Feasibility of an EPR system for micro-pollutants

(070201/2020/837586/SFRA/ENV.C.2)

Final Report

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GLOSSARY

Terminology		Description
APIs	Active Pharmaceutical Ingredients	Biologically active components or components of a drug product providing the intended therapeutic effects.
ATC	Anatomical Therapeutic Chemical Classification System	Anatomical Therapeutic Chemical Classification System is a drug classification system that classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
BDEW	Federal Association of the German Energy and Water Industries	Representation of the German gas-supplying companies, water-supplying companies and wastewater management companies in political, economic, legal and technical questions.
CAPEX	Capital Expenditure	The money used to buy, improve, or extend the life of fixed assets in an organization, and with a useful life for one year or more.
CAS	Chemical Abstract Service	Division of the American Chemical Society, a source of chemical information.
CECs	Contaminants of Emerging Concern	Any chemical discovered in water or in the environment that had not previously been detected or were only present at insignificant levels.
CLP	Classification, Labelling and Packaging Regulation	European Union regulation from 2008, which aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS).
DDDs	Defined Daily Doses	The average dose prescribed according to a representative sample of prescriptions.
DOC	Dissolved Organic Carbon	The amount of organic matter in water bodies that can be passed through a filter (pore size between 0.7 and 0.22 um, commonly 0.45 µm).
DrugBank		Database on drugs and drug targets.
EBITDA	Earnings Before Interest, Taxes, Depreciation, and Amortization	Alternate measure of profitability, adds depreciation and amortization back into a company's operating profit.
EE2	Ethinylestradiol	Oestrogen used in birth-control pills.
EMA	European Medicines Agency	Agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products.
ERA	Environmental Risk Assessment	A process for evaluating how likely it is that the environment may be impacted as a result of exposure to one or more environmental stressors, such as chemicals, disease, invasive species, and climate change.
EQS	Environmental Quality Standard	A limit for environmental disturbances, in particular from ambient concentration of pollutants and wastes, that

Terminology		Description
		determines the maximum allowable degradation of environmental media.
HMDB	Human Metabolome Database	Collection of human metabolite and human metabolism data.
JRC	European Commission's Joint Research Centre	European Commission's science and knowledge service which employs scientists to carry out research in order to provide independent scientific advice and support to European Union (EU) policy.
OPEX	Operating Expenses	Ongoing expenses a business incurs for running a product, business, or system.
OTC	Over the counter	Medicines sold without a prescription
PBT	Polybutylene Terephthalate, polymer	A thermoplastic engineering polymer.
PCP or CP	Cosmetic Products	A group of organic compounds that are added as ingredients to formulate a variety of cosmetic products widely used in daily human life, generally for personal hygiene, cleaning, grooming, and beautification.
PPP	Polluter Pays Principle	
PNEC	Predicted No-Effect Concentration	The concentration limit of a chemical at which no adverse effect is expected to occur for a specific organism or ecosystem.
PRO	Producer Responsibility Organisation	A professional organisation authorised or financed collectively or individually by producers to act on their behalf to administer an extended producer responsibility or product stewardship program.
Pubchem		Collection of freely accessible chemical information.
RxList		Online medical resource of US prescription medications.
SSRIs	Selective Serotonin Reuptake Inhibitors	A class of drugs that are typically used as antidepressants in the treatment of major depressive disorder, anxiety disorders, and other psychological conditions.
UWWTD	Urban Waste Water Treatment Directive	European Union Directive requiring Member States to ensure that urban areas collect and treat waste water which would otherwise pollute rivers, lakes and seas.
UWWTPs	Urban Waste Water Treatment Plants	Treatment plants receiving a mixture of storm water, industrial wastewater, domestic household waste, and resulting residues called biosolids which are sufficiently treated to allow these waste streams to be safely applied to land.
VHI	Voluntary Health Insurance	A medical service, which takes care of the costs of treatments, hospitalization and surgery in case of an illness and usually contracted by the insured person.

Terminology		**Description**
WWTPs	Waste Water Treatment Plants	A facility that treats wastewater, making it considerably cleaner and safer to be released into water bodies.

1. INTRODUCTION

This document is the draft final report for the study to assess the feasibility of an EPR system for micropollutants (Contract 070201/2020/837586/SFRA/ENV.C.2).

This study aims to assess the feasibility of establishing an Extended Producer Responsibility (EPR) system for dealing with some products responsible for introducing micropollutants in waste water.

1.1. Polluter pays principle

The Polluter Pays Principle (PPP) was first introduced by the Organisation for Economic Co-operation and Development (OECD) in 1972. The Polluter Pays Principle is now one of the cornerstones of the European Union's (EU) environmental policy, introduced in Article 191(2) of the 2007 Treaty on the Functioning of the European Union (TFEU): "Union policy on the environment (…) 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".

"Application of the principle means that polluters bear the costs of their pollution including the cost of measures taken to prevent, control and remedy pollution and the costs it imposes on society"[1]. By applying the PPP, the cost of pollution that was before a "negative environmental externality", i.e. that was not accounted for in economic flows, becomes "internalised". This process incentivises polluters to reduce environmental damage by making the cost of pollution visible to them, reducing their bills, and remaining competitive in the market. It also transfers the financial burden from the taxpayer to the polluter.

Extended Producer Responsibility is one of the effective instruments that can be implemented to apply the PPP.

The Waste Framework Directive requires that "in accordance with the PPP, the costs of waste management, including for the necessary infrastructure and its operation, shall be borne by the original waste producer or by the current or previous waste holders". Member States decide to charge the cost to the end-user or partly or wholly to the producer of the product that has become waste. The latter is the concept of Extended Producer Responsibility.

As part of the Waste Framework Directive, EPR aims to contribute to the prevention of pollution (waste prevention) as well as to finance remediation (waste collection and treatment): "In order to strengthen the re-use and the prevention, recycling and other recovery of waste, Member States may take legislative or non-legislative measures to ensure that any natural or legal person who professionally develops, manufactures, processes, treats, sells or imports products (producer of the product) has extended producer responsibility". The Extended Producer Responsibility and its principles are further defined in articles 8 and 8a of the Waste Framework Directive.

1.2. Study objectives

Following the polluter-pays principle, an EPR system aims to better our ecosystems and human health. It shall ensure that those who place the concerning products on the EU market (producers, importers, retailers, etc.) are responsible for the complete lifecycle of

[1] European Court of Auditors (2021) The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions

the products, including the reduction of discharges into the environment. They could achieve this by:

- improving product composition so that their environmental impacts at the end-of-life are eliminated or reduced at least, and/or
- financing additional costs of end-of-pipe treatment of micropollutants.

In particular, the study provides an evidence base using the latest available information for analysing the feasibility of different options of an EPR scheme and potential impacts on different actors of the value chain.

1.3. Report Structure

In addition to this introductory section, the report is structured as follows:

2. Study scope

3. Market research

4. EPR system for micropollutants

5. Scenario definition

6. EPR costs

7. EPR modulated fee structure

8. Economic impacts of EPR

9. Mechanisms of behavioural change

10. Alternative approaches

11. Conclusions

2. STUDY SCOPE

2.1. Definition of micropollutants

Micropollutants have been the subject of growing concern because of their specific characteristics:

- They are substances found in water bodies and waste water with a negative impact on humans or ecosystems; some of them are hazardous even in small concentrations (e.g. endocrine disruptors), and there is concern about their chronic effect and so-called cocktail effects when combining diffuse exposition to multiple pollutants;
- They are found in small concentrations (in a range of a few µg/l or less) in water, from which they get their name and which also increases challenges to measuring and treating them;
- Their emissions are often not regulated at the source and not treated (or poorly treated) at the end-of-pipe, i.e. Waste Water Treatment Plant (WWTP)[2].

There is no consensus around a standard definition of micropollutants in scientific or political spheres. In the context of this study, micropollutants are defined as substances (including their breakdown products) that are usually present in the environment, and urban wastewaters in concentrations below milligrams per litre and which can be considered hazardous to human health or the environment based on any of the criteria set out in Part 3 and Part 4 of Annex I to CLP Regulation[3].

2.2. Identification of sectors

An essential element for defining the scope of this study is identifying the sources of micropollutants in waste water, i.e. substances, products and sectors manufacturing the products and substances which could release micropollutants.

The study specifications already identified pharmaceuticals for human use as one of the sectors to be covered by this study, given that the presence of pharmaceuticals residues is a known environmental problem. This has been highlighted in previous work conducted in the context of the Water Framework Directive[4], Environmental Quality Standards Directive[5] and research publications[6].

The study defines the approach to identify a second sector (to start with) that would also contribute to the EPR scheme. Further, the study analyses various approaches for sharing the cost of setting up and operating an EPR scheme between different actors.

One could take inspiration from the concept of Ecodesign (Directive[7]), which bases the product selection on three main criteria: products sold in large volumes (via a medical

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[2] Based on JRC estimations, approximately 2/3 of the input load of micropollutants to WWTP is unaffected by conventional UWWT technologies (primary, secondary and tertiary) and are thus emitted in water bodies.

[3] Regulation EC 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 353 31.12.2008, p 1).

[4] Strategic Approach to Pharmaceuticals in the Environment. https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm

[5] https://ec.europa.eu/environment/water/water-dangersub/pri_substances.htm

[6] See for example, Wilkinson et al. (2022) Pharmaceutical pollution of the world's rivers. PNAS Vol. 119 | No. 8 https://doi.org/10.1073/pnas.21139471

[7] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products. A proposal for a

prescription and Over-the-Counter (OTC) sales in the case of pharmaceuticals), products causing significant environmental impacts, and products having significant improvement potential in terms of reducing their environmental impacts (hazardousness in the case of micropollutants). In the context of the present study, these criteria were further adapted as follows:

1. Micropollutants measured above a defined threshold using a standardised testing protocol in urban wastewater along with their physico-chemical properties and concentrations (see JRC work on chemicals[8]) and products containing these substances;
2. Substances which can be treated by fourth (or quaternary) treatment;
3. Substances for which an environmentally less harmful alternative is available (i.e., change in product composition and/or ease of substitution) but not used;
4. Products sold in large quantities (market data); and
5. Substances which we can map back to pharmaceuticals and other sectors.

Several chemical compounds can be considered micropollutants which can be released by household products, such as human pharmaceuticals, plant protection products, biocides, cosmetic products, household chemicals, and detergents.

Treatment technologies capable of treating these micropollutants more efficiently now exist (ozonation, powdered active carbon, etc.)[9] and have been implemented in several WWTPs across Europe. These technologies are grouped under "fourth treatment" or "quaternary treatment".

Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC (COM(2022) 142 final) (ESPR) has been placed recently which broadens the scope covering all products, including the intermediatory ones.

[8] Alberto Pistocchi, Nikiforos A. Alygizakis, Werner Brack, Alistair Boxall, Ian T. Cousins, Jörg E. Drewes, Saskia Finckh, Tom Gallé, Marie A. Launay, Michael S. McLachlan, Mira Petrovic, Tobias Schulze, Jaroslav Slobodnik, Thomas Ternes, Annemarie Van Wezel, Paola Verlicchi, Caroline Whalley, (2022) European scale assessment of the potential of ozonation and activated carbon treatment to reduce micropollutant emissions with wastewater, Science of The Total Environment, Volume 848, 2022, 157124, ISSN 0048-9697, https://doi.org/10.1016/j.scitotenv.2022.157124.

[9] JRC treatment expert working groups

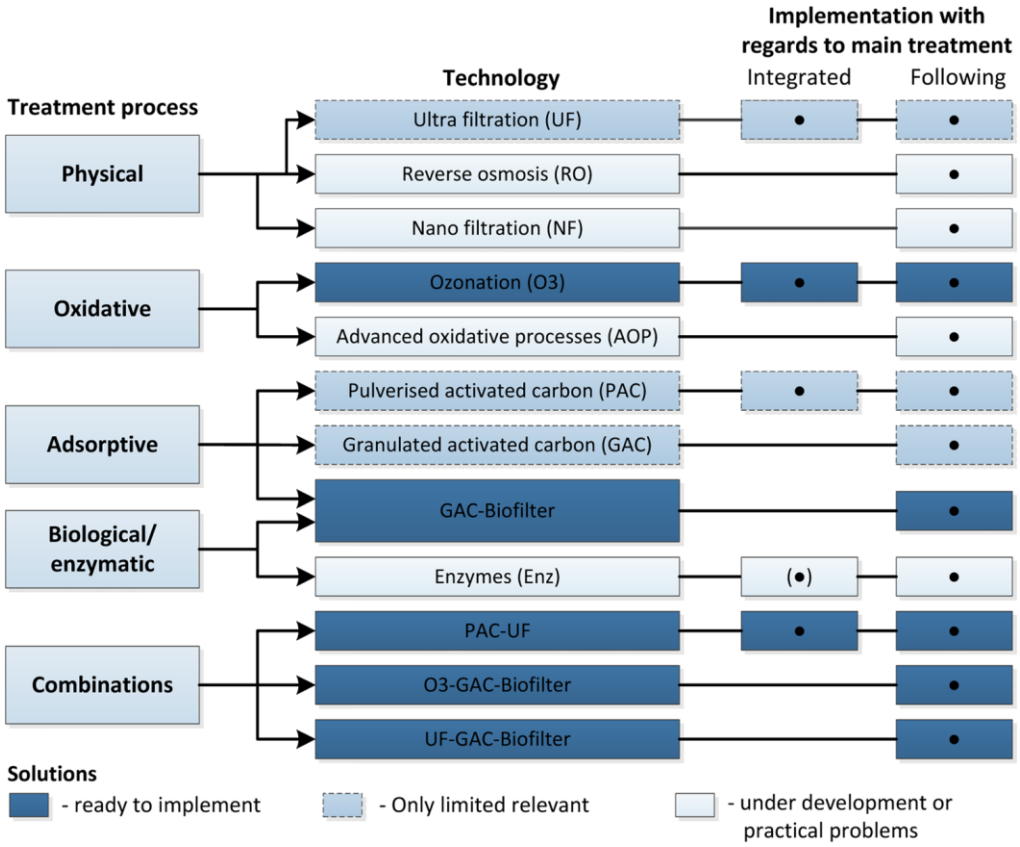

Figure 1: Treatment technologies for micropollutants

Source: Baresel et al. (2019) Sustainable treatment systems for removal of pharmaceutical residues and other priority persistent substances. Water Sci Technol.

Regarding the micropollutants found in urban waste water, knowledge of relevant trace substances is fragmented because of the diversity of substances. Such knowledge depends on technical advances in analytics, research findings, and studies about substances' impacts. This is why the precautionary principle is pivotal. When new relevant findings concerning trace substances in waters become available, the analysis presented in the study can be adjusted. Clustering substances in chemically related groups appears purposeful for the determination of the sector/sub-sector and the feasibility of tackling them through EPR.

From the perspective of removal efficiency, the main criteria are molecular weight, molecular size, charge, adsorption, hydrophobicity, biodegradability, and volatility.

Note: Microplastics are not covered in this study because

- Passing through conventional primary, secondary and tertiary urban wastewater treatment, they are captured in the sludge, and at present, there is no treatment technology, but this can change in the future;
- storm waters/ urban runoff are a significant source of microplastics. A future idea might be to finance infrastructure measures under EPR to deal with microplastics in runoff and stormwater overflows.

Also, a parallel study is evaluating the measures dealing with the unintentional release of microplastics, and ECHA is studying their intentional release to tackle them through

REACH. The Commission is also exploring measures for tackling the unintentional release of microplastics.[10]

The first version of the chemicals list (JRC) had more than 10,000 substances, and a revised version had about 1,200. The list was established from different sources: a survey conducted by UFZ, Dutch waste water monitoring data, 167 substances indicated by the German UBA, Boxall (University of York), and lists provided by other experts. Waste water contains complex mixtures of substances, including parent compounds, their metabolites and transformation products. Moreover, the mixtures of parent compounds and metabolites may undergo further abiotic and/or biotic transformation in the environment.

2.2.1. Pharmaceutical sector

In the absence of substance level data, an alternative approach was adopted, i.e., top-down analysis of the impacts of substances on receiving water, primarily studied on fauna.

Due to intense consumption, the environmental effect of therapeutics class of drugs such as antibiotics, painkillers and cardiovascular pharmaceutical agents are currently the most investigated (Hughes et al.[11]). Following are some of the relevant pharmaceutical groups of medicines.

- **Antibiotics**: the environmental effect of antibiotics is mainly studied for their effect in spreading antimicrobial resistance and selecting bacterial strains resistant to the most commonly used antibiotics for human consumption. Moreover, the WHO considers antibiotic resistance is one of the biggest threats to global health.
- **Contraceptive drugs**: Natural and synthetic oestrogens are not entirely broken down by conventional treatment in existing waste water treatment plants (WWTPs) and, as a result, are discharged into waters and found in the aquatic environment at low parts per trillion concentrations (typically <5 ng/L). Within this group of substances, the oestrogen used in birth-control pills, EE2, is one of the more potent oestrogens and has been linked to the feminization of male fishes in rivers receiving municipal waste water to such a level that it impacts the very sustainability of fish population (Kidd et al. PNAS 8897, 104 (2007)). Moreover, in the environment, multi-component mixtures of steroidal pharmaceuticals are present. In an animal study, a significant combined effect was observed when several steroidal pharmaceuticals were present in a mixture at a concentration that would produce no statistically significant effect (something from 'nothing'). A proof-of-principle study suggests that multiple steroids present in the aquatic environment must be analysed for their potential combined environmental risk. (Thrupp et al.)[12].
- **Antidepressants**: Antidepressants, particularly the serotonin reuptake inhibitors (SSRIs), are among the most widely prescribed pharmaceuticals, with antidepressant use up over 60% over the last decade[13]. These compounds directly target the serotonergic system, which plays a vital role in regulating many physiological and behavioural processes. The increased prescription rate is likely responsible for why SSRIs are one of the most commonly detected pharmaceuticals in the aquatic environment, with concentrations ranging between 0.15 and 32 ng/L

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[10] See https://environment.ec.europa.eu/topics/plastics/microplastics_en for more details.

[11] Hughes et al. (2012) Global Synthesis and Critical Evaluation of Pharmaceutical Data Sets Collected from River Systems. Environmental Science and Technology

[12] Thrupp et al. (2018) The consequences of exposure to mixtures of chemicals. Science of the total environment

[13] OECD Health at a glance 2019. Available at https://www.oecd-ilibrary.org/sites/43146d4b-en/index.html?itemId=/content/component/43146d4b-en#:~:text=Consumption%20of%20anti-depressant%20drugs,%2C%202017%5B1%5D).

in waste water, 0.5 and 8000 ng/L in surface water, and 0.5 and 1400 ng/L in drinking water. It has been experimentally demonstrated that Fluoxetine, Prozac's active ingredient, exposure decreases feeding rates in multiple fish species, reducing fitness if individuals encounter prey less frequently and eat less. It has also been demonstrated that even short-term exposure to small doses of fluoxetine may have severe consequences as changes in activity levels and exploratory behaviour may impact survival. Moreover, even brief periods of exposure could potentially produce chronic effects (Dzieweczynski et al.)[14].

- **Anticancer drugs**: These drugs are continuously released into waste water, where they, most commonly, only undergo conventional treatment in WWTPs. Numerous studies have demonstrated the presence of anticancer drugs in different water resources that failed to be eliminated by conventional WWTPs. Considering their significant effect on human cells and hormone systems, there is a concern about their environmental risks also because, due to the increasing cancer incidence, the production and consumption of anticancer drugs are on the rise. It is largely believed that, unless a spill occurs in the waste water treatment pipeline, acute effects are improbable since concentrations that are likely to cause adverse effects are more significant than the concentrations detected in the water. Instead, some studies have detected concentrations in water higher than the EC50 (half-maximal effective concentration) in water, raising concerns that trace concentrations of anticancer drugs in the water may provoke long-term adverse effects and/or if they are present in a mixture. A systematic review of anticancer drugs in the aquatic environment was conducted in 2020 by Nassour et al.[15]. Experimental data showed that the common anticancer drugs (cyclophosphamide, tamoxifen, ifosfamide and methotrexate) have concentrations ranging between 0.01 and 86,200 ng/L. Still, significant variation exists in the methodologies employed due to a lack of available guidelines to address sampling techniques, seasonal variability, and analytical strategy. In scientific literature, recovery percentages as low as 11% are reported, and detection limit as high as 1700 ng/L. This indicates the inadequacy of some methods to analyse anticancer drugs and the failure to obtain reliable results.

2.3. Cosmetic Products

The discussion during the beginning of the study pointed to a couple of sectors, viz. biocides/pesticides used in homes (though not certain, how many of them will reach waste water) as mainly applied to surfaces. Some bleaching agents could potentially be a target. However, from the additional literature review, cosmetic products seem to be the strongest candidate because:

- They have several substances in common with the pharmaceutical sector, so we could target more sources for the same set of substances.
- A significant amount of recently published research[16] tackles pharmaceuticals and cosmetic products together from a waste water treatment perspective. This sector

[14] Dzieweczynski et al. (2016) Dose-dependent fluoxetine effects on boldness in male Siamese fighting fish. Journal of experimental biology

[15] Nassour et al. (2019) Occurrence of anticancer drugs in the aquatic environment: a systematic review. Environmental Science and Pollution Research

[16] Rogowska et al. (2020) Micropollutants in treated waste water. Ambio

Oluwole et al. (2020) Pharmaceuticals and personal care products in water and waste water: a review of treatment processes and use of photocatalyst immobilized on functionalized carbon in AOP degradation. BMC Chemistry

Jjemba (2019) Pharma-Ecology: The Occurrence and Fate of Pharmaceuticals and Personal Care Products in the Environment. Wiley

is also highlighted by the recent report by UN Environment and Stockholm Environment Institute.[17]

- They have a high level of persistence ;[18]
- They are sold in large volumes
- This sector could be useful from the EPR perspective on cost-sharing as targeting similar substances.
- As the sector has already started to think about alternative formulations, it will probably be more open to the idea of EPR.

Prasad et al. (2019) Pharmaceuticals and Personal Care Products: Waste Management and Treatment Technology - Emerging Contaminants and Micropollutants. Elsevier

Freyria et al. (2018) Nanomaterials for the Abatement of Pharmaceuticals and Personal Care Products from Waste water. Applied Sciences.

