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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

FINAL REPORT

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EurEau

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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

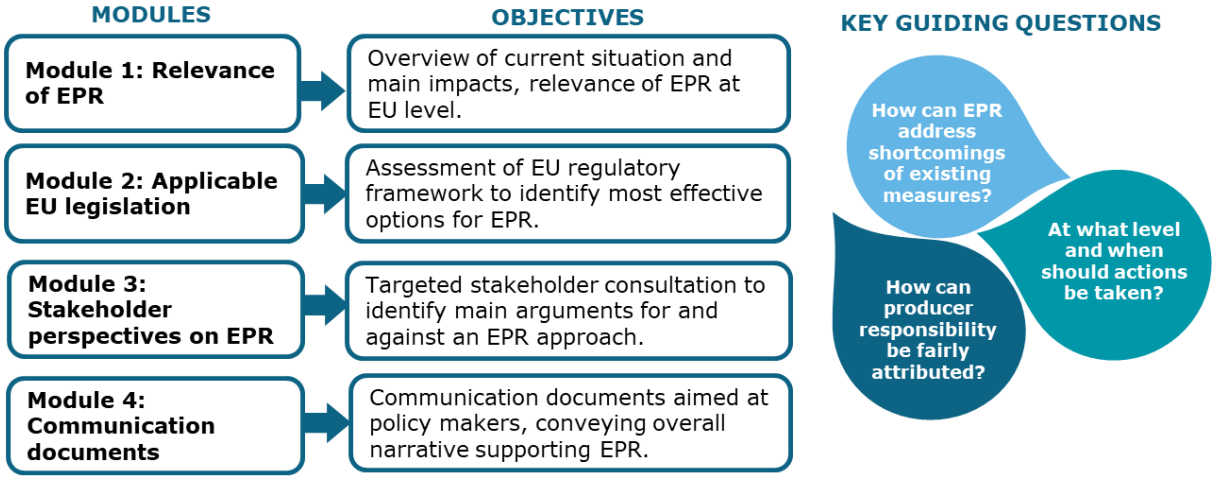
Part I. Objectives, scope & methodology

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:

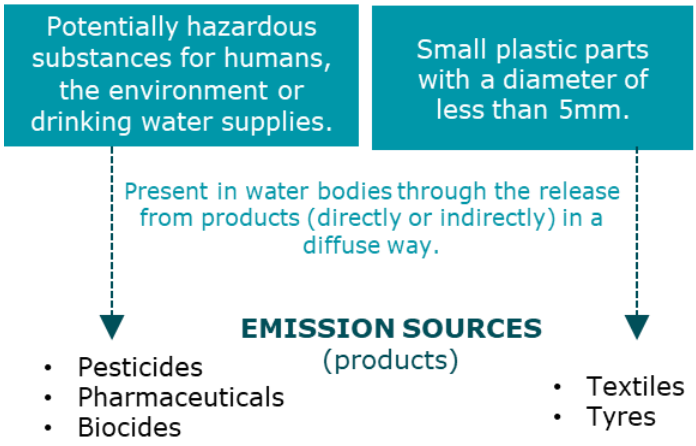
- Part I summarises the objectives, scope and methodology
- Part II evaluates applicable cross-cutting EU legislation
  Part III evaluates applicable product-specific EU legislation
- Part IV assesses the possible options for the way forward
- Annex provides supporting technical information and list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

