmental bodies, Joint Research Centre, Road Authorities, as well as representatives from industry, science, water management and NGO's. In particular, the platform aims to share knowledge on the generation and fate and transportation of TRWP in the environment (for example achieve a common understanding of the possible effects of particles generated during normal tyre use and wear) and to explore potential mitigation options for a balanced and holistic approach to reduce the generation and transportation of microplastics into the environment.

In June 2019, an Action Plan was developed, with the aim to prevent and mitigate microplastics stemming from tyres. The Action Plan includes a number of measures, notably develop a methodology to analyse TRWP composition, establish incentives for more sustainable driving behaviour, address knowledge gaps, develop a platform to share and disseminate knowledge, identify hotspots and create awareness campaigns.

10.3 Potential legislative changes and EPR opportunities

Of the potentially applicable product-specific legislation assessed (General Safety of Tyres Regulation 661/2009; Tyre Labelling Regulation 1222/2009 and End-of-Life Vehicles Directive 2000/53), the **Tyre Labelling Regulation 1222/2009** is found to serve as the most relevant piece of EU legislation to serve as the legal basis for the implementation of EPR on tyre microplastics emissions.

While both the General Safety of Tyres Regulation 661/2009 and End-of-Life Vehicles

[25] European Council, 27 November 2019: Interinstitutional File: Proposal for a Regulation on the labelling of tyres with respect to fuel efficiency and other parameters, amending Regulation 2017/1369 and repealing Regulation 1222/2009: https://data.consilium.europa.eu/doc/document/ST-14495-2019-INIT/en/pdf

Directive 2000/53 present important opportunities for the application of EPR principles, the Tyre Labelling Regulation 1222/2009 holds the most potential in regard to overall regulatory clarity due to the recent agreement on important new provisions (see Box 11) and based on the assumption that suitable testing methods become available:

- **Establishment of a dedicated tyre registration in a product database:** It is assumed that producer registration at earlier life stages would more effective in designating relevant tyre producers e.g. before the use phase instead of at end-of-life, particularly as the main pathway for emissions is during use.
- **Inclusion of re-treaded tyres and provision on tyre abrasion:** Monitoring and reporting data, including the establishment of a dedicated database on tyre abrasion rates/ microplastics emissions could be used as basis for setting EPR fees. There is currently no such database that exists at EU level.

In light of the above, it would nonetheless be important to ensure that supporting measures are applied in the context of a dedicated EPR scheme, which could be enacted through other existing legislation, for example:

- **General Safety of Tyres Regulation 661/2009:** Implementation of supporting measures to further address the release of microplastics from tyres through inclusion of additional technical and environment criteria, setting minimum thresholds or ecodesign criteria on abrasion rates in product design requirements, etc.
- **ELV Directive 2000/53:** The ELV Directive is the first EU waste directive where the concept of extended producer responsibility was originally introduced and addresses several important aspects along the life-cycle of vehicles e.g. collection and treatment requirements, treatment costs, producer registration, etc. As such, the scope of existing EPR requirements could potentially be extended to cover microplastics emissions and treatment costs. However, an important weakness of the ELV Directive in relation to microplastics emissions from tyres is that similar to textile products, the **use phase** represents an important pathway for microplastics release.

Specific provisions on appropriate collection, recycling and disposal of end-of-life tyres and mitigation measures e.g. information and awareness campaigns to promote sustainable best practices in driving behaviour, establishing monitoring and data collection systems would also be key to effectively support a potential EPR scheme.

In terms of possible approaches for applying EPR financing mechanisms, modulated EPR fees could be established based on best manufacturing practices and product design criteria (ecodesign) e.g. tyre abrasion, wear and tear, durability, recyclability, etc. One of the main pathways for the release of secondary microplastics from tyres into the aquatic environment stem from car tyre abrasion (during use/road wear). In particular in urban areas, these abrasion particles may enter the sewer network through road run-offs. In the case of separate sewers, the abrasion particles might directly end up in water bodies. In the case of combined sewers, tyre abrasion particles will mostly be removed by WWTP and, hence, end up in the sewage sludge. This may trigger regulation by certain MS to limit the use of sludge as fertilisers. During extreme rain events, combined sewers may also directly release tyre abrasion particles in the receiving water body through combined sewer overflows (CSOs). However, incineration is a more expensive option and cannot today fulfil the ambitions of a circular economy to recycle nutrients and organic matter to agricultural soil. Producers and/ or consumers could be required to pay a fee based on the quantities of certain tyres placed on the market or during the purchase of a car tyre.

EPR fees could then be used to fund mitigation measures e.g. additional waste water treatment in WWTPs, initiatives aimed at more efficiently removing microplastics from road run-off before they enter sewage system, etc. Some examples include:

- Using green infrastructure to reduce storm water flows
- Improved street and roadside cleaning to remove microplastics from road runoff or the application of special porous asphalt
- Separate treatment of storm water from roads
- Installing storage tanks or creating retention basins to hold overflow during storm event
- Expanding waste water treatment capacity
- Separating storm water and sewer lines: Provided the storm water evacuation system is designed to remove tyre (and road) wear particles before discharge in surface waters, because although separated systems are designed to minimise the load of relative clean rainwater to WWTPs and have the advantage of treating undiluted waste water, an important disadvantage is that sewer lines are always designed to ensure capture of microplastics released from tyre wear and tear from runoff.

The possible changes in EU legislation and opportunities for EPR to address the release of microplastics from tyres are summarised in Table 18.

Table 18: Potential legislative changes & EPR opportunities for tyres

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
Marketing authorisation	**General Safety of Tyres Regulation 661/2009:** Revision of requirements that take into account microplastics emissions (e.g. based on ecodesign criteria) for obtaining marketing authorisation. • Additional technical and environmental requirements could include for example tyre abrasion rates e.g. resistance to wear and tear and thresholds for microplastic emissions. • Restrictions that take into account poor performing tyres (in respect of tyre tread abrasion) where tyres with the highest rates of tread abrasion (i.e. very high level of microplastics emissions) could be banned from sale completely, based on a set threshold and suitable test and quantification methods on microplastics emissions, while guaranteeing safety.	Authorisation and restrictions	–	Data collected can serve as basis for setting EPR fees and identifying re producers e.g. producer registration, volume placed on market, impacts, hotspots, etc.
Manufacturing	**Industrial Emissions Directive 2010/75:** Include specific provisions on secondary microplastics emissions from tyre production • Set limit values for microplastics emissions during manufacturing to encourage producers to use the best techniques available (BAT) e.g. filters for industrial use, reducing microplastics release in the aquatic environment. • Installation of post-filtration systems during manufacturing process to ensure a pre-treatment of industrial effluents before discharge into sewer system	Best available techniques (BAT)	–	Incentivise best practices through financial incentives
Distribution and use	**Tyre Labelling Regulation 1222/2009:** Amended to serve as the regulatory framework for the implementation of a dedicated EPR scheme for secondary microplastics released from tyres. • The EPR scheme could apply modulated EPR fees (including reduction and exemptions) to tyre producers based on the amount and the type of product that is placed on the market and associated treatment (and remediation costs) and specific ecodesign criteria that account for microplastics emissions during use e.g. resilience to abrasion, durability, biodegradability, risk of microplastic emissions, use of alternative materials, etc. • Dedicated EPR fees could be used to help cover additional treatment costs, establishment of a producer register and monitoring and data collection system to ensure sufficient control and enforcement, as well as funding of information and awareness campaigns.	–	**EPR financing mechanism** (based on modulated EPR fees)	**LEGAL BASIS FOR EPR**

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
	General Safety of Tyres Regulation 661/2009: Launch dedicated awareness raising campaigns e.g. information on potential environmental and health impacts of microplastics emissions, best practices for more sustainable use of tyres, etc..	–	Awareness campaigns	Mitigation measures to support (and financed by) EPR
Monitoring	**Water Framework Directive 2000/60:** Allow monitoring data to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees. EQS Directive 2008/105: Inclusion of additional parameters to allow for monitoring of secondary microplastics emissions and allow monitoring data to be used within a possible EPR scheme to designate priority substances/ products and set corresponding fees.	–	Monitoring & reporting	Monitoring and reporting data can be used as basis for setting EPR fees e.g. frequency, impacts, hotspots, etc.
	Air Quality Standards Directive 2008/50: Add microplastics to the list of priority air pollutants for monitoring. These pollutants have been reported mainly in outdoor air from tyre wear, road traffic and urban dust, and can be found in waterbodies via atmospheric deposition.			
	REACH Regulation 661/2009: Update the Chemical Safety Assessment to include additional toxicity properties that take account of secondary microplastics emissions and ensuring that environmental risks are assessed across the entire water cycle.			
End-of-life	**ELV DIRECTIVE 2000/53:** Ensure that existing provisions and future amendments are in align/ support a possible EPR scheme. • Use of producer registry to identify relevant producers under EPR scheme • Use data reported on treatment costs to help establish appropriate modulated EPR fees • Further investigate possibility of Extend the scope of ELV Directive to integrate specific requirements related to microplastics released from tyres and ensure that EPR is considered as a possible option for secondary microplastics in evaluations carried out the Plastics Strategy.	–	• Product labelling • Monitoring and reporting	Supporting mitigation measures under a dedicated EPR scheme e.g. data on treatment costs, designation of producer responsibility, etc.

Life-cycle stage	Specific measures	Type of measure		EPR opportunities
		Control-at-source	Post-marketing	
	Complementary downstream (end-of-pipe) measures to support control-at-source and EPR measures: Urban waste water treatment Directive 91/271: Review of the UWWTD should assess (1) the relevance and feasibility of additional treatment requirements (technology and coverage of costs by producers) in hotspots, where relevant, to treat microplastics from tyres (2) ensure that quantities treated and associated treatment costs are reported and (3) assess ways to reduce tyre (and road) wear particles release through CSOs e.g. separate collection within sewer systems.	–	• Monitoring and reporting • Waste water treatment requirements	Monitoring and reporting data can serve as basis for setting EPR fees e.g. substance and quantity treated, costs of treatment, etc.

10.4 Potential obstacles and success factors

Obstacles	Success factors
Knowledge gaps: The diffuse nature and multiple pathways of tyre microplastics emissions can make it difficult to clearly designate producer responsibility. There are remaining gaps in knowledge on the sources and entry pathways in quantitative terms, on analytic methods to identify TWP and TRWP and on the cost and benefits of mitigation measures. Furthermore, there is currently no reliable method for determining appropriate abrasion rates, while taking into account technical performance e.g. climatic conditions and the use of winter tyres), nor for measuring microplastics released via CSOs.	**Support scientific research:** TWP and TRWP are by far the most important source of secondary microplastics, hence, action is needed even if some knowledge gaps still need to be filled. The principle of EPR could be applied to create a private-led fund for financing investment in innovative solutions and new technologies aimed at: reducing the environmental impact of microplastics release, developing some effective detection methods to quantify the release of microplastics and ensure a better monitoring. Funds collected under EPR could also be used to support R&D programmes for alternative materials. Furthermore, **industry and market data** e.g. abrasion rates, tyre performance, etc. should be considered to help determine responsibility of individual producers. **Carry-out and prioritise cost-benefit analyses**: To ensure that an EPR scheme would contribute to financing the most effective mitigation measures.
Tyre safety and availability of alternative materials: One of the main obstacles to alternative materials releasing less microplastics is tyres safety. In fact the performance of tyres has a critical contribution to road vehicle performance. Thus the big challenge is to find a material that is more resilient to wear and tear and/or biodegrades safely and effectively in the environment, but is highly effective and tough enough not to disintegrate too easily or quickly in everyday use.	**Information and awareness raising:** The recent public awareness about the plastic pollution could be a key driver to incentive consumers to actively change their behaviour. For example a clear label mentioning the amount of microplastics released for every 1000 km of service could be a powerful lever to raise awareness. Information campaigns could help consumers understand the conditions (speed, climatic conditions, and certain types of tyres) under which microplastics loss happens.
Consumption trends: Towards more road transport, SUV (larger cars) and electrical cars, all increasing overall emissions.	**Reduction of car traffic in hot spots (urban areas):** Better informing drivers on the negative impacts of microplastics emissions from tyres, encouraging more sustainable modes of transport and, as a minimum, best practices such as eco-driving etc.

Part IV. Analysis of options for the way forward

11. Policy options & comparative analysis

This chapter describes the policy options assessed as well as the methodology employed for the assessment of the options for the way forward.

11.1 Policy options assessed

Based on the findings of the legislative assessment, four policy options were identified and analysed in further detail in regard to the extent that they contribute to meeting the following objectives:

- (1) Reducing and/ or avoiding the release of micropollutants and microplastics at source from the product categories assessed into the aquatic environment; and/or
- (2) Financing the costs of additional treatment (both drinking water and waste water treatment costs) and related mitigation measures by water operators, or other mitigation measures in the downstream supply chain.

In light of the above, the four policy options assessed for the most promising way forward for applying EPR on products that release micropollutants and microplastics into the aquatic environment include (Table 19):

- **Option A**: Voluntary control-at-source & post-marketing measures (including EPR)
- **Option B**: Mandatory control-at-source measures
- **Option C**: Mandatory control-at-source & post-marketing measures (including EPR)
- **Option D**: Mandatory EPR measures

The principal distinctions of the policy options include the overall implementation approach and type of measures covered:

- **Implementation approach**: Voluntary versus mandatory approach
- **Specific measures**: Each policy option covers either upstream and/ or downstream measures:
  - Upstream (control-at source) measures: targets the early stages of the product life-cycle i.e. before placing on the market and includes requirements on product design, substance approvals and restrictions, marketing authorisation, manufacturing processes, etc.
  - Downstream (post-marketing, including EPR) measures: targets the later stages of the product life-cycle; after placement on the market e.g. product labelling, consumption, end-of-life.

The following table provides an overview of the types of specific measures included in the four policy options assessed.

Table 19: Specific measures included in policy options

Specific measures	Type of measure		Policy option			
	Control-at-source	Post-marketing	A	B	C	D
Substance approval, market authorisation, restrictions	●		X	X	X	

Specific measures	Type of measure		Policy option			
	Control-at-source	Post-marketing	A	B	C	D
Information provision (product labelling, etc.)	●	●	X	X	X	X
Best available techniques (manufacturing)	●		X	X	X	
Awareness campaigns (end-uses, consumers)		●	X		X	X
Application (use) conditions		●	X		X	X
Monitoring and reporting		●	X		X	X
Additional water treatment steps/ end-of-life treatment		●	X		X	X

11.2 Scope and approach for assessment of policy options

The overall approach for the analysis of the most promising options for the way forward is illustrated in Figure 13. Although the options aim to fulfil the same objectives listed above, they differ significantly in terms of *scope* e.g. mandatory versus voluntary approach and the type of specific measures covered e.g. upstream and/or downstream. Therefore, the analytic framework was developed in order to assess both (1) the options at an aggregated level as well as (2) take into account specificities of EU legislation in relation to the product groups covered.

Figure 13: Approach for analysis of options

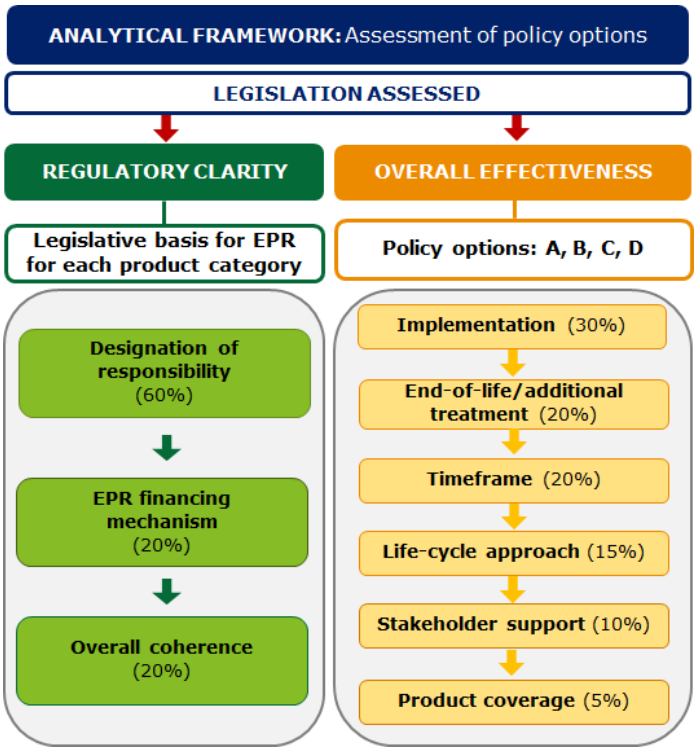
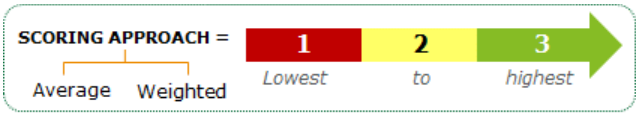


Figure 14: Scoring approach



The policy options are assessed based on an a simplified numeric scoring system (1 = lowest 2 = medium 3 = highest) (Figure 14), which incorporates a **weighted average** of the individual parameters assessed (Figure 13) with the aim of providing a more realistic evaluation on of the options i.e. some of the evaluation criteria have more "weight" compared to others and consequently overall effectiveness. It should be noted that the weighting of the different assessment parameters was based on expert judgement of the project team, which were

established with the overall aim of reflecting the key priorities and most relevant parameters for the water sector.