Ewadh et al. (2017) Pharmaceuticals and Personal Care Products: Sources, Toxicity in the Environment, Regulations and Removal Technologies. Journal of Chemical and Pharmaceutical Sciences

Ebele et al. (2017) Pharmaceuticals and personal care products in the freshwater aquatic environment, Emerging Contaminants

Yang et al. (2017) Occurrences and removal of pharmaceuticals and personal care products in drinking water and water/sewage treatment plants: A review. Science of the Total Environment

[17] Andersson, K., Rosemarin, A., Lamizana, B., Kvarnström, E., McConville, J., Seidu, R., Dickin, S. and Trimmer, C. (2020). Sanitation, Wastewater Management and Sustainability: from Waste Disposal to Resource Recovery. 2nd edition. Nairobi and Stockholm: United Nations Environment Programme and Stockholm Environment Institute. https://cdn.sei.org/wp-content/uploads/2021/03/sanitation-wastewater-management-and-sustainability-by-sei-and-unep.pdf (page 78)

[18] Ebele et al. (2017) Pharmaceuticals and personal care products (PPCPs) in the freshwater aquatic environment Author links open overlay panel. Emerging Contaminants

3. MARKET RESEARCH

This section provides an overview of the market research, i.e. volumes of products sold and substances released to waste water systems.

3.1. "Total pollution proxy substances" guide

The JRC developed the general chemical landscape of European waste water. This chemical landscape was further broken down into sectors. This section provides an overview of the process of database development, i.e. attributing substances to their relevant sectors.

3.1.1. Identification of substances

Our starting point was the JRC's list of chemicals and different product groups/sectors from which micropollutants could find their way into waste water. The chemicals were grouped on the basis of their usage and/or the pathway to waste water. The following table summarises the sectors and specific product categories in each sector.

Table 1: Summary of sectors, specific product categories and numbers of chemicals

Sector	Substance Categories (non-exhaustive)	Number of chemicals
Pharmaceuticals (human and veterinary products)	• Pills, • Injections, • Topicals, • Metabolites, • Pharmaceutical manufacture reagents,	358
Cosmetic Products	• Emulsifiers, • Surfactants, • Fragrances, • Emollients,	127
Pesticides	• Pesticides, • Fungicides, • Herbicides, • Insecticides, • Rodenticides,	290
Food Products	• Preservers, • Artificial sweeteners, • Food colourants, • Metabolites	35
Household Products	• Biocides, • Surfactants, • Fragrances,	33
Plastic Products	• Polymer starting materials, • Flame retardants, • Colourants, • UV protectors,	177
Other	• Industrial reagents, • Industrial solvents, • Heavy metals, • Dyes, • Illegal drugs	209

3.1.2. Sources used for collecting data on chemicals

Three search rounds were performed to identify the data on chemicals and map it to products/sectors, as explained below.

1. An array of publicly available databases was used to assign the substances to a sector[19]:
    - The NORMANN databases
    - The UBA database
    - The CosIng database
    - The COMPTOX databases relevant to the sorting
2. The substances that were not linked to a sector in the first round were characterised using a combination of chemical speciality websites:
    - PubChem (PubChem (nih.gov)),
    - ECHA (Accueil - ECHA (europa.eu)),
    - EPA (United States Environmental Protection Agency | US EPA),
    - Drugbank (DrugBank Online | Detailed Drug and Drug Target Information),
    - Human metabolome database (Human Metabolome Database (hmdb.ca)),
    - Rxlist (RxList - The Internet Drug Index for prescription drug information, interactions, and side effects).
3. To link the remaining substances to sectors, research articles, books and patents were used.

3.1.3. Database Structure

The database was built in six steps. The first two steps dealt with populating the database through the information collected from different sources indicated above. In the third step, the categories of substances were mapped to different sectors. In the fourth and fifth steps, the chemicals for the Pharmaceuticals and Cosmetic products sectors were identified.

3.1.3.1. Step 1. Database development

Here, for each chemical listed by the JRC, a source database was used for identifying the contributing sector(s). The mapping was done by comparing the Chemical Abstract Service (CAS) registry number (which is specific to each molecule) provided by the JRC with the CAS number used in the source databases.

3.1.3.2. Step 2. Pubchem, ECHA, EPA refining

In this step, the chemicals that could not be identified through the existing databases were allocated to sectors by looking up their CAS registry numbers in Pubchem, ECHA and EPA. Unless specified otherwise, these three chemical indexes were the source used.

3.1.3.3. Step 3. Sectors

In this step, the categories of chemicals were linked to different sectors.

3.1.3.4. Step 4. Pharmaceuticals

Here, all the chemicals attributed to the pharmaceutical sector were listed. This includes the CAS registry number, the usage name of the chemicals, their function (anti-hypertensives, antibiotics, antihistamines, etc.), their use (as a human or veterinary drug), if they are a parent molecule or a transformation product (if so, the parent molecule is also listed), some of the generic names of the molecule, and for some chemicals, their excretion rates are listed as well.

[19] See annex A

The sources used to gather that information are RxList, Drugbank, The Human Metabolome Database, Pubchem, and others.

3.1.3.5. Step 5. Cosmetic Products

In this tab, the chemicals attributed to the Cosmetic product sector were listed with their function attributed using the S13 database, PubChem, ECHA, the CosIng database and other sources.

3.1.3.6. Step 6. Sectors not covered by this study

A list of chemicals belonging to the sectors not considered for the study was developed. It contains the CAS number and the molecule's name, corresponding to the substances linked to household products, plastic products, food products, pesticides, and others. This list could be useful if the feasibility of the EPR system has been proven and additional sectors are to be added.

3.1.4. Uncertainties and limitations

The CAS registry number is unique to each substance. Still, one substance can have multiple CAS numbers that adds complexity to the database building and process and mapping a substance to a product/sector as the CAS number in the JRC's list of chemicals was sometimes not used in the databases.

As expected, the database development process represents several uncertainties. The chemicals were attributed to different sectors, but some chemicals were present in multiple areas of the chemical landscape. Thus, they occur more than once in the database to account for their prevalence. Moreover, most of the time in the database, the chemicals were put in the sector that was referenced as their main usage domain. Hence, the main sector they belong to cannot account for the full amount of that chemical put on the market.

To prioritise data sources, the following approach was used:

1. European databases were given priority when attributing a chemical to a sector
    a. Among European databases, the ones identifying chemicals used in a single sector were used first (e.g., Norman databases S9 and S14 listing PFAs, which are overwhelmingly used in plastics).
    b. Then, chemicals identified in one single database were allocated.
    c. Finally, when substances were present in multiple databases, a decision was made to allocate them to a single sector or multiple ones based on available knowledge and research.
2. International databases (e.g., the American database Comptox) were used, and the same protocol was applied to these databases.
3. For the remaining substances which could not be identified using these databases, extensive research on chemical speciality websites was done. Similarly to the approach used for the databases used, European websites were prioritised, so the order in which these resources were used is the following:
    a. the ECHA website,
    b. the EPA website,
    c. the PubChem website,
    d. the Drugbank, human metabolome and Rxlist websites.

After applying the process described above, only 19 chemicals could not be linked to a specific consumer or industry usage. This is most likely because they are used in small quantities in research labs or are part of chemical synthesis either as a reagent or an intermediate.

Regarding the 19 chemicals not linked to a sector, there are different factors:

- 14 are not registered in REACH and thus are most likely:
  - manufactured or imported in Europe for less than 1 tonne per year,
  - "intermediates that during the synthesis are not intentionally removed from the equipment in which the synthesis takes place (except for sampling)"[20],
- Four are pre-registered in REACH under Annex III and thus are imported by companies in volumes of 1 and 10 tonnes per annum, the smallest range of chemicals importation/manufacture in REACH.

One is pre-registered in REACH but could not be put in a sector, and no information about its import/manufacture volume could be found. Still, it is highly unlikely to be found in large quantities in European waste waters.

3.2. Estimating volumes of active pharmaceutical ingredients (APIs) and substances contained within cosmetic products in waste water

3.2.1. Approach

This section sets out the approach used for estimating the quantities of APIs and substances within cosmetic products reaching waste water treatment plants. An initial suite of pharmaceutical substances was identified for quantification based on a German assessment of measured values and the hazardousness of different substances (discussed further below).

A seven-step procedure for **estimating volumes of APIs** was carried out for the identified suite of substances as follows:

- **Step 1:** the major sources and pathways of APIs into waste water are considered. The primary pathway of interest is the excretion of APIs following human consumption (orally and through other application methods). Disposal of APIs in sinks and toilets or releases from other sources (e.g. production) are not within the scope of the study. Unused pharmaceuticals are considered within step 4 of the framework to refine the proportion and volumes of pharmaceuticals used.
- **Step 2:** using publicly available datasets and responses from a survey of EU Member States, pharmaceutical sales at the national level are quantified.
- **Step 3:** national-level data are extrapolated to EU-27 level based on population. As an additional step, a factor is applied to the up-scaled values to account for differences in national pharmaceutical markets.
- **Step 4:** a distinction is drawn between 'used' pharmaceuticals (those reaching waste water through human consumption and subsequent excretion) and 'unused' pharmaceuticals (those which are not consumed, some of which reach waste water through disposal via sinks and toilets). The latter are not accounted for in this quantification as they are not within the scope of this study.
- **Step 5:** APIs quantities are projected to 2035 and 2050 to gain an insight into future volumes reaching waste water treatment plants. A simple extrapolation method and an approach that accounts for per population sales and projected future population change is used.

[20] Does my substance need to be registered? - ECHA. (2021). Retrieved 29 March 2021, from https://echa.europa.eu/support/registration/your-registration-obligations/does-my-substance-need-to-be-registered

- **Step 6:** excretion rates are defined and used to determine the fraction of consumed pharmaceuticals reaching waste water. This step does not apply to cosmetic products.

Following the above stages, a final **Step 7** brings together the different steps to calculate quantities of APIs reaching waste water as follows:

Mass of API reaching waste water = (Total sales x Share of API used x Excretion rate)

For **substances used in cosmetic products**, a similar four-step process is used:

- **Step 1:** the mass of substances in cosmetic products sold in EU-27 is quantified using one of the following approaches:
    - **Approach 1:** national-level data are extrapolated to EU-27 level based on population. As an additional step, a factor is applied to the up-scaled values to account for differences in national cosmetic product markets.
    - **Approach 2:** masses at EU-27 level are quantified based on per capita cosmetic product use, population, and the content of substances of interest in cosmetic products.
    - **Approach 3:** masses at EU-27 level are quantified based on the outcomes of the Member State survey (and any follow-up consultations) as well as the outputs of the JRC analysis.
- **Step 2:** a distinction is drawn between 'used' cosmetic products (those washed into waste water through their intended use) and 'unused' cosmetic products (those not used, but a portion of which may be disposed of directly to waste water amongst other routes). The latter are not accounted for in this quantification as their release occurs because of inappropriate disposal.
- **Step 3:** cosmetic product quantities are projected to 2035 and 2050 to gain an insight into future volumes potentially reaching waste water treatment plants.

Step 4 combines the calculations in the preceding steps to quantify the mass of substances in cosmetic products reaching waste water as follows:

Mass of a cosmetic product substance reaching waste water = Mass of a substance sold x Share of CP used

The following sections outline the steps in greater detail, identify the uncertainties and limitations associated with the approach, and present a worked example using a group of five APIs and the Danish national pharmaceutical sales database. Following discussion and agreement on the overall framework defined here and which additional substances are of interest, this can be expanded to assess quantities of other substances (subject to data availability).

3.2.2. Quantifying APIs

3.2.2.1. APIs of interest

Tests conducted at waterbodies in North Rhine-Westphalia (NRW)[21] indicate that the ten substances listed in Table 2 had the highest level of harmfulness[22] of all detected substances; together, these substances accounted for over 95% of the relative harmfulness. Of these top ten substances, five are APIs (ibuprofen, diclofenac, 17β-estradiol, carbamazepine and clarithromycin). Because these substances present the greatest relative harmfulness in water bodies, the quantification of APIs in waste water presented in this note initially focuses on these five substances. With further information on the substances of most significant concern, the quantification can be expanded to consider other APIs and substances within PCPs.

Table 2: Top ten most harmful substances detected in waterbodies in North Rhine-Westphalia (NRW)

Substance	Primary use or source of substance
Ibuprofen	Pharmaceutical active ingredient
Perfluorooctanoic acid + derivatives (PFOS)	Impregnating products, fire extinguishing agents, electroplating
Diclofenac	Pharmaceutical active ingredient
17β-estradiol	Pharmaceutical active ingredient
Imidacloprid	Pesticide (insecticide)
Triclosan	Antiseptic (e.g. disinfectant, cosmetic)
Carbamazepine	Pharmaceutical active ingredient
Clarithromycin	Pharmaceutical active ingredient
Selenium	Nutritional supplements, semiconductors, etc.
Flufenacet	Pesticide (insecticide)

3.2.2.2. Step 1: Sources of APIs in waste water

The major pathway of pharmaceuticals into the environment is excretion by humans (including releases from skin application). The subsequent steps elaborate an approach for quantifying the mass of pharmaceuticals reaching waste water. The Danish dataset used in quantifying pharmaceuticals sales discussed later accounts for pharmaceuticals sales at pharmacies and to hospitals, treatment centres and clinics and, therefore, fairly comprehensively represents the market and movement of pharmaceuticals.

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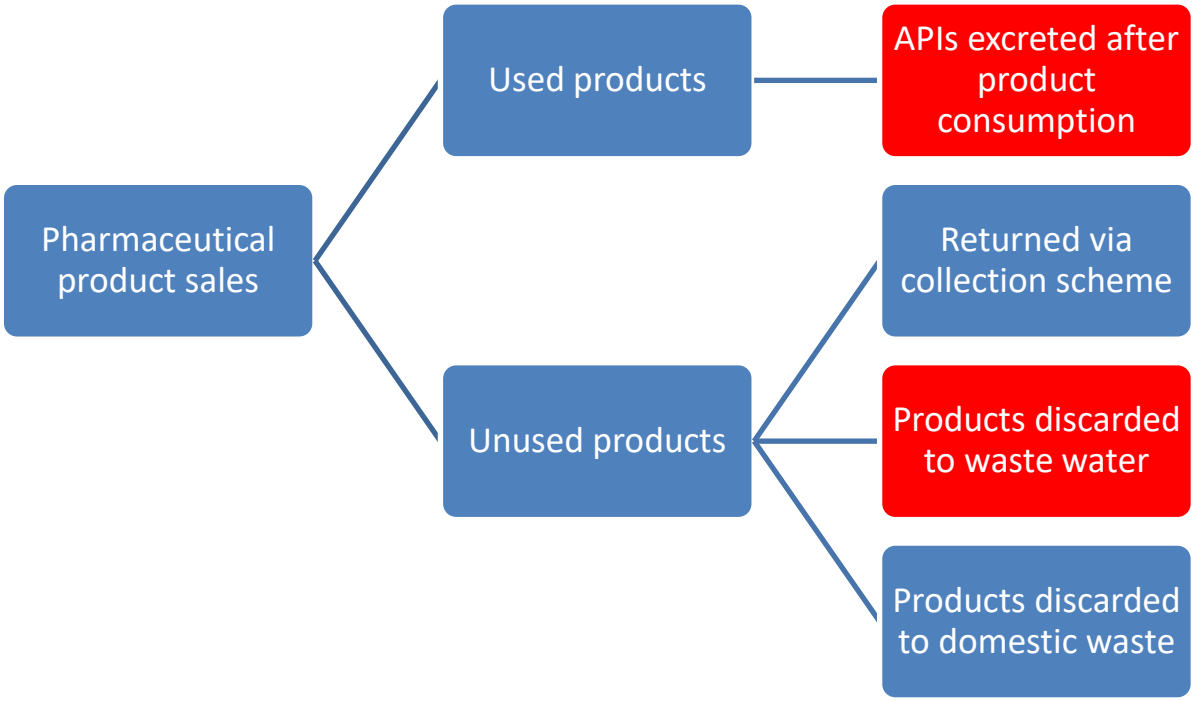
[21] Water Solutions (2020) Fund-based solution for trace element reduction. Available at: https://www.bdew.de/media/documents/gwf_engl_final_Research_Czichy_Oelmann_Schitthelm_Fund-based_solution_Druck_PDF.pdf

[22] The study defines harmfulness as the product of the concentration of a micropollutant in the study waters, and the reciprocal of the corresponding environmental quality standard (EQS), representing the relative hazard of the substance.

Nonetheless, pharmaceuticals can reach waste water through other pathways. Another pathway is the incorrect disposal of unused pharmaceuticals, typically through flushing down sinks and toilets. The fate of unused pharmaceuticals is beyond the scope of this assessment and has therefore been excluded from the estimations (although some quantification has been made to subtract it from the overall estimates).

Figure 2 summarises the fates and pathways of APIs from sold pharmaceutical products. The pathways leading to waste water that are considered in this quantification are highlighted in red (noting that unused products discarded to waste water are outside the assessment's scope and have only been quantified to avoid overestimating volumes arising from product use and excretion).

Figure 2: Fates and pathways of APIs



3.2.2.3. Step 2: Defining masses of pharmaceuticals sold at the national level

Data on pharmaceutical sales and prescriptions are publicly available in national datasets for at least some Member States. In contrast, quantification of pharmaceutical residues in waste water has been conducted in a few Member States. This section outlines the available data and how they have been used. Subsequent sections explain how the data can quantify sales and volumes at the EU level.

Note that checks were made on both the REACH and EMA databases, but data was not relevant or available in a sufficient level of detail (e.g. only very broad tonnage figures are presented) to be of use within this study.

Denmark

The Danish Health Data Authority gathers detailed data on the sales of pharmaceutical products in Denmark. Reporting on medicine sales is mandatory in Denmark, and data reported by pharmacies and non-pharmacy vendors of medicines are compiled in a

comprehensive database accessible online[23]. The database includes medicines sold to treatment centres and hospitals and is a comprehensive register of all sales in Denmark. Pharmaceutical products are listed in the database by Anatomical Therapeutic Chemical (ATC) code, and volumes sold are expressed as defined daily doses (DDDs) of an API. The database also includes information on the product name, dosage form and package size.

The World Health Organisation's (WHO) ATC/DDD Index[24] identifies the DDD mass associated with each pharmaceutical product by ATC code. For some substances, the index provides different DDDs depending on the dosage form (oral, nasal, parenteral, etc.). Using the WHO ATC/DDD Index, it is possible to translate the sales volumes in the Danish Medstat database, expressed in DDDs, into the mass of APIs sold. This produces a robust estimation of the mass of APIs placed on the Danish market annually.

To give an example, the ATC/DDD Index identifies that one DDD of products containing ibuprofen, taken in oral, parenteral or rectal form, is equivalent to 1.2 g of ibuprofen. The Danish Medstat database indicates that the ibuprofen product 'Actavis' sold in film-coated tablet form in package size of 100 pieces corresponded to sales of 1,910,500 DDDs of ibuprofen in 2019. This can be converted into a mass of ibuprofen sold as follows:

Mass sold (kg) = Volume sold (DDD) x Mass per DDD (g) ÷ 1,000

In this case:

Mass of ibuprofen sold as Actavis in package size 100pc (kg) = 1,910,500 DDDs x 1.2 g ÷ 1,000 = 2,293 kg

This approach has been applied to calculate the mass of the APIs listed in Table 2 placed on the Danish market. Masses of ibuprofen, diclofenac, estradiol, carbamazepine and clarithromycin sold in Denmark between 2010 and 2019 are displayed in Figure 3, Figure 4 and Figure 5.

The data indicate no discernible trend in ibuprofen sales over the past ten years. Sales of diclofenac, carbamazepine and estradiol have declined steadily since 2010, while clarithromycin sales have increased slightly over the same period. This decline is just for these 5 substances, but similar declines are not anticipated for all substances.

The OECD gathers data on pharmaceutical sales and consumption in its member countries, including 22 EU Member States, which are publicly available through an online database[25]. Data are defined for different ATC codes but only for up to the first three levels of the ATC classification. As such, it is not possible to obtain data for particular pharmaceutical products (e.g. M01AE01 ibuprofen); instead, data are only accessible for high-level categories (e.g. M01A anti-inflammatory and antirheumatic products non-steroids). Trends observed in the figures below have been compared with consumption data for other EU Member States for the corresponding ATC classifications. The trends observed in the Danish Medstat database are broadly consistent with consumption trends reported by the OECD, except for carbamazepine; the OECD reports an increase in consumption of ATC code N (nervous system) pharmaceuticals in the past ten years. However, this data accounts for all code N medications and is unlikely to accurately reflect the trends associated solely with carbamazepine.