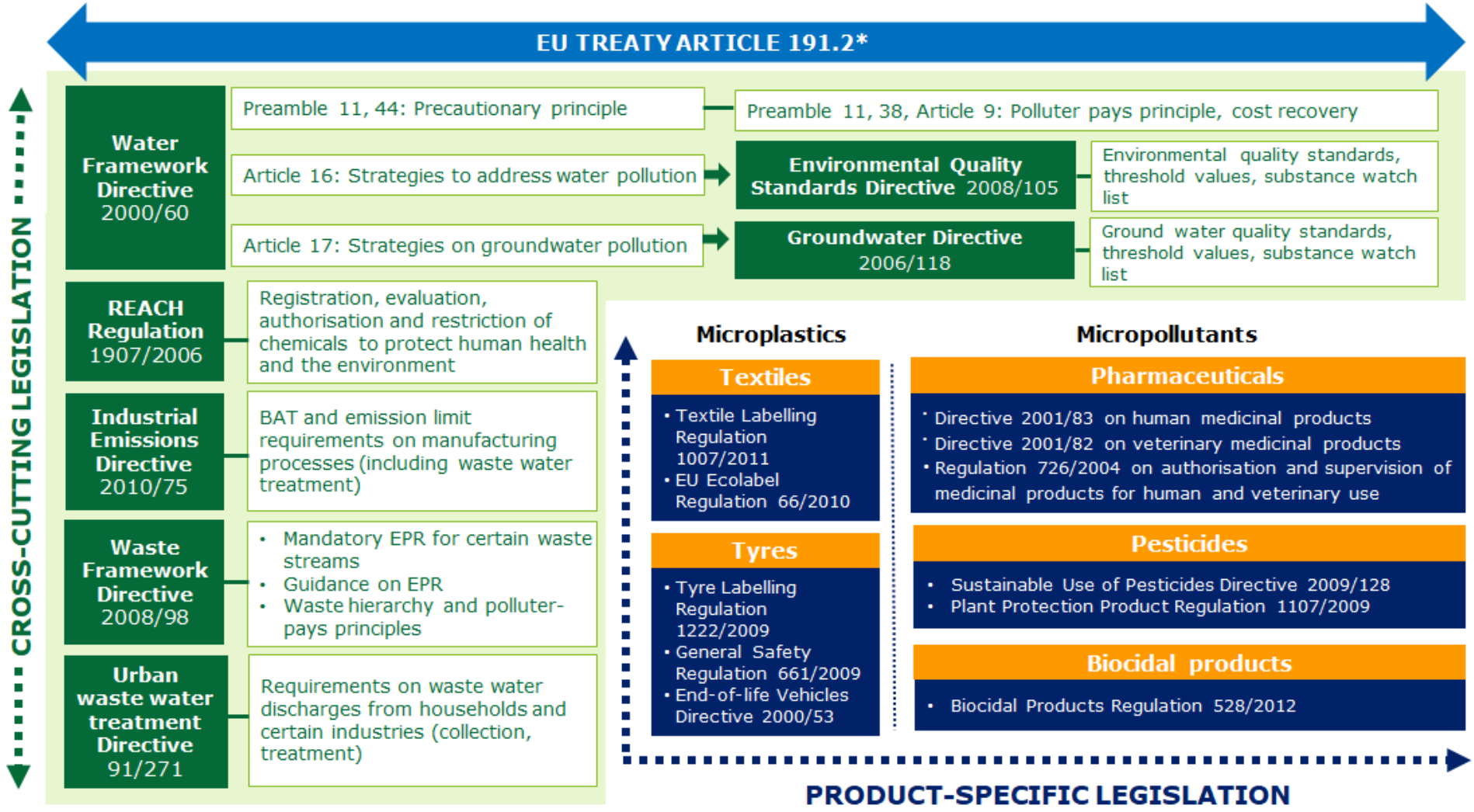
Table 1: Summary of most relevant EU legislation assessed

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

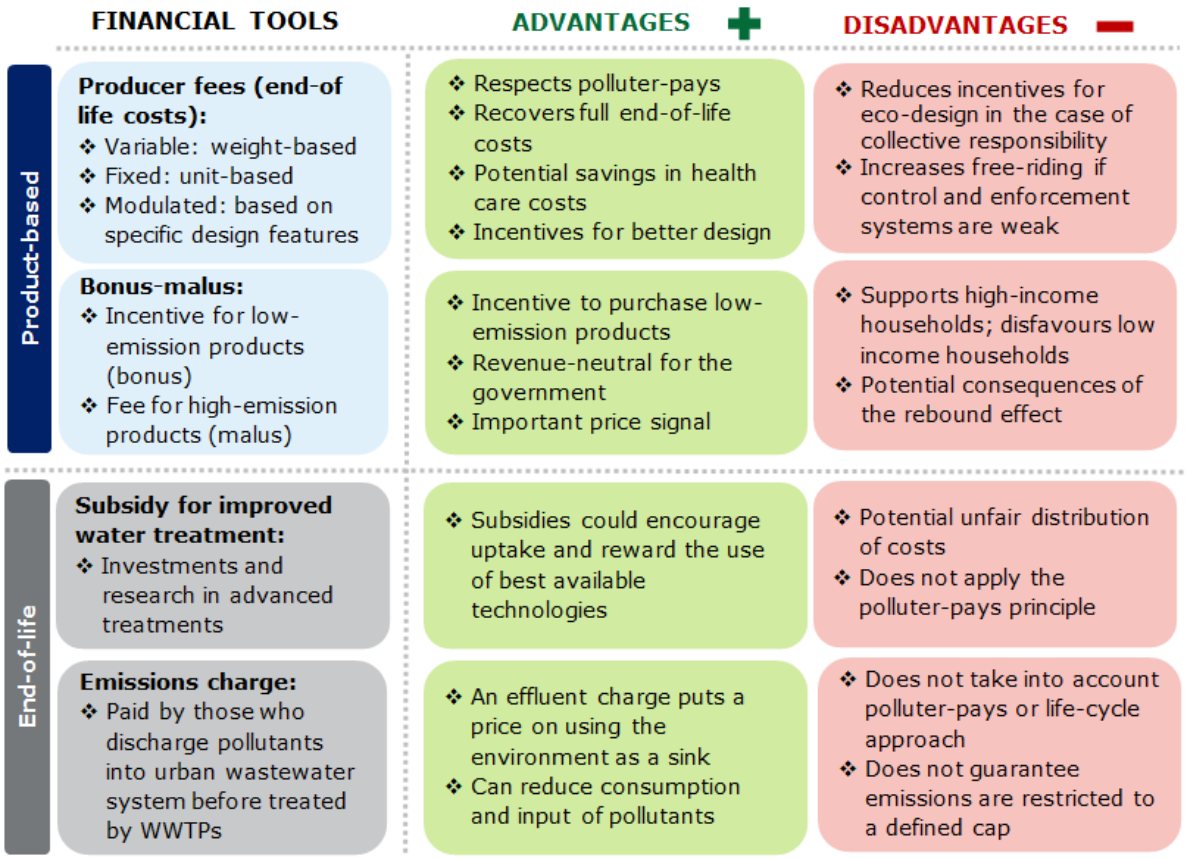
The key components of the methodology used for the assessment of applicable EU legislation for the selected product categories are described in the following chapter.