The comparative analysis of the legislation assessed was carried at two levels:

(1) **Regulatory clarity** of the identified potential legal basis for the EPR scheme.
(2) **Overall effectiveness** of the different policy options based on criteria covering implementation approach, drinking and waste water treatment costs, coverage of the product life-cycle, stakeholder acceptance and timeframe for implementation of **specific measures** .

11.2.1 Regulatory clarity of the legal basis for EPR

Based on the results of the previous analysis of the applicability of existing EU legislation for EPR, the most relevant legislation to serve as the legal basis was selected for each of the product groups assessed. The assessment of regulatory clarity aims to determine the extent that the legal basis for the implementation of EPR is based on **clear legal provisions** and applies the following assessment criteria:

- **Identification and designation of producer responsibility** (financial and physical) (Weight=60%): Extent that the legislation allows for the identification of all relevant actors (producers) who would be financially and physically responsible for their products during the use phase and at end-of-life (cover costs of end of life management of products: treatment or disposal) in the context of a dedicated extended producer responsibility scheme.
- **Applicability of EPR financing mechanism** (Weight=20%): Extent that the legislation allows for the establishment of a financing mechanism to cover costs of treatment based on EPR/ polluter-pays principles.
- **Coherence and synergies with other EU legislation** (Weight=20%): Assesses the overall coherence (synergies, inconsistencies, overlaps) of the legislation with other existing initiatives (EU and national legislation as well as voluntary initiatives).

11.2.2 Overall effectiveness of policy options

The aim of the assessment of the overall effectiveness of policy options (and associated specific measures) is to determine the extent that they meet the two main objectives (reducing and/or avoiding the release of micropollutants and microplastics and covering the costs of additional treatment). The comparative analysis of the overall effectiveness of the four policy options include the following assessment criteria and weighting:

- Implementation approach (Weight = 30%): Refers to the legal basis of the option. Mandatory options are assumed to be more effective than voluntary options.
- Timeframe (Weight = 20%): Refers to estimated timeframe for the implementation of specific measures based on the legislation under which they would be applied.
- EOL/ treatment costs (Weight = 20%): Extent that the option takes into account full financial responsibility (polluter-pays principle) of end-of-life treatment costs (by producers).
- Life-cycle approach (Weight = 15%): The extent that the option considers a life-cycle cycle approach, including supporting mitigation measures.
- Stakeholder support (Weight = 10%): Extent of overall stakeholder support for the proposed option.

- Product coverage (Weight = 5%): Extent that the option covers all product groups.

12. Analysis of policy options

This chapter assesses the policy options described previously based on the approach established for evaluation of regulatory clarity and overall effectiveness for the application of extended producer responsibility.

12.1 Regulatory clarity of potential legal basis for implementation of EPR

For each of the product groups, the most relevant legislation identified to serve as the legal basis for EPR is assessed for regulatory clarity based on the three following parameters:

- Identification and designation of producer responsibility (Weight = 60%)
- Applicability and effectiveness of a financing mechanism for EPR (Weight = 20%)
- Coherence and synergies with other EU legislation (Weight = 20%)

In addition to the assessment of legislation specific to each product category, the UWWTD was also considered in terms of its potential to serve as the legal basis for EPR, which would be applicable to all product groups. For the criteria on applicability of a financing mechanism for EPR, it should be noted that any existing fee systems established under the different legislation assessed do not currently cover costs related to additional treatment of products placed on the market e.g. water and waste water treatment costs. As such, the scoring on financing is based on whether the legislation currently provides for an existing fee system as it is assumed that additional efforts and time would be needed to establish a dedicated fee system "from scratch". Based on the above assessment parameters and findings from the analyses on cross-cutting and product-specific legislation. Table 20 presents the results of the assessment on overall regulatory clarity for EPR. Table 27 in Annex provides additional qualitative information on the assessment results.

Table 20: Comparison of regulatory clarity of potential legal basis for EPR

	Assessment criteria				
Legal basis - EPR	**Responsibility** [1] *Weight=60%*	**Financing** [2] *Weight=20%*	**Coherence** [3] *Weight=20%*	**Score**	
				Avg.	**Wtd.**
Pharmaceuticals: Regulation 726/2004	3	3	3	*3.0*	**3.0**
Pesticides: Regulation 1107/2009	3	3	2	*2.7*	**2.8**
Tyres: Tyre Labelling Regulation 1222/2009	3	3	1	*2.3*	**2.6**
Biocides: Regulation 528/2012	2	3	2	*2.3*	**2.2**
Textiles: Waste Framework Directive 2008/98	1	2	2	*1.7*	**1.4**
All product groups: UWWTD 91/271	2	1	2	*1.3*	**1.2**

Legend:	1	= Low	2	= Medium	3 = High

Responsibility [1]**:** Designation of producer responsibility and traceability
1 = Low: Identification of a limited number of relevant actors (producers) under EPR.
2 = Medium: Identification of some of the relevant actors (producers) under EPR.
3 = High: Identification of the majority of relevant actors (producers) under EPR.

Financing [2]**:** Applicability and effectiveness of a financing mechanism to apply EPR
1 = Low: No existing requirements under the legislation related to a fee system.
2 = Medium: Some existing mechanisms under the legislation related to a fee system.
3 = High: Specific reference to use of financial tools for EPR and/or polluter-pays.

Coherence [3]**:** Potential overlaps and/ or inconsistencies with other legislation
1 = High level of possible overlaps and/or inconsistencies
2 = Medium level of possible overlaps and/or inconsistencies
3 = Low level of possible overlaps and/or inconsistencies

Our findings suggest that Regulation 726/2004 on the authorisation and supervision of medicinal products for **human use** (weighted score=3.0), followed by Regulation 1107/2009 on placing of plant protection products on the market for **pesticides** (weighted score=2.8) would present the highest regulatory clarity in terms of serving as the legal basis for EPR. The Waste Framework Directive 2008/98 as the legal basis for EPR on textiles (weighted score=1.4) and the UWWTD for all product groups (weighted score=1.2) are found to demonstrate the lowest level of regulatory clarity in terms of the legal basis for EPR. The key findings of the assessment on regulatory clarity are summarised below:

- Regulation 726/2004 on the authorisation and supervision of medicinal products (**pharmaceuticals for human use**) followed by Regulation 1107/2009 on the placing of plant protection products on the market (**for pesticides**), would provide the most regulatory clarity in terms of the legal basis for an EPR scheme. Since these legislation govern the marketing authorisation phase, it is assumed that the identification of all relevant manufacturers under a potential EPR scheme would be relatively straight-forward due to existing requirements e.g. producer registration, reporting of volumes placed on the market, intended use, etc.
- **For biocides**, a potential key weakness of Regulation 528/2012 as the legal basis for a dedicated EPR scheme is its very wide scope in terms of the range of different product groups, sectors, end-use applications, etc. concerned. This could increase the risk of potential overlaps and inconsistencies with other relevant legislation, as well as lead to increased administrative burden.
- For secondary **microplastic emissions from tyres**: The recent adoption of important new provisions, namely the establishment of a dedicated tyre registration in a product database and inclusion of re-treaded tyres and provision on tyre abrasion would make the identification and designation of producers relatively straightforward. However, similar to biocidal products, an important element that could impact overall regulatory clarity is the potential overlap, incoherence and inconsistencies with other legislation, notably possible future revisions to existing marketing authorisation provisions laid out under Regulation 661/2009 on General Safety of Tyres e.g. development of a standard measure of tyre tread abrasion, market restriction of worst performing tyres in respect to tyre tread, etc. and the ELV Directive 2000/53.
- For secondary **microplastic emissions from textiles,** the assessment results on regulatory clarity of an EPR scheme established under the Waste Framework Directive

2008/98 indicate the lowest score compared to all other product groups. Several factors explain this, namely the absence of specific provisions on market authorisation for textile products, which does not allow for the establishment of important tools such as producer registration and volumes placed on the market and product volume registration. In addition, the fact that the Waste Framework Directive focuses mainly on the end-of-life phase of products, whereas the main pathway of microfibre release from textile products stems from the use and pre-marketing phase could present important challenges in regard to possibility of identifying relevant producers in an EPR scheme.

12.2 Overall effectiveness of policy options

The results of the comparative analysis of the options assessed are summarised below in Table 21. A summary of the key strengths, weaknesses, opportunities and threats (SWOT) of each of the options are summarised in Table 22.

Table 21: Comparative analysis of overall effectiveness of options

Policy option	Assessment criteria							
	Approach *Weight= 30%*	**Time** *Weight= 20%*	**Treatment** *Weight= 20%*	**Life-cycle** *Weight= 15%*	**Stakeholders** *Weight= 10%*	**Products** *Weight= 5%*	**Score**	
							Av.	**Wt.**
A	1	3	1	3	3	1	*2.0*	**1.9**
B	3	2	1	1	2	2	*1.8*	**2.0**
C	3	1	3	3	2	3	*2.3*	**2.4**
D	3	2	3	1	1	2	*2.2*	**2.4**

Legend: 1 = Low 2 = Medium 3 = High

Option A: Voluntary at-source and EPR
Option B: Mandatory at-source measures
Option C: Mandatory at-source and EPR
Option D: Mandatory EPR

[1]	**Implementation approach:** Refers to whether the option is based on a voluntary or mandatory approach 1 = Low effectiveness for voluntary options 3 = High effectiveness for mandatory options
[2]	**Timeframe:** Feasibility of the options in terms of the timeframe constraints to implement specific measures 1 = Low: For mandatory options covering all stages of the life-cycle 2 = Medium: For mandatory options covering only part of the life-cycle 3 = High: For voluntary measures
[3]	**Treatment:** Extent that the option takes into account full responsibility (polluter-pays principle) of water treatment costs (by producers) 1 = Low: Option only considers control-at-source measures 2 = Medium: Option considers EOL/treatment to some extent 3 = High: Option considers EPR measures and coverage of EOL/treatment costs

[4]	**Life-cycle approach**: The option considers a life-cycle cycle approach and supporting measures for the operation of the EPR scheme 1 = No (The option only considers upstream or downstream measures) 3 = Yes (The option considers both upstream and downstream measures)
[5]	**Stakeholder support**: Extent of overall stakeholder support for the proposed option 1 = Low level of stakeholder support 2 = Some level of stakeholder support 3 = High level of stakeholder support
[6]	**Coverage of product groups:** Extent options covers the product groups assessed 1 = Partial coverage (1 - 3 product groups) 3 = Full coverage (5 product groups)

Based on the weighted scoring results, of the four options assessed, Option C (mandatory control-at-source and EPR measures) and Option D (mandatory EPR measures) are found to be the most effective options in regard to the assessment approach. Both options C and C are based on mandatory approaches deemed to be effective in terms of implementation approach. A key strength of Option C is the fact that it addresses the entire product life-cycle and would be applicable to all products, whereas Option D focuses mainly on post-marketing/ end-of-life stages. As such, it is assumed that there would be a higher level of stakeholder acceptance for Option C compared to Option D since Option C would imply a wider scope and share of responsibility in terms of the potential actors across the supply chain concerned.

Option A is found to be the least effective option based on the parameters assessed due to several factors, particularly its voluntary approach in terms of implementation. Although voluntary approaches offer many advantages such as more flexibility and less legislative complexity, there are important limitations in the overall effectiveness of voluntary initiatives; notably the absence of a legislative framework, which could lead to higher risks of ineffective and weak monitoring systems, insufficient participation and free riders. On the other hand, while mandatory approaches would be more effective in addressing free riders, promoting an even playing field and harmonising practices and costs, there would be important challenges related to potential legislative complexity e.g. overlaps with existing legislation as well as timeframe for implementation of new measures.

Regarding the parameter on timeframe, the analysis is based on the assumption that Option C would face the most significant challenges in regards to the timeline for implementing specific measures because it covers a much wider scope of measures, across all life-cycle stages. Therefore, compared to the other options, more legislation and associated time and procedures would be needed for amendments or revisions. For Options B and C, there would also be challenges in relation to timeline limitations, however less so compared to Option C as Option B and D focus specifically on one phase of the life-cycle e.g. control-at-source or post-marketing/EPR. Finally, Option A would be the most feasible in terms of timeframe as it assumed voluntary measures or initiatives would not be bound to specific legislative procedures and therefore time restrictions to be put in place.

Table 27 in the Annex provides a more detailed summary of the estimated timeframe of review of the different legislations assessed.

Table 22: SWOT analysis of policy options assessed

Options	Strengths	Weaknesses	Opportunities	Threats
Option A – Voluntary control-at-source and EPR measures	• Cost-effective and autonomous alternative to direct regulation or the imposition of binding standards and requirements. • Covers both upstream and downstream measures across the life-cycle. • Less legislative complexity and associated administrative burdens for authorities and industry.	• Not legally binding – limited effectiveness • Risks of insufficient participation of producers and representation in the EPR scheme and measures. • The voluntary nature of the EPR scheme may not sufficiently address the issue of free riders. • Despite examples of industry initiatives, more efforts are required from industry to drastically curb emissions given the fact that emissions continue to increase.	• Demonstrated evidence of the successes (or potential advantages) of existing voluntary initiatives demonstrate some industry-level willingness to contribute to reducing emissions and could drive future policy developments. • Voluntary measures could offer industry an opportunity to take a proactive role in helping to address environmental problems. • Improve the credibility, reputation and image of industry. Increase confidence and trust from consumers and policy-makers.	• Risks of overlaps and incoherencies, including conflict with trade and competition rules. • Remaining gaps in knowledge on the sources and entry pathways in quantitative terms could be important barriers to gathering stakeholder support in the absence of legally binding requirements. • If the schemes do not work in practice, much valuable time will be lost to effectively reduce emissions.
Option B – Mandatory control-at-source measures	• Reduction and/or avoidance of micropollutant and microplastics emissions before they ever reach the aquatic environment, which could substantially reduce potential of overall risks to human health and the environment. • Higher chance of avoiding free riders compared to voluntary approaches (Option A).	• Does not take fully take into account producer responsibility and polluter pays-principle • Administrative burdens • Lower level of support from the producers compared to voluntary approaches (Option A) • Timeframe for the implementation of mandatory measures would be more significant compared to voluntary approaches.	• Policy makers demonstrate the relative urgency of actions needed to protect the environment and human health. • Increase in innovation and research in alternative substances and products, including the use of green chemistry and ecodesign.	• Could be considered as over-regulation and unnecessary administrative burden by certain critics. • Not all emissions can be sufficiently reduced nor treated through control at source measures alone. Measures along the entire supply chain may be necessary, however this option would not be covered by EPR or any other post-marketing measures.
Option C - Mandatory	• Promote more harmonised practices at both national and EU level	• Lower level of support from the producers compared to voluntary approaches.	• Increase in innovation and research in alternative substances; creation of new	• Could be considered as overregulation and an unnecessary administrative

Options	Strengths	Weaknesses	Opportunities	Threats
control-at-source and EPR measures	• Highest likelihood of achieving results because Option C a takes a life-cycle approach by including both upstream and downstream measures, covering all relevant stages of the value chain. • Most effective way to cover all relevant life-cycle stages and to avoid free riders • Ensure compliance with the EU Treaty (control-at-source and polluter pays)	• Potentially higher administrative and financial burdens compared to voluntary options. • Timeframe for implementation of specific measures would most likely be more significant compared to other options.	markets. • Effective policy to meet health and environment protection objectives.	burden by certain critics. • Diversity and number of stakeholders concerned could create challenges for wider stakeholder acceptance. • Potential impacts of future policy, market and technological developments e.g. new waste streams/ substances, more stringent standards and requirements on treatment processes, etc.
Option D - Mandatory EPR measures	• Use of market-driven instruments to incentivise emissions reductions and cover treatment costs through application of the polluter pays principle and producer responsibility • Higher chance of avoiding free riders compared to voluntary approaches.	• Limited effectiveness in terms of overall protection of human health and the environment because without control-at-source measures, EPR alone cannot cover all possible pathways to the environment. • Lower level of support from producers compared to voluntary approaches.	• Increase in innovation and research in alternative substances; creation of new markets e.g. reuse and recycling markets, new products. • Increase in awareness of consumers, which could further drive demand for "greener" products and substances.	• Risk of not fully tackling the micropollutant and microplastics challenge in the case control-at-source measures are not implemented to support EPR and other relevant downstream measures. • Lack of adequate control, monitoring and enforcement and monitoring could result in transparency issues, free riding and market fragmentation. • Potential impacts of future policy, market and technological developments e.g. new waste streams/ substances, more stringent standards and requirements on treatment processes, etc.