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[23] https://medstat.dk/en

[24] WHO (2021) ATC/DDD Index 2021. Available: https://www.whocc.no/atc_ddd_index/

[25] OECD.Stat (2021) Pharmaceutical market. Available: https://stats.oecd.org/Index.aspx?DataSetCode=HEALTH_PHMC

Figure 3: Mass of ibuprofen sold in Denmark 2010-2019

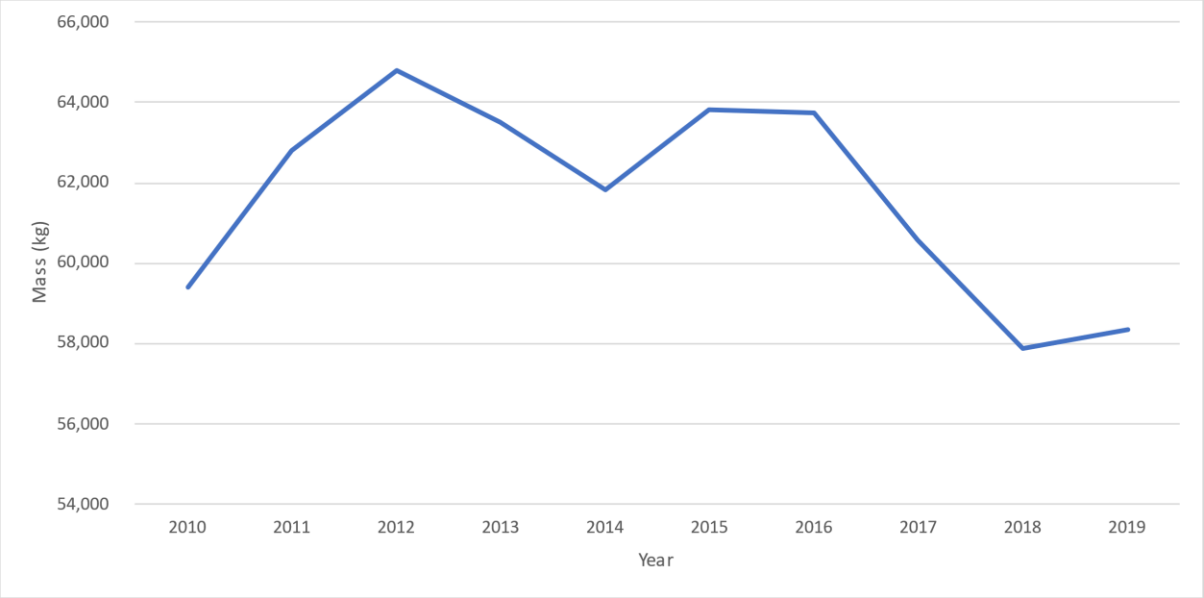


Figure 4: Mass of diclofenac, carbamazepine and clarithromycin sold in Denmark 2010-2019

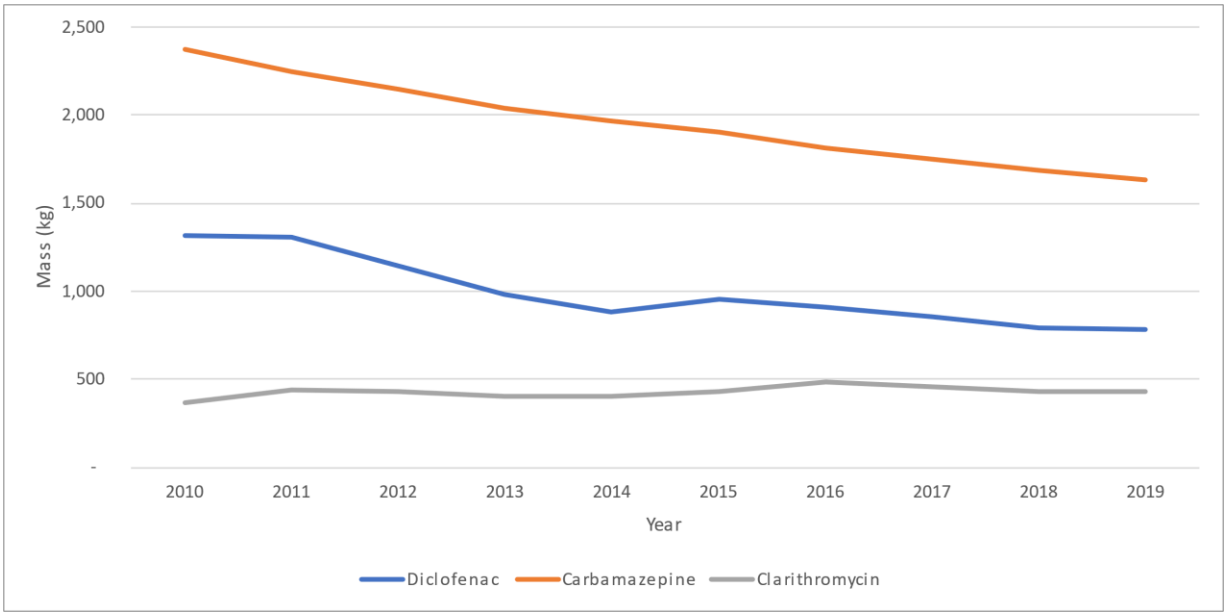
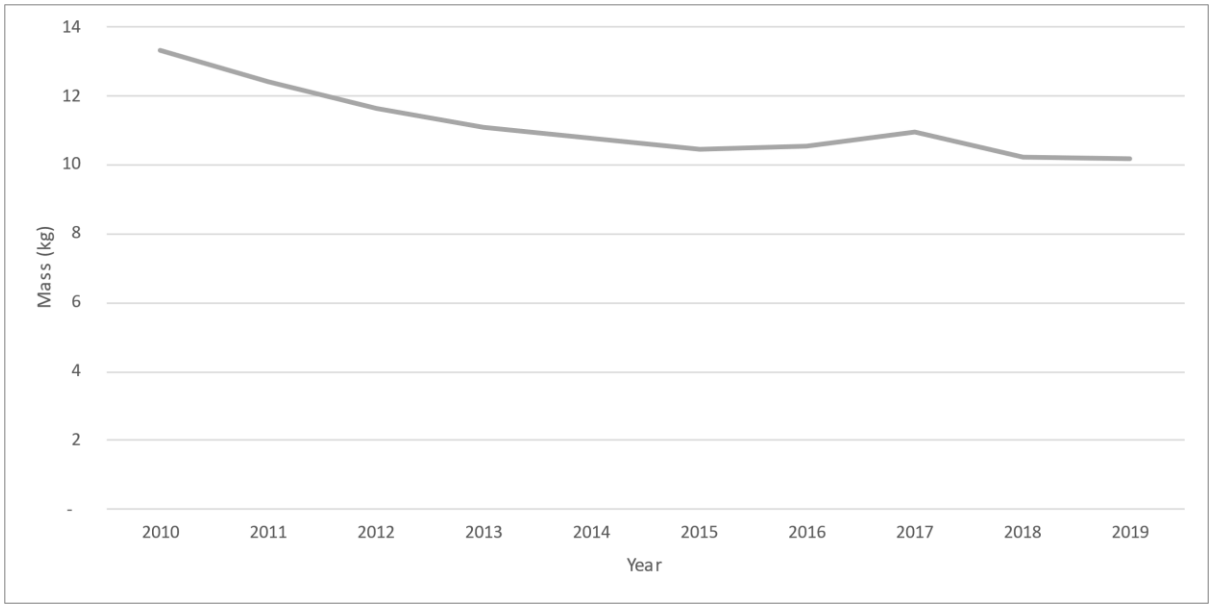


Figure 5: Mass of estradiol sold in Denmark 2010-2019



Germany

Prescription data gathered through the German statutory health insurance programme are publicly available online via the PharMaAnalyst database[26]. The database lists approximately 3,000 APIs and identifies their yearly numbers of prescriptions expressed in DDD.

Unlike the data available in the Danish Medstat database, the PharMaAnalyst database only accounts for pharmaceuticals prescribed through statutory health insurance. Non-prescription pharmaceuticals, i.e. those dispensed 'over-the-counter' at pharmacies and those prescribed outside the statutory health insurance schemes, are not included in the database. This is especially an issue considering that many APIs of concern, including ibuprofen and diclofenac, are principally obtained through non-prescription preparations. As such, the PharMaAnalyst database only provides a partial picture of pharmaceuticals sold in Germany, and any calculations based on it would only partially represent the volumes of APIs in waste water. The German data has, therefore, not been used in calculating total APIs reaching waste water but may be used for verifying estimations.

Netherlands

An analysis of pharmaceuticals and water quality in the Netherlands concluded that at least 140 tonnes of pharmaceuticals are discharged by sewage treatment plants into surface waters every year[27]. The study also found that five substances (diclofenac, azithromycin, clarithromycin, sulfamethoxazole and carbamazepine) are present in concentrations higher than safety thresholds for water organisms.

Member State survey data

A survey of EU Member States was conducted to assess the scale of the issue of micropollutants, such as pharmaceuticals in waste water, to gauge the current policy

[26] Wissenschaftliches Institut der AOK (2021) PharMaAnalyst. Available: https://arzneimittel.wido.de/PharMaAnalyst/?3

[27] Rijksinstituut voor Volksgezondheid en Milien (2016) Geneesmiddelen en waterkwaliteit. Available: https://www.rivm.nl/bibliotheek/rapporten/2016-0111.pdf

response to the risks posed and understand the level of deployment of fourth-stage treatment technologies which may remove micropollutants at waste water treatment plants. The survey did not provide additional information on the sales of pharmaceuticals in Member States and the volumes of APIs reaching waste water.

3.2.2.4. Step 3: Scaling national datasets to the EU-27

The national-level data sets listed above were used to approximate the masses of different APIs placed on the market at the EU-27 level.

Step 3.1: Population-based projection

Population data for the EU Member States are published by Eurostat, along with future population projections[28]. Population data for 2019 for Denmark, Germany, the Netherlands and the EU-27 area are displayed in Table 3.

Table 3: Eurostat 2019 population data

Territory	2019 Population	As Percentage of EU-27
Denmark	5,806,081	1.3%
Germany	83,019,213	18.6%
Netherlands	17,282,163	3.9%
EU-27	446,824,564	100%

Using population data, it is possible to factor up national-level data to approximate pharmaceutical sales for Member States where data are not available and also for the EU-27 as a whole. This approach has been used to extrapolate the mass of pharmaceuticals sold from the Danish dataset for the remaining EU Member States and the EU-27 as a whole. Extrapolated values are displayed in Table 4.

Table 4: Extrapolated masses of APIs sold in EU27, 2019

EU Member State	Mass sold in 2019 (kg)				
	Ibuprofen	Diclofenac	Estradiol	Carbamazepine	Clarithromycin
Denmark [29]	*58,341*	*782*	*10*	*1,631*	*432*
Austria	89,015	1,193	16	2,489	658
Belgium	115,108	1,543	20	3,218	851
Bulgaria	70,338	943	12	1,967	520
Croatia	40,959	549	7	1,145	303

[28] Eurostat (2021) Population on 1st January by age, sex and type of projection. Available: https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_19np&lang=en

[29] National-level sales data from the Danish Medstat database. These data are the basis of extrapolated values for other Member States.

EU Member State	Mass sold in 2019 (kg)				
	Ibuprofen	Diclofenac	Estradiol	Carbamazepine	Clarithromycin
Cyprus	8,801	118	2	246	65
Czechia	107,012	1,435	19	2,992	791
Estonia	13,312	178	2	372	98
Finland	55,446	743	10	1,550	410
France	675,020	9,050	118	18,872	4,993
Germany	834,201	11,184	145	23,323	6,170
Greece	107,764	1,445	19	3,013	797
Hungary	98,199	1,317	17	2,745	726
Ireland	49,279	661	9	1,378	364
Italy	601,055	8,058	105	16,804	4,445
Latvia	19,292	259	3	539	143
Lithuania	28,077	376	5	785	208
Luxembourg	6,169	83	1	172	46
Malta	4,959	66	1	139	37
Netherlands	173,656	2,328	30	4,855	1,284
Poland	381,562	5,116	66	10,668	2,822
Portugal	103,262	1,384	18	2,887	764
Romania	195,082	2,615	34	5,454	1,443
Slovakia	54,767	734	10	1,531	405
Slovenia	20,910	280	4	585	155
Spain	471,637	6,323	82	13,186	3,488
Sweden	102,796	1,378	18	2,874	760
EU-27	**4,486,021**	**60,144**	**781**	**125,420**	**33,179**

Step 3.2: Accounting for national market trends in population-based projection

Projecting pharmaceutical sales based on population alone, as presented in Table 4, fails to account for any differences in pharmaceutical sales volumes across the different EU Member States. However, it is possible to take into account national pharmaceutical market sizes in the estimation method by using data from the OECD.

The OECD gathers data on the pharmaceutical market for its Member countries, which are accessible through an online database[25]. Data are available for pharmaceutical consumption (expressed in DDD per 1,000 inhabitants per day) and pharmaceutical sales (expressed in various economic metrics, including million US$).

Consumption data, expressed in DDD per 1,000 inhabitants per day, have been obtained from the OECD database for the ATC categories corresponding to the pharmaceuticals of interest. For each Member State, a ratio has been calculated per population sales relative to the figures for Denmark, effectively benchmarking per population pharmaceutical sales to the Danish market. These ratios are displayed in Table 5.

Table 5: Pharmaceutical sales ratios relative to Denmark

		Consumption ratios relative to Denmark			
ATC code in OECD database		**G03**	**J01**	**M01A**	**N**
Corresponding APIs		**Estradiol**	**Clarithromycin**	**Ibuprofen, diclofenac**	**Carbamazepine**
EU MS	**Year of data**				
Denmark	*2019 and 2017*	*1.0*	*1.0*	*1.0*	*1.0*
Austria	2018	0.8	0.2	0.5	0.8
Belgium	2018	1.0	0.7	1.2	1.0
Bulgaria [30]	Non-OECD	1.4	0.2	0.7	1.0
Croatia [30]	Non-OECD	1.4	0.2	0.7	1.0
Cyprus [30]	Non-OECD	1.0	0.1	1.1	0.4
Czechia	2018	1.7	0.7	1.0	1.6
Estonia	2019	1.0	0.4	0.7	1.9
Finland	2018	1.6	1.1	0.9	2.2
France [30]	2018	1.1	0.6	1.4	1.0
Germany	2018	1.2	0.4	0.7	1.0
Greece	2019	1.0	0.1	1.2	0.2
Hungary	2019	1.6	0.1	0.8	0.8
Ireland [30]	2018	1.3	0.3	1.2	0.7
Italy	2019	1.0	0.1	1.0	0.5

[30] Data were not available for Bulgaria, Croatia, Cyprus, Malta and Romania, therefore data from neighbouring countries have been used as a proxy. Data for ATC codes A, G03, M01A and N were not available for France, Ireland and Poland, therefore data for Belgium and Germany (France), the UK (Ireland), and Slovakia, Czechia, Estonia and Latvia (Poland) have respectively been used as a proxy.

		Consumption ratios relative to Denmark			
ATC code in OECD database		**G03**	**J01**	**M01A**	**N**
Corresponding APIs		**Estradiol**	**Clarithromycin**	**Ibuprofen, diclofenac**	**Carbamazepine**
EU MS	**Year of data**				
Latvia	2019 and 2018	1.7	0.1	0.7	1.8
Lithuania	2018	0.8	0.2	1.2	1.8
Luxembourg	2019	2.4	0.2	1.1	1.2
Malta [30]	Non-OECD	1.3	0.2	1.0	0.8
Netherlands	2018	1.7	0.4	0.6	0.5
Poland [30]	2018	1.4	0.4	1.3	1.6
Portugal	2019	1.3	0.2	1.1	2.0
Romania [30]	Non-OECD	1.4	0.2	0.7	1.0
Slovakia	2018	1.5	0.3	1.2	1.2
Slovenia	2018	1.3	0.4	0.7	1.3
Spain	2018	1.6	0.3	1.1	1.2
Sweden	2019	1.5	1.1	0.7	1.6

The ratios in Table 5 can be applied to extrapolated sales figures in Table 4 to factor the sales figures according to a Member State's scale of pharmaceutical consumption. Therefore, the resulting sales figures, displayed in Table 6, account for both the population of a Member State and the scale of its pharmaceutical consumption.

Table 6: Extrapolated masses of APIs sold in EU27, 2019, factored according to market size

EU Member State	**Mass sold in 2019 (kg)**				
	Ibuprofen	**Diclofenac**	**Estradiol**	**Carbamazepine**	**Clarithromycin**
Denmark [31]	*58,341*	*782*	*10*	*1,631*	*432*
Austria	68,740	922	2	1,255	356
Belgium	109,673	1,470	14	1,790	1,020

[31] National-level sales data from the Danish Medstat database. These data are the basis of extrapolated values for other Member States.

EU Member State	Mass sold in 2019 (kg)				
	Ibuprofen	Diclofenac	Estradiol	Carbamazepine	Clarithromycin
Bulgaria	71,218	955	3	1,014	371
Croatia	41,471	556	2	591	216
Cyprus	3,239	43	0	115	73
Czechia	172,706	2,315	14	1,977	805
Estonia	25,478	342	1	187	69
Finland	119,208	1,598	11	1,565	370
France	656,269	8,799	66	10,000	6,850
Germany	827,249	11,091	61	11,744	4,197
Greece	24,846	333	1	1,769	982
Hungary	73,922	991	1	1,271	545
Ireland	32,853	440	2	1,116	443
Italy	303,867	4,074	8	5,806	4,549
Latvia	33,976	456	0	213	95
Lithuania	51,240	687	1	450	244
Luxembourg	7,454	100	0	128	52
Malta	4,174	56	0	102	38
Netherlands	90,205	1,209	11	2,102	709
Poland	617,653	8,281	26	5,832	3,774
Portugal	203,369	2,727	4	3,720	853
Romania	197,521	2,648	8	2,814	1,028
Slovakia	64,960	871	3	965	469
Slovenia	26,602	357	2	333	104
Spain	555,483	7,447	21	14,787	3,711
Sweden	160,190	2,148	19	3,371	530
EU27	**4,601,906**	**61,698**	**291**	**76,647**	**32,883**

Analysis conducted by Svenskt Vatten looking at pharmaceuticals reaching waste water treatment plants[32] estimated total diclofenac sales in Sweden in 2019 to be 4,413 kg. This is over double the diclofenac sales estimated in the table above. Where such national-level quantifications are identified and available, they supersede estimations using the abovementioned method.

While efforts have been made to account for population and economic factors in upscaling data, it is inevitable that other country-specific factors will be overlooked in the extrapolations. Where discrepancies are identified between our estimations and reported data, such as the Swedish example identified above, they can be used to investigate whether the quantification method displays a consistent skew or bias. If this is found to be the case, the method can be refined accordingly.

3.2.2.5. Step 4: Discounting unused pharmaceuticals

Not all of the pharmaceuticals sold are ultimately consumed as quantified in the preceding steps. These unused pharmaceuticals are either returned to pharmacies where collection schemes are widely prevalent, disposed of in domestic waste, or flushed into waste water streams. Data collected by Cyclamed[33], the French body responsible for collecting and recovering unused medicines, indicate that in 2018, about 23% of sold pharmaceuticals in France were ultimately unused. In the absence of other data, this rate of non-use has been applied in the quantification. Should additional data become available, they can be used to refine the quantification.

3.2.2.6. Step 5: Projecting sales to 2050

Once quantified as above, it is possible to project the masses of different APIs into the future to gauge the levels of substances that will reach waste water treatment plants in future years. This can be achieved through a simple linear extrapolation of historical data - Figure 3, Figure 4 and Figure 5 indicate historic trends in pharmaceuticals sales for ibuprofen, diclofenac, estradiol, carbamazepine and clarithromycin for the past 10 years in DK, which can then be projected into the future.

Alternatively, it is possible to project the linear trend of pharmaceutical sales per population for future years, combine these forecasts with corresponding population projections from Eurostat[34], and account for the forecast ageing population profile in future years. Unlike a simple linear extrapolation of trends, this approach accounts for both changes in per capita sales of pharmaceuticals and overarching population trends. Following this method, the pharmaceutical sales figures quantified in previous steps have been projected for 2050 for the EU Member States. Projections of ibuprofen, diclofenac, estradiol, carbamazepine and clarithromycin combined sales for the EU-27 are displayed in Figure 6, Figure 7, Figure 8, Figure 9 and Figure 10. In the case of diclofenac, estradiol and carbamazepine, power trendlines were found to more closely fit historical data than linear trends; therefore, future projections are made on this basis. These extrapolations project the past trends in reducing trends, however, with the ageing population, these trends could reverse.

[32] Available at: https://vattenbokhandeln.svensktvatten.se/wp-content/uploads/2021/03/Wast-water-treatment-pains_SvenskVatten_M150.pdf

[33] Cyclamed (2019) Rapport d'activité 2019. Available: https://www.cyclamed.org/wp-content/uploads/2020/06/RA-Digital-2019.pdf

[34] Eurostat (2021) Population on 1st January by age, sex and type of projection. Available: https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_19np&lang=en

Data from a 2014 study[35] by Eurostat indicate the rate of prescribed medication use over a two-weeks period for different age groups; for example, 87% of study participants in the 65-74 years age bracket reported using prescribed medicines during the study period, compared with 25.7% of respondents in the 25-34 years age bracket. These consumption rates have been applied to the Eurostat population forecast data, available by age group, to weigh projected future consumption of APIs according to future population age profiles. As a result, an uplift has been applied to consumption in future years to account for their forecasted increasingly elderly population profiles.

The projections presented below are based on datasets up to 2019 and do not reflect any changes that have arisen due to the Covid-19 pandemic. They also do not take into account any changes in the availability of APIs, changes due to sustainability reasons or listing of these substances in (environmental) legislation and/or strategies, e.g. impacts of the European Pharmaceutical and Chemicals Strategies, Zero Pollution Action Plan, etc.