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

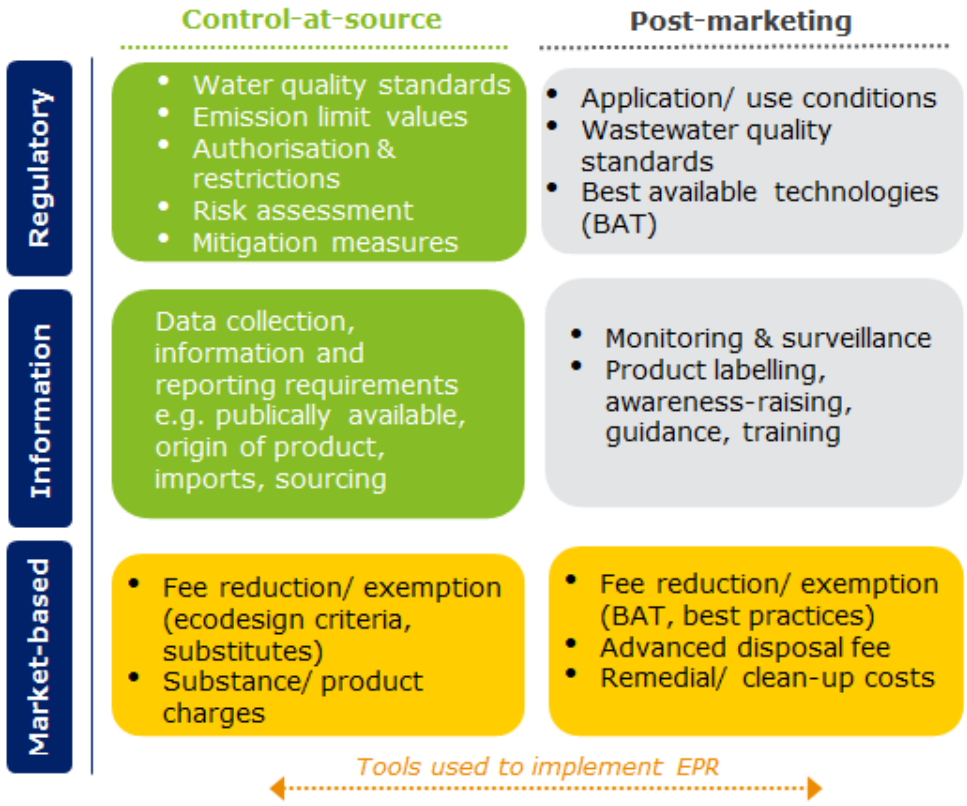
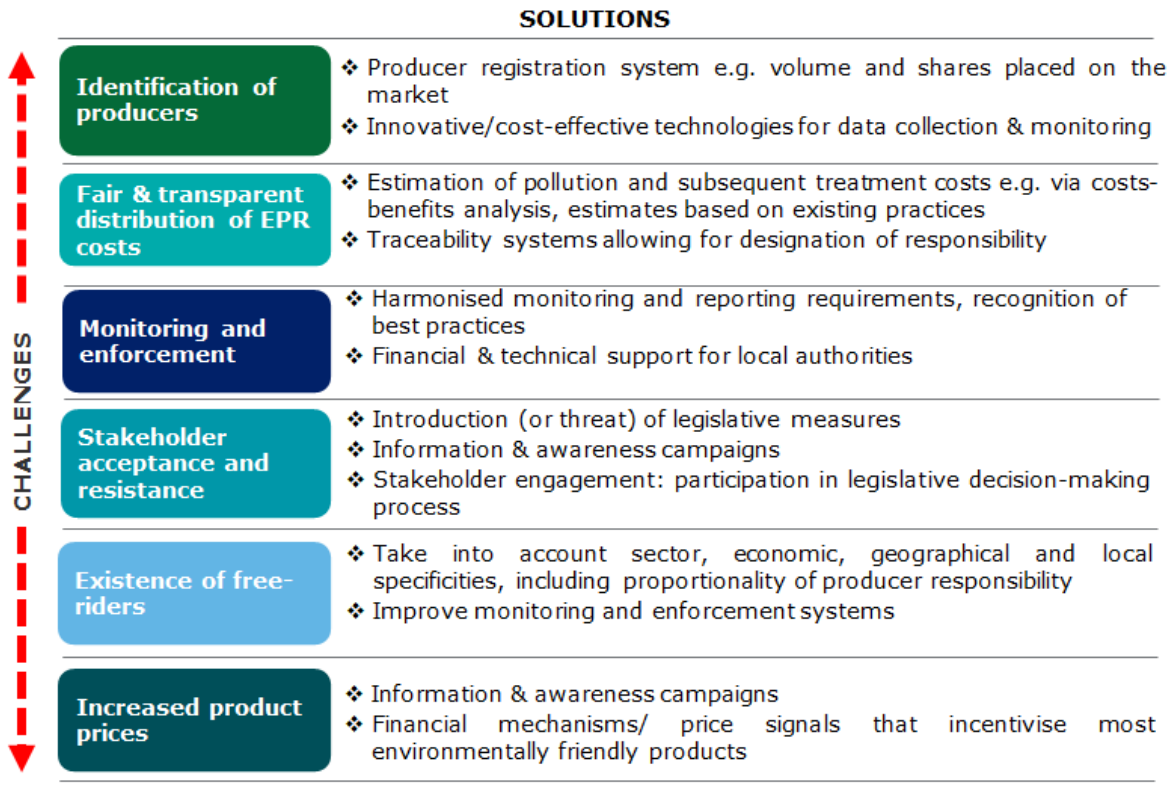