13. Key findings of legislative assessment

The need to substantially reduce the release of micropollutants and microplastics to the aquatic environment is widely recognised. This is reflected in the Commission's on-going and forthcoming policy priorities and ambitious zero pollution goals. When designing mitigating measures, article 191.2 of the Treaty on the Functioning of the European Union must be the basis for action.

> *Article 191.2: "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."*

Building on this TFEU article and other relevant provisions e.g. the Water Framework Directive (Recitals 11 and 40), this study analysed the feasibility and effectiveness of potential options to apply the polluter pays principle through EPR within the existing European legislative framework.

13.1. Regulatory clarity of a potential legislative framework at EU level

There is currently no overarching regulatory framework at EU level, which specifically targets micropollutants and microplastics emissions that stem from products during their life-cycle. Relevant provisions are laid out in existing cross-cutting legislation e.g. Water Framework Directive 2000/60, REACH Regulation 1907/2006, etc. and product-specific legislation e.g. Regulation 726/2004 on authorisation and supervision of pharmaceutical products, Regulation 1107/2009 on Plant Protection Products, Biocidal Products Regulation 528/2012. Against this backdrop, the assessment of **regulatory clarity** of a potential regulatory framework at EU level for EPR focused on the three following main criteria:

- Possibility to identify the main producers concerned and designation of producer responsibility;
- Applicability and effectiveness of a financing mechanism for EPR; and
- Coherence and synergies with other EU legislation.

A key finding of the legislative assessment is that due to the **diffuse nature** of the occurrence of micropollutants and microplastics in the aquatic environment, measures should be implemented **as early on as possible** during the product life-cycle e.g. substance/product design, authorisation and restriction. Specific measures implemented during early life-cycle phases e.g. registration of type, volume, etc. of substances/products placed on the market, etc. would be more effective in identifying producers and therefore responsibility compared to measures applied further downstream. This would best respond to the first point listed above concerning the identification and designation of producer responsibility and facilitate regulatory clarity.

At **product level**, study findings identify the following product-specific legislation as the most promising options in regard to ensuring the highest level of regulatory clarity for the implementation of an EPR scheme:

- **Pharmaceuticals for human use:** Regulation 726/2004 on the authorisation and

supervision of medicinal products for human and veterinary use; and

- **Pesticides:** Regulation 1107/2009 on the placing of plant protection products on the market.

The above pieces of legislation specifically target the **marketing authorisation phase**, requiring manufacturers to comply with a range of approval procedures before products can be placed on the EU market e.g. registration of producers, volumes of substances/products placed on the market, results of environmental risk assessments, etc. More specifically, as legislation governs the marketing authorisation phase, identification of all potential manufacturers under a dedicated EPR scheme would be **relatively straight-forward**.

Key findings on the main limitations identified concerning the other product groups in regard to ensuring a high level of regulatory clarity for the application of EPR are summarised below:

- **Biocides**: The identification and designation of all relevant producers e.g. producers of biocidal products that release potentially hazardous substances to the aquatic environment in the context of a dedicated EPR scheme under Regulation 528/2012 could be particularly challenging due to the wide-range of different product groups, sectors, use applications, etc. and consequently associated legislation concerned. Particular efforts would be needed to ensure that all the key producers (and products) can be identified, while taking into account possible overlaps and inconsistencies with other legislation and avoiding any unnecessary administrative burdens.
- **Tyres**: The recent adoption of important new provisions, namely the establishment of a dedicated tyre registration in a product database and inclusion of re-treaded tyres and provision on tyre abrasion would make the identification and designation of producers relatively straightforward. However, similar to biocidal products, an important element that could impact overall regulatory clarity is the potential overlap, incoherence and inconsistencies with other legislation, notably possible future revisions to existing marketing authorisation provisions laid out under Regulation 661/2009 on General Safety of Tyres e.g. development of a standard measure of tyre tread abrasion, market restriction of worst performing tyres in respect to tyre tread, etc. and the ELV Directive 2000/53.
- **Textiles**: The final assessment of regulatory clarity of an EPR scheme for secondary microplastics emissions from textiles established under the Waste Framework Directive 2008/98 scored the lowest compared to other product groups. The absence of specific provisions on market authorisation for textile products and the fact that the Waste Framework Directive focuses mainly on the end-of-life phase of products, whereas the main pathway of microfibre release from textile products stems from the use and pre-marketing phase could make it challenging to identify all relevant producers. As such, the possibility of implementing an EPR scheme through eco-design requirements should be further explored.
- **UWWTD to implement EPR**: Findings indicate that the Urban Waste Water Treatment Directive 91/271 could be further enhanced to include EPR-related requirements, provided certain conditions are met. While the directive could address several of the pollutants/types of microplastics covered by the study, waste water represents only one pathway out of many. Furthermore, the directive defines "end-of-pipe" measures which, according to the OECD "*should only be used in complementary*

to source-directed and use-orientated measures." (OECD, 2019). As such, there is a risk that, once requirements are set for waste water treatment, control-at-source measures will not find sufficient political support. Therefore, assuming that EPR is implemented through the UWWTP, it is critical that the following aspects are considered:

- Priority to effective control-at-source and mitigation measures during other life-cycle stages;
- Evidence that available treatment technologies can deliver the results expected by policy;
- Results of cost-benefit analysis demonstrates that additional treatment at the level of the WWTP is more cost-effective than measures taken at other life-cycle stages;
- Effective application of the polluter-pays principle, through for example the application of EPR, before any additional new requirements on extra treatment; and;
- The EPR scheme covers all relevant micropollutants/microplastics to ensure an even playing field and fair distribution of producer responsibility.

13.1.1. Recommendations on amendments to existing provisions on pharmaceuticals and pesticides

Although marketing authorisation provisions for pharmaceuticals and pesticides – notably requirements on environmental risk assessments for active substances – consider potential environmental and health risks of active substances, they/their metabolites continue to be released into the aquatic environment, resulting in increased costs mainly through additional cleaning steps in drinking water production and waste water treatment. This indicates that existing provisions may not take into account all relevant factors that could contribute to reducing or avoiding micropollutant emissions. The study identified the following areas where further actions could be implemented to apply the principles of polluter-pays (in accordance with EU Treaty Article 191(2)[26] and EPR in order to more effectively address micropollutant emissions to the aquatic environment:

Recommendations for (human) pharmaceutical products:

- Require the results of the ERA as a condition for obtaining marketing authorisation: Under Regulation 726/2004, results of the environmental risk assessment (ERA) do not currently constitute a condition for the refusal of marketing authorisation. Although producers are required to establish appropriate risk mitigation measures for any identified risks, they are **not formally responsible for their products once they reach the aquatic environment at end-of-life**. Contrary to human pharmaceuticals, ERA results for veterinary pharmaceuticals are one of several parameters considered by authorities before marketing authorisation is granted.
- Update the Environmental Risk Assessment for human pharmaceuticals: With additional assessment criteria and parameters e.g. impacts of metabolites and transformation/degradation products, risks related to antibiotic resistance, mixture toxicity assessments, extending testing scope to higher organisms, etc., which reflect **more exhaustive, accurate and up-to-date findings from the scientific**

[26] "EU environmental policy should be based on four main principles: Precautionary principle, Prevention principle, Rectification at source principle and Polluter pays principle"

community on potential environmental and health risks.

- ERA results to serve as potential basis for setting EPR fees: In the case of an eventual EPR scheme, the results of the ERA for human pharmaceuticals could be used as a basis for establishing modulated EPR fees e.g. based on severity of impacts, level of concentration found in the environment, volumes placed on the market, etc. In this light, further discussions with ECHA and other relevant stakeholders would be particularly important to determine the overall feasibility and relevance of using ERA results on pharmaceuticals to establish appropriate EPR fees.

Recommendations for pesticide products:

- Increase synergies between Regulation 1107/2009 and Directive 2009/128 through a dedicated EPR scheme: An important strength of the existing EU regulatory framework governing pesticides is the existence of product-specific legislation, which targets two distinct life-cycle phases of plant protection products: Regulation 1107/2009 on the placing of PPPs on the market (pre-marketing phase) and Directive 2009/128 on sustainable use of Pesticides (post-marketing phase). Despite a relatively clear regulatory framework at EU level, current provisions do not specifically address micropollutants emissions during use, nor do they sufficiently encourage or require producers to accelerate the deployment of specific actions that would contribute to reducing/ avoiding the release of micropollutants from pesticide products into the aquatic environment. A dedicated EPR scheme could contribute to achieving the objectives of both Regulation 1107/2009 and Directive 2009/128 by not only encouraging producers to use less hazardous substances in pesticide products placed on the market (e.g. application of EPR fee based on ERA results) but also encouraging more sustainable use (e.g. application of EPR fee reductions, exemptions, subsidies, etc. to incentivise best practices during use/end-of-life). Further investigation is therefore recommended to determine how an EPR scheme for pesticides could be applied in practice, particularly in regard to ensuring overall coherence between Regulation 1107/2009 and Directive 2009/128 as well as other relevant agricultural polices e.g. EU's Common Agricultural Policy (CAP).
- Revisions to the Environmental Risk Assessment for active substances used in PPPs: Contrary to human pharmaceutical substances, Regulation 1107/2009 (Recital 24)[27] on plant protection products establishes more stringent marketing authorisation requirements in that any active substance used in PPPs that poses potential risks to human health and the environment **cannot be approved for marketing authorisation**. Furthermore, as laid out in Article 4[28], the approval of active substances should also be based on current scientific and technical knowledge. With this in mind, the study identified several areas where the ERA could be further updated to be more aligned with most recent scientific findings, notably in regard to long term toxicity, mobility of substances and potential harmful effects of metabolites in order to adequately assess potential risks of active substances used in pesticides.

[27] "The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment."
[28] "An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3."

13.2. Overall effectiveness of policy options assessed

The assessment of the overall effectiveness of possible policy options was carried out based on **two main guiding principles**: the extent that the policy option contributes to (1) reducing and/or avoiding the release of micropollutants and microplastics into the aquatic environment; and (2) covers the costs of additional treatment; and **six assessment criteria**: (1) implementation approach, (2) timeframe for implementation, (3) coverage of additional treatment costs, (4) coverage of life-cycle stages, (5) coverage of product categories assessed; and (6) stakeholder support. It should be further noted that an in-depth **cost-benefit analysis was not within the study scope**, therefore aspects related to the potential economic impacts of policy options e.g. investment costs and net benefits, job implications, impact on water prices, willingness to pay, environmental externalities including climate change potential, etc. were not considered in the assessment.[29]

Of the four policy options assessed, **Option C** (mandatory control-at-source and post-marketing measures, including EPR) and **Option D** (mandatory EPR measures) were found to be the most effective options in regard to the overall effectiveness for implementation of EPR to address micropollutants and microplastics emissions from the product categories assessed.

Options C and D are both based on **mandatory approaches**. Voluntary measures offer advantages such as more flexibility and less legislative complexity, however, there are important limitations that can affect their overall effectiveness; notably the **absence of a clear legislative framework**, which can lead to insufficient participation and free riding as well as ineffective and weak monitoring systems and enforcement. On the other hand, while mandatory approaches would be more effective in addressing the problem of free-riders, promoting a level playing field and harmonising costs and practices across the EU, important challenges such as defining the scope and objectives of a possible EPR schemes, ensuring overall coherence with other existing legislation and initiatives, taking into account impacts on the EU market, etc. would need to be considered.

Although the results of the assessment of options C and D indicate the same final weighted score (2.4), there is a slight **difference** in their final **average score** (2.3 for Option C and 2.2 for Option D). The key strengths of option C (mandatory control-at-source and post-marketing measures, including EPR) that are worth nothing include the fact that it addresses the entire product life-cycle and would be applicable to all products, whereas Option D focuses on the post-marketing/ end-of-life stages (and therefore characterised by more limited coverage in terms of relevant life-cycle stages addressed). As such, option C would fully respond to the provisions of article 191.2 TFEU in regard to respecting the precautionary principle and preventive action through the application of control-at-source measures. Furthermore, it is assumed that there would be a higher level of stakeholder acceptance for Option C compared to Option D, since Option C would imply a wider scope of actors and therefore **share of responsibility** across the supply chain.

[29] Refer to Module 1 report for overview of some of the key economic impacts that could be considered in the context of an in-depth cost-benefit analysis.

14. Recommendations for the way forward

The main recommendations proposed in the following section are drawn based on the following key study findings:

- Control-at-source measures should be the starting point of mitigation measures aimed at reducing/avoiding micropollutant and microplastics emissions. They are usually more effective due to the large number and diffuse nature of emission pathways into the environment. However, the release and presence of these substances continue to be a concerning issue at EU level. This indicates that control-at-source measures are not fully implemented and/or that they alone are not sufficient to effectively address the problem. **Products containing potentially hazardous substances continue to be placed on the market and humans and other living organisms continue to be exposed to their potentially harmful effects.** This demonstrates the urgency of immediate regulatory actions, which is supported by a solid existing knowledge base (including scientific findings) to justify corrective measures; and therefore applying the precautionary principle.
- In addition to control-at-source measures, the existing legislative basis at EU level provides **clear opportunities where EPR could be applied in order to more effectively contribute to avoiding and/or reducing micropollutants and microplastics emitted from products during their life-cycle**. EPR can serve as the basis for a potential solution to the problem by ensuring that producers remain responsible for their products throughout their life-cycle, including for pollutants directly or indirectly released into the aquatic environment. Some of the main opportunities identified where EPR could be applied in existing EU legislation to ensure producers are held financially and physically responsible for their products throughout their life-cycle, include:
  - Designating **legal and financial responsibility** for the products placed on the market, and consequently a transparent system of traceability;
  - Applying **appropriate product/substance fees** that reflect the full costs of treatment of these products;
  - **Promoting eco-design** by providing incentives to producers to implement more efficient and sustainable product-design and manufacturing practices i.e. through incentivising the use of more sustainable alternatives. This should, however, be thoroughly assessed for each category of micropollutants, while considering the main pathways through the environment and the efficacy of existing treatments to remove them.
  - From a practical point of view, EPR is generally **more acceptable to society** compared to for example a tax imposed to finance downstream measures. EPR is more targeted in that it aims to use collected funds to finance pollution mitigation measures, leaving more flexibility to polluters to decide about the most effective ways to spend these funds.
- While EPR holds significant potential to ensure producers take on full physical and financial responsibility of their products, the study concludes that similar to control-at-source measures, EPR as a stand-alone policy is not the magic solution to solving Europe's water pollution challenges. Instead, only a combination of both upstream and downstream measures would be able to adequately tackle the full extent and scope of the problem.