[35] Eurostat (2021) Self-reported use of prescribed medicines by sex, age and educational attainment level. Available: https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hlth_ehis_hc9&lang=en

Figure 6: Projected mass of ibuprofen sold in the EU27

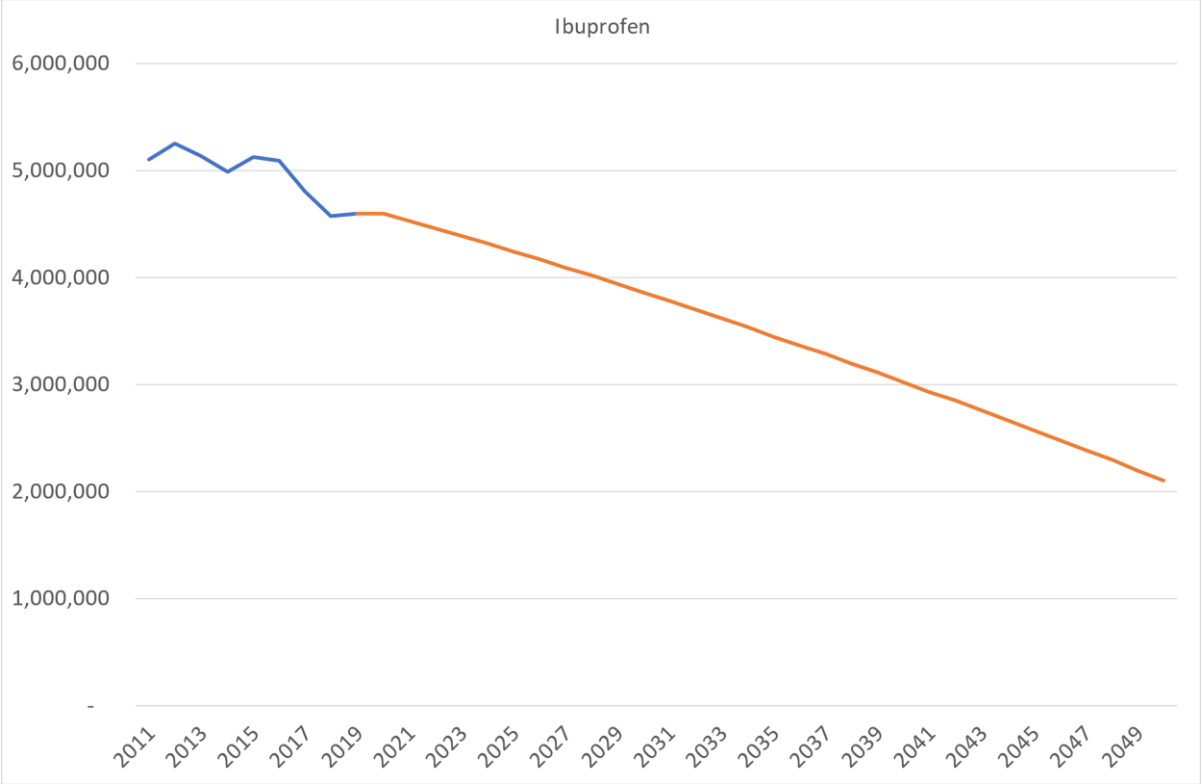


Figure 7: Projected mass of diclofenac sold in EU27

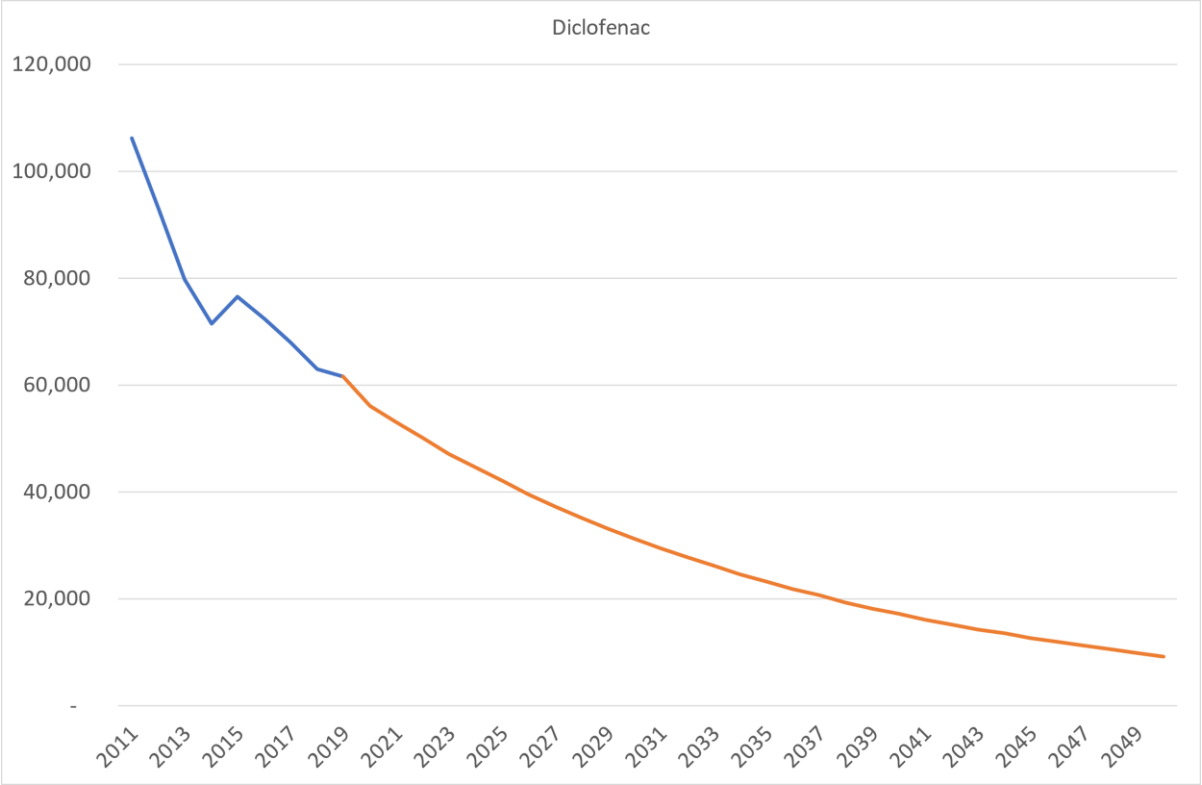


Figure 8: Projected mass of estradiol sold in EU27

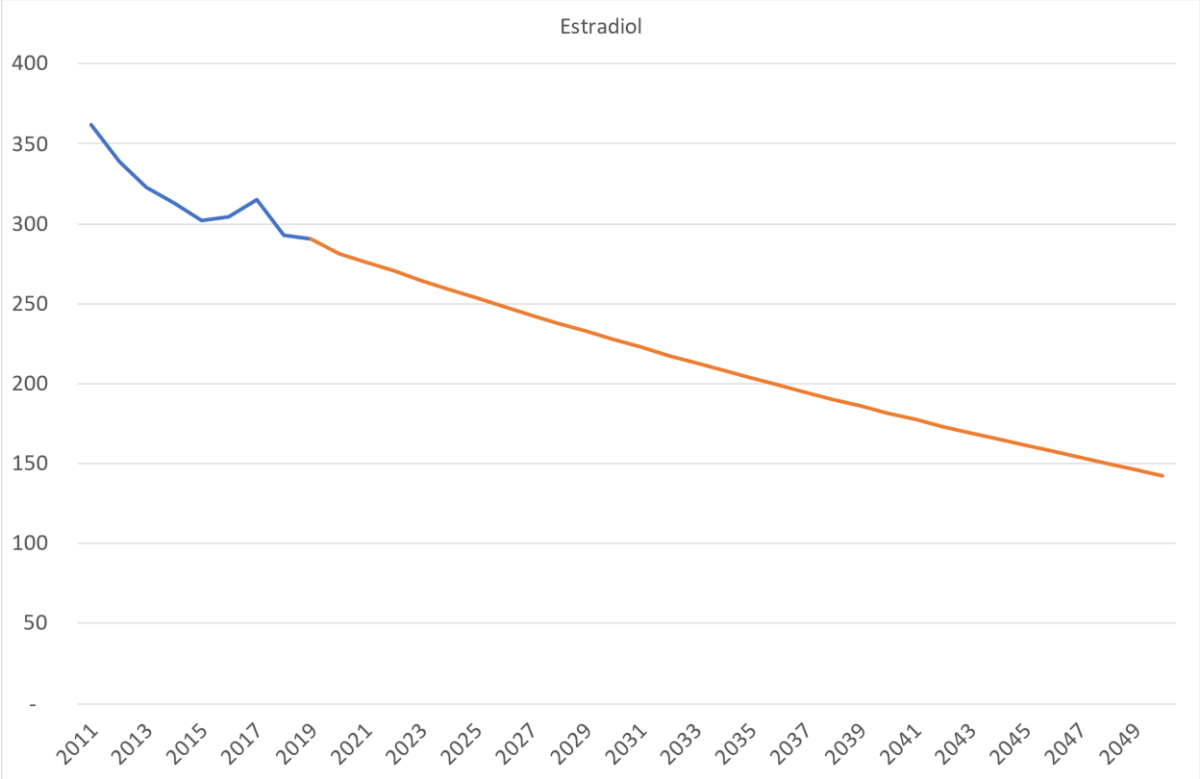


Figure 9: Projected mass of carbamazepine sold in the EU27

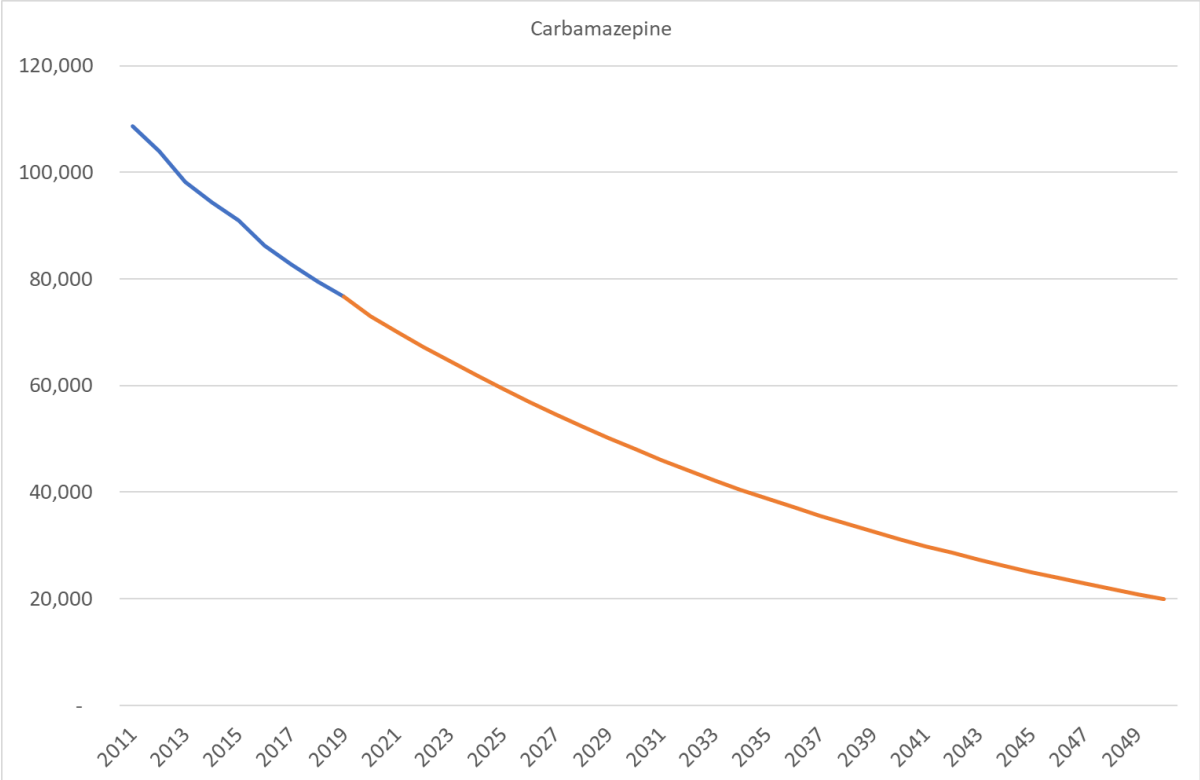
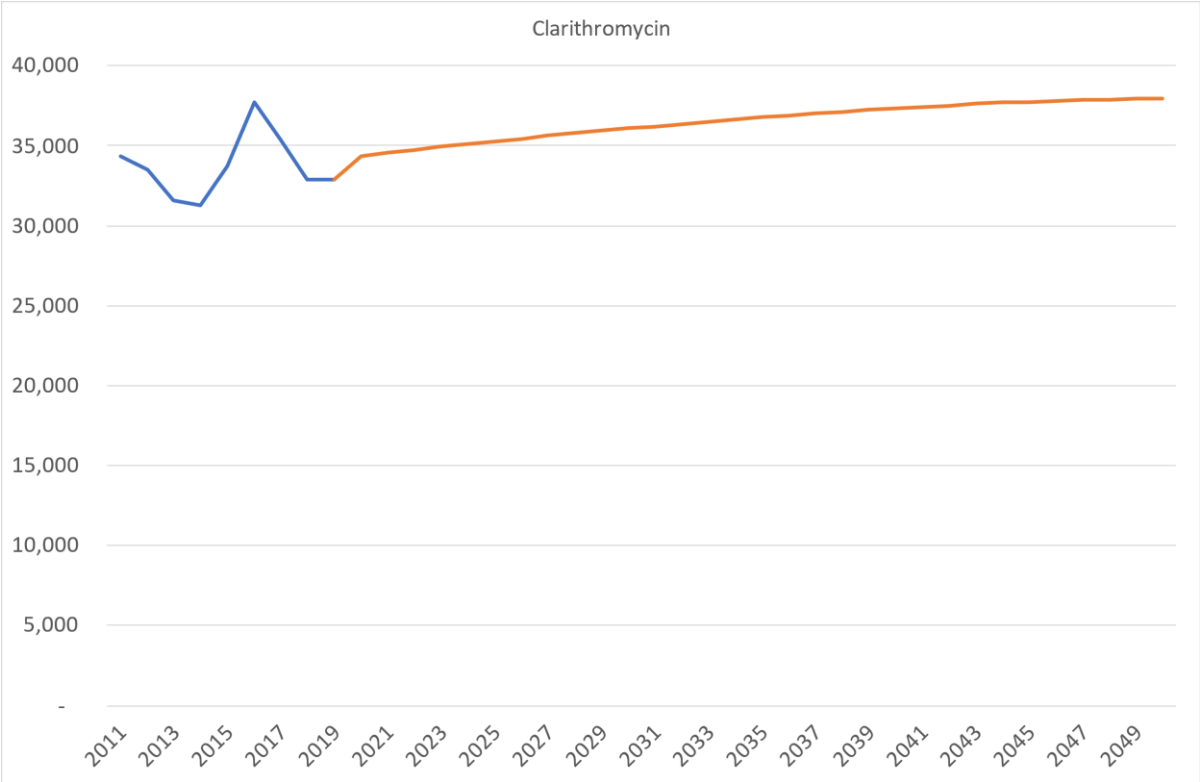


Figure 10: Projected mass of clarithromycin sold in the EU27



3.2.2.7. Step 6: Defining excretion rates for assessed pharmaceuticals

The major pathway of APIs into the environment is excretion by humans (including from skin application). The previous steps ascertain the masses of APIs sold and used in the EU Member States and the EU-27. Of these 'used' masses of APIs, only a certain portion will enter waste water following consumption and subsequent excretion. Therefore, it is necessary to consider the excretion rates applied to the quantified masses of pharmaceuticals sold to estimate the quantities reaching waste water treatment plants. A literature review of excretion rates for APIs indicates that excretion rates range from 0% to 100% for different human medicines. For pharmaceuticals, there are different ways of administering the drug to the patient: ingesting a pill, injecting the drug intravenously, injecting it into the muscle, and spreading it over the area to be treated in gel or cream form, etc. These variations in delivery mode add uncertainty to the excretion rates as the drug metabolism is not the same when the drug is absorbed through the gastrointestinal tract, through the skin or delivered directly into the bloodstream. Although the entirety of the dose can be assumed to have been processed by the patients' bodies when ingested as a pill or injected, the same cannot be said for gels or creams. Their pharmacokinetics has been studied by researchers, but there is no standard exact absorption value for topical drugs, and there can be significant variations in amounts that end up being washed off and/or end up on clothes. This can give rise to big uncertainties regarding the amounts of metabolites that are excreted from a specific drug[36]. Another uncertainty that needs to be considered is that the drug metabolism varies with subjects (according to their age, sex,

[36] Waste water Treatment Pains, (2021). Retrieved 23 March 2021, from https://vattenbokhandeln.svensktvatten.se/wp-content/uploads/2021/03/Wast-water-treatment-pains_SvensktVatten_M150.pdf

general size, ethnicity, pre-existing conditions, etc.)[37,38] and with the environment as the food being consumed by the patients as well as the other drugs that they are taking can also have an impact.

While looking for APIs individually on specialised websites (Pubmed, Rxlist, and Drugbank), the lack of precision for excretion rates was striking. Indeed, the drug's curative properties and side effects are well studied and documented with extensive and rigorous double-blind testing procedures. In contrast, the procedures for excretion rates are not as thorough. The reported sizes of the patient group used to test the drug's pharmacokinetics were usually in the 10 to 20 range, whereas phase-3 clinical trials for drugs involve at least 1,000 patients. Moreover, the group is usually made of healthy volunteers, which does not reflect the variability of the general population. This is problematic as a wide variety of factors can influence pharmacokinetics: age, gender, weight, size, Body Mass Index, ethnicity, pre-existing diseases, other prescribed drugs, etc., all having an impact on the pharmacokinetics of a drug[39,40]. Another component of the pharmacokinetics issue is the lack of total recovery of the parent drug and its metabolites; the testing and analysis focus on the parent compound and a few key metabolites, which do not account for the entirety of the dose administered to the patient, in addition, the duration of the test period sometimes may not be enough to recover the entirety of the drug dose. This leads to excretion rates often given as ranges and not absolute values.

The extreme variability of the pharmacokinetics data obtained due to the factors discussed above led to considering another approach with some expected uncertainty but still allowing for a close connexion with the excretion data: using a general excretion rate for different molecules grouped either by drug family (anti-inflammatory, NSAIDs, antibiotics, etc.) or by chemical properties (hydrophobicity, hydrophilicity, molecular weight, etc.). These approaches were not considered because of the following reasons:

- The drug family does not influence its pharmacokinetics, but only its chemical properties. As often within a drug family, there are different chemical families (see, for example, antibiotics: ß-lactams, tetracyclines, fluoroquinolones, aminoglycosides etc., the same is true for others such as anti neo-plastics etc).
- Some chemical properties of drugs are often the same (e.g., log Pow range, water solubility) as they all must overcome the same metabolic barriers when ingested (the majority of drugs are administered orally) to reach the organ that they are targeting. Thus most drugs:
    - meet a range of polarity (log Pow), which is desired to be in the range of 0 to -3 (in other words, most compounds are polar enough to be mobile in the environment and soluble at environmental concentrations)
    - are often called small molecules as the molecular weight is most often below 500 Da or 1000 Da (else uptake in the intestine etc., is low)
    - usually comply with Lipinski's Rule of 5 (no more than 5 hydrogen bond donors (the total number of nitrogen–hydrogen and oxygen-hydrogen bonds), no more than 10 hydrogen bond acceptors (all nitrogen or oxygen

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37 Gibson, G., & Skett, P. (1996). Factors affecting drug metabolism: internal factors. *Introduction To Drug Metabolism*, 107-132. doi: 10.1007/978-1-4899-6844-9_4

38 Interindividual Variability in Human Drug Metabolism. (2021). Retrieved 25 March 2021, from https://www.routledge.com/Interindividual-Variability-in-Human-Drug-Metabolism/Pacifici-Pelkonen/p/book/9780748408641

39 Willmann, S., Höhn, K., Edginton, A., Sevestre, M., Solodenko, J., & Weiss, W. et al. (2007). Development of a Physiology-Based Whole-Body Population Model for Assessing the Influence of Individual Variability on the Pharmacokinetics of Drugs. Journal Of Pharmacokinetics And Pharmacodynamics, 34(3), 401-431. doi: 10.1007/s10928-007-9053-5

40 US Food and Drug Administration (2021). Retrieved 24 May 2021, from https://www.fda.gov/media/71364/download

atoms), a molecular mass less than 500 Da, an octanol-water partition coefficient (log P) that does not exceed 5).

Given the similarity of their chemical properties on the one hand and their high diversity regarding molecular structures and metabolism, on the other hand, it was not possible to define a general excretion rate when grouping drugs as families.

Based on this information, a simplistic but realistic and precautionary approximation of the excretion rate for future estimation has been applied: 100% excretion of the drug as a parent compound. The following elements support this assumption:

1. 100% excretion as a parent compound accounts for the entirety of the consumed drug.
2. Some metabolites (typically glucuronide metabolites) are cleaved back to the parent compound in the environment[41].
3. The metabolization process involves hydroxylation or carboxylation of the parent drug, which adds a hydroxy or carboxy group respectively to the parent molecule but removes parts of it, keeping the overall molecular weight of the metabolite close to the parent compounds.
4. Often activity is reduced by metabolism, but sometimes metabolites have the same range and type of hazardousness; other times, they have different and even more active environmental hazardousness.
5. Environmental Risk Assessment (ERA) is based on single compounds. However, in the environment, some mixtures could act independently but also as an additive, synergistic or antagonistic.
6. Some anti-cancer drugs interact directly with the DNA. For them, a safe threshold cannot be given.

Therefore, using a 100% excretion rate as the parent compound for substances included in the quantification leads to a good approximation of the overall mass of drug-related products reaching the waste water system.

3.2.2.8. Step 7: Quantifying the pharmaceuticals load to WWTPs

The preceding steps can be brought together to estimate the quantities of APIs reaching waste water. In **Step 2**, sales data for five pharmaceutical products were obtained from the Danish Medstat database and converted into masses of particular APIs. In **Steps 3.1 and 3.2**, these data were scaled to EU-27 level based on population and market sizes. These scaled figures are presented in Table 7.

Table 7: Mass of APIs sold annually in Denmark and EU-27

	Mass sold in 2019 (kg)				
	Ibuprofen	**Diclofenac**	**Estradiol**	**Carbamazepine**	**Clarithromycin**
Denmark	*58,341*	*782*	*10*	*1,631*	*432*
EU-27	**4,601,906**	**61,698**	**291**	**76,647**	**32,883**

[41] Celiz, M., Tso, J., & Aga, D. (2009). PHARMACEUTICAL METABOLITES IN THE ENVIRONMENT: ANALYTICAL CHALLENGES AND ECOLOGICAL RISKS. *Environmental Toxicology And Chemistry*, *28*(12), 2473. doi: 10.1897/09-173.1

Step 4 considered the rates of use and non-use of pharmaceutical products and concluded that approximately 23% of medicines sales remain unused. **Step 6** considers the excretion rates associated with each API and its metabolites.

Bringing these steps together, the quantities of APIs reaching waste water can be quantified as follows:

Quantity of API reaching waste water = Mass sold x Share of API used x Excretion rate

The quantification of APIs and metabolites excreted to waste water is presented in Table 8 on the following page.