Figure 5: EPR implementation: overview of challenges and solutions



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

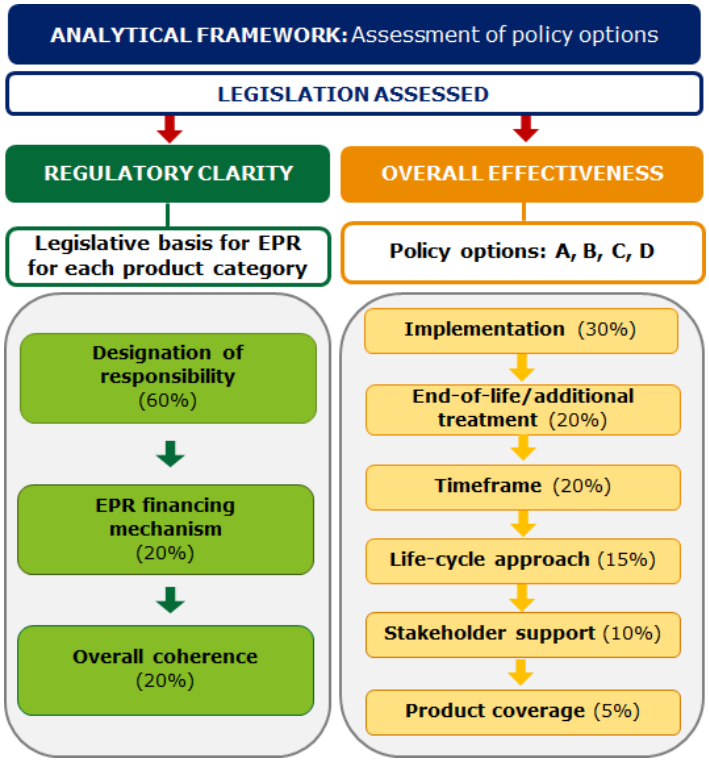
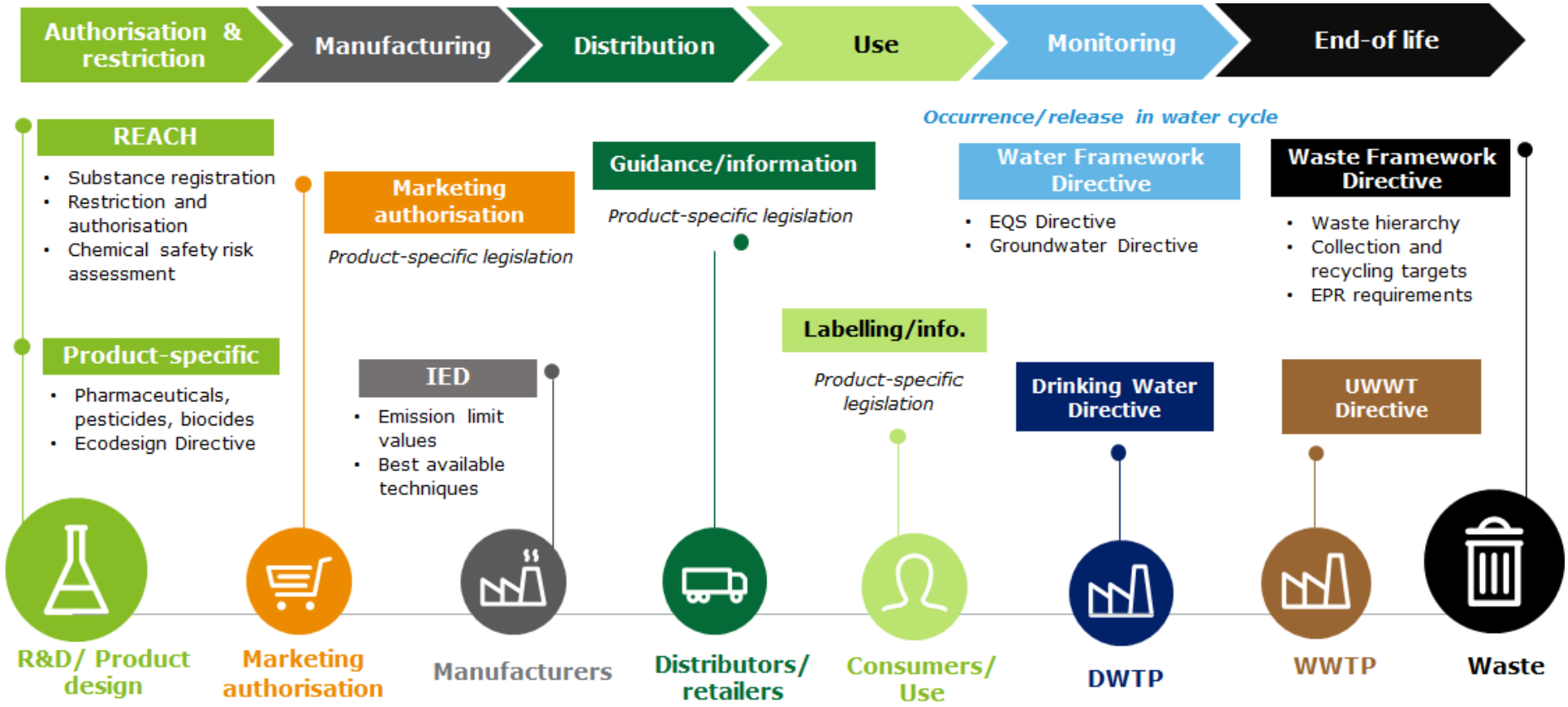