14.1. Recommendations for the way forward

Based on the key findings of the study as summarised previously, the following recommendations are proposed for the effective application of potential EPR schemes on products emitting micropolluants and microplastics into the aquatic environment:

- **Control-at-source is key:** Due to the diffuse nature of the occurrence of micropollutants and microplastics in the aquatic environment, measures should be implemented as **early on as possible** in the product life-cycle e.g. substance/product authorisations and restrictions before they can be placed on the market. The legislative framework for the implementation of EPR as mentioned in the previous bullet point, should **build on control-at-source measures** and include mitigation measures, which could be financed through funds collected under an EPR scheme.
- **Develop a clear legislative framework for EPR:** While the polluter-pays principle is enshrined in the TFEU and stipulated in the Water Framework Directive (Recital 38 on use of economic instruments and Article 9 on recovery of costs for water services), these principles are not applied in practice when it comes to micropollutants and microplastics in the aquatic environment. As such, there is a need for a clear regulatory framework based on a full life-cycle approach at EU level for the implementation of the polluter-pays principle through EPR. This could be **established through the formal recognition of polluter-pays and EPR principles.** For example, explicit reference to polluter-pays and EPR are not currently laid out within the product-specific legislation e.g. Regulation 726/2004 on authorisation and supervision of pharmaceutical products, Regulation 1107/2009 on Plant Protection Products, Biocide Products Regulation 528/2012, etc. Formal recognition of EPR and polluter-pays (through amendments to existing legislation) would contribute significantly to ensuring regulatory clarity. In addition, it would also be important to ensure overall coherence and compliance with other relevant legislation such as the Waste Framework Directive, which serves as the guiding regulatory framework for EPR schemes across the EU.
- **Ensure that treatment costs are adequately covered and financed by producers:** Based on a fair and transparent cost recovery system that reflect real-life treatment costs. This should be supported by **mitigation measures** that could be financed through funds collected under EPR, for example:
    - R&D and scientific programmes to increase research on alternative (substitute) materials, methods to ensure traceability, and detection and monitoring tools;
    - Information and awareness-raising campaigns: Targeted information campaigns to further increase awareness on sustainable consumption and disposal practices e.g. appropriate use and disposal of products at end-of-life, existence of alternative substances/ products, etc.
- **Cost-benefit analysis**: An in-depth assessment should be conducted on all possible measures from product design to end-of-life, including mitigation measures that EPR funds could help finance. Other important parameters to evaluate include the impact of the proposed solutions on energy consumption, CO_2 emissions, circular economy objectives, the internal market and society, etc. Along the same lines, best practices and lessons learnt from the waste sector where EPR is more common should be carefully considered. The example of CO_2 charges to be paid by energy producers could be part of the assessment.

- **Traceability and designation of the responsible producers:** The development of a fair and proportionate EPR scheme must address these two points in cooperation with the producers concerned. The experience of existing EU legislation such as waste directives and the Single Use Plastics Directive should be used.
- **Consideration of local and national specificities:** EPR schemes should be sufficiently flexible to accommodate regional peculiarities such as concentration of 'hotspots', specific local conditions e.g. economic and waste infrastructure systems, material and waste flows, etc.
- **Cross-sectoral stakeholder dialogue:** It is crucial to establish and maintain dialogue between all relevant stakeholders in order to exchange knowledge and best practices, coordinate research and innovation and ensure full application of EU legislation and functioning of the internal market.
- **Boost scientific research**: As scientific understanding of the potential effects of pollutants has increased, so has public and political concern on their potentially hazardous impacts. Public health and environmental concerns, increased scientific knowledge and awareness are important drivers that could further boost innovation, changes to the existing regulatory framework and consumer behaviour.
- **Stay up-to-date on policy evolutions:** National, European and international policy developments should be monitored to avoid potential overlaps, inconsistencies and administrative burden. Likewise, it is essential that policy reflects the latest technological and innovative solutions to anticipate future challenges in regard to new potentially hazardous substances, but also innovative and cost-effective mitigation measures.

Annex

Overview of other relevant EU legislation

Box 13: Ecodesign Directive 2009/125 – Relevant provisions & possible amendments

General provisions:

The Ecodesign Directive 2009/125 was adopted in 2005, with the aim of reducing the environmental impact of Energy-using Products (EuPs) during their life-cycle. The Directive was extended in 2009 to also cover Energy-related Products (ErPs). The Directive sets ecodesign requirements for energy-related products through the establishment of product specific regulations aiming to increase energy efficiency and the level of protection of the environment. Ecodesign applies environmental awareness during the design phase or improvement of a product to reduce negative environmental impacts, while preserving its quality of use. Annex I of the Directive lays down ecodesign parameters for the relevant products groups, including emissions to water. The latter is only applicable to the emissions of heavy metals.

Key relevant provisions:

Although the Ecodesign Directive does not presently cover any of the products evaluated by the study or potentially hazardous substances and microplastics emissions, the current Ecodesign Working Plan 2016-2019 calls for European standardisation organisations to develop mandatory product standards on material efficiency to be considered in future Ecodesign requirements and implementing measures on durability, reparability and recyclability of products. Material efficiency requirements can also be applied to non-energy related product groups. One potential candidate is **clothing and textile products**. (Nordic Council of Ministers, 2018).

Possible legislative changes and opportunities for EPR:

In light of the above, possible legislative amendments to the Ecodesign Directive that could further contribute to reducing micropollutants and microplastics emissions include:

- **Revision of ecodesign criteria and parameters** by integrating **'benign by design'** principles for current or additional product groups. In the context of chemicals, the benign by design concept (or green chemistry) encourages potentially hazardous substances that remain in waste waters to be designed in such a way so that they can be quickly and completely degraded in effluent treatment or surface waters. The concept of environmentally benign chemicals implies that future chemicals and associated products must be assessed to meet this requirement at the very beginning of their life cycle (Kümmerer, 2018). This approach is notably laid out by the EU's Strategy for Pharmaceuticals in the Environment.[30] In the case of pharmaceuticals, green chemistry in product formulas could include criteria related to for biodegradability and the use of safer and less toxic alternatives provided comparable health benefits can be provided. For textiles, benign by design criteria could include the use of natural textiles instead of synthetics.
- **Extend the scope of the Directive to include additional product groups**:
  - Textiles: Establishing material efficiency criteria e.g. minimum content of recycled material in new textile products; Setting thresholds for microplastics emissions.
  - Tyres: Setting minimum requirements for tyre design on abrasion and durability, taking into account secondary microplastics emissions and technical quality e.g. tyres used in winter climates.
- Application of ecodesign criteria e.g. biodegradability, ease of recyclability, etc. to establish modulated EPR fees.

[30] http://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

Box 14: Industrial Emissions Directive 2010/75 – Relevant provisions & possible amendments

General provisions:

Industrial processes account for a considerable share of the overall pollution in Europe due to their emissions of air pollutants, discharges of waste water and waste generation. Directive 2010/75 on industrial emissions (Industrial Emissions Directive or IED) entered into force on 6 January 2011 and serves as the main EU instrument regulating pollutant emissions from industrial installations.

The IED establishes the general framework for the control of industrial activities, giving priority to **intervention at source,** ensuring prudent management of natural resources and taking into account, when necessary, local specificities and economic situations of industrial activity. The IED encourages the application of the polluter pays and prevention principles (Preamble 2) as well as liability when assessing the level of soil and groundwater pollution (Preamble 25). More specifically, the IED establishes Best Available Techniques (BAT). BAT refers to the most effective techniques (including both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned) to prevent and reduce emissions and the impact on the environment.

Key relevant provisions:

The IED lays out **BAT for waste treatment,** providing national authorities with the technical basis for setting permit conditions for installations. BAT have been established for several common waste treatment techniques, including mechanical, biological and physico-chemical treatments and treatment of water-based liquid waste. They also apply to temporary waste storage and waste water treatment plants whose main share of treated effluent originates in waste treatment installations.

BAT for treating waste was recently updated in 2018. For the first time, BAT-associated emission levels (BAT-AELs) were established for emissions to water and air from aerobic and mechanical treatments of waste (shredders), with the aim of significantly reducing emissions from the waste treatment sector. Existing waste treatment installations (i.e. first permitted before the publication of the BAT conclusions) have four years to comply with the new standards, whereas new installations (i.e. first permitted after the publication of the BAT conclusions) must comply immediately with the new requirements.[31]

Operators of industrial installations listed in Annex I of the IED are required to obtain a permit from MS authorities. In particular, **chemical industrial installations** are included in Annex I, defined as installations which produce substances or groups of substance through chemical or biological processing. This includes the production of organic chemicals (plastic materials such as polymers, synthetic fibres, and cellulose-based fibres), surface-active agents and surfactants, PPPs or biocides and pharmaceutical products, including intermediates.

Possible legislative changes and EPR opportunities:

Possible changes to the IED and EPR opportunities at product specific level are discussed, where relevant, in Part III (Assessment of applicable product-specific EU legislation). In addition to product level amendments, changes at a wider scale include for example, greater synergies between the IED and other related legislation such as the REACH Regulation 661/2009 and the Water Framework Directive 2000/60 in the areas of data and knowledge sharing e.g. use of a harmonised database in order to reduce administrative

[31] European Commission - JRC: New EU environmental standards for waste treatment, 17 August 2018. Accessible at: https://ec.europa.eu/jrc/en/news/new-eu-environmental-standards-waste-treatment

burdens, facilitate data collection and improve overall monitoring and reporting.

Despite regulatory action under the IED, pollutants from industrial sources continue to be released to the aquatic environment where they pose a threat to the quality of water resources (EEA, 2018a). Water suppliers have to invest in increasingly sophisticated, expensive and energy-intensive treatment processes to remove pollutants and comply with - among others - the stringent requirements of the Drinking Water Directive. It runs counter to EU water legislation, especially Art. 7.3 of the Water Framework Directive 2000/60. IED and the related best available technologies (BATs) should include requirements for the protection of water resources in order to avoid deterioration of the quality of water bodies and increased treatment by drinking water suppliers according the precautionary principle, the control at source principle and the polluter pays principle taken up in the TFEU. The presence of GenX and Pyrazole in recent years in Dutch water sources used for the production of drinking water is a case in point.

Public access to information on emitted chemical substances

A significant part of the water used for the production of drinking water is impacted by industrial WWTPs. Currently, chemicals or industrial WWTPs are under no obligation to report on emitted substances beyond those substances reported under by the E-PRTR. Complete registers with all chemical substances and by-products that are produced or used in the chemical plant are therefore not publicly available. Accessibility of such information to all water users and regulators in a specific river basin area would enable water suppliers to better predict the effects on abstraction points of water used for the production of drinking water. It furthermore enables targeted measures to remove those substances from.

Box 15: Waste Framework Directive 2008/98 – Relevant provisions and possible amendments

General provisions:

EU waste management policies are governed by the Waste Framework Directive 2008/98. It sets the basic concepts and definitions related to waste, recycling, and recovery. It establishes 'end-of-waste status' or end-of-waste criteria (i.e. when waste ceases to be waste and becomes a secondary raw material) and introduces the concept of the 'waste hierarchy'. **Waste prevention** – has been and continues to be the first and most important objective of the EU waste management policy. Reduction in the generation of waste, usually **at source** is the most effective waste management option. Waste prevention include measures taken for products, i.e. before a substance, material or product has become waste, which reduce:

- The quantity of waste, including through the re-use of products or the extension of the life span of products;
- The adverse impacts of the generated waste on the environment and human health;
- The content of harmful substances in materials and products.

The Waste Framework Directive also specifically refers to the **polluter-pays principle** (ensuring that the costs of preventing, controlling and cleaning up pollution are reflected

in the cost of goods), and sets guidelines regarding the implementation of **extended producer responsibility**. At EU level, EPR is currently established for several specific waste streams: end-of-life vehicles, (ELV), waste electrical and electronic goods (WEEE) and batteries and accumulators, and most recently several product categories under the newly adopted Single-Use Plastics Directive (food containers, packets and wrappers, drinks containers and cups, tobacco products, wet wipes, balloons, and lightweight plastic bags). EPR is also widely used in support of the implementation of the Packaging and Packaging Waste Directive 94/62, although the Directive itself does not impose the principle.

EU Circular Economy Plan – EU Plastics strategy

The EU Circular Economy Action Plan includes numerous measures addressing product recycling and reuse, including rules to harmonise EPR schemes to ensure consistent implementation between MS and proposals to strengthen measures introduced under the EU's ecodesign working plan covering reparability, durability, and recyclability.

Under the Circular Economy Action Plan, the European Union's **Strategy for Plastics in a circular economy** was adopted in 2018. The EU Plastics Strategy aims to protect citizens and the environment from plastic pollution whilst fostering growth and innovation, proposing actions to improve the way plastics and plastics products are designed, produced, used and recycled. The Plastics Strategy refers to specific actions on microplastics: restrictions through the REACH Regulation 661/2009 for deliberately added microplastics. Within the EU Plastics Strategy, the Directive on the reduction of the impact of certain plastic products on the environment, also referred to as the **Single-use plastics Directive 2019/904** aims to tackle **marine litter at its source**, targeting the 10 plastic products most often found on beaches as well as abandoned fishing gear[32]. More specifically, the Directive introduces EPR obligations for producers (Part E, Article 8 on extended producer responsibility) in relation to financing the costs of waste management and clean-up and awareness raising measures. The industry will also be given incentives to develop less polluting alternatives for these products.

Key relevant provisions:

The Waste Framework Directive 2008/98 establishes special conditions applicable to hazardous waste (Articles 17 to 20), which could potentially apply to certain substances used in the products evaluated (see specific chapters on product-specific assessments). Compared to non-hazardous waste, hazardous waste poses a greater risk to the environment and human health and thus requires a stricter control regime. Requirements include additional labelling, data collection, monitoring and control obligations across the product life-cycle i.e. from the waste production to the final disposal or recovery. Mixing of hazardous waste is also banned to prevent risks for the environment and human health.

Possible legislative changes and opportunities for EPR:

Potential loopholes regarding coherence and synergy across the EU's strategies on waste, the circular economy and product design requirements is an important limitation that has been highlighted in literature. For example, product development and design are addressed separately from end-of-life management, which does not directly encourage or require a full life-cycle and systems-design approach. In this context, EPR principles could be an opportunity to better establish the link between product design and end-of-life, and therefore further encourage the uptake of circular economy solutions by rewarding and incentivising products designed to reduce environmental impact e.g. using less hazardous materials (Kunz, 2018). Likewise, actions that further encourage the participation and knowledge of consumers/end-users are also essential as they play a vital role in waste management.