Table 8: Masses of APIs and metabolites excreted to waste water

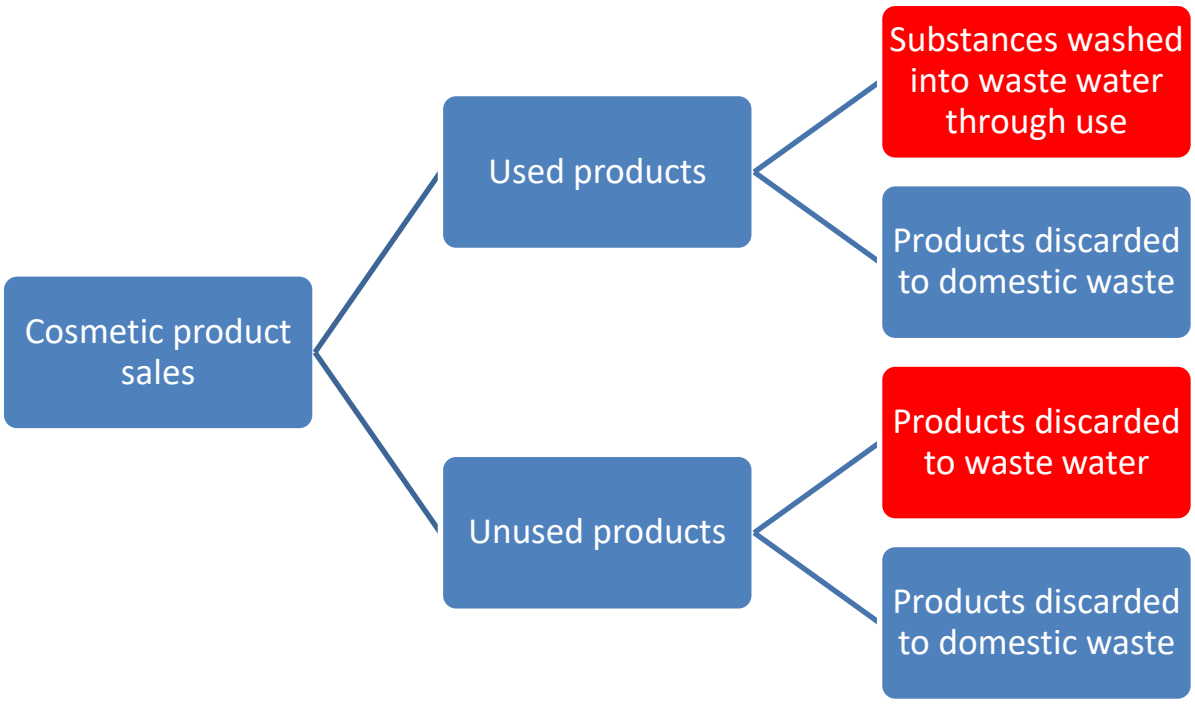
API	Mass sold in EU-27 (kg)	Rate of use (%)	Rate of non-use (%)	Mass unused 2019 (kg)	Mass excreted to waste water 2019 (kg)	Mass excreted to waste water 2035 (kg)	Mass excreted to waste water 2050 (kg)
Ibuprofen (as parent compound)	4,601,906	77	23	1,067,452	3,534,454	2,654,478	1,618,307
Diclofenac (as parent compound)	61,698	77	23	14,311	47,387	17,832	7,152
Estradiol (as parent compound)	291	77	23	67	223	156	109
Carbamazepine (as parent compound)	76,647	77	23	17,779	58,868	29,792	15,326
Clarithromycin (as parent compound)	32,883	77	23	7,627	25,255	28,245	29,148

3.2.3. Quantifying substances in cosmetic products

Sales and consumption data for cosmetic products are not as readily available as for pharmaceutical products, and the category also includes a highly diverse range of products and formulations. This section presents three approaches to quantify the substances from cosmetic products reaching waste water.

The fates and pathways of substances in cosmetic products are summarised in Figure 11. Some sold cosmetic products that are used are eventually washed directly into waste water. Unused or expired products may be disposed of (incorrectly) directly to waste water (through flushing in sinks and toilets) or discarded in solid household waste. The pathway considered in this quantification, washing away through the use to waste water, is highlighted in red.

Figure 11: Fates and pathways of substances in cosmetic products



3.2.3.1. Step 1: Quantifying masses of substances in cosmetic products sold in the EU-27

Approach 1: Quantifying substances based on national-level data

The EU-28[42] cosmetics and cosmetic products market was valued at €76.6 billion in 2019[43], with the largest markets listed in Table 9. However, no datasets at this stage have been identified on volumes of cosmetic products sold (overall or broken down for different types of products) or the volumes of specific substances within cosmetic products sold.

[42] Includes EU27 and the UK.

[43] Cosmetic, Toiletry and Perfumery Association (2021) Market statistics. Available: https://www.ctpa.org.uk/eu-and-worldwide

Table 9: Cosmetics products market sizes

Member State	Cosmetics products retail sales value (€ billion)
Germany	14.0
France	11.4
UK	10.7
Italy	10.5
Spain	7.1
Poland	4.1
Netherlands	2.8
Belgium and Luxembourg	2.0
Sweden	2.0
Switzerland	2.0
EU-27	**74.9**
EU-27, Norway and Switzerland	**69.1**

Note: The UK is not a Member State but presented for information purpose.

Data from 2018 indicate that of the European cosmetics market, skin care products form the largest portion (€20.4 billion), followed by toiletries (€19.9 billion), hair care products (€14.9 billion), fragrances and perfumes (€12.3 billion), and decorative cosmetics (€11.1 billion)[44]. This split can be used to estimate national-level data according to cosmetic product type.

Once masses of cosmetic products sold are estimated, the mass of particular substances within different cosmetic products placed on the market are estimated using the following calculation:

Mass of cosmetic product substance used per year = (Mass of cosmetic product 1 sold in EU x Percentage content of substance in cosmetic product 1) + (Mass of cosmetic product 2 sold in EU x Percentage content of substance in cosmetic product 2) + …

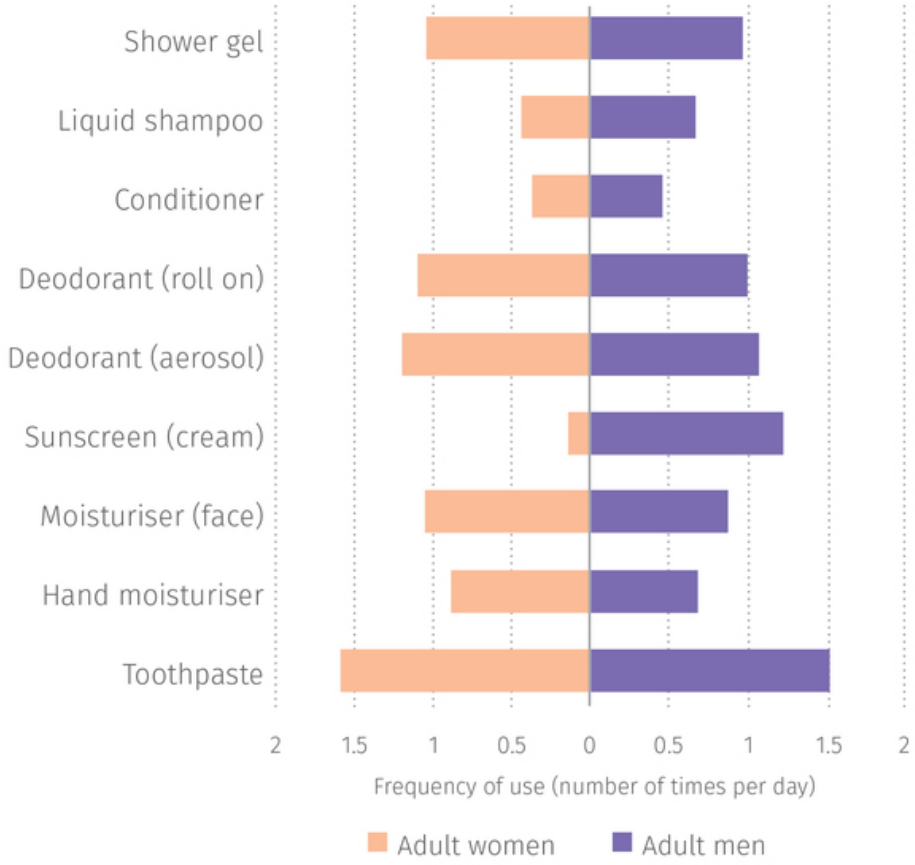
Approach 2: Quantifying substances in cosmetic products based on usage

A study in France looked into the frequency of daily use of a variety of cosmetic products[45], the results displayed in Figure 12.

[44] Cosmetics Europe (2019) Socio-economic contribution of the European cosmetics industry 2019. Available at: https://www.cosmeticseurope.eu/files/4715/6023/8405/Socio-Economic_Contribution_of_the_European_Cosmetics_Industry_Report_2019.pdf

[45] Ficheux et al. (2015) Consumption of cosmetic products by the French population. First part: Frequency data. Food and Chemical Toxicology 78: 159-169.

Figure 12: Frequency of daily use of personal care and cosmetic products[45]



Combining these daily frequencies with Eurostat population data[34], it is possible to quantify the number of 'doses' of each cosmetic product used annually in the different EU Member States and the EU-27. It is then necessary to define (i) the mass of product consumed in each 'dose' and; (ii) the percentage content of active ingredients in each cosmetic product (for example, parabens in cosmetics; triclosan in facial cleansers and soaps). The total quantity reaching waste water can be estimated as follows:

Mass of cosmetic product substance used per year = Population x Daily 'doses' of cosmetic product x Mass per dose x Percentage active ingredient content

The frequency data from the French study are not available for all types of products. In addition, data are available for aggregated classifications making it difficult to account for differences between different type of cosmetic products.

Approach 3: Quantifying substances based on Member State survey and JRC analysis

The JRC has developed estimates of concentrations of different substances before and after waste water treatment, which will in turn be used to estimate emission loads.

3.2.3.2. Step 2: Discounting unused cosmetic products

A portion of cosmetic products sold will remain unused. As summarised in Figure 11, unused products are typically flushed into waste water streams or discarded in solid domestic waste. The unused portion of cosmetic products are beyond the scope of this assessment, and the quantification focuses only on used cosmetic products. At present, there is insufficient information on the rates of unused cosmetic products to conduct a robust quantification.

3.2.3.3. Step 3: Projecting sales to 2050

The quantified masses of cosmetic products used can be projected into the future. This could follow a similar approach to that defined in **Step 5** of the APIs quantification. Projections can take the following approaches:

- A simple extrapolation of historical use trends;
- Pairing extrapolated per capita use trends with Eurostat population projections.

Depending on the historical data available, it is unlikely that any changes to trends associated with the Covid-19 pandemic will be accurately captured in the projection. Furthermore, they will also not take into account any changes due to sustainability reasons or listing of these substances in (environmental) legislation and/or strategies e.g. impacts of the European Pharmaceutical and Chemicals Strategies, Zero Pollution Action Plan etc.

3.2.3.4. Step 4: Quantifying the mass of substances in cosmetic products reaching waste water

The figures calculated in the preceding steps can be brought together to quantify the mass of substances in cosmetic products reaching waste water annually as follows:

Mass of cosmetic product substance reaching waste water = Mass of substance sold x Share of cosmetic product used

4. EPR SYSTEM FOR MICROPOLLUTANTS

As part of the UWWTD revision, the European Commission envisages to require of Member States that they implement the fourth treatment to some extent in order to reduce the exposure of citizens and ecosystems to micropollutants.

In the absence of an additional instrument, the cost of implementing the fourth treatment would need to be reflected in water tariffs, potentially differentiated between users[46]. However, a recent report by the European Court of Auditors shows that with current tariff systems, "polluters do not bear the full costs of water pollution"**Error! Bookmark not defined.**.

Therefore, an EPR scheme for micropollutants is thus explored as a tool to support this obligation of the fourth treatment and to improve the application of the PPP in this context.

The potential benefits of such an EPR system are:

- the availability of funds to finance remediation, i.e. fourth treatment;
- increased efficiency of the waste water treatment sector by introducing a dialogue between entities placing products on the EU market and the waste water treatment actors and making sure that eligible costs are based on cost-efficient processes;
- increased awareness of entities placing products on the EU market which can lead to prevention measures;

This section aims to define and assess the feasibility of a possible approach for an EU Extended Producer Responsibility scheme on micropollutants, especially its goal and targets, its organisation and the roles and duties of stakeholders.

Because existing EPR schemes are dedicated to different waste streams and not to waste water, some specificities related to the implementation of such a scheme for waste water have been identified and tackled, among which the definition of the type of products and substances that should be part of the scope, the organisation for paying the fees and receiving support, as well as registration and reporting requirements.

The definition of this potential EPR scheme is in line with relevant parts of the Waste Framework Directive, which sets minimum requirements for an EPR scheme in the waste sector.

4.1. Objectives

The generic objective of an EPR scheme for micropollutants would be to reduce the environmental and health impacts related to exposure to micropollutants by reducing micropollutants emissions in water bodies via urban waste water, and in water and soil via sewage sludge produced by urban waste water treatment plants (UWWTP).

This objective can be met in two main ways:

- Reduction of micropollutants release into upstream waste water
- Reduction of micropollutant discharge by Waste Water Treatment Plant (WWTP)

An EPR scheme can contribute to both objectives.

- By applying the polluter pays principle, the entities that place products on the market that later generate micropollutants can be encouraged to ecodesign to foster

[46] Article 9 of the Water Framework Directive, Ruling C-525/12 by the CJEU

prudent use and correct disposal of products that generate micropollutants. This is called a behavioural change.

- By directly financing the treatment of micropollutants in WWTP, the EPR system accelerates the roll-out of such treatment that would otherwise need to be borne by taxpayers or water users.

It should be noted that the EPR scheme is not considered as a way to reduce emissions of micropollutants from the industrial emissions; these emission sources are outside the scope of the present feasibility study and outside the intervention area of the UWWTD. They are notably tackled by the Industrial Emissions Directive (IED).

4.2. EPR targets

If the UWWTD were to impose an EPR scheme at EU level, **minimum targets should be set at the EU level** and should consider:

- **type of WWTP required to implement advanced treatment for micropollutants**

  Different criteria may be used to define obligated WWTP: size, dilution factor in receiving water body, the sensitivity of the receiving water body, etc. Potentially, substances in raw waste water could also be monitored to decide if a fourth treatment must be implemented. These options are further developed in section 5 on Definition of scenarios.

- **removal rate target:** efficiency of treatment for given reference substances.

  The JRC's work on treatment technologies has shown that in order to implement an efficient fourth treatment for micropollutants, it is necessary to have a "third treatment" in place that reduces nitrogen emissions. Nitrogen treatment is currently not implemented in all waste water treatment plants in the EU. However, as the third treatment is focused on nitrogen abatement, its costs are not directly related to the reduction of micropollutants and should not be covered by the EPR for micropollutants. Other EU instruments, such as the **obligation as part of the UWWTD to implement nitrogen treatment** whenever a fourth treatment is imposed, would be helpful for the implementation of EPR. The cost of nitrogen treatment (CAPEX, OPEX) may be covered by different instruments at the EU, MS or local levels: water tariffs, specific taxation or EPR schemes on nitrogen-producing sectors, and/or subsidies.

In order to ensure that the EPR system is proportionate, its ambition level (e.g., type of treatment required, number and type of substances covered, removal rate targets) needs to consider the cost of upgrading existing treatments on the one hand and the benefits of a reduced exposure on the other. The cost of upgrading existing treatment must be considered as a marginal cost.

4.3. Scope of EPR

4.3.1. Allocation of the financial burden between pollution sources

The waste water treatment system has two particularities that need to be addressed when applying the Polluter Pays Principle.

- **Different sources of waste water** are mixed in the urban waste water network: households, but also possibly runoff, effluents from small industries, etc. One given

substance can stem from multiple sources, and therefore the share of pollution responsibility between different sources cannot be distinguished at end-of-pipe.

Despite the fact that the EPR only aims to finance the fourth treatment for urban waste water, this calls into question if only the entities that place household products on the market should be called to pay for the fourth treatment or if other entities should also pay in proportion to their contribution to urban waste water pollution.

After analysing both options, it is recommended that only the entities placing products consumed by households on the market should pay for the fourth treatment because:

- most of the waste water load comes from households; industrial emissions being regulated via environmental permits, and larger industries have their own industrial WWTP;
- linking the concentration of micropollutants in waste water with emission pathways and sources in order to refine cost allocation between sources is difficult due to a lack of data;
- industrial producers who could be at the origin of the emission into the urban network may already contribute to EPR as entities placing on the market and be mobilised via that route;

- **Different categories of consumer products contribute to micropollutants pollution, some of them potentially not being covered by EPR initially or at all;**

  At the beginning of the implementation of the EPR scheme, only some sectors/products may be covered by EPR (e.g. this study analyses the potential to cover pharmaceuticals and Cosmetic Products, whereas other sectors could be included in the EPR later.

  This calls into question if the entities that place covered products on the market should be called to pay for the full cost of the fourth treatment or only in proportion to their contribution to urban waste water pollution.

  Data on input concentration to urban waste water has been used to compile the contribution of the different sectors to input load and input toxic-weighted load, both of which can be considered as relevant proxies of the treatment cost.

  It shows that pharmaceuticals and cosmetic products contribute to 73% of the input load to WWTP[47], 65% of the toxic-weighted load[48] based on the chronic toxicity indicator[49], and 92% of the toxic-weighted load based on the Potential No Effect

[47] Concentration of micropollutants entering WWTP

[48] Sum of ratios between micropollutants concentration and toxicity indicators (threshold concentrations). In this indicator, more importance is given to substances that are close to their respective toxicity thresholds.

[49] Chronic toxicity is the development of adverse effects as the result of long term exposure to a toxicant. Indicators used to measure toxic-weighted load are HC20 (sample standard deviation of EC10 which is the effect concentration at which 10% effect (mortality, inhibition of growth, reproduction, etc) is observed compared to the control group) or NOEC (the highest tested concentration for which there are no statistical significant difference of effect ($p<0.05$) when compared to the control group in long-term ecotoxicity studies)

concentration indicator[50]. The rest of the load mostly comes from substances that do not originate from consumer products (13% of the load, 1-2 % of toxic-weighted load: a significant amount of pesticides can originate from runoff, the "other" sector mostly includes industrial products). Food products and plastic additives can be related to consumer products but are relatively smaller contributors (7% and 4% of input load, respectively, 5 and 28% to toxic-weighted load chronic, and 1 and 3% of toxic-weighted load PNEC).

Therefore, it appears logical that the pharmaceuticals and cosmetic product sectors contribute to the total cost of the fourth treatment and that the smallest contributors[51] are exempted, at least during the initial stage. The PPP would be followed by ensuring that the main contributors pay and that the remediation cost is fully paid for, but without placing a significant administrative burden on the smaller contributors.

Food products and plastic additives could be asked to participate in a second stage, either in proportion to their contribution to the load or via a flat fee[52].

Table 10: Contribution of sectors to the input load to waste water

Sector	% of input load to WWTP	% of input load to fourth stage treatment	%of total toxic load (chronic)	% of total toxic load (PNEC)
Pharmaceuticals	59%	63%	48%	66%
Cosmetic Products	14%	9%	17%	26%
Pesticides	7%	8%	0%	2%
Household products[53]	0%	0%	0%	0%
Food product	7%	4%	5%	1%
Plastic additive[54]	4%	4%	28%	3%
Tobacco	0%	0%	0%	0%
Other[55]	6%	6%	1%	0%
Uncategorized	3%	5%	0%	1%
Total	100%	100%	100%	100%

Note: Primary, secondary and tertiary treatments reduce the load of chemicals and change the proportion of chemicals from the different sectors. The contribution of cosmetic products to the load entering the fourth treatment is relatively lower, whereas the contribution of pharmaceuticals is relatively higher.

[50] The predicted no effects concentration (PNEC) is calculated from toxicity tests to determine the concentration that is not thought to cause adverse effects to aquatic organisms

[51] Article 8a 1(d) of Waste Framework Directive - Member States shall ensure equal treatment of producers of products regardless of their origin or size, without placing a disproportionate regulatory burden on producers, including small and medium-sized enterprises, of small quantities of products.

[52] It is common practice in waste-related EPR that small producers placing less than X units on the market per year can be charged a fixed amount per year instead of a fee per quantity of product (examples include packaging EPR in Belgium, textile EPR in France or lubricants EPR in Belgium).

[53] includes biocides, surfactants and fragrances

[54] includes polymer starting materials, flame retardants, colorants, UV protectors

[55] industrial reagents, Industrial solvents, Heavy metals, Dyes, Illegal drugs

4.3.2. Scope of substances covered

In a waste-related EPR the relationship between product and waste is usually straightforward, one kilogram (kg) of product can be assumed to generate one kg of waste to be treated. An EPR for micropollutants is peculiar in the sense that the products placed on the market (pharmaceuticals or cosmetic products) are composed of substances that will generate micropollutants found in the effluents of WWTP, and also of other substances (rapidly biodegradable substances, harmless substances, inorganic substances) that will not need a fourth treatment. A correct application of the PPP should ensure that entities placing products on the EU market only pay in proportion to the additional cost of treatment, hence only for the former category of substances.

Therefore, a list of common criteria needs to be set at the EU level to establish which entities placing products on the EU market must be asked to pay and which must not. These common criteria must be set at the substance-level based on precise characteristics because no sufficient commonalities can be found :

- at sector-level. For example, there is no generic proportion of micropollutants inside cosmetic products since there are many formulations on the market.

- at product category-level. For example, oestrogen can biodegrade fast, but it is not the case for other categories of hormones;

These generic criteria could be listed as an Appendix to the UWWTD.

There is no known definition of micropollutants and no consensus over it in the scientific or policy world. In this report, micropollutants are defined as substances (including their breakdown products) that are usually present in the environment and urban wastewaters in concentrations below milligrams per litre and which can be considered hazardous to human health or the environment based on any of the criteria set out in Part 3 and Part 4 of Annex I to CLP Regulation[56].

Also, only organic substances are considered as part of micropollutants and will bear the cost of the fourth treatment because:

- EPR aims at financing the fourth treatment; only few metals and inorganic compounds will be affected by ozonation, and if they are, it could actually increase hazardous activity; treatment of these substances would thus not be financed via EPR;
- most concerning metals and inorganic compounds are regulated via REACH restrictions, but not the pharmaceutical sector; the focus should be placed on organic substances;
- heavy metals and inorganic compounds largely stem from diffuse pollution / can be attributed less to a given sector than organic substances, making them less relevant in an EPR.

Criteria to define the scope of substances that EPR should cover are further developed in the following paragraphs in view of including them in the UWWTD.

Inorganic substances

Inorganic substances and water contained in pharmaceutical preparations and Cosmetic Products should be excluded from the scope of EPR because the fourth treatment does not

[56] Regulation EC 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 353 31.12.2008, p 1).

target them. Inorganic substances can be defined as substances that do not contain carbon-hydrogen bonds.

Rapid biodegradability

Substances that rapidly biodegrade and mineralise before reaching the input to the fourth treatment should be excluded from EPR because they do not need to be treated.

Annex I, part 4 of the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[57] defines criteria for organic substances to be classified as rapidly degradable. According to this regulation, rapidly biodegradable substances can be quickly removed from the environment, and their effects – if any – can occur locally and for a short duration.