Figure 6: Full life-cycle approach to reduce emission of water pollutants



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

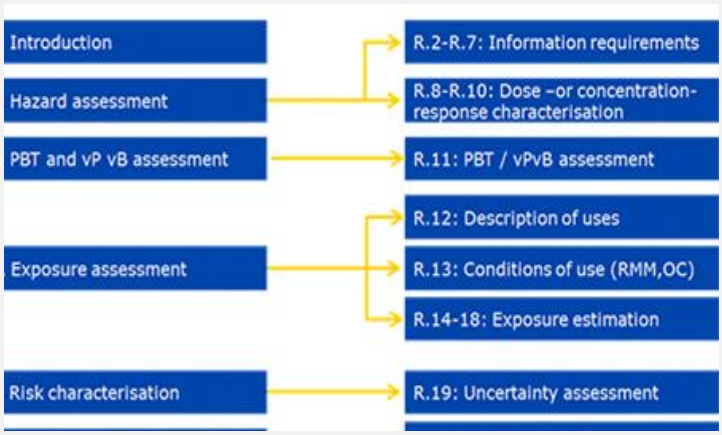
[5] ECHA website on the REACH regulation: https://echa.europa.eu/regulations/reach/understanding-reach
[6] ECHA (2018) Strategy to promote substitution to safer chemicals. Accessible at: https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf/bce91d57-9dfc-2a46-4afd-5998dbb88500

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

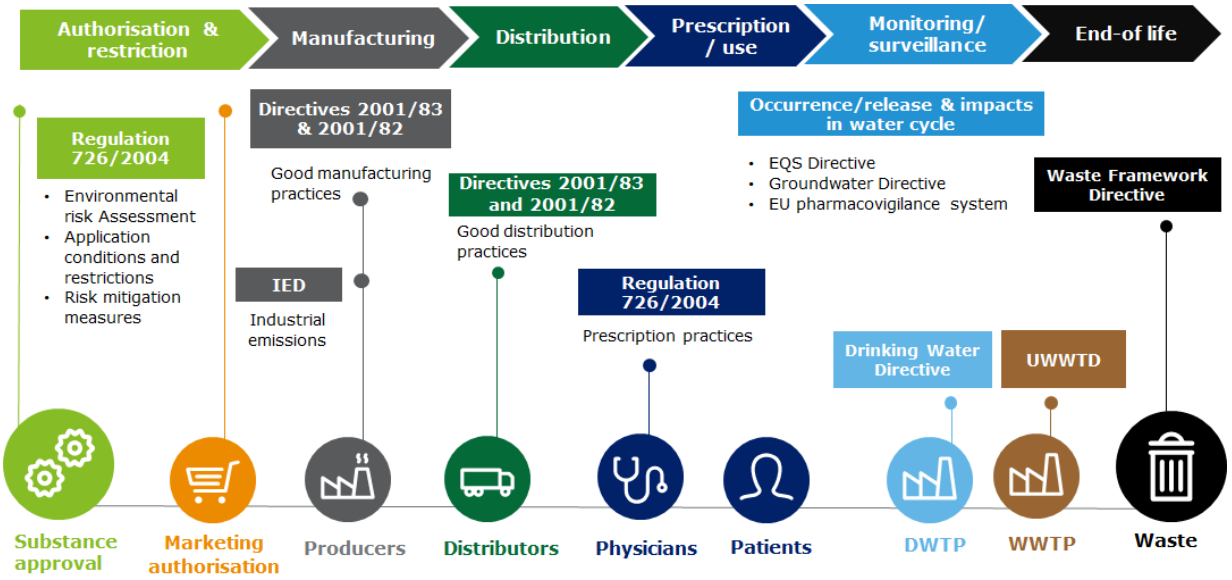
6.1 Overview of supply chain and relevant EU legislation