[32] Legislative text of the Directive: https://eur-lex.europa.eu/resource.html?uri=cellar:fc5c74e0-6255-11e8-ab9c-01aa75ed71a1.0002.02/DOC_1&format=PDF

Table 23: Priority substances (Environmental Quality Standards Directive 2008/105)

Priority substance		Priority hazardous substance
1	Alachlor	
2	Anthracene	X
3	Atrazine	
4	Benzene	
5	Brominated diphenylethers	X
6	Cadmium and its compounds	X
7	Chloroalkanes, C 10-13	X
8	Chlorfenvinphos	
9	Chlorpyrifos (Chlorpyrifos-ethyl)	
10	1,2-Dichloroethane	
11	Dichloromethane	
12	Di(2-ethylhexyl)phthalate (DEHP)	X
13	Diuron	
14	Endosulfan	X
15	Fluoranthene	
16	Hexachlorobenzene	X
17	Hexachlorobutadiene	X
18	Hexachlorocyclohexane	X
19	Isoproturon	
20	Lead and its compounds	
21	Mercury and its compounds	X
22	Naphthalene	
23	Nickel and its compounds	
24	Nonylphenols	X
25	Octylphenols	
26	Pentachlorobenzene	X
27	Pentachlorophenol	
28	Polyaromatic hydrocarbons (PAH)	X
29	Simazine	
30	Tributyltin compounds	X
31	Trichlorobenzenes	
32	Trichloromethane (chloroform)	
33	Trifluralin	X
34	Dicofol	X
35	Perfluorooctane sulfonic acids	X
36	Quinoxyfen	X
37	Dioxins and dioxin-like compounds	X
38	Aclonifen	
39	Bifenox	
40	Cybutryne	
41	Cypermethrin	
42	Dichlorvos	
43	Hexabromocyclododecanes	X
44	Heptachlor, heptachlor epoxide	X
45	Terbutryn	

Table 24: List of substances on the surface water Watch List

First watch list, 2015	Current watch list, 2018
Diclofenac (NSAID)	17-Beta-estradiol (E2), Estrone (E1)
17-Beta-estradiol (E2), Estrone (E1)	17-Alpha-ethinylestradiol (EE2)
17-Alpha-ethinylestradiol (EE2)	Methiocarb
Oxadiazon	Imidacloprid
Methiocarb	Thiacloprid
2,6-ditert-butyl-4-methylphenol	Thiamethoxam

First watch list, 2015	Current watch list, 2018
Tri-allate	Clothianidin
Imidacloprid	Acetamiprid
Thiacloprid	Erythromycin
Thiamethoxam	Clarithromycin
Clothianidin	Azithromycin
Acetamiprid	Amoxicillin
Erythromycin	Ciprofloxacin
Clarithromycin	Metaflumizone
Azithromycin	
2-Ethylhexyl 4-methoxycinnamate	

Legend:

Removed from 1st list in 2015	*New substances in current watch list
Nonsteroidal anti-inflammatory drug (NSAID)	Neonicotinoid
Estrogen hormone	Antibiotic
Pesticide	Antioxidant
Chemical compound used in cosmetics to absorb UV rays	

Table 25: PBT assessment criteria for pharmaceuticals[33]

Property	PBT criteria	vPvB criteria
Persistence	A substance fulfils the persistence criterion (P) in any of the following situations: (a) the degradation half-life in marine water is higher than 60 days; (b) the degradation half-life in fresh or estuarine water is higher than 40 days; (c) the degradation half-life in marine sediment is higher than 180 days; (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days; (e) the degradation half-life in soil is higher than 120 days.	A substance fulfils the "very persistent" criterion (vP) in any of the following situations: (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days; (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days; (c) the degradation half in soil is higher than 180 days.
Bioaccumulation	A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2000.	A substance fulfils the "very bioaccumulative" criterion (vB) when the bioconcentration factor in aquatic species is higher than 5000.
Toxicity	A substance fulfils the toxicity criterion (T) in any of the following situations: (a) the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0.01 mg/L; (b) substance meets the criteria for classification as carcinogenic (category 1A[2] or 1B[3]), germ cell mutagenic (category 1 or 1B), or toxic for reproduction (category 1A[4], 1B[5] or 2[6]) according to Regulation EC No 1272/2008[7] (c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.	

[33] To include EMA guidance link

Box 16: Strategic Approach to Pharmaceuticals in the Environment[34]

The EU's Strategic Approach to Pharmaceuticals in the Environment was published in 2019 as a requirement of the Commission under Article 8c of the Priority Substances Directive (2008/105 as amended by Directive 2013/39) obliges the Commission to propose a strategic approach to the pollution of water by pharmaceutical substances. It complements existing EU legislation on medicinal products as well as a number of other current and initiatives such as the recently adopted Strategy on Endocrine Disruptors[35] and evaluations of EU chemicals legislation, the UWWTD and Water Framework Directive. Some of the main objectives of the Strategy are to:

- Identify actions to be taken or further investigated to address the potential risks from pharmaceutical residues in the environment and contribute to actions on combatting antimicrobial resistance
- Identify remaining knowledge gaps and possible solutions to address them

The Communication on the EU's Strategic Approach to Pharmaceuticals in the Environment highlights the significant increase of active pharmaceutical ingredients in the past three decades, both in terms of the quantities of pharmaceuticals sold on the European market and the consumption of pharmaceutical products per person. The Communication further recognises the evidence of pharmaceutical residues of various categories (antibiotics, antineoplastic, nonsteroidal anti-inflammatory drugs (NSAIDs), antiepileptics, antidiabetics) present in surface and ground waters, soils and animal tissues across Europe, in their original form, as metabolites or other transformation products. Traces of pharmaceutical substances found in drinking water include for example Ibuprofen, Diclofenac, Carbamazepine and Azithromycin. The APIs detected in the environment include medicinal products put on the market several decades ago and no longer on the market as well as new medicines. Finally, the Strategy also calls on the EU pharmacovigilance legislation to examine the scale of the problem of pollution of water and soils with pharmaceutical residues.

[34] Communication from the European Commission on Strategic Approach to Pharmaceuticals in the Environment: ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF
[35] European Commission - Press release, 7 November 2018 Endocrine disruptors: A strategy for the future that protects EU citizens and the environment: http://europa.eu/rapid/press-release_IP-18-6287_en.htm

Table 26: Assessment of regulatory clarity of legal basis of EPR

	Assessment criteria		
Legal basis for EPR	**Responsibility**	**Financing**	**Coherence**
Pharmaceuticals: Regulation 726/2004	As legislation governs the marketing authorisation phase, identification of all potential manufacturers under a dedicated EPR scheme could be relatively straight-forward.	Dedicated fee system established at EU level (Reg. 297/95).	No major potential inconsistencies with existing legislation identified.
	Assessment score = 3	Assessment score = 3	Assessment score = 3
Pesticides: Regulation 1107/2009	As legislation governs the marketing authorisation phase, identification of all potential manufacturers under a dedicated EPR scheme could be relatively straight-forward.	Dedicated fee system established at EU level (Reg. 1107/09).	Possible overlaps with other legislation e.g. food-related policies, etc.
	Assessment score = 3	Assessment score = 3	Assessment score = 2
Biocides: Regulation 528/2012	The BPR may not allow for the designation of all relevant actors due to the large variety of applications and final products placed on the market and diffuse nature of water pollution.	Dedicated fee system established at EU and MS level (Reg. 564/13).	Possible overlaps with other legislation e.g. PPP and Cosmetics Regulation, Detergents Directive, etc.
	Assessment score = 2	Assessment score = 3	Assessment score = 2
Textiles: Waste Framework Directive 2008/98	The Waste Framework Directive 2008/98 targets the EOL phase, making it more difficult to identify all relevant producers due to diffuse nature of pollution.	The Directive specifically establishes EPR and polluter-pays, however there is currently no established fee system at EU level specific to textile products.	Possible overlaps with other legislation e.g. national legislation (mandatory EPR schemes on textiles), Toys Directive, etc.
	Assessment score = 1	Assessment score = 2	Assessment score = 2
Tyres: ELV Directive 2000/53	Identification of tyre producers would be relatively straight-forward e.g. existing registration and de-registration systems. However, reported systemic problems with statistically missing ELVs (vehicles of 'unknown whereabouts') could create challenges in tracking all relevant producers.	The ELV Directive specifically applies EPR through physical (set up collection systems, ensure ELVS are transferred to authorised treatment facilities) and financial responsibility (free take back). However, producer responsibility does not specifically address costs of microplastics emissions.	Possible overlaps with several other legislation e.g. Directive 1999/37 on vehicle registration, General safety of tyres Regulation 661/2009, Tyre Labelling Regulation, Directives on Batteries, ROHS, WEEE, etc.
	Assessment score = 3	Assessment score = 3	Assessment score = 1
All products: UWWTD 91/271	Identification of polluters is possible to the same extent as it can be done through the product-specific legislation, provided a link is established between these pieces of legislation. The UWWTD	The UWWTD does not specifically refer to EPR nor does it include a dedicated fee system.	Possible overlaps with other legislation e.g. Industrial Emissions Directive 2010/75 (BAT)

Legal basis for EPR	Assessment criteria		
	Responsibility	**Financing**	**Coherence**
	cannot identify players but set requirements for their identification.		
	Assessment score = 2	Assessment score = 1	Assessment score = 2

Table 27: Estimated timeframe for implementation of specific measures based on EU legislative review process

Legend: Based on expected timeline for EU legislative review process

1 = Not expected within next 5 years (after 2025) 2 = Within 3 to 5 years (2023 - 2025) 3 = Within 2 years (2020-2022) and/ or currently undergoing review

EU legislation	Review clauses/ requirements	Status (as of June 2019)	Expected timeline for review	Timeframe
Water Framework Directive 2000/60	**Art. 16, Art. 18:** Commission to review implementation progress every six years.	Currently under review.[36]	*Within 2 years*	3
Groundwater Directive 2006/118	**Art. 10**: Commission to review Annexes I and II every 6 years.		*Within 2 years*	3
EQS Directive 2008/105	**Art. 8b (1):** Substances on the Surface Water Watch list should be updated every 2 years.		*Within 2 years*	3
Drinking Water Directive 98/83	**Art. 11:** Commission to adapt Annexes II and III in light of scientific and technical progress every five years.	Currently under review.[37]	*Within 2 years*	3
REACH Regulation 1907/2006	**Art. 138:** Commission to implementation progress every 5 years.	Not currently under review.	*Not expected within 5 years*	1
	Roadmap for SVHC (2013): Identify all relevant SVHC) by 2020.	In progress.	*Within 2 years*	3
Urban waste water treatment Directive 91/271	**Art. 17:** Commission to review implementation progress every two years.	Currently under review[38]	*Within 2 years*	3

[36] Expected completion of fitness check: 2019.
[37] Co-decision procedure expected to conclude in 2020.
[38] Expected completion of legislative review: 2019.

EU legislation	Review clauses/ requirements	Status (as of June 2019)	Expected timeline for review	Timeframe
Directives 2008/50 and 2004/107/EC on Air Quality	**Art. 32:** Commission to review progress on implementation;	Currently under review[38]	*Within 2 years*	3
Ecodesign Directive 2009/125	**Art. 16(1):** Commission to review and push updated working plan every three years. **Art. 18:** Commission to assess extending scope to non-energy-related products.	Not currently under review.	*Within 3 to 5 years*	2
Industrial Emissions Directive 2010/75	**Art. 73:** By 7 January 2016, and every 3 years thereafter, the Commission shall review implementation of the Directive.	Currently under review.	*Within 2 years*	3
Waste Framework Directive 2008/98	**Art. 37:** Commission to review progress on implementation every 3 years.	Not currently under review.	*Within 3 to 5 years*	2
Regulation 726/2004 on authorisation and supervision of human and veterinary medicinal products	Grants power to the Commission to implement delegated acts and temporary measures	Not currently under review.	*Within 2 years*	3
Guidance on environmental risk assessment of human medicinal products	See Regulation 726/2004.	Public consultation open until 30 June 2019.	*Within 3 to 5 years*	2
Regulation 520/2012 on EU Pharmacovigilance system	See Regulation 726/2004.	Not currently under review.	*Within 2 years*	3
Regulation 2019/6 on veterinary medicinal products	See Regulation 726/2004.	Not currently under review.	*Within 2 years*	3
Sustainable Use of Pesticides Directive 2009/128	**Art. 4(3):** National Action Plans to be reviewed every five years**.**	Not currently under review.	*Within 3 to 5 years*	2
Plant protection products Regulation 1107/2009	**Art. 42:** By 30 June 2022 the Commission to carry out an ex-post evaluation.	Currently under review.[39]	*Within 3 to 5 years*	2
Biocidal Products Regulation 528/2012	**Art. 15:** Active substances should be regularly examined to take account of developments in science and technology.	Not currently under review.	*Within 2 years*	3

[39] Expected completion of legislative review: 2019.

EU legislation	Review clauses/ requirements	Status (as of June 2019)	Expected timeline for review	Timeframe
	Art. 65: Every five years, from 1 September 2015, Member States to submit implementation report to the Commission.			
Textile Labelling Regulation 1007/2011	**Art. 23**: By 8 November 2014, the Commission shall submit a report on the application of this Regulation.	Not currently under review.	*Within 3 to 5 years*	2
Eco-label Regulation 66/2010	**Art. 14:** By 19 February 2015, the Commission shall report on the implementation of EU Ecolabel scheme.	Not currently under review.	*Within 3 to 5 years*	2
Tyre Labelling Regulation 1222/2009	Commission to carry out evaluation and report on implementation by 2027.	Currently under review.[38]	*Not expected within 5 years*	1
General Safety of Tyres Regulation 661/2009	Proposal for a new General Safety Regulation expected to be adopted in 2019.	Currently under review.[38]	*Not expected within 5 years*	1
End-of-life vehicles Directive 2000/53	**Art. 10a**: By 31 December 2020, the Commission to review the Directive accompanied by a legislative proposal, if appropriate.	Currently under review.[40]	*Not expected within 5 years*	1

[40] Expected completion of legislative review: 2019.

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STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Module 3 – Assessment of stakeholder positions on EPR

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STUDY ON THE FEASIBILITY OF APPLYING EXTENDED PRODUCER RESPONSIBILITY TO MICROPOLLUTANTS AND MICROPLASTICS EMITTED IN THE AQUATIC ENVIRONMENT FROM PRODUCTS DURING THEIR LIFE CYCLE

Module 3 – Assessment of stakeholder positions on extended producer responsibility

FINAL REPORT

December 2019

EurEau

CONTENTS

1. Objectives & methodology 3
1.1 Module 3 objectives 3
1.2 Methodology 3
2. Overview of stakeholder participation 5
3. Summary of key stakeholder feedback 8
3.2 Understanding of EPR 8
3.3 Existing measures at EU level 9
3.4 Other measures 11
3.5 Relevance of a potential EPR scheme 13
3.6 Effectiveness of a potential EPR scheme 14
3.7 Potential legislative framework for an EPR scheme 16
3.8 Challenges and barriers 17
3.9 Opportunities and success factors 18
3.10 Options for the way forward 18
3.11 Arguments for and against a potential EU-wide EPR scheme 20
4. Annex 25

List of tables and figures:

Table 1: Key stakeholder groups targeted for stakeholder consultation 3
Table 2: Status of stakeholder participation 6
Table 3: Summary of key arguments for and against a potential EPR approach 20

Figure 1: Stakeholder interviews 5

1. Objectives & methodology

1.1 Module 3 objectives

The objective of module 3 is to analyse stakeholder arguments for and against the application of an EU-wide extended producer responsibility (EPR) scheme on products releasing micropollutants and microplastics in the aquatic environment. Based on the arguments against a potential EPR scheme, robust and well-founded counter arguments for EPR have been developed.

1.2 Methodology

A targeted stakeholder consultation was carried out for a period of two months, between January 2019 and February 2019. The aim of the stakeholder consultation was to collect the views from stakeholders on a potential EPR scheme on the products emitting micropollutants and microplastics into the aquatic environment. Where relevant, the analysis of stakeholder perspectives were also supported by information collected through an in-depth literature review e.g. for specific stakeholders groups that were less represented in the consultation. In addition, a workshop hosted by EurEau was held on 14 February 2019 to gather insights from policy makers and national authorities on possible solutions for the way forward.

The first step of the stakeholder consultation was to identify the priority stakeholder groups and contacts in relation to the product categories assessed. Table 1 summarises the main stakeholder groups and their relevance to the stakeholder consultation.

Table 1: Key stakeholder groups targeted for stakeholder consultation

Stakeholder group	Description and relevance for stakeholder consultation
Producers	Producers refers to individual companies and trade associations representing specific industrial sectors responsible for the manufacturing of products that emit micropollutants and microplastics into the aquatic environment. Key perspectives from producers included the potential tehcnical and economic challenges and obstacles of EPR, notably in regard to financial burdens incurred e.g. impact of the final purchasing price of their products, investment costs, etc. and technical complexity in ensuring traceability and designating producer responsibility.
Water sector	Stakeholders from the water sector provided valuable insights on the technical and economic challenges related to the costs of additional treatment steps (end-of-pipe) treatment of micropollutants and microplastics released into the aquatic environment. Stakeholders from the water sector include actors that provide water services in relation to drinking and waste water treatment e.g. EurEau, national water services associations, etc.

Stakeholder group	Description and relevance for stakeholder consultation
Policy / governance	Policy or governance stakeholders are those involved in the decision-making process, whether at international, EU, national or local levels e.g. national environment ministries, European institutions such as the European Commission, European Chemicals Agency (ECHA), the Organisation for Economic Co-operation and Development (OECD), etc. Policy stakeholders provided input related to legislative aspects such as the regulatory framework needed for successful implementation of EPR. Other aspects such as the consideration of national contexts and specificities e.g. national markets, national regulatory measures, etc. and coherence with international regulations and trade were also important factors investigated within this stakeholder group.
NGOs	NGOs (non-governmental organisations) representing the interests of citizens, the environment and scientific community provided important feedback on current initiatives and best practices as well as key concerns from the viewpoint of local communities and environmental consequences. Examples of key actors in this stakeholder group include the Pesticide Action Network, International Union for Nature Conservation, etc. as well as independent research and development organisations.