Several standardised methods enable to assess rapid biodegradability of organic substances:

Table 11: Standards to identify rapidly biodegradable substances

Method	Criteria	Conditions	Related standards[58]
Tests based on dissolved organic carbon (DOC)	≥ 70% degradation in 28 days	These levels must be achieved within 10 days after the degree of biodegradation has reached 10%[59]	OECD 309:2004[60] OECD 301:1992[61]
Tests based on oxygen depletion	≥ 60% of the maximum theoretical oxygen demand		OECD 301:1992
Tests based on carbon dioxide generation	≥ 60% of the maximum theoretical CO_2 production		ISO 14593:1999[62] OECD 301:1992
Tests based on BOD5/COD ratio[63]	BOD5/COD ≥ 0.5	Only if no other data is available	ISO 10708:1997[64]
Other scientific evidence (hydrolysis, degradation half-lives)	> 70% degradation in 28 days	Full mineralisation must be achieved or degradation profucts do not fulfil the criteria for classification as hazardous to the aquatic environment	-

57 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20211001

58 ISO/TR 15462:2006 gives an overview of biodegradation tests for the aquatic environment standardized by ISO

59 Unless the substance is identified as an "UVCB or as complex, multi-constituent substance with structurally similar constituents"

60 https://www.oecd.org/chemicalsafety/testing/33653757.pdf

61 https://www.oecd.org/chemicalsafety/risk-assessment/1948209.pdf

62 https://www.iso.org/standard/24154.html

63 Biochemical oxygen demand / chemical oxygen demand

64 https://www.iso.org/obp/ui/fr/#iso:std:iso:10708:ed-1:v1:en

In addition to standardised methods, other scientific evidence shows that degradation of the substance in the environment > 70% in 28 days can be used to classify a substance as rapidly degradable, provided that the degradation is demonstrated under environmentally realistic conditions (biotic and/or abiotic).

The following methods are mentioned in the (EC) 1272/2008 CLP Regulation:

- **Degradation half-lives**: These can be used in defining rapid degradation only if ultimate biodegradation of the substance (full mineralisation) is achieved. Primary biodegradation can suffice to define rapid degradation (>70% in 28 days), provided that the degradation products do not fulfil the criteria for classification as hazardous to the aquatic environment.
- **Hydrolysis**: This method can be used if the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment.

Degradation must be achieved under environmentally realistic conditions (biotic and/or abiotic).

In conclusion, the above-listed standards and methods listed as part of CLP could potentially be used to define rapidly biodegradable substances in the context of an EPR for micropollutants. However, a duration of 28 days is too long in the present context since the residence time of wastewater in the sewer network can be as short as a few hours[65]. Therefore, more research would be required to analyse the relevance and adaptability of the existing methods for micropollutants.

Harmless organic substances

Organic substances that are not classified as hazardous for the aquatic environment will be counted as rapidly biodegradable under the previously-mentioned definition.

One could argue that harmless substances that do not biodegrade (or only slowly) will also contribute to the consumption of reactants for the fourth treatment and should therefore pay for it. However, the cost of a fourth treatment is mostly related to the volumes of waste water to be treated and the need to treat hazardous substances. Therefore, it makes sense to exempt harmless substances from contributing to the cost of the fourth treatment and the financial burden to be shared only between hazardous substances emitting products.

Substances may be considered harmless if:

- they are not hazardous to the aquatic environment;
- they are not hazardous for human health (carcinogenic, mutagenic, reprotoxic, toxic or very toxic, harmful, sensitisers, corrosives, irritant[66])

Both chronic and acute toxicity shall be considered. Standards to test substances' hazards are listed in Annex I of CLP Regulation.

[65] Kapo et al. (2017) Estimation of U.S. sewer residence time distributions for national-scale risk assessment of down-the-drain chemicals *Science of the Total Environment* - median sewer residence time for the U.S. of 3.3 hours.

[66] Physical hazards are not relevant for wastewater emissions: explosive, oxidant and flammable substances

4.3.3. Implementation of the scope of substances

Producer Responsibility Organisations (PROs) will enforce these criteria by either adopting a list of substances inside the scope of EPR (positive list) or a list of substances exempted (negative list). On the one hand, the revisions of the list of substances should not be the sole responsibility of the PRO, as this could lead to a conflict of interest since a PRO is a representative of the entities placing products on the EU market, which could influence and bias the assessment. On the other hand, the participating companies would check each other as being part of the PRO, and peer pressure in the market could work. It could also be supervised by a competent authority at the MS level to ensure that the scope is based on criteria defined in the UWWTD, on clear evidence, and related to the polluter pays principle.

To anticipate the risk of having very different lists of substances depending on MS and PROs, leading to undesired market fragmentation, as well as to ensure economies of scale in the assessment of substances, the Directive should foresee that the European Commission adopts implementing acts. These texts could lead to a more precise definition of criteria and measurement standards or even draw an actual list of substances, potentially with the support of other European Agencies such as ECHA or a sectoral agency such as EMA (in the case of pharmaceuticals).

When setting a list of substances, a negative list should be preferred to a positive list because:

- It will be a shorter list;
- It is more precautionary: all new substances are included unless they are listed on the negative list, which needs to be based on evidence of passing exemption criteria;
- It will highlight virtuous substances based on exemption criteria (e.g. biodegradable) that should not be asked to pay, which can help to foster substitution by highlighting the way forward;

4.3.4. Scope overview

The following table (Table 12) summarises the different scope possibilities that have been considered according to the following criteria:

- **respect of the polluter pays principle:** all entities placing products that release micropollutants are concerned about their role in pollution control. On the other hand, the polluter pays principle can also be viewed as a Pareto approach which aims to tackle the most important sources of pollution (in terms of quantities, concentration or harmfulness).
- **distortion between sectors:** if some sectors are selected for the EPR (obligated) because they are the largest contributors to (hazardous) load, they may be unfairly burdened with the total cost if some other sectors are contributors to the (hazardous) load as well but do not contribute to EPR. This distortion depends on the share of obligated sectors to the total (hazardous) load.
- **ease of implementation:** the ease of implementation considers the simplicity of defining substance-specific fees, complexity of declarations, effluent monitoring, etc. The more substances and entities placing products on the EU market, the more complex the implementation.

- **reliability of declarations:** if the declarations are complex, companies may have a natural tendency to be less precise (especially on some substances that have lower contributions to the (hazardous) load-), leading to an increasing risk of free-riding or lack of precision.

- **administrative costs:** administrative costs are linked with the ease of implementation and costs of declaration audits. Additionally, the more substances and companies are included in the scope, the more expensive it is to declare because it takes more time to fill declarations, control, monitor and track free riders.

- **incentives to substance substitution:** If the number of substances in the scope is high, it may be less clear to companies which substances they should focus on for substitution. As a result, efforts may be diluted by a scattered approach to substitution without prioritisation. Companies' strategies may vary, and substitution for a given substance may take longer than if prioritisation had taken place.

Table 12: Discussion on the scope and its impacts on different criteria of EPR frame

+++ very high to --- very low

Alternatives for the scope of EPR	Polluter pays principle	No distortion between sectors	Easiness of implementation / Administrative costs	Declaration reliability	Substitution
All substances, all sectors	++	+	- - -	- - -	--
All substances, only 2 sectors (pharma & cosmetic product)	+	-	- -	- -	- -
A selection of substances[67], all sectors	+++	+	+	-	+
A selection of substances, only 2 sectors (pharma and cosmetic product)	++	-	++	+	++

In conclusion, we observe that if only a few sectors are covered by the EPR, this could lead to a greater distortion between sectors. However, this may lead to better efficiency of EPR with more reliable reporting and declarations, lower administrative costs, and better incentives for substitution. The choice of obligated sectors should rely on their contribution to the fourth treatment cost. If only some sectors are selected, then the polluter pays principle is interpreted as a form of the Pareto approach, meaning that the most contributing sectors should pay for the others. According to our assessments based on the list of around 1400 substances listed by JRC as relevant to water, the pharmaceuticals and

[67] This selection of substances that fall in the scope of EPR would be the result of a negative list.

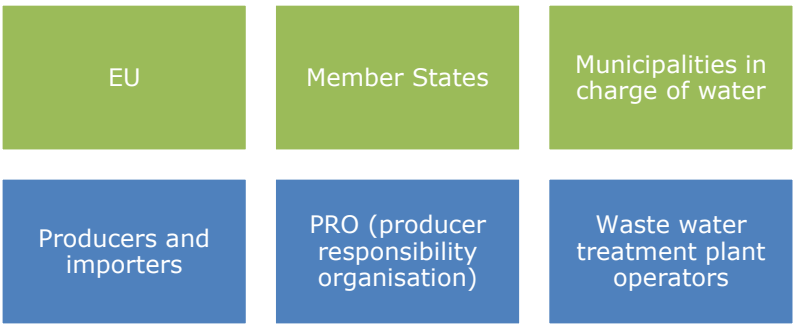
cosmetic product sectors are the main contributors in terms of concentration of micropollutants in waste water.

A selection of substances, if based on objective criteria that relate to the contribution to the cost of the fourth treatment (biodegradability), improves the application of the PPP. The selection of substances fosters substitution and could reduce the administrative burden while improving the reliability of declarations by focusing the scope on key contributors only.

4.4. EPR actors and roles

The actors that an EPR scheme for micropollutants may impact are presented in the following figure. Different schemas can be envisaged to distribute responsibilities between these actors and/or their role in the governance of the EPR scheme.

Figure 13: Actors potentially involved in an EPR scheme for micropollutants



4.4.1. Roles and responsibilities of stakeholders involved in the definition and implementation of EPR

The role of stakeholders involved in the EPR is clarified in the following paragraphs, in line with article 8 of the Waste Framework Directive.

4.4.1.1. EU

EU would define minimum objectives, targets, and common principles to be complied with by the Member States, in line with the generic principles of an EPR defined in the Waste Framework Directive.

The issues that should be defined at the EU level are detailed in section 4.5.1.

4.4.1.2. Member States

EU legislation should make Member States responsible for defining the framework of the EPR system and for overseeing the proper implementation of EPR, which covers especially the following points[68]:

- ensuring a good definition of EPR (scope, geography, type of WWTP) and not only from a profitability point of view;

[68] Article 8a 3

- clarifying the roles and responsibilities of the actors[69]; roles and responsibilities could be inspired by the discussions laid out in this section (4.4.1) of the report;

- ensuring that a reporting system is in place[70] and verifying its proper functioning[71] to collect data on products placed on the market and waste treatment;

- making sure that PROs have the financial and organisational means to meet the EPR obligations;

- requiring PROs to establish self-control mechanisms controlled by regular independent audits for both EPR financial management and quality of data collected and reported;

- providing public information on the EPR results (at least regarding ownership and membership, amounts of financial contributions and selection of operators).

- verifying that the EPR fully covers the cost of collection and treatment[72];

- verifying that entities placing products on the EU market and consumers are adequately informed;

- creating incentives for the waste holders to fulfil their responsibility;

- ensuring a regular dialogue between relevant stakeholders (entities placing products on the EU market and retailers, private or public waste water treatment operators, local authorities, civil society organisations, etc.)[73].
  Many EPR schemes in Europe have already implemented such dialogue:
  - either through specific commissions, where the different stakeholders regularly meet and discuss the results and roles of each other or the main issues to tackle; or
  - by requiring that different types of parties are included in the PRO boards.

In some Member States, this competency is further delegated to regional authorities.

PROs should be accredited by competent authorities to implement EPR based on evaluating a dossier demonstrating their technical and financial capacity to meet the minimum criteria set in national legislation and regulations (transposing the EU Directive, with potentially additional requirements).
Competent authorities will approve the dossier at a given frequency (every X years) and thus authorise the applicant to act as a recognised PRO and ensure producer responsibility on behalf of entities placing products on the market.

4.4.1.3. Producers and importers

Definition

Obligated companies will be the entities placing substances and/or products on the market which are responsible for micropollutants emissions. It appears easier to focus on the final

[69] Article 8a1(a)

[70] Article 8a (c)

[71] Article 8a 5

[72] Article 8a 4

[73] Article 8a 6

part of the value chain, i.e. to define obligated companies as "the entities placing products on the market that will release micropollutants in waste water" because:

- considering both (placing substance and product on the market) could lead to double counting of substances;
- the fate of substances during their use may affect the final load of substances in waste water; therefore, the type of product and end-use could be relevant to take into account when setting the fees, which can only be done at the product level.

Obligated companies can be:

- manufacturing companies based in an EU Member State in charge of formulating the final product (last manufacturers who transform substances into a final product) before placing it on the EU market;
- distributors/retailers of manufactured products if sold under their own brands;
- importers of products in the EU.

To connect with the terminology used in registration and reporting obligations applicable to pharmaceuticals and cosmetic products, this would mean the holder of an authorisation for medicines, the cosmetic manufacturer for cosmetic products, the importer, or the wholesaler.

Note: for the pharmaceuticals sector, pharmacies that make some in-house compounding could enter the scope of obligated companies. However, because these activities are small in quantities of preparations and turnover compared to commercial pharmaceuticals, they could be exempted[74] or only be charged with a flat fee[75]. This could be supported by the principle of equal treatment in the Waste Framework Directive[76] and the competent body in Member State should verify the relevance of their exclusion.

Linking sales declarations of products with the quantities of substances used and emitted via product consumption and emission factors is the simplest way to determine substance quantities due to data availability for entities placing products on the EU market. To make this link, good traceability must be managed throughout the supply chain and, in particular, with the producers of substances. The EU legislation already requires the product composition to be declared for both Cosmetic Products and medicines. The more effective the existing regulation is, the more reliable the data will be in view of EPR, particularly in terms of monitoring and tracking free riders.

Responsibilities

Entities placing products on the EU market must bear **financial responsibility** for the end-of-life of micropollutants released or generated by their products, meet mandatory targets and comply with the scheme's mandatory procedures (fee payment, reports and related evidence).

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[74] Garattini, L., Padula, A.: From pharmacy faculty to pharmacy shop: still a logical pathway in Europe? Drugs Ther Perspect. 34(2), 85–88 (2018)

[75] Examples of PROs having implemented a forfeit fee: VALORLUB for waste oils in Belgium, Fostplus for packaging in Belgium, Refashion for textiles in France

[76] Article 8a 1. d) ensure equal treatment of producers of products regardless of their origin or size, without placing a disproportionate regulatory burden on producers, including small and medium-sized enterprises, of small quantities of products

The producers will strive to do it at an **optimised cost**. This cost can be taken from their profit margin or transferred to the price of products.

They are incentivised and responsible for implementing eco-design actions that can reduce the micropollutant load in waste water (e.g., improved dosage, formulation, substance substitution), and provide information to users about the appropriate use and disposal of their products, including dosage. These measures may be required by the EPR scheme or adopted voluntarily to reduce their financial burden.

The more social security covers the possible price increase of the end product (in the case of pharmaceuticals), the less incentive is there for entities placing products on the EU market to implement eco-design measures (this case will only be explored if the industry decides to integrate the fees in the product price).

Note: The legal definition of EPR **allows entities placing products on the EU market to bear individual responsibility** for their products. However, individual responsibility is **impossible to implement** for micropollutants that are necessarily mixed with substances stemming from other entities placing products on the EU market (and sectors) and treated together at a WWTP. Hence, a collective organisation where entities placing products on the EU market of one or several sectors come together to finance a PRO which takes over their financial responsibility is required.

4.4.1.4. The Producer Responsibility Organisation (PRO)

The PRO is in charge of different actions that are defined in the Waste Framework Directive[77] through article 8 on how an EPR should be implemented and supervised by Member States:

- **Collecting the financial contributions** from obligated entities placing products on the EU market (so-called EPR fees) by contracting; these fees cover the financial means necessary to ensure that entities placing products on the EU market meet their obligations, i.e. **end-of-life treatment** via ad hoc contracts with the water treatment operators, **information** to entities placing products on the EU market and **reporting** costs with a principle of **full cost recovery[78]**;
    - these fees can be substance-specific;
    - an incentivising fee scale can be defined based on relevant parameters (hazardousness, excretion rates, substitution, etc.)[79]

[77] Directive 2008/98/EC of 19 November 2008

[78] Article 8.4.a ; Article 8 4 c) suggests that some exceptions are possible: Where justified by the need to ensure proper waste management and the economic viability of the extended producer responsibility scheme, Member States may depart from the division of financial responsibility as laid down in point (a), provided that:
(i) in the case of extended producer responsibility schemes established to attain waste management targets and objectives established under legislative acts of the Union, the producers of products bear at least 80 % of the necessary costs.

[79] Article 8.4. b of the Waste Framework Directive

- **Controlling free-riders**[80]. This responsibility falls on the PRO and public authorities[81];
    - Collecting and controlling declarations about quantities placed on the market by eligible entities placing products on the EU market;
    - Control that each producer declares in the appropriate fee level, potentially via mandatory reporting of entities placing products on the EU market.
- **Monitoring the achievement of EPR mandatory targets**, potentially with the support of partners (e.g., external audit companies, customs, associations representing entities placing products on the EU market, waste water treatment plants, etc.)[82];
- **Reporting to public authorities** and the public;
- **Informing other stakeholders** of their obligations and contracting with them to ensure the achievement of the EPR targets;
- **Informing the public** on actions that should be taken to reduce pollution due to the use of these substances;
- **Supporting R&D activities.**

Interface with two mains actors: entities placing products on the EU market and treatment plant operators

The **management of contracts** with both entities placing products on the EU market and with WWTP could be a major issue for a PRO, which will result in administrative costs.

Especially at the beginning of the EPR scheme, a PRO needs human resources to engage with its members, contracting procedures, etc.

These contracts define the roles and responsibilities of entities placing products on the EU market, PROs and WWTP operators. The data to be monitored and provided needs to be clearly defined as well as the reporting process (upstream declarations, downstream monitoring in waste water, etc.).

The EPR should ensure equal treatment of producers of products regardless of their origin or size according to the Waste Framework Directive.[83]

Monitoring issues

[80] Free-riders = Obligated producers that fail to declare quantities placed on the market and fail to pay their EPR fees.

[81] Depending on Member States, the role of public authorities ranges from pursuing free-riders identified by PROs to being responsible for a register of producers. Article 8.a (c) of the Waste Framework Directive stipulates that Member states shall ensure that a reporting system is in place to gather data on the products placed on the market of the Member State by the producers of products subject to extended producer responsibility and data on the collection and treatment of waste resulting from those products specifying, where appropriate, the waste material flows, as well as other data relevant for the EPR targets

[82] Article 8.5 expresses that Member states shall establish a monitoring and enforcement framework, which implicitly means that the producers and their representative organisation shall implement such monitoring

[83] Article 8.1.d Waste Framework Directive

Following **monitoring tools** are necessary for the PRO to ensure that a reporting system is in place, but it can also be managed by Member States.

- database or register of the entities placing products on the EU market that will be able to enter, each year, their data: tons of products/substances put on the market, excretion rates, etc.;

- database of efficiency indicators (e.g., treatment efficiency) to be reported and follow the EPR implementation.

The PRO will have to **cross-check the relevance of declarations** against other sources, such as data collected under mandatory regulations (product composition, excretion rates, possible substitution) and specific company-level surveys. They can also be helped in that task by Member states[84].

Clearinghouse

Due to the multi-sectoral approach of EPR for micropollutants, it is possible that several competing PROs are set up within a Member State or at the EU level. However, it is quite common that there is a dominant PRO on the market.[85]

In almost all cases, competition among PROs leads to the need for coordination by a central organisation which is recommended by the Waste Framework Directive[86].

The tasks of the clearinghouse, under the supervision of Member States, may include:

- Centralising and aggregating data reported and inspection of data quality and completeness ('Registry' role);

- Verifying compliance (free-rider identification) in cooperation with public authorities in charge of enforcement;

- Ensuring that all competing PROs work on a level-playing field by verifying that all requirements are met, including fair competition (e.g., no geographic repartition of their market or no specific focus on profit only); and

- Calculating market shares and ensuring a fair determination of the PRO's individual objectives.

In addition, and when necessary, cost-sharing related to specific operations can be organised (e.g. reimbursement of local authorities, national communication campaigns) through common agreements with local public authorities or joint calls for tenders. This structure may also manage common communication and R&D activities. The clearinghouse can also manage a common communication fund with contributions from each PRO's communication budget.

[84] Article 8.5 Waste Framework Directive

[85] Source: Development of Guidance on extended producer responsibility (EPR), European Commission, 2014

[86] Article 8.5. Where, in the territory of a Member State, multiple organisations implement extended producer responsibility obligations on behalf of producers of products, the Member State concerned shall appoint at least one body independent of private interests or entrust a public authority to oversee the implementation of extended producer responsibility obligations.

Member States shall ensure there is appropriate control of PROs activities, including their statistics and their financial data, where relevant, by requesting this control to be done independently by external audit companies financed by the PRO[87].

4.4.1.5. WWTP operators (private companies or municipalities),

Depending on the adopted scenarios, all operators managing WWTPs or only a part of them **will be required to implement the fourth treatment** and obtain a contract with the PRO to cover their CAPEX[88] and OPEX[89] and provide **adequate monitoring performance results,** with the intermediation of municipalities having delegated their water treatment competency to the WWT operators (public or private).

The contract could require minimal treatment performances, monitoring of discharges to waterbodies after treatment, and monitoring of discharges to sludge.

As the EPR aims at respecting the polluters pays principle, WWTP operators will pay attention to **full cost recovery** from the EPR scheme.

The EPR aims to focus on the marginal costs, which means only the additional costs compared with existing waste water treatment costs.

The perimeter of the costs of treatment to be considered may vary depending on:

- the decision to retroactively cover CAPEX for plants that have already put in place the fourth treatment. Plants with existing fourth treatment could receive similar downstream support than the plants being newly upgraded of the same size during a specific timeframe. Note that the CAPEX share of the total fourth treatment cost is low (Figure 14);
- the number of plants with already the third (nitrogen) treatment, which is a pre-requisite of the fourth treatment;
- other existing instruments.

Ideally, only the advanced treatment should be managed by EPR, while other costs should be covered by water tariffs and/or complementary instruments (e.g. regulation and a tax on the population to cover the implementation cost for nitrogen treatment, European regional cooperation fund, etc.).

Contracts between WWTP and PROs based on a reference support scale and performance incentives will contribute to increasing the cost-efficiency of WWTP.

[87] Article 8a 3b) of the Waste Framework Directive

[88] CAPEX = capital expenditure (all expenses to acquire, upgrade, and maintain physical assets such as property, plants, buildings, technology, or equipment)

[89] OPEX = operating expenses (costs a company incurs for running its day-to-day operations, for instance: rent and utilities, wages and salaries, accounting and legal fees, overhead costs such as selling, general, and administrative expenses (SG&A), property taxes, business travel, interest paid on debt

4.4.2. Other affected stakeholders

4.4.2.1. Consumers

Consumer behaviour may be affected by the EPR system. Depending on the EPR fees, the industry can decide to take EPR fees from their profit margin or incorporate the fees in the product price, which may influence consumption patterns. For pharmaceuticals, this effect will also depend on how the social security and pharmaceutical companies will react.

The PRO communication activities can also raise awareness and affect consumption, use, dosage and end-of-life management.

4.4.2.2. Role of social security and health insurance (pharmaceuticals)

Social security partially or fully covers the price of pharmaceuticals, depending on Member States and pharmaceutical categories.