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.

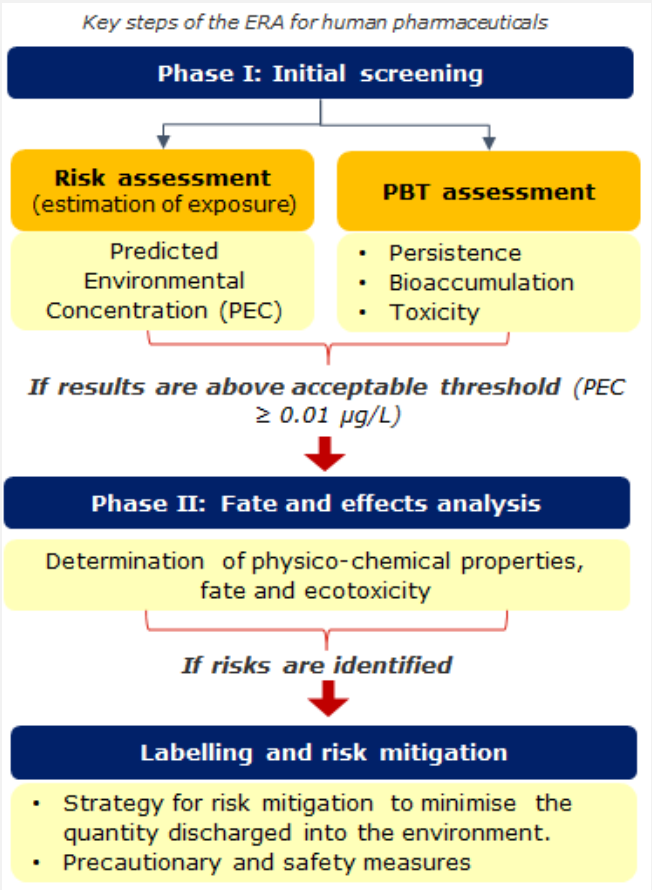
In the event that the initial risk assessment results reveal PEC ≥ 0.01 µg/L, additional testing must be carried out in Phase II. Some substances, however, (e.g. endocrine active substances, antiparasitics) must undergo a Phase II assessment regardless of PEC value due to their potential hazardous effects 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

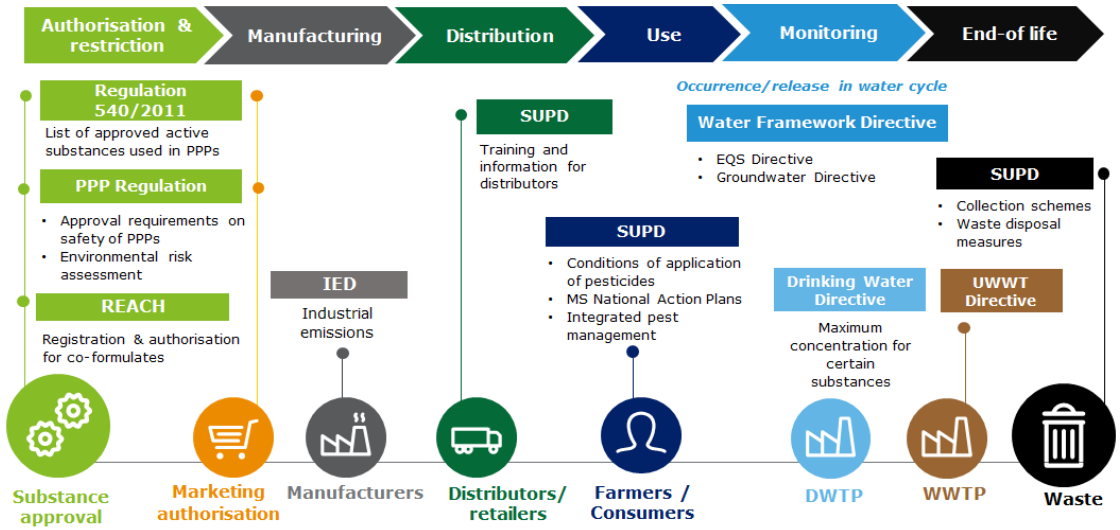
The pesticides supply chain begins at the **research and development** phase, involving both plant protection companies and the research community. Many plant protection products (PPPs) include **active substances**, which must be approved and registered at both national and EU levels before they can 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.