Based on the above stakeholder groups, a list of approximately 40 relevant stakeholder organisations were identified (Table 2). The process for selecting stakeholders was based on several aspects, notably ensuring that the final stakeholder list reflected representativeness: coverage of all product categories assessed, proponents and opponents of a potential EPR scheme and the level of stakeholder interest and involvement e.g. presence and participation in related initiatives, events, political causes and publications. The final stakeholder list was developed in close cooperation with EurEau.

In a next step, a background document was prepared, which included a brief introduction, context of the study and a list of the key questions for discussion relevant to the stakeholder group targeted (see Annex). A first round of emails was sent to all stakeholder contacts with the background document, timeline for feedback, as well as a letter of support from EurEau, inviting them to participate in a phone interview or provide written feedback. Follow-up phone calls and reminder emails were sent where relevant to encourage maximum participation in the consultation process.

Detailed minutes of all interviews carried out were produced by the project team. For confidentiality reasons, the stakeholder feedback is in an aggregated manner, in order to maintain a certain level of confidentiality of responses, while allowing for overall conclusions from key stakeholder groups or positions.

2. Overview of stakeholder participation

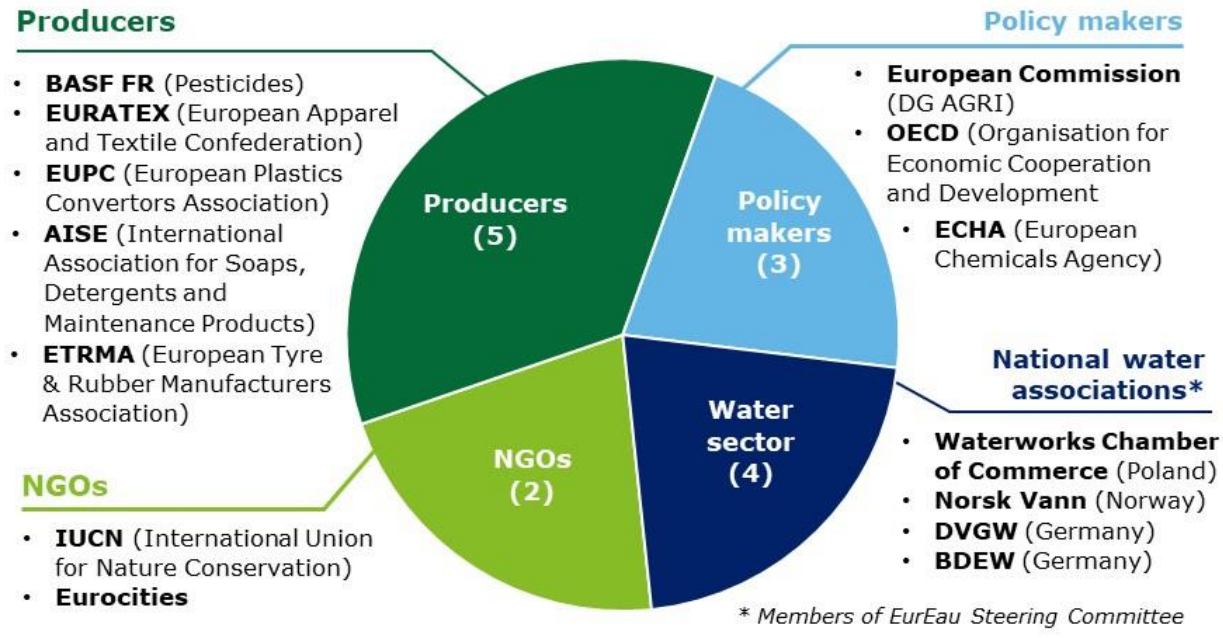
Stakeholders from all of the four main target groups participated in the stakeholder consultation. A total of 37 stakeholders were contacted as follows:

- Producers = 13
- Water sector = 10
- Policy/ governance = 5
- NGOs = 9

Furthermore, all of the product categories assessed by the study – with the exception of PFASs and pharmaceuticals – were represented in the stakeholder contributions. For PFASs and pharmaceuticals in particular, viewpoints were gathered from available literature such as position papers and company websites in order to complete the summary table on arguments against a potential EPR scheme. Finally, none of the consumer organisations contacted, responded to the invitation to participate in the stakeholder consultation.

Of the 37 stakeholders contacted, 19 contributed to the study: 14 were interviewed or provided written feedback (Figure 1). The remaining stakeholder contributions (5) reflected input by EurEau members (national water associations), which were provided throughout the duration of the study, and not only within the context of the stakeholder consultation. For example, review and input on project deliverables, provision of data and literature sources, discussions during project meetings, participation in the EurEau stakeholder workshop, etc. These contributions were also taken into account in the final summary on stakeholder feedback (chapter 3). The final results of stakeholder participation are summarised in Table 2.

Figure 1: Stakeholder interviews[1]



[1] Interviews in the figure refers to inputs collected through the specific stakeholder consultation process e.g. phone interview or written questionnaire feedback. As such, input provided from EurEau members in the context of project meetings or workshops are not included in the graphic.

Table 2: Status of stakeholder participation

Legend:

✓ Interview /Provided written feedback	✓ No response/ Did not wish to participate

	Organisation	Type	Status
1	**ACR+** (Association of Cities and Region for Sustainable Resource management)	NGO - local governance	✓
2	**AISE** (International Association for Soaps, Detergents and Maintenance Products)	Producer	✓
3	**ANEC** (European Association for Consumer Representation in Standardisation)	NGO - consumers	✓
4	**Aquafin** (Belgian national association representing waste water treatment)	Water sector	✓
5	**BASF** (Producer of chemical-based products)	Producer	✓
6	**BDEW** (German Association of Energy and Water Industries)	Water sector	✓
7	**Belgaqua** (Belgian national association representing drinking water and waste water treatment)	Water sector	✓
8	**BEUC** (European Consumer Organisation)	NGO - consumers	✓
9	**CEJA** (Young Farmer's association)	Producer	✓
10	**Copa Cogeca** (European farmers' association)	Producer	✓
11	**DANVA** (Danish Water and Wastewater Association)	Water sector	✓
12	**Der DBV** (German farmers' association)	Industry association	✓
13	**DVGW** (German Technical and Scientific Association for Gas and Water)	Water sector	✓
14	**ECHA** (European Chemicals Agency)	Policy - governance	✓
15	**EC** (European Commission)	Policy - governance	✓
16	**EFPIA** (European Federation of Pharmaceutical Industries and Associations)	Producer	✓
17	**EMA** (European Medicines Agency)	Policy - governance	✓
18	**EPR Club / ACR+** (Platform for exchange and debate about EPR in Europe)	NGO - local governance	✓
19	**ETRMA** (European Tyre & Rubber Manufacturers Association)	Producer	✓
20	**EUPC** (European Plastics Convertors Association)	Producer	✓
21	**EURATEX** (European Apparel and Textile Confederation)	Producer	✓

Organisation		Type	Status
22	**Eurocities** (Network of large cities in Europe)	NGO - local governance	
23	**EUROFEU** (European Manufacturers of Fire Protection Equipment)	Producer	
24	**ECPA** (European Crop Protection Association)	Producer	
25	**FEAD** (European Federation of Waste Management and Environmental Services)	Water sector	
26	**FoodDrinkEurope** (European food and drink industry association)	Producer	
27	**IGWP** (Polish Waterworks Chamber of Commerce)	Water sector	
28	**IBMA** (International Biocontrol Manufacturers' Association)	Producer	
29	**IUCN** (International Union for Nature Conservation)	NGO - environment	
30	**Norsk Vann** (Norwegian national water association)	Water sector	
31	**OECD** (Organisation for Economic Cooperation and Development)	Policy - governance	
32	**PAN** (Pesticide Action Network)	NGO - environment	
33	**Svenskt Vatten** (Swedish Water Association)	Water sector	
34	**UBA** (German Environment Agency)	Policy - governance	
35	**Verbraucherzentrale Nordrhein-Westfalen** (German consumers' association)	NGO - consumers	
36	**Water UK** (UK Water Association)	Water sector	
37	**WWF** (World Wildlife Fund)	NGO - environment	

3. Summary of key stakeholder feedback

This chapter presents the principal messages gathered from the stakeholder consultation, which are grouped according the topic addressed. Based on stakeholder feedback and literature where relevant, the chapter concludes with a summary table of the main arguments for and against an EPR scheme on products emitting micropolluants and microplastics into the aquatic environment (Table 3).

3.2 Understanding of EPR

As highlighted in Module 1, extended producer responsibility is interpreted and implemented in a wide variety of ways, which can impact the overall position on a potential EPR scheme in the context of products that release micropolluants and microplastics. During the course of the stakeholder consultation, several stakeholders provided their overall understanding of extended producer responsibility, its principles and overall objectives, summarised as follows:

- EPR schemes are intended to reduce negative environmental impacts throughout the product life cycle with two primary goals:
    - (1) Incentivise the design of products with lower negative environmental impact e.g. ecodesign; and
    - (2) Ensure effective end-of-life collection, increase collection rates, improve end-of-life treatment and incentivise recycling and recovery.
- The aim of EPR is to:
    - (1) Establish financial instruments (incentives for producers); and
    - (2) Uphold the principle that those who cause environmental damage are held financially and legally accountable.
- EPR was first implemented to ensure the funding and recycling process of products put on the market. These products are collected, treated or recycled with the aim of being incorporated or made into new products. To this end, the rationale behind the implementation of EPR was to promote recycling at international level. EPR is thus a tool that can be used to efficiently achieve environmental policy objectives, by extending the producer's financial and material obligations.
- EPR is a concept whereby the producer (in most cases), is held financially responsible. EPR can be implemented in many different ways. In particular, it is important to distinguish between voluntary and mandatory application of EPR, as each approach has different implications, requirements, scope, etc.
- Since EPR is interpreted in many different ways, it does not have one unique definition. For some, "extended" can be seen as increased stress and additional financial and administrative burdens, which could imply the need to re-define the concept of extended producer responsibility and raise awareness of its benefits and objectives. EPR has already proven not only feasible, but effective in improving solid waste management practices.

3.3 Existing measures at EU level

Feedback regarding whether existing EU measures are sufficient to control the release and presence of micropolluants and microplastics into the aquatic environment was divided among stakeholders. With few exceptions, those who felt that existing measures at EU level are sufficient were mainly producers, whereas stakeholders from the water services sector viewed existing measures as insufficient.

Sufficient existing legislative framework

Most producer viewpoints reflected the argument that since certain sectors are already heavily regulated to ensure the safe production, use and disposal of their products, additional measures would not be necessary. Producers felt that they already carry significant regulatory responsibility as required through national and EU legislations for their products placed on the market. For example the research and financial implications for registering substances through the REACH Regulation or through project-specific legislations. Examples of specific legislations that were cited by producers during the stakeholder consultation included:

- **REACH Regulation**: Requires that the ingredients used in specific mixture substances are safe for use and for the environment before they can be placed on the market;
- **CLP (Classification Labelling and Packaging) Regulation**: Specific restriction on the use of CMR (carcinogenic, mutagenic or toxic for reproduction) substances in consumer products (however, the restriction does not apply to substances used in professional products);
- **Industrial Emissions Directive (IED)** (previously the integrated pollution prevention and control Directive): Regulates industrial emissions from manufacturing processes;
- **Environmental quality Standards (EQS) of the Water Framework Directive (WFD)**: On good chemical status for a clean aquatic environment to ensure minimum water quality to protect human health and the environment
- **Drinking water quality standards (Drinking Water Directive)**: Drinking water standards establishes a very low threshold for the concentration of active substances used in pesticides at 0.1 mg. This is not the case for arsenic, a widely known toxic substance, which has a much a higher threshold with a concentration limit of 10 mg;
- **Detergents Regulation**: Places biodegradability requirements for all surfactants placed on the market;
- **Biocidal Products Regulation**: Need for a special approval process for active substances, including an assessment of the effect of the substance on the environment.

One producer noted that if no EPR scheme currently exists for the so-called products that emit substances into the environment, it is because there is no sufficient evidence demonstrating the need for one. Another stakeholder from the manufacturing sector also added that it is the **responsibility of distributors** to ensure that the final end-user is sufficiently informed on how to use and dispose of the product properly. To illustrate this point, the example of a car accident was provided, whereby, it would be unfair to put full responsibility on the car manufacturer as other parameters such as the driver's behaviour,

lack of proper road infrastructure and quality, lack of effective regulation also causes accidents.

For a stakeholder representing the water services in Norway, no extra or end-of pipe treatment measures has been implemented to tackle the micropollutant and microplastic problem. As such, existing measures are currently sufficient in the specific case of Norway, since the competent authority has not yet identified the need to establish end-of-pipe solutions. The polluter-pays principle and the source-control principle are therefore still applying. However, several examples from different European Member States indicate that existing measures are not enough, since end-of-pipe solutions are already being established.

Insufficient existing legislative framework

Feedback received from water sector stakeholders (drinking water, waste water) pointed to an insufficient and ineffective legislative framework at EU level, which has led to the current problem of micropollutants and microplastic in Europe's water bodies, especially from the view of a circular economy. Existing measures in European water policies, especially in the field of environmental protection are a valuable basis. Despite well-placed intentions, strict procedures and objectives of existing EU and national policies, **implementation remains weak**. Although measures have been effective to a certain extent in reducing the release of some hazardous substances into the environment e.g. lead, mercury, etc., other types of hazardous substances continue to be emitted into the water cycle, particularly emerging substances and microplastics. There is a real **need for innovation**, efforts to explore new ideas and to investigate what is more or less working. Certification and labelling could contribute to the efforts needed, however their impact remains limited.

Regarding end-of-pipe solutions, according to a stakeholder from the NGO sector, in the majority of EU MS, there are no standards at national level for treating hazardous substances once they end up in WWTPs. Some standards are established and respected at the local level e.g. requiring WWTPs to reach a certain removal rate for micropolluants are insufficient because such measures concern only a small portion of WWTPs, indicating that the vast majority of WWTPs are not required to specially remove certain micropollutants and microplastics, leading us to an increasingly urgent situation. For water service stakeholders, **end-of-pipe treatment in drinking water production or waste water treatment is seen as the second option** to achieve the quality standards of the Drinking Water Directive and the Urban Waste Water Directive. The option of end-of-pipe-treatment must always be applied in parallel with control at source measures since end-of-pipe-treatment will not be able to solve the problem for all sizes of treatment plants – in terms of ensuring the quality of nutrients and guaranteeing that the organic matter to be delivered back to agriculture soil complies with circular economy principles.

Finally, for one producer in particular, a key weakness of the existing EU legislative framework is the **lack of a strong and transparent enforcement system,** notably in regards to **imports**. Therefore, any update in existing or new measures would only be useful if there was also an effective enforcement system at EU level to support it.

3.4 Other measures

In addition to input on the effectiveness of existing EU regulatory framework, stakeholders also provided feedback on how other measures are contributing to or could be further optimised to reduce the release of hazardous substances into the aquatic environment.

EU initiatives

Policy stakeholders referred to recent and on-going initiatives at EU level such as buffer zones and projects on plastic additives and alternative substances:

- **Buffer zones in agriculture**, are applied between an agricultural field and a watercourse to prevent run-off of potential hazardous substances, are not a part of control at source measures, however can be effective in preventing hazardous substances from entering water ways.

- The EU provide MS with a considerable amount of **financial support towards more sustainable farming practices**, notably the organics sector. For example, the EU funds the entire transition from conventional to organic farming and also provides an annual incentive as a premium for organic farming. Further, the EU sets minimum standards and conditionality requirements, including environmental standards (sustainable use of pesticides directive). Other obligations include agricultural practices like crop rotation and minimal soil coverage during winter seasons. There are penalties applied when farmers do not respect existing legislations. Rewards are also applied to encourage good behaviour – for example to reduce the use of nitrogen and pesticides.