Pharmaceutical companies may decide to take the EPR fees from their profit margin. If they decide to impact the product price instead, the reaction of social security schemes will influence the impact on consumers.

The negotiation margin between pharmaceuticals and social security schemes may influence the decision of producers to take EPR fees from their profit margin or not.

4.4.2.3. Citizens as water users

If the WWTP had already implemented nitrogen treatment, the additional cost of setting up the fourth treatment would be covered entirely by the EPR, and water tariffs would remain in the same order of magnitude.

However, for some WWTPs, a third treatment (for nitrogen) must be implemented before implementing the fourth treatment efficiency, and this will not be covered by EPR. In this case:

- either Member States decide to cover this through the public budget or via new instruments, or
- water tariffs will increase to cover the third (nitrogen) treatment.

4.4.3. Organisation

4.4.3.1. Financial versus operational responsibility

The EU definition of an EPR scheme, as expressed in the Waste Framework Directive, states that entities placing products on the EU market must bear financial responsibility or financial and organisational responsibility.

There are three main approaches: mere financial responsibility, financial and partial operational responsibility, or financial and full operational responsibility[90].

- **Mere financial EPR schemes:** In such schemes, the responsibility of operations is left to existing waste management actors (e.g., WWTP operators selected by municipalities or municipal operators) who must fulfil the targeted results in the

[90] Watkins, E., Gionfra, S., Schweitzer, J.-P., Pantzar, M., Janssens, C., ten Brink, P.: EPR in the EU Plastics Strategy and the Circular Economy: a focus on plastic packaging (2017)

exchange of (partial) cost coverage taken over by entities placing products on the EU market. The cost coverage is generally based on an optimized cost, usually estimated based on the cost of existing good-performing systems and/or the cost of available technologies with considerable improvement potential.

- **EPR schemes bear partial or full operational responsibility**: Two types of EPR schemes can exist depending on their implication in waste management operations:
    - either the entities placing products on the EU market, **select waste management operators** (i.e., WWTP) and contract with them so that they implement actions to achieve EPR targets on their behalf. It is assumed that the costs are optimised through competition between potential contractors.
    - or entities placing products on the EU market **take over part of the operations** (for instance, some specific facilities managed directly by them), some other operational activities being kept under the responsibility of actors that already manage waste (i.e., WWTP operators).

The main advantage of EPR schemes that ensure operational responsibility is that the entities placing products on the EU market directly oversee their waste management. Hence, it fosters ecodesign more efficiently as entities placing products on the EU market benefit directly from their effort in the treatment. As a result, it can also provide a broader global efficiency of the scheme.

On the other hand, simple financial responsibility ensures that waste water management operations remain organised by public authorities, responsible for ensuring a sound and clean environment[91].

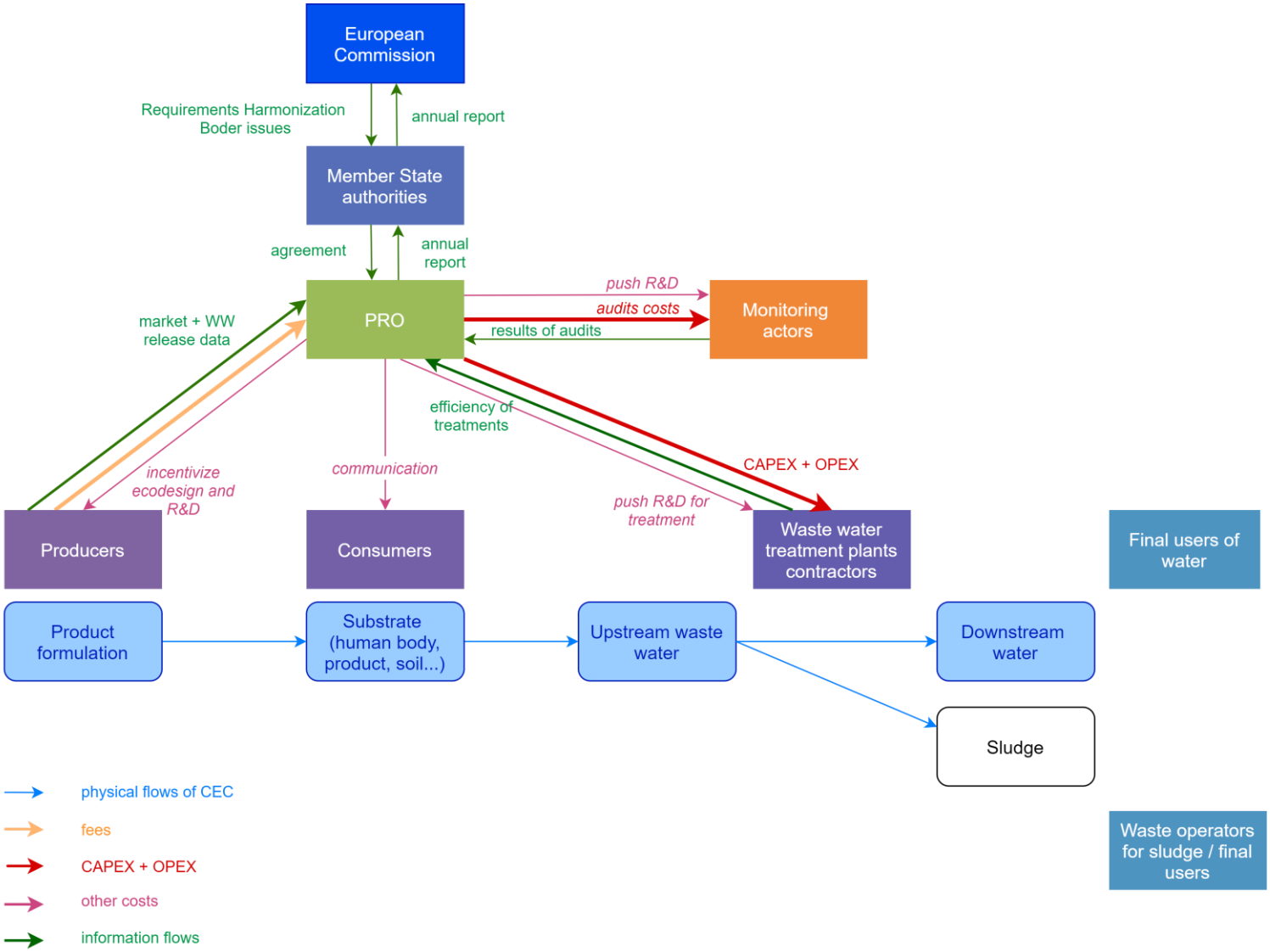
Looking at the specific case of an EPR scheme for micropollutants, there are significant advantages in using existing WWTP infrastructure and upgrading it to implement advanced treatment (reduction of infrastructure needs, economies of scale for monitoring, etc.). The existing waste water treatment infrastructure is managed by municipalities (or subcontracted to private parties), whose main purpose is to treat carbon and nutrient pollution, whose costs should not be covered by an EPR scheme for micropollutants. **Hence, a potential EPR scheme for micropollutants must be a financial scheme. In a financial EPR, operational objectives (e.g., targets) can still be set in the EU legislation and later reflected in contracts signed between PROs and WWTPs.**

4.4.3.1. Interaction between EPR stakeholders

The following figure presents the different interactions between stakeholders.

[91] Bio by Deloitte (2014) Development of Guidance on Extended Producer Responsibility (EPR). Report for DG ENV of the European Commission https://www2.deloitte.com/content/dam/Deloitte/fr/Documents/sustainability-services/deloitte_sustainability-les-filieres-a-responsabilite-elargie-du-producteur-en-europe_dec-15.pdf

Figure 14: Possible physical, financial and data flows between EPR stakeholders



4.5. Implementation issues for EPR

4.5.1. At which decision level should EPR issues be decided?

Defining an EPR for micropollutants at the European level can be more or less prescriptive, depending on the flexibility given to Member States to implement the principles in their own way, provided the overall objectives are achieved cost-effectively.

The following table presents the main implementation issues and discusses which level would be best suited.

Table 13: Issues on the level of implementation of EPR

Issues	EU, MS or PRO level?	Comments
General objective of the EPR	EU	The general objective (reducing environmental and human health impacts of micropollutants by reducing the load in water bodies and possibly via sewage sludge) has to be followed by all the EPR organisations in the different Member States. Multiple instruments can concur with this objective, including but not limited to EPR.
Sub-objective (of results): treatment efficiency	EU	The treatment efficiency objective will be set in UWWTD. NB: The treatment efficiency requirement is independent of the decision to set up a mandatory EU EPR scheme for micropollutants to finance the fourth treatment.
Sectors to be covered	EU	The selection of sectors for EPR at the EU level will allow for a more consistent approach, as the problematic substances are the same in the EU. The greater the number of sectors covered, the greater the number of PROs created (one per sector).
Contribution of each sector (percentage of the costs)	EU MS/PRO	Setting the principle for the distribution of costs between sectors is more consistent at the EU level. It would avoid distortion between companies and countries and a difference in mobilising a sector across the EU. Member States have to play a role in ensuring these principles are met and checking the full cost recovery. If a single PRO covers all sectors, the PRO will define the contribution of each sector. If each sector has its own PRO or if there are competing PROs in general, MS will have to oversee the repartition of contributions between PROs.
Scope of substances / new substances	EU	At the EU level, the definition of common criteria for a positive or negative list is necessary. The EC could foresee the possibility of adopting implementing acts specifying further criteria and assessment methods or drawing up the list of substances in case there is a lack of harmonisation and distortion between MS. Setting up the list at the EU level leads to economies of scale for assessing substances. It can provide a clear prioritisation for substitution (negative list). It limits cross-border problems as substances are considered in the same way on both sides of a border. At the EU level, the

Issues	EU, MS or PRO level?	Comments
	MS/PRO	support of EU agencies (ECHA, EMA) can be purposeful in setting this list (positive or negative). MS and PRO should oversee that criteria are complied with by obligated entities.
Scope of the costs to be covered	EU	A European clarification of eligible costs could stress that entities placing products on the EU market should not be asked to contribute to cover the costs of treatments that Member States should already have implemented to comply with the current UWWTD (e.g., the third treatment). This would ensure the Member States lagging on targets do not use EPR and affected entities placing products on the EU market to bridge a compliance gap. The principle of full marginal cost recovery could also be explained in EU legislation.
Cost allocation/fee modulation principles within a sector	EU MS /PRO	Generic cost allocation principles should be defined at the EU level, such as the principle of full cost recovery and the criteria to be considered for cost allocation: quantities, hazardousness, substitution potential, prices, etc. These principles enable more harmonised approaches between countries for more scientific robustness and fewer distortions across countries, especially on substitution push. MS and/or PRO will define more precisely how to apply these criteria (e.g. define the maximum level of fee modulation per sector) and exclude some criteria where justified.
EPR fee scale and cost allocation	PRO	The final fee scale should be defined at the PRO level to enable competition and update fees depending on financing needs. When MS excludes competition, the fee scale can be set in national regulations.
Reporting and monitoring obligations	EU MS PROs cooperation	EU should harmonise the type of statistics to follow and maybe their scope to harmonise the feedback from MS to the EC, especially in link with cross-border issues and UWWTD requirements. MS should implement the reporting to European Commission, especially if several PROs are present in their country. They should verify that the PROs do their job of reporting and self-controlling through audits on sensitive points such as free-riding, the efficiency of treatment, and full cost recovery. Reporting tools may be harmonised between PROs to ensure coherence and reduce administrative costs for entities placing products on several MS markets (e.g. WEEELABEX for WEEE EPR).
Downstream scale	EU / MS	Generic principles (scope of the costs, recovery of costs, taking into account other financial instruments) can be

Issues	EU, MS or PRO level?	Comments
		defined at the EU level and adapted when necessary at the MS level.
	PRO / MS / WWTP	The final downstream scale should be defined at the PRO level in collaboration with WWTP representatives under the supervision of MS or external auditors to ensure that all and solely necessary costs are covered.
Cross border issues	EU Coordination between MS	Check that every MS comply with their obligations regarding EPR. If some specific issues may occur in terms of cross-border issues, the discussion could be directly established between the concerned MS. However, the EU can define a general framework to organise these discussions (as the issues might be very similar)

4.5.2. Fee scale

The fee scale may be defined either at the Member State level or at the PRO level.

It must reflect the full cost recovery principle, the polluter pays principle and incentivise producers to change of behaviour, according to the Waste Framework Directive.

- Ideally, financial contributions paid by entities placing products on the EU market should be expressed **per amount of eligible substances** contained in products as operational treatment cost is proportional to the concentration level entering the fourth treatment. However, this approach requires large amounts of data to calculate the adequate fee level per substance, which will increase the administrative cost for the PRO and entities placing products on the EU market.
- A potential simplification of this approach is to have a common EPR fee **per group of substances or per type of product use**. Several approaches can be envisaged to define a group of substances: hazardousness level, chemical family, target organ (pharmaceuticals), and type of cosmetic product categories reflecting different proportions of substances likely to be emitted to waste water (creams, make-up, etc.). Considering existing legislation, defining such groups can be a difficult task, especially for cosmetic products, for which no common nomenclature of use exists. Some simplifications and proxies will be necessary.
- Finally, fees could be decided **per product weight**. The main advantage of an approach per ton of product is that data collection is much easier as it can be based on the sole evidence of quantities placed on the market. The drawback is that it does not fairly reflect the cost associated with individual products and can lead to some inequity between actors.

This basis for fee scale will be closely linked with the availability and accuracy of information to define the source impact pathways and related loss rate between products and substances placed on the market, final releases, and efficiency of the fourth treatment.

According to the EPR fee scale, some default data to model these pathways will have to be defined.

4.5.3. Fee modulation

The **fee modulation** could consist of two components:

- a "generic" fee for the substances considered as covered by the fourth treatment;
- a modulated fee.

The modulation could represent a difference in treatment cost (for instance, if some substances need the fourth treatment whereas others don't or if some need more reactant than others). However, no relevant difference in treatment cost depending on the type of substance has been identified. The modulated fee can also express the difference in harmfulness between substances: the more harmful they are, the higher the fee. This would imply a hazardousness assessment for each substance.

Considering the substance behaviour will not depend on Member State but vary based on common factors, using harmonised rules to define the principles of fee modulation at the EU level would lead to economies of scale to develop these factors.

According to the discussions of the two previous sections, the principles that could guide the fee scale definition can rely on:

- a general fee based on the product tonnages put on the market and based on the application of the 'true cost' principle as defined in the waste legislation;
- modulation of fees according to the harmfulness of the substances. A list of relevant hazardousness indicators should be recommended at the EU level: chronic toxicity and PNEC indicators appear more relevant than acute toxicity indicators to represent the environmental and health issues at stake;
- modulation of fees depending on the fourth treatment efficiency compared with the average required removal rate.

4.5.4. Downstream scale

The downstream scale aims at distributing the collected fees to WWTP according to their costs.

The downstream financial support shall cover the marginal cost for the fourth treatment (OPEX+CAPEX). Tertiary treatment should not be covered by downstream support.

Downstream support can be based on an average marginal cost by m³ treated, but it is recommended to refine the support scale to take into account the following:

- WWTP size (number of inhabitants covered by WWTP (person equivalent) or treated quantities (m³)) to give relatively more support to small WWTP per m³ treated due to lower economies of scale on CAPEX[92];

- measured efficiency of the fourth treatment (Abatement load rate) to give a performance incentive to WWTP[93].

Potential input load stemming from industries should be excluded from the support scale and pay for the fourth treatment via a dedicated tarification.

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92 Local context is taken into account in some existing EPR schemes such as municipal packaging EPR scheme. For example, in France, touristic activity is considered in the support scale calculation and a higher support scale is awarded to oversea territories.

93 Examples of performance incentive in municipal packaging EPR scheme. For example, in France, part of the financial support awarded by the PRO to municipal authorities in charge of waste management is based on an indicator calculated based on achieved material recycling rate by category of material.

4.5.5. Transboundary issues

Transboundary issues could occur in two cases:

1. If a Member State fails to implement EPR and fourth treatment adequately, this will result in undue emissions of micropollutants in neighbouring countries via transboundary movement of micropollutants;

2. If a product is purchased in one Member State but used in another, this will lead to distortions of economic flows between Member States because fees would be collected in the MS where the product is consumed while the cost of the fourth treatment would be borne in a different MS.

The first issue can be dealt with by ensuring that the EPR scheme is established at the EU level and that all MS comply with their obligations regarding EPR and by clarifying minimal requirements if need be.

On the second issue:

- urban waste water is treated locally and not exported. Therefore, product consumption in a Member State and emissions in waste water will be linked.

- some particular consumer practices may occur in cross-border areas, such as purchasing products (pharmaceuticals[94] or cosmetic products) in a neighbouring country. If such practices were importantly related to the EU market, some corrections might have to be implemented between PROs collecting fees and WWTP of the neighbouring countries that would have to pay for products bought in another country. We expect this effect to be marginal and balance out between countries and do not recommend that the EU impose MS to deal with it. It has to be noted that a clear definition of the scope and requirements of EPR in the EU legislation is needed to avoid differentiation of prices observed by consumers and preserve the internal market.

[94] Mostly over-the-counter medicines, though, since social security regimes encourages consumption of reimbursed pharmaceuticals in the country of social security affiliation.

5. DEFINITION OF SCENARIOS

Scenarios used to compute the cost of the fourth treatment and the cost of EPR reflect different compromises between the proportion of EU micropollutant emissions being treated and cost-effectiveness.

The proportion of EU micropollutant emissions being treated is reflected by the number of "Population Equivalent" required to implement the fourth treatment.

Cost-effectiveness will be ensured by making sure that the fourth treatment focuses on:

- the largest WWTP first because the marginal cost for the fourth treatment decreases with WWTP size, whereas the proportion of micropollutants being treated increases faster with large WWTP ;
- the WWTP that causes the highest adverse impacts first to ensure more benefits. Priority WWTP are the ones that discharge in sensitive areas (sensitive ecosystems, drinking water, low dilution rate etc.) or WWTP that discharge in already polluted water bodies (risk-based approach), potentially bringing hazardousness levels above thresholds of concern to human health or the environment.

After analysing the availability of quantitative indicators to reflect sensitivity, it was concluded that there is no consistent dataset in the EU to identify WWTP that discharges in sensitive areas such as drinking water catchments or Natura 2000 areas.

As for the risk-based approach, no consistent dataset could be identified to assess the risk associated with each WWTP in the EU with a meaningful indicator.

Approaches adopted by Switzerland and the Netherlands to define WWTP that shall implement the fourth treatment were analysed to explain how more detailed sensitivity and risk-based criteria can be applied when specific data is available and how such approaches compare to the selected quantitative scenarios. Discussion is provided in Appendix.

In this report, seven scenarios were developed, using several indicators to reflect the sensitivity of the area:

- the dilution rate D (effluent load/load of the receiving water body): the less the WWTP discharge is diluted in the receiving water body, the more potential impact it has on human health and the environment; therefore, 4th treatment should be applied first on WWTP having low D;
- discharge in coastal areas: WWTP located in coastal areas will see their discharge diluted, even if dilution is weak at the point of discharge per se thus, they will exhibit less impact on human health and the environment;

After concertation with JRC, seven quantitative scenarios were defined:

1. S1 – all WWTP having a WWTP size > 5 000 PE and D <100 are equipped with 4th treatment
2. S2 - all WWTP having a WWTP size > 50 000 PE and D< 100 are equipped with 4th treatment
3. S3 - all WWTP having a WWTP size > 50 000 PE and D< 10 are equipped with 4th treatment
4. S4 - all WWTP having a WWTP size > 100 000 PE and D< 5 are equipped with 4th treatment
5. S5.1 optimised: all plants above 100 000 PE and all plants between 10 000 and 100 000 PE with D <10 are equipped with the fourth treatment

6. S5.2 optimized+: all plants above 100 000 PE and 70% of the plants between 10 000 and 100 000 PE with D<10 are equipped with the 4th treatment. 70% is the estimated number of WWTP whose effluent would be classified as at risk for MP if local risk assessments were conducted. This value is based on surveys on European WWTPs, analysed by JRC, suggesting that approximately 70% of WWTPs could have an effluent close to or above the hazardousness threshold.
7. S5.3 optimized++: all plants above 100 000 PE and all plants between 10 000 and 100 000 PE with D <10 are equipped with the fourth treatment, except those whose discharge is located in coastal areas.

The table below shows the PE coverage and proportion of WWTP covered for each scenario.

Table 14: PE and WWTP coverage

	S1	S2	S3	S4	S5.1	S5.2	S5.3
Population coverage (in Population Equivalent)	70%	47%	34%	22%	63%	60%	59%
Number of WWTP	7329	1319	831	314	2862	2279	2114
% of WWTP covered	31%	6%	4%	1%	12%	10%	9%

The correlation between the scenarios and the terms of reference is discussed in Appendix.

6. ESTIMATION OF TOTAL EPR COST

Firstly, the marginal cost of treatment that results from an obligation to implement the fourth treatment is computed for the 7 scenarios and discussed. This estimation is valid, whatever the instrument is chosen to finance the fourth treatment (EPR or another).

Secondly, the administrative cost resulting from the choice to finance this fourth treatment via an EPR scheme is computed per scenario.

Thirdly, the total EPR cost is computed for each scenario.

6.1. Marginal cost of treatment

There are two types of marginal costs (CAPEX and OPEX) to upgrade the WWTP:

- secondary to tertiary treatment
- tertiary to fourth treatment

Secondary to tertiary treatment

As explained in the JRC paper[95], "The effluent of a biological treatment must meet the requirements of a biological plant with effective nutrient removal before we can implement an advanced treatment in a cost-effective way".

Implementing 4th treatment will require the implementation of nitrogen removal (3rd treatment), which is not yet generalised in the EU.

If a given WWTP needs to upgrade to tertiary treatment before implementing the fourth treatment, the cost of upgrading to 3rd treatment will not be charged to entities placing micropollutants on the market since it is aimed firstly at treating nitrogen. The cost would need to be reflected in water tariffs or passed on to the entities responsible for nitrogen pollution via different policy options.

As the EU plans to strengthen nitrogen removal requirements independently from the policy targeting micropollutants, it was assumed that the requirement to implement 4th stage treatment would not cause an additional upgrading cost. The cost of upgrading from secondary to tertiary treatment is thus not computed in this report.

Tertiary to fourth treatment

To compute the marginal cost (CAPEX and OPEX) of the fourth treatment, the JRC[96] cost function has been used. These cost functions have been applied to all WWTP covered in each scenario. Given the uncertainty of the cost[97], JRC used an average cost function, a lower bound cost function (min) and a higher bound cost function (max):

[95] Pistocchi et al. (2021), Treatment of micropollutants in wastewater: balancing effectiveness, costs and implications.