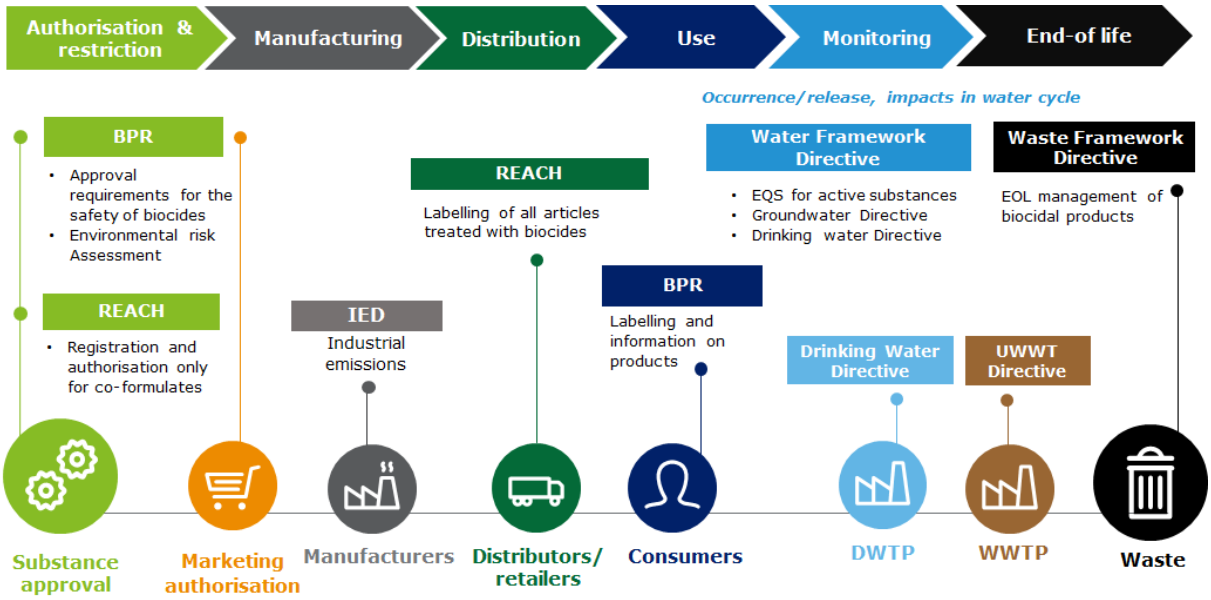
Obstacles	Success factors
Gaps in existing regulatory framework: Although there is a clear regulatory framework at EU level governing pesticides, current provisions do not specifically address micropollutants emissions, nor do they sufficiently encourage or require producers to accelerate the deployment 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.

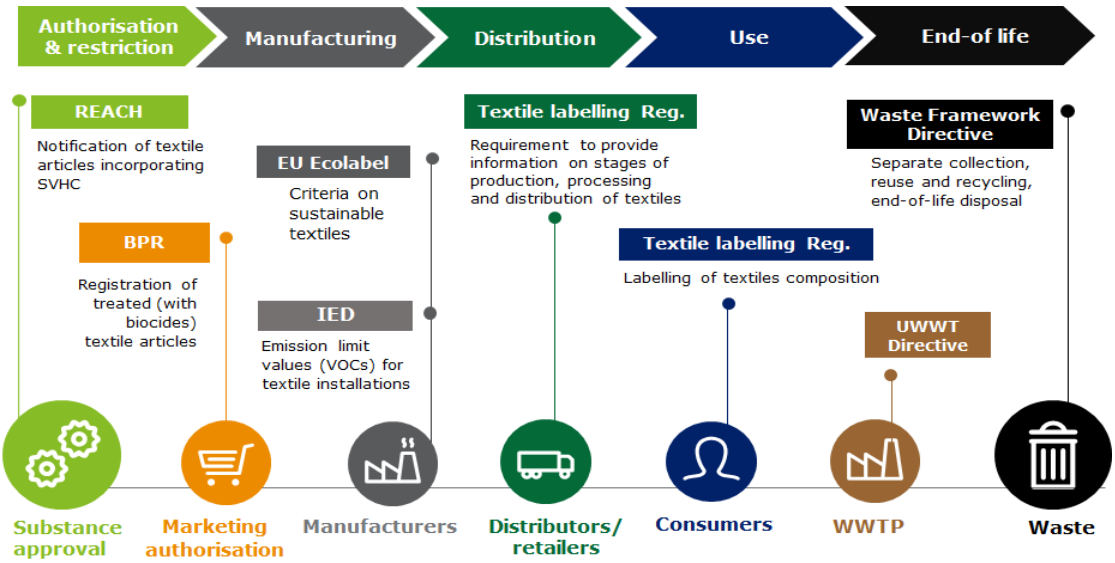
9. Textiles

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.