- In 2016, the European Chemicals Agency (ECHA) launched the **two-year plastic additives initiative**, with the cooperation of 21 industry sector organisations, to characterise the uses of plastic additives and the extent to which the additives may be released from plastic articles. The project generated an overview of 428 additives in plastics used in high volumes in the EU, and looked at how use and exposure information could be used to focus the regulatory work by authorities under REACH. The substances are divided into: antioxidants; flame retardants; nucleating agents; plasticisers; heat and UV/light stabilisers; and pigments. The work included the development of a method for comparing the release potential of different additives. Companies can use the method to determine which registration dossiers they should update as highest priority and to identify where safe use information communicated down the supply chain needs to be further improved. For substances of very high concern, ECHA has launched several initiatives to further encourage the use of alternative and safer chemicals. For example, the recent **Strategy to support substitution of chemicals of concern** as well as a workshop to present and discuss the actions implemented in 2018 and 2019 in relation to ECHA's strategy to promote substitution to safer chemicals through innovation.

Voluntary industry initiatives and measures

Producers highlighted several voluntary initiatives to demonstrate their efforts in addressing micropollutants and microplastics:

- Cross-sector industry research projects and agreements: Initiatives include for example research on quantification and testing methods, which aims to quantify and identify the point of release of certain micropollutants and microplastics. For microplastics in particular, a range of on-going projects are being implemented e.g. phase-out of microbeads, alternative practices for managing surface water from roads, prototypes to test textile resistance and the potential impacts of washing. A company in the research sector is currently exploring the possibility of a system that can downgrade old tyres into monomers. An EPR scheme could finance this type of research and technology investment, however it does not solve the problem of microplastics being released into the environment. Other actions include raising awareness and address microplastics issues such as Operation Clean Sweep® (OCS), an international program that strives to prevent plastic pellet, flake and powder loss and to ensure that these materials do not end up in the environment. Finally, research is also being carried out on filtration technologies for effluents treatment.

  Regarding the use of **alternative substances**, according to the stakeholders interviewed, industry research projects have not currently identified a suitable alternative that would maintain necessary tyre performance in regards to ensuring minimum safety requirements e.g. friction and road holding between tyres and roads.

- The European Tire and Road Wear Particles (TRWP) Platform, launched in July 2018, serves as a multi-sectorial stakeholder roundtable. The aim of the initiative is to share intelligence, build up solid scientific knowledge and engage all relevant parties to explore a balanced and holistic approach to TRWPs mitigation options.

- ADIvalor[2] is a private non-profit eco-organisation tasked with several missions on the collection, recycling and recovery of agri-plastics waste. It is funded by several companies and sectors, reflecting the notion of shared responsibility. In 2016, a working group was created on pesticide metabolites in drinking water.

- EcoTLC is a mandatory EPR scheme for textiles in France[3]. The EPR scheme has now been established for 11 years and is organised to collect and sort garments, which are then sold as second-hand. The scheme targets business operators that place garments into the market (mainly distributors and retailers). A fee is paid based on the amount of product that is placed on the market. EcoTLC has participated in several policy and industry debates – including some of the challenges based on the France experience, notably that a well-established EPR system can only be effective if there is a **well-defined product category**. The system has been successful in raising awareness, however it has been less effective in several other areas, notably in terms of addressing what happens to the garments once they are collected. In general, they are disposed of via incineration because at the moment, there is still no other viable solutions to treating garments at their end-of-life.

[2] www.adivalor.fr
[3] www.ecotlc.fr

3.5 Relevance of a potential EPR scheme

Concerning the relevance of a potential EPR scheme, none of the producers interviewed felt that EPR would be relevant nor applicable in their respective sectors, whereas responses were more nuanced and varied amongst interviews from other stakeholder groups.

An EPR scheme is not relevant, nor applicable

For many of the producers interviewed, the **diffuse nature** of these substances makes identifying the products and overall responsibility extremely complicated. This was supported by the argument that the **lack of concrete data on the impacts of micropollutants and microplastics** and uncertainty behind a direct link between their products and the presence of potentially hazardous substances in the environment is not straight-forward nor sufficiently proven scientifically. The fact that there is currently no standardised test method to measure the quantity and distinguish the sources of certain substances found in WWTPs further exacerbates the problems that stem from a lack of a harmonised information base and concrete data. Potential EPR schemes on micropollutants and microplastics should be put in this context, which implies the necessity of a thorough preliminary analysis and impact assessment addressing all the specificities and needs related to each of the different micropollutants/ microplastics concerned. For example, microplastics is a very wide term that covers a large range of different kinds of materials, with very different properties and behaviour. This affects both how such particles reach the aquatic environment, the treatment required to capture them and at which stage it is more effective to intervene. Therefore, EPR should be considered separately for each type of micropollutant and microplastic as they reflect different types of substances, sources and emission pathways.

Other responses from producers pointed to **end-of-pipe solutions**, where there would be more potential to tackle the micropollutant and microplastic problem. Before considering the possibility of EPR for a certain product/ source of micropollutants/ microplastics emissions, one producer mentioned that it is essential that advanced treatment is available, additional costs for the treatment can be identified and put in relation to treatment efficiency, so that the mitigation pathway of enhanced wastewater treatment can be evaluated against other mitigation options. For another producer of products emitting microplastics in particular, EPR is not currently a feasible solution because the performance of existing WWTPs should already be able to capture microplastic particles. Interestingly, another manufacturer stated the opposite – that there is currently no advanced waste treatment technology that can efficiently and completely remove microplastics, therefore producers cannot be expected to pay for a technology or treatment process that does not yet exist.

Similarly, another producer mentioned that more efforts should be targeted at **the use phase**. Consumers need to be better educated on the potential impacts of their consumption behaviour. Producers, on the other hand, are already well-aware of their responsibility and are implementing good practices to reflect this. For EPR on microplastics stemming from the agricultural sector, its applicability and effectiveness is doubtful due to the characteristics of microplastics use in agriculture, notably their release into the environment, which usually occurs during the use phase and with **the final user**. Further, not only are microplastics difficult to identify, but also hard to recover (i.e. difficult and

expensive to physically identify and recover once they are present in the aquatic environment).

An EPR scheme that would incentivise ecodesign and improve effective end of life collection would not be applicable in the case of tyres and road particles because product design is made considering the **trade-off between tyre abrasion and performance**. This is a phenomenon which directly results from the tyre grip on roads and which cannot be reduced without negatively impacting the overall tyre performance. Additionally, the release of microparticles from tyre abrasion is influenced by several external factors and not solely by tyre design, for example, driver behaviour, overload and overflow due to weather conditions.

Finally, according to a stakeholder in the policy-making and governance sector, the micropollutants and microplastics evaluated in the current study are being released from products that were not originally intended to be recycled and reused (with the exception of a few active pharmaceutical ingredients that could be recycled and reused in product formulation and for which research is on-going to develop these technologies), implying that an EPR scheme may not be the most appropriate solution for these substances.

An EPR scheme is relevant and applicable

All water sector stakeholders supported the relevance and applicability of an EPR scheme, particularly due to an overall **greater need for producer responsibility**. It is important to establish EPR schemes in order to put the polluter-pays-principle to practice. Otherwise, it will be the principle that the community pays. Manufacturers who produce products, which contain substances that are likely to end up one way or another in the environment and especially in the water cycle must be made aware and accept their responsibility as stipulated under the polluter pays principle.

Two stakeholders from the NGO and water sector, respectively, considered EPR as a relevant solution for products that release micropollutants and microplastics into the aquatic environment, especially if applied as a **complementary measure** along with regulation, phase-out, other source-control measures and end-of-pipe solutions. If producers are making concerted efforts on their side, micropollutants will be present at lower concentrations in the water cycle. Consequently, less fossil fuels would be needed to treat water and it would also be less costly for WWTPs.

3.6 Effectiveness of a potential EPR scheme

Stakeholders were asked about the factors that would be important to consider for the operational effectiveness e.g. financial mechanism, scope and coverage, etc. of a potential EPR scheme.

Producers mentioned the following factors in regards to the effectiveness of an EPR scheme:

- Alternative substances cannot be considered as a viable solution for certain products, especially for products which require a certain level of performance in regards to human health and safety.

- Sufficient data and information on aspects such as the level of contamination at waste water treatment plants and sites, emission sources and the impacts of substances, is lacking to ensure a well-established, fair and justified solution.
- A thorough impact assessment and cost benefit analysis addressing the specificities of each type of micropollutant and microplastic should be foreseen before the definition of any EPR scheme. Without solid findings from a cost-benefit analysis, a fee system established under EPR for example would not be possible.
- EPR for microplastics treatment is not the most effective way to reduce their release, as the major entry pathway is the use stage.

Feedback on the effectiveness of a potential EPR scheme from water sector stakeholders covered issues such as scope, costs and funding:

- Measures within an EPR scheme can cover a wide range of possible compensation models. Covering costs for additional treatment in drinking water production or waste water treatment can be an approach, notably by ensuring that producers are financially responsible for restoring drinking water resources once they have been contaminated by hazardous substances. Co-financing for the monitoring of water resources and feasibility studies are other possibilities.
- All actors concerned across the production value chain should be actively engaged in the EPR scheme. This includes not only producers, but also online-based producers, distributors and retailers.
- Any new financial mechanism will influence prices. When costs and benefits are estimated, the costs of micropollutants in the environment and for end-of-pipe treatment (which are also being financed by consumers) must be sufficiently highlighted. A financial tool such as imposing a tax or similar measure on products would risk shifting producers (financial) responsibilities onto the shoulders of patients, consumers etc.

Policy and NGO stakeholders provided the following feedback concerning the effectiveness of a potential EPR scheme:

- For EPR to be effective, we need to be able to determine if there is an available alternative substance that provides the same technical function and performance, but that can also keep the costs of products (production) down.
- One of the key elements needed in order to implement an efficient EPR scheme for micropollutants and microplastics is to **assess the supply chain of each substance** that is considered a micropollutant or microplastic, then identify whether or not there are existing measures and technologies to treat these substances at their end-of-life. If these measures (control at source and end-of pipe measures) are not efficient, nor effective, then EPR could be considered as an additional measure to tackle these pollutants. It could be established based on for example, an "eco-contribution", which is calculated based on the amount of substance used, the conception of products (composition and design) as well as the mitigation measures implemented on-site by industries (eco-contribution scales depending on the efficiency of mitigation measures.). If the objective of the EPR scheme is to upgrade WWTPs by integrating technologies to treat more efficiently micropollutants and microplastics, the EPR would be less relevant.

- It is important to note that the starting point for EPR implementation should be **based on existing systems**, otherwise the EPR scheme would be difficult to implement in an efficient manner. For example, there are existing EPR schemes for textiles and car tyres. We can imagine expanding the scope of these existing EPR schemes to more effectively cover end-of-life management. However, if there are no existing measures to tackle these substances, the best way forward is to implement a mandatory tax system, managed by industries, which would be easier to apply.
- For EPR to be effective, **information on costs is essential**. This would be the basis for determining how the costs could be fairly distributed amongst the actors concerned. In Switzerland, ozone or activated coal investment cost is paid by public taxes so in this case, the entire population contributes. In Germany, one of the regions initiated a crowdfunding system to finance wastewater treatment operational costs. Another possibility is to require producers to finance the investment costs to upgrade WWTPs.

3.7 Potential legislative framework for an EPR scheme

Regarding the potential legislative framework for an EPR scheme, most of the producers interviewed felt that the **regulatory framework is already quite exhaustive and demanding**. As such, there is already a clear legislative framework governing safe and sound production practices, product use and end-of-life. The application of EPR through existing legislation is immature because more information is needed on these substances before targeting specific sectors and producers. Regarding the **precautionary principle** in particular, it is obviously an important principal, however in practice, the precautionary principle should be carefully considered because, if implemented incorrectly, it could have unintended negative consequences on the economy For example, in the case of genetically-modified organisms (GMO) in Europe, significant public funding was spent on research that finally concluded that the health and environmental risks of GMOs are low. However, the findings came too late because the public perspective had already changed. Consumers continue to refuse purchasing of GMO-based products, which has been a big hit to the industry.

Stakeholders from the water sector felt that the introduction of an EPR scheme at EU level would be best placed within the **chemicals authorisation process.** The water industry heavily relies on stringent EU policy on chemicals authorisation to ensure the quality of water sources. Another suggestion included the introduction of EPR as part of wider EU policy, for example via a Directive, which would allow more flexibility, but which should adhere closely to **principles of the EU Water Framework Directive (WFD).**

Moreover, viewpoints from the water sector reflected the argument that the **legislative framework must be established at EU level** e.g. REACH, Pesticides regulation, Biocidal products regulation, pharmaceuticals legislations, etc. as Micropollutants and microplastics is an EU-wide problem and must be addressed at EU level – in other words, environmental issues should be approached at the broadest scale possible. Mandatory measures are more effective and efficient than voluntary agreements in this area. Problems caused by micropollutants and microplastics are often local or regional. The advantages of an EPR scheme at EU level is that producers are often EU-wide, therefore economic incentives would be more effective at EU level than at national level. Applicability within a European context has many question marks, associated with the Brexit situation for example, therefore initiatives would be further supported if backed up by European institutions. A level playing field is essential for ensuring economic development in Europe.

Other stakeholders pointed to the recently adopted **Single Use Plastics Directive**, which could present some potential opportunities to transpose EPR approaches at national level, and also provide some insights for the case of micropollutants and microplastics.

3.8 Challenges and barriers

The key challenges mentioned by stakeholders for a potential EPR scheme on products emitting micropollutants and microplastics into the aquatic environment included:

- **Gaps in scientific knowledge** concerning the impacts and effects of micropollutants and microplastics, their emission sources, pathways and levels of concentration in water bodies; which makes the **traceability of hazardous substances** and chemicals in the environment to a specific producer and/ or sector extremely difficult.
- The **lack of stakeholder engagement and acceptance**:
    - This is particularly the case for producers, who tend to place more importance on the technical performance or efficiency of their products, rather than the eventual environmental and human health impacts and/ or who do not acknowledge that their products release substances that could have detrimental impacts (due to lack of data, contradictory information, etc.);
    - Some stakeholders indicated that many regulations are already in place so if an additional EPR scheme is added, it may raise further resistance from the manufacturing sector;
    - Decision-makers are another key stakeholder group that need to be further involved in terms of **raising awareness and priority on the political agenda**.
- In addition to lack of concrete information on their impacts and effects, the **increased efficiency, performance or potency of certain active substances** used in pesticides is also becoming quite concerning, as this could mean increased risks to the environment, even if the quantity of pesticide products placed on the EU market is more or less stable. For pharmaceuticals on the other hand, the quantity placed on the market has increased over the years.
- **Existence of free-riders**: refers to certain products/ producers that manage to bypass relevant regulatory requirements, notably importers/ imported products, online platforms, etc. For example, textiles are being imported from Asia that contain substances not allowed in Europe.
- Although viable and safer **alternative substances do exist, they are generally more expensive**, which usually means that the price of the final product will also increase. This would have a significant impact on sectors such as agriculture and on consumers. One could also even imagine a scenario where the price for certain EU products increase to such an extent that buyers will **increasingly look to non-EU markets and imported goods** – which cannot be as effectively controlled. It is important to ensure that **consumers are aware** of the potential impacts of the products they consumer as they play a key role in driving product design and more sustainable production practices.
- Europe has the highest environmental and chemical use standards in the world, however, **control and enforcement is a major weak point**.

- There is a **wide-range of definitions and understanding of extended producer responsibility,** which can be challenging because a key factor for a successful EPR scheme is a well-defined and established system for all the actors involved.