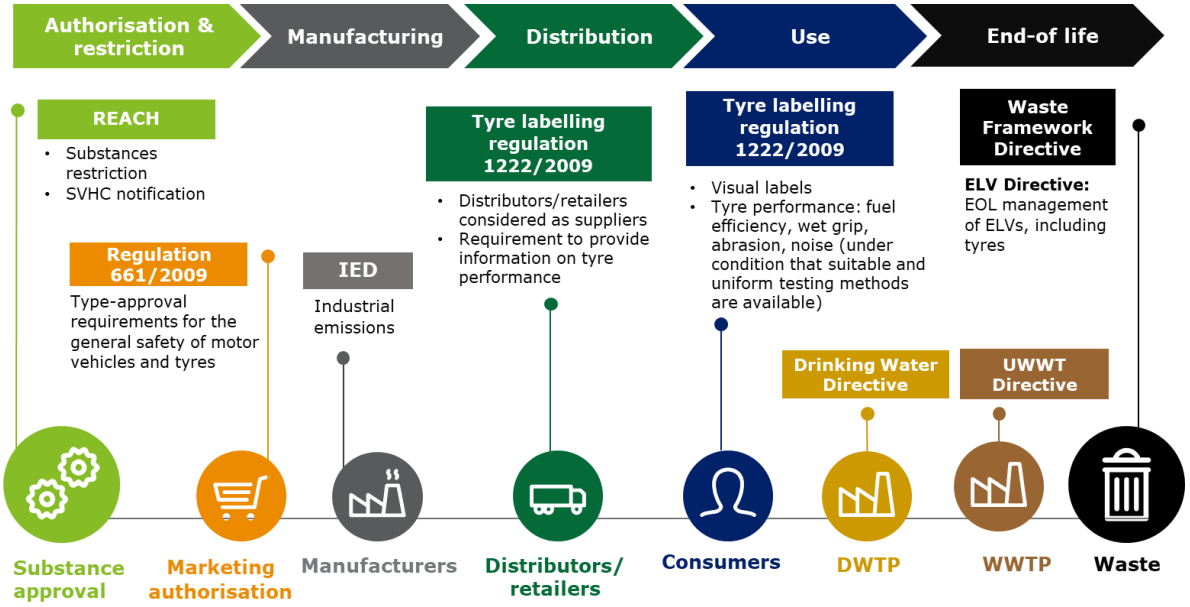
Obstacles	Success factors
Absence of sufficient regulatory framework: Currently, the release of microplastics from textiles are not regulated by existing EU legislation.	**Application of mitigation measures:** Current scientific research and public pressure point to the urgent need of addressing microplastic 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

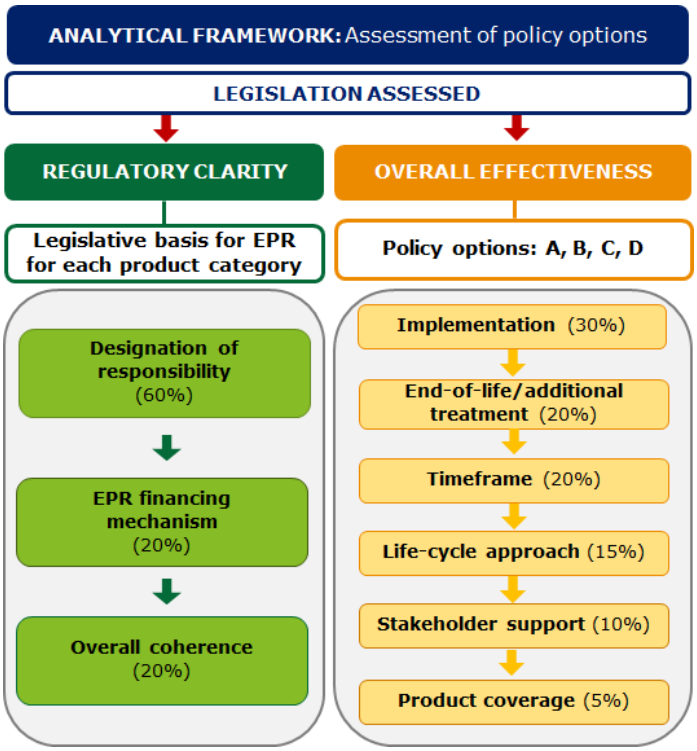
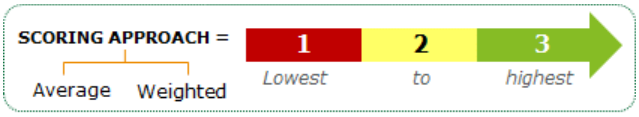


Figure 14: Scoring approach



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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