3.9 Opportunities and success factors

The key opportunities and success factors identified by stakeholders included:

- For EPR to be generally accepted by all concerned, it needs to be demonstrated, based on concrete evidence that it is the most effective solution. In other words, implementing an EPR scheme must be based on an **analytic approach**: detailed assessment to identify the causes and costs, developing targeted actions and then designating responsibilities. If producers "pay" without knowing what the impact of their fee is and what it is based on, then the EPR scheme has no sense. In this sense, **transparency is crucial.**
- **Raise public and political awareness and interest**, including information on the rational and benefits of extended producer responsibility. There is a real opportunity to encourage changes in consumer behaviour.
- **Stakeholder collaboration and dialogue** is very important in order to further advance discussions. This includes not only the involvement of major manufacturing sectors but also organisations such as EurEau, the European Crop Protection Association, FP2E (French water sector federation), etc. Similarly, it is important to find a solution that is acceptable for all stakeholders. The involvement of the different stakeholder groups concerned can be diverse – and can range from financing additional monitoring in the water catchment areas to providing information and recommendations on best practices. What is important is to remain flexible and open-minded to other perspectives and ideas.
- Ensure that the **financial mechanism sufficiently compensates treatment costs** in drinking water production or waste water treatment by considering aspects such as the overall treatment objective and efficiency rates (what substance treat and how much), which can vary.
- Further encourage the **uptake of viable and available alternatives** – such as biodegradable plastics – for which an EU new standard is currently available.
- In some cases, producers are required to submit substances under both REACH requirements and other applicable legislation. In the case of pharmaceuticals, depending on the substance and its intended use, companies may have to comply with requirements under the Directive on human medicinal products. There are certainly **areas for improved synergies and harmonisation** in terms of the information generated through REACH and other relevant legislation such as the Water Framework Directive and product-specific legislation.

3.10 Options for the way forward

Regarding possible solutions and options for the way forward, feedback was mixed among the different stakeholder groups and reflected a wide-range of suggestions as summarised in the following:

- An EPR scheme could be applied if restricted to substances that are found in WWTPs and for which their pathways to WWTPs are well-known. EPR is just one of many possible tools that could employed, however it must be adapted and applied based on what the overall objective to be achieved is.
- For microplastics, one of the main contributors to their release are from car tyre abrasion, however it is a very **diffuse source**. In urban areas, microplastics are collected by WWTPs and can end up in sludge. In some countries, sludge is used as fertilisers and therefore microplastics ends up in the soil, however incineration is a more expensive option and cannot today fulfil the ambitions of a circular economy to recycle nutrients and organic matter to agricultural soil. A solution could be to incinerate the sludge, instead of spreading it on the soil. Producers and/ or consumers could be required to pay a fee based on tyres placed on the market or during the purchase of a car tyre. This money could be used for waste water treatment in WWTPs.

  In addition to EPR, Europe needs to enact a **combination of different solutions and supporting measures** such as a speed reduction on roads, ecodesign criteria for more resistant, less noisy tyres, capacity of tyre abrasion, tyre labelling and implementing a fee based on driving behaviour.
- For some pollutants, EPR schemes could be an option to incentivise measures at the **design phase**, where an alternative exists or to increase the collection of the particles with additional treatments steps. However, this should be thoroughly assessed for each category of micropollutants, considering their pathways through the environment and the efficacy of existing treatments to remove them.
- **Lessons learnt** from the waste sector where EPR is more common should be carefully considered. Existing EPR models can provide insights on how a potential EPR scheme could work for micropolluants and microplastics. For example, energy producers are required to pay CO_2 taxes according to the amount of the pollutant emitted (e.g. greenhouse gas). Emissions are measured, and the concrete charge to pay is calculated based on this (price of Mg of CO_2 emitted). The impact on the environment is defined based on how the substance is treated at its end of life. In order words, impacts based on whether coal, gas, oil, biomass, renewable energy, etc. is used for the incineration process.
- Although **labelling has its limitations**, it can be used as an additional measure to further address the micropolluants and microplastics problem. For example, organic food labelling is increasingly sought out and popular with consumers, indicating its effectiveness in raising awareness on the issue. When potential contaminants are transparently indicated on products, consumers could be less motivated to purchase such products, which could then encourage producers to design more environmentally-friendly products.
- Other options that could address the micropollutant problem in the context of the pharmaceutical sector is to ensure that **unused medicines are more effectively collected** to avoid being thrown away in the environment.

3.11 Arguments for and against a potential EU-wide EPR scheme

Table 3: Summary of key arguments for and against a potential EPR approach

Arguments AGAINST EPR scheme	Arguments FOR EPR scheme
Topic: Responsibility	
A. The producer is not always the polluter, in particular, for products that release micropolluants and microplastics mainly during their use or end-of-life phase.	Consumers and the water services sector are currently bearing the increased water treatment costs associated with the presence of micropollutants and microplastics in the aquatic environment – rather than industry. In this context, EPR could provide the basis for setting an appropriate financing mechanism for water pricing in accordance with the **polluter pays principle** by ensuring that producers are also held financially accountable and responsible. An EPR scheme can contribute towards the reduction and shift of financial and physical responsibility for treating difficult-to-treat drinking or waste water from local authorities and public utility services (and citizens' in regards to their water bills) to producers, in order to ensure **a fair and just distribution of costs between producers, the water sector and citizens**. The decision of who shall bear the costs not only determines who has to contribute to a measure and how much, but also has significant effects that could lead directly and indirectly to further reduction of pollution. In all cases, cost recovery as stipulated by Article 9(1) of the EU Water Framework Directive – whether it is established within an EPR scheme or not – should not result in a situation where industry is not held financially responsible and only citizens, public authorities and the water sector bear the costs. An EPR system based on a full life-cycle approach and a harmonised method to identifying and designating producer responsibility at EU level would ensure that all actors across the different supply chains of these substances are held accountable. Life cycle thinking allows for the consideration of long term environmental and social issues and avoidance of short term decisions that can lead to environmental degradation – such as over-fishing or water pollution. By improving entire systems rather than single parts of systems, decisions that fix one environmental problem but can cause another unexpected or costly environmental problem (like mitigating air pollution yet increasing water pollution) can be avoided. Focusing on one specific life-cycle stage as suggested by some producers would prevent life cycle thinking, which helps to avoid shifting problems from one life cycle stage to another, from one geographic region to another and from one environmental medium (air, water or soil) to another.
Topic: Technical aspects	

Arguments AGAINST EPR scheme	Arguments FOR EPR scheme
B. It is too complicated due to a lack of sufficient data to identify the main emission sources and the relevant producers of the associated products due to the diffuse nature of the substances concerned.	EPR principles can be applied in a variety of approaches. For example, it can be used as a driver for additional research and monitoring activities that are needed in order to establish a consensual knowledge base concerning the traceability of substances and products. In this case, major industrial sectors could contribute for example to a collective dedicated fund that could be used to pay for EU wide data collection, monitoring and assessment related to targeted substances and the actors involved. EU funds such as LIFE or Horizon Europe could finance projects on developing and implementing efficient monitoring systems.
C1. There are currently no viable, alternatives for certain substances which are safer and/ or less harmful to human health and the environment.	The absence of viable alternatives and the low recyclability or reuse potential of a particular substance is not a justified argument for producers to be exempt or exonerated from their responsibility regarding the negative environmental impacts caused by their products. As mentioned earlier, EPR can be used to drive research and innovation, targeting all stages of a product's life-cycle. As such, funds collected from a dedicated EPR scheme could also be used to help cover treatment costs. Moreover, by taking into account the full cost coverage of the end-of-life of products, extended producer responsibility schemes could provide incentives that could have both short-term effects (such as substitution of micropollutants or relevant products with already available alternatives) and medium to long-term effects (such as research and development of new environmentally friendly approaches or substitutes). For example, an EPR approach that incorporates an incentive system that applies a flat wastewater charge for discharging micropollutants but which offers the possibility of exemption and/ or reduction if certain efficiencies or targets are reached or which offers the opportunity to offset potential investment costs. By holding producers responsible for the full costs caused by their products, companies will be incentivised to design products that can be more easily recycled or prepared for reuse or less costly to treat at its end-of-life.
C2. An EPR scheme that would incentivise ecodesign would not be applicable for products such as car tyres in the case of tyres and road particles because product design is made considering the trade-off between tyre abrasion performance and minimum safety requirements.	
C3. The low recyclability and reuse potential of the substances/ products concerned would make it difficult to apply EPR principles.	
Topic: Effectiveness and efficiency	

Arguments AGAINST EPR scheme	Arguments FOR EPR scheme
D. End-of-pipe solutions offer the most effective way forward. Advanced treatment technologies exist to adequately treat these substances.	Traditional drinking and wastewater treatment plants are not specifically designed to treat new and persistent substances, which results in their release into the aquatic environment where they are often left untreated. End-of-pipe solutions in the form of advanced treatment does not provide any incentive to prevent or reduce the release of potentially hazardous substances, nor does it adhere to the **polluter pays principle**. The additional treatment steps required to tackle micropollutants and microplastics in drinking water production and wastewater often entail the use of **advanced treatment technologies,** which entail **increased costs** and **technical limitations**: • Increased energy demand: Advanced treatment technologies and technology combinations assessed result in an increased use of energy and therefore emissions during energy production. • Use of harmful chemicals: Some treatment technologies such as oxidative treatments require chemicals that can cause some environmental impact during production and use and a risk that new potentially toxic contaminants will form as a result of certain technologies used. • Need for increased training & skills: additional competence requirements (and associated labour costs) may be needed in order to operate and monitor certain advanced treatment technologies. This is a particular challenge for smaller treatment plants. • Generation of by-products/ transformation products with potentially adverse effects • Higher space requirements and sludge production for treatment technologies such as powder activated carbon, which usually require multiple tanks and pumping systems. • Reduced sludge quality and circular economy options: If sludge is too contaminated for the recycling to agricultural soil, there are currently no end-of-pipe technologies that can sufficiently remove these pollutants and at the same time fulfil the ambitions in a circular economy to recycle several nutrients and organic matter to agricultural soil. • Varying removal efficiencies: the efficiency rates of different advanced water treatment technologies vary greatly depending on the technology, the way in which the technique is implemented and the substance targeted. Even if advanced treatment technologies implemented result in higher removal efficiencies, there is no guarantee that they will continue to be effective for treating future new and emerging substances including substances formed spontaneously when mixed together in the aquatic environment.
E. Any additional (financial) charges put on producers would increase the	Many of the most problematic substances present in the aquatic environment in terms of risks to the environment and human health and difficulty in removal through traditional drinking and waste

Arguments AGAINST EPR scheme	Arguments FOR EPR scheme
final purchasing price of products. In the case of pharmaceuticals, putting the financial burden on the manufacturer would lead to increased prices for medication for patients, which is socially unacceptable. Making the manufacturer responsible for environmental damage would stifle investment in life-saving drugs.	water treatment are not those that stem from "life-saving drugs" often referred to by pharmaceutical companies, rather widely available and consumed medicines such as painkillers, antidepressants, contraceptives, antiparasitics, etc. Such medicines frequently have viable alternative substances available that are less toxic for the environment. In addition to the counter arguments presented under points A, B and C, it is important to note that EPR as a tool is often implemented as a complimentary measure or along with supporting measures for maximum effectiveness and in order to fully address all stages of a product's life cycle. This includes measures such as information provision and awareness raising, labelling and in some cases the use of more "hard instruments" such as government support in the form of subsides to help offset the price of medications for consumers. In fact, this is already the case in many European countries through various social welfare and public health regimes. Furthermore, the uncertainty of the impacts and effects of active pharmaceutical ingredients found in the aquatic environment on humans and other organisms indicates that the issue could also be seen as a potential public health concern. Several studies highlight the rapidly increasing consumption of drugs over the years to come, which could lead to higher concentration levels of potentially dangerous substances. Although there is currently no danger to human drinking water the rising quantities of substances calls for immediate actions to protect the environment including water sources.
Topic: Governance & legislative framework	
F. EPR schemes for products releasing pollutants would be extremely complex to manage and would involve significant administrative burdens (e.g. additional reporting and authorisation requirements). The manufacturing sector is already heavily regulated and any additional requirements would raise further resistance from the sector.	The application of EPR principles does not have to be complex or administratively complicated as it could be integrated into the existing EU regulatory framework. For example, via the chemicals authorisation process under REACH or product-specific legislation such as the Biocidal Products Regulation or the Directive on the use of human pharmaceutical products. EU legislation is constantly being reviewed, re-adapted and evolving to reflect the current situation, advances in technology, etc. to ensure that it remains fit for purpose, responds to current societal needs and addressing underlying problems. In addition, continuing on-going stakeholder discussions and information exchanges focused on concrete impacts and data based on the increasing number of studies and initiatives on how the presence of micropollutants effects drinking water and wastewater treatment requirements and costs as well as the potential effects on human health and

Arguments AGAINST EPR scheme	Arguments FOR EPR scheme
	the environment are part of the efforts needed to raise awareness and provide relevant information to all stakeholders concerned.
G. Existing measures are sufficient for addressing the problem of micropollutants and microplastics. Voluntary measures can address the issue effectively, therefore, additional legislative requirements are unnecessary.	Existing measures have proven to be insufficient in tackling the increasingly concerning problem of micropollutants and microplastics. Recent studies have found a wide-range of micropollutants, including emerging substances and microplastics in drinking and waste water. The situation will become increasingly concerning and serious, aggravated by increasing population and consumer demands, if no concrete action is taken in time to combat the problem. Water treatment operators and citizens are currently paying for the additional steps needed to ensure that water quality meets requirements under relevant legislation such as the Drinking Water Directive and the Water Framework Directive, whereas in most cases producers are not being held accountable. Further, voluntary measure has its limitations and cannot fully combat the problem, particularly in terms of engaging the participation of all major industries (and polluters) and addressing the problem of free-riders. The current free-rider and license to pollute situation currently observed in the EU is creating an uneven playing field. Finally, water pollution is a transboundary phenomenon and should be addressed as such, at EU level, highlighting that it is an issue of human health. The advantages of an EPR scheme at EU level is that economic incentives are more at EU level compared to national level especially in regards to ensuring a level playing field, a basis for economic development in Europe.

4. Annex

Stakeholder interview template

STAKEHOLDER QUESTIONNAIRE & INTERVIEW GUIDANCE
Study on Feasibility of Extended producer responsibility for micropollutants and microplastics released into the water cycle

INTRODUCTION & CONTEXT

Deloitte Sustainability (France) is conducting a study for EurEau on "Exploring the feasibility of Extended Producer Responsibility (EPR) schemes for micropollutants and microplastics emitted in the aquatic environment from products during their life cycle". The objective of the study is to analyse and identify the most effective approach – both in terms of practical feasibility and legislative applicability – for applying an EPR scheme to products releasing pollutants and microplastics into the aquatic environment during their life cycle. The following product categories are being assessed – pharmaceuticals, pesticides and biocides, products containing perfluoroalkylated substances, textiles and car tyres. An important part of the analysis is to gather key stakeholder feedback on the practical and legislative feasibility of EPR, with the aim of providing an in-depth overview of different stakeholder perspectives. The results of the stakeholder consultation will present findings on the pros and cons of an EPR approach, the feasibility and applicability at EU level, lessons learned and options for the way forward. All responses will be kept confidential so that any information included in the study deliverables does not identify you as the respondent.

KEY QUESTIONS & DISCUSSION POINTS

- *What is your understanding of EPR? Do you think EPR is a relevant and applicable solution in the context of products that release micropollutants and microplastics into the aquatic environment?*
- *What is the role of different stakeholders in addressing the health and environmental risks associated with the release and presence of micropollutants and microplastics in the aquatic environment? What would be the main impacts be on specific stakeholders?*
- *Are existing measures e.g. control at source, quality standards, current treatment technologies, voluntary industry initiatives, etc. sufficient?*
- *What would be the most relevant & applicable EU legislation to consider for the legal framework of an EPR scheme at EU level? What would be the advantages, disadvantages and overall implications of applying an EPR scheme at EU versus national level?*
- *Are you aware of any other measures that are being (or could be) applied to address the micropollutants and microplastics problem?*
- *What would be the main challenges and barriers to consider for the effective application of a potential EPR scheme for micropollutants and microplastics? What are important success factors, lessons learned and best practices?*
- *How could an effective financial mechanism be established under an EPR scheme to ensure that operational treatment costs are covered while ensuring that prices for water services remain affordable and producers are incentivised to take into account environmental considerations e.g. improve product design, use of alternative substances, etc. ?*
- *What costs should an EPR scheme cover? Do you have specific information on costs that would need to be considered in an EPR approach e.g. treatment costs, costs for producers, etc.?*
- *How could a potential EPR scheme address issues such as free-riders, to ensure a fair and level playing field in regards to the distribution of costs and responsibility across the different sectors and producers involved?*