[96] Pistocchi et al. (2021), Treatment of micropollutants in wastewater: balancing effectiveness, costs and implications.

[97] The uncertainty comes mainly from the technology choice for the fourth treatment and the local operation conditions of the WWTP. Note that the sludge cost may vary (volume increase and change of use, especially with PAC) but is not a critical aspect of the total cost according to Alberto Pistocchi (JRC). The sludge cost variation uncertainty is encompassed in the lower and upper bound cost functions.

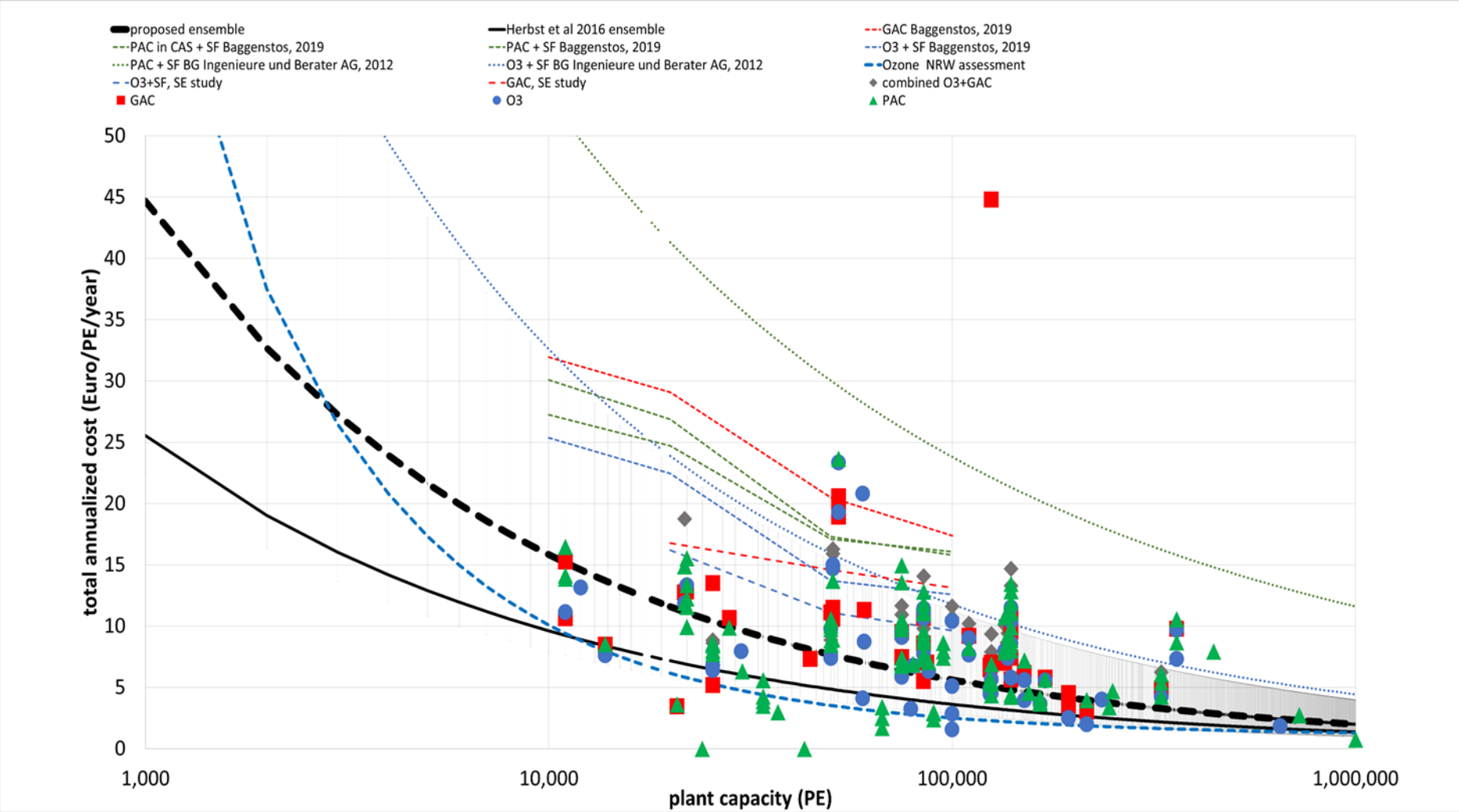
- Min: $500 * PE^{-0.45}$
- Average: $1000 * PE^{-0.45}$
- Max: $2000 * PE^{-0.45}$

  Where PE = treated loads in population equivalent of the WWTP

Figure 15 shows these cost functions and the case-specific cost data.

Figure 15: Comparison of cost functions and case-specific data.

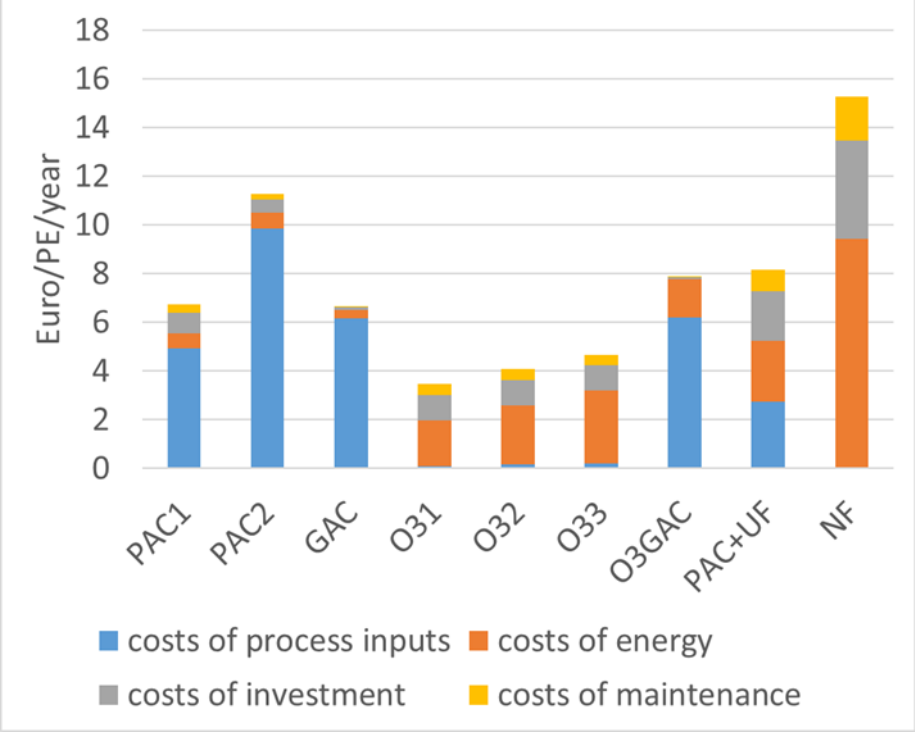
The proposed ensemble expenditure function is superimposed to the data with error bars representing a factor 2 variation.



Source: Pistocchi et al. (2021), Treatment of micropollutants in waste water: balancing effectiveness, costs and implication

Figure 16 presents the detailed cost structure for a representative fourth treatment configuration. The OPEX (costs of process inputs, energy, and maintenance) is significantly higher than the CAPEX (costs of investments).

Figure 16: Breakdown of costs of the nine representative configurations of advanced treatment for a waste water treatment plant of 50 000 PE



Source: Pistocchi et al. (2021), Treatment of micropollutants in waste water: balancing effectiveness, costs and implications.

For the disambiguation of the X-axis, see the table below.

X-axis code	Description
PAC1	Advanced treatment processes, Powedered Activated Carbon, after sec. treatment, 1.5 mg PAC/mg DOC
PAC2	Advanced treatment processes, Powedered Activated Carbon, into CAS, 2-3 mg PAC/mg DOC[98]
GAC	Advanced treatment processes, Granular Activated Carbon, EBCT[99] >20 min; v < 9 m/h >20,000 BVT[100]
O31	Advanced treatment processes, Ozone, <0.4 mg O3/mg DOC
O32	Advanced treatment processes, Ozone, 0.4-0.6 mg O3/mg DOC
O33	Advanced treatment processes, Ozone, >0.7-1.0 mg O3/mg DOC

[98] Dissolved organic carbon.

[99] Empty bed contact time.

[100] Bed volume time.

O3GAC	Advanced treatment processes, Ozone, 0.2-0.3 mg O3/mg DOC combined with Granular Activated Carbon, EBCT > 20 min; v < 9 m/h; BVT < 20,000
PAC+UF	Membrane filtration, Ultrafiltration + Powedered Activated Carbon, 15 mg/L
NF	Membrane filtration, Nanofiltration MWCO[101] < 200 Dalton

OPEX (costs of process inputs, costs of energy and cost of maintenance) is significantly higher than CAPEX (costs of investments). Inside OPEX, the cost of ozonation mostly comes from energy consumption for in-situ ozone production, and the cost of activated carbon treatment mostly comes from the consumption of activated carbon. In short, most of the cost of the fourth treatment comes from the dosage of activated carbon or ozone.

The dosage of activated carbon or ozone mostly depends on Dissolved Organic Carbon (DOC) and suspended solids concentrations in the influent. Micropollutants only have a small contribution to DOC (approximately 1mg/L micropollutants in the influent[102] compared to residual DOC after previous treatment stages (DOC threshold after tertiary treatment comprised between 5 and 10 mg/L). Some substances remaining in the effluents are inhibitors of ozonation (nitrite, bromide, iodide, carbonate ions, bicarbonates, hydrogen phosphates, etc.)[103] and further increase ozone consumption. Excess reactants may also be applied to reduce residence time and CAPEX (site-specific decision). Although some substances have stronger reactivity to ozonation than other substances depending on their functional groups[104], dosage does not depend on the detailed composition of the influent but aims at reaching an average treatment performance.

In conclusion, whether the fourth treatment is based on ozonation or adsorption technologies, the cost of the fourth treatment mainly depends on the properties of the water stream entering the fourth treatment independent from micropollutant concentration (mostly DOC). **In the end, for a given WWTP, the cost of the fourth treatment thus mostly depends on the water volumes to treat.**

Marginal cost of treatment - results

The marginal cost of 4th treatment at the EU level (cost of upgrading from third to fourth treatment, including CAPEX and OPEX) varies between 0.31 and 2.17 billion € per year, depending on the chosen quantitative scenario.

Figure 17 shows the total operational cost and PE coverage per scenario. Due to the variation in the number of WWTP covered by each scenario, there is a large variation in operational cost to upgrade the WWTP from the third to fourth treatment. In the most ambitious scenario (S1), 70% of PE is covered at a cost (fourth stage only) of 2.17 billion € per year. In the least ambitious scenario (S4), 22% of PE is covered at a cost of 0.31 billion € per year. S2 and S3 cover 47 and 34 of the total PE in the EU. The three optimised

[101] Membrane material, molecular weight cut-off.

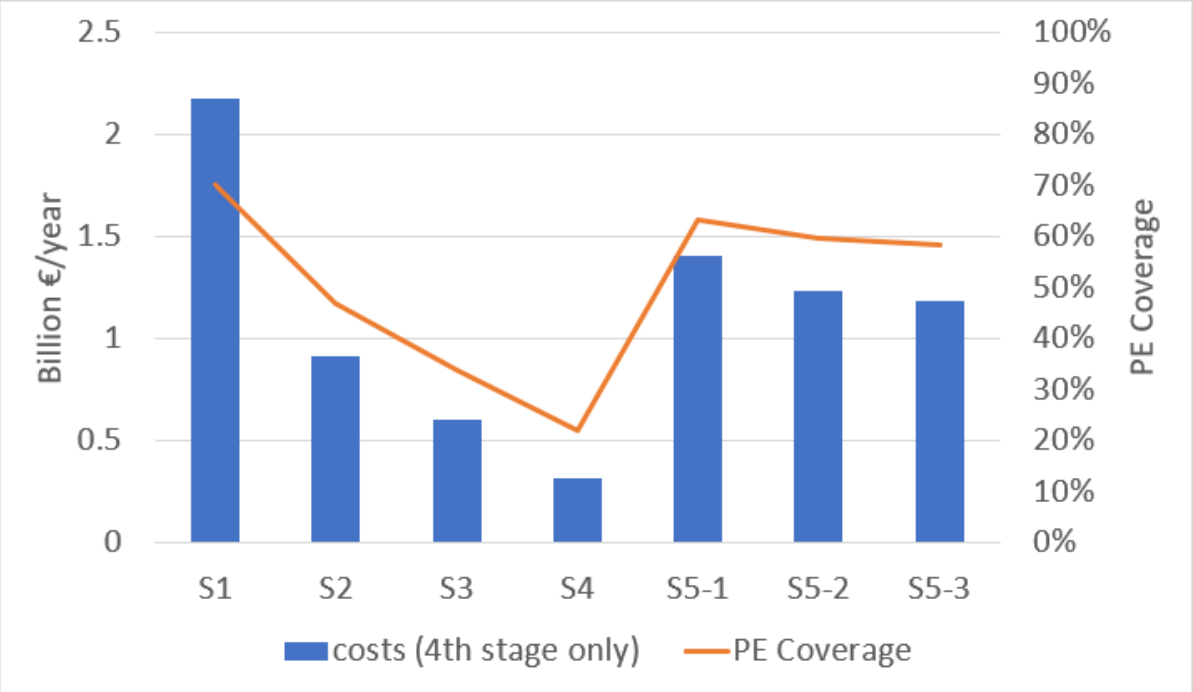
[102] Calculations made in this project based on concentrations by substance compiled by JRC Pistocchi et al. (2021)

[103] Gottschalk et al., 2009 Ozonation of Water and Waste Water: A Practical Guide to Understanding Ozone and its Applications

[104] phenolic groups, aromatic bonds, amines are more reactive based on Pistocchi et al. (2021)

scenarios, S5.1, S5.2 and S5.3, cover respectively 63%, 60% and 59% of the total PE at the following costs: 1.4 billion € per year, 1.23 billion €/year, 1.18 billion €/year.

Figure 17: Marginal cost of treatment (third to fourth) and PE coverage – Average value per scenario



NB: There is uncertainty over the cost of the fourth treatment based on treatment cost data collected by JRC due to differences in technology and setup. For each selected scenario, the cost of upgrading the WWTP from the third to fourth treatment is estimated with a lower bound, an average value, and a higher bound. JRC estimated uncertainty as a factor 2 around the average value. In other terms, for the most ambitious scenario (S1), the cost varies between 1.08 (lower bound) and 4.34 billion € per year (upper bound). For the least ambitious scenario (S4), the cost varies between 0.15 and 0.63 billion € per year. For the most optimised scenario (S5.3), it varies from 0.59 to 2.37 billion € per year. All estimates are provided in Appendix. In the rest of the report, values represent the average value.

6.2. Administrative cost

The administrative cost of the EPR encompasses the cost for the following actors:

- WWTPs
- Entities placing pharmaceuticals and cosmetic products on the EU market
- EPR organisations across the EU
- Member states

Additionally, as part of the UWWTD, WWTP will require quality control measures to measure fourth treatment efficiency. However, the cost of such quality control would also be required without an EPR and is not foreseen to be covered by the EPR.

Methodology

The administrative cost for the PROs has been assessed by carrying out a survey sent to 16 PROs across Europe. 5 PROs responded to the survey. The PROs were also consulted on the costs for entities placing products on the EU market (manufacturers, distributors and importers) to declare quantities placed on the market, but they could not give data related to those costs. These costs were thus taken from a study carried out for the PRO Fost Plus[105]. Finally, the costs for WWTP were determined through an interview with EurEau. Table 15 lists the data gathered and the associated sources.

Table 15: Intermediate data gathered to determine the total administrative cost of the EPR

Description	Data	Unit	Year	Source
WWTP				
Number of WWTP – S1	7 329	number of WWTP	2021	JRC
Number of WWTP – S2	1 319	number of WWTP	2021	JRC
Number of WWTP – S3	831	number of WWTP	2021	JRC
Number of WWTP – S4	314	number of WWTP	2021	JRC
Number of WWTP – S5-1	2 862	number of WWTP	2021	JRC
Number of WWTP – S5-2	2 279	number of WWTP	2021	JRC
Number of WWTP – S5-3	2 114	number of WWTP	2021	JRC
Average length of a contract EPR-WWTP	7.5	years	2021	EurEau interview
Time to organise a contract for the WWTP	40	hours/contract	2021	Assumption based on EurEau interview

[105] RDC Environment, Emploi et investissements liés aux activités de collecte sélective, tri et recyclage des projets FOST PLUS, 2000

Description	Data	Unit	Year	Source
One shot time to organise the EPR - WWTP (all)	81	FTE	2021	Assumption based on EurEau interview
PRO				
Number of FTE for the EPR in the EU	183	FTE	2021	PROs survey[106]
One shot consultancy cost to organise the EPR	1.3	Million €	1999 - 2006	PROs survey[107]
Number of days for financial audit per PROs and of the quality of the declaration and statistics of the PRO members	50	days/year	-	RDC Environment assumption
Entities placing on the market				
Number of companies (pharmaceuticals and cosmetic products)	70 440	number of companies	2018	Eurostat NACE[108]
Annual FTE for EPR	0.001	FTE	2000[109]	Fost Plus study[110]
One shot time to organise EPR	0.001	FTE/company	-	RDC Environment assumption
Overheads for the companies, EPR and WWTP	11	%	2021	PROs survey

[106] The extrapolation made is described in Appendix 12.6

[107] Average of the figures reported by the PROs in the survey, adapted to take inflation into account.

[108] The NACE categories considered are listed below. They comprise both producers and importers of pharmaceuticals and personal care products.
20.42: Manufacture of perfumes and toilet preparations
21.20: Manufacture of pharmaceutical preparations
46.45: Wholesale of perfume and cosmetics
46.46: Wholesale of pharmaceutical goods

[109] While the reference is a bit old, the principles still remain the same. Also, the declaration process is largely automated, so less human resources are needed and no significant impact on results.

[110] RDC Environment, Emploi et investissements liés aux activités de collecte sélective, tri et recyclage des projets FOST PLUS, 2000

Description	Data	Unit	Year	Source
Member States				
Number of days per Member State	20	days/year		RDC Environment assumption
General				
Average annual EU FTE admin cost	52,309	€/FTE	2021	Eurostat
Average annual EU FTE financial and insurance activities	82,430	€/FTE	2021	Eurostat
Average EU number of working hours per day	7.98	h/day	2021	Eurostat
Average EU number of working days per year	230	days/year	2000	Fost Plus study[110]
Amortisation of the one-shot cost	20	years	-	RDC Environment assumption

According to the NACE codes (Eurostat), the number of entities placing products on the market (i.e. the number of pharmaceuticals and cosmetic products companies) includes manufacturers and wholesalers, but not retailers. Besides, it was assumed that big companies selling or manufacturing products in more than one country within the EU are registered as distinct entities in the NACE database.

Results

The annual costs presented in this section comprise the one-shot cost (primary investments to implement the EPR at the WWTP, PRO and company level). To amortise this cost, it was assumed that the EPR scheme would be in place for 20 years.

Table 16: Total administrative cost

Scenario	Total annual administrative cost (€/year)
S1	17 503 563
S2	16 489 556
S3	16 407 221
S4	16 319 993
S5-1	16 749 891

Scenario	Total annual administrative cost (€/year)
S5-2	16 651 443
S5-3	16 623 689

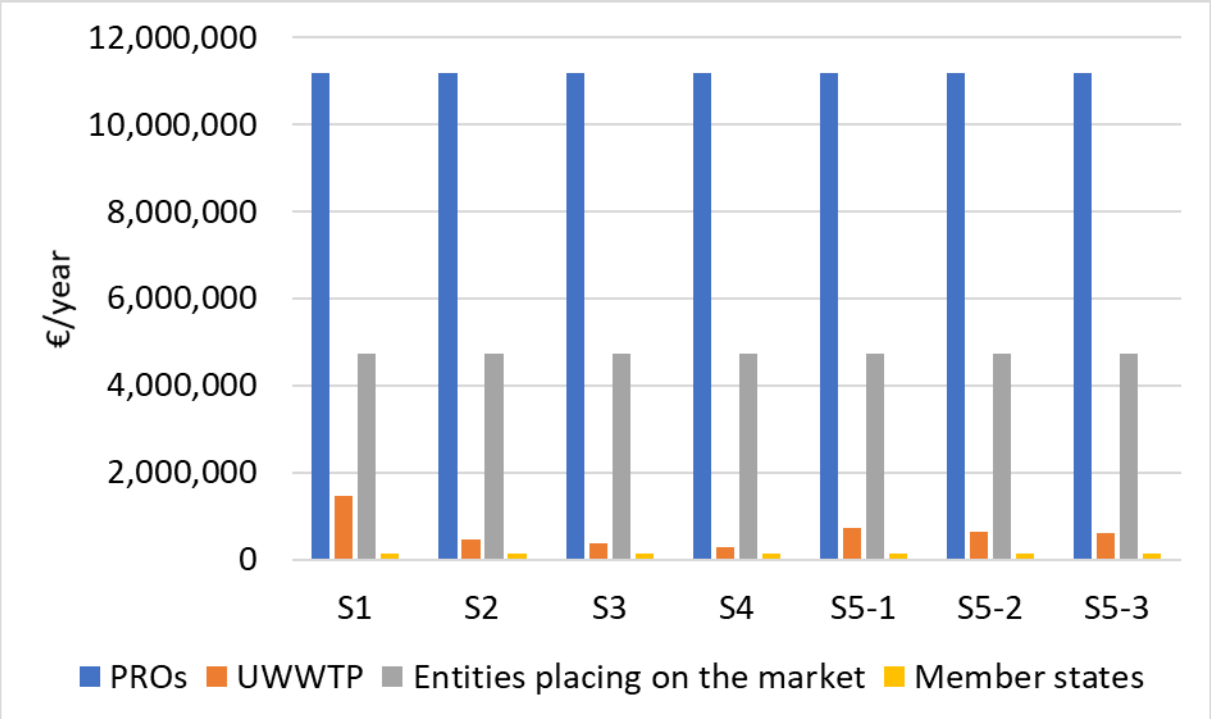
The total administrative cost varies between 16.3 and 17.5 million € per year.

As illustrated in Figure 17, the direct administrative cost of EPR to be supported by the PRO (PRO workforce and financial audits) amounts to 11,177 878 €/year (in blue). It does not vary across different scenarios.

The indirect administrative cost of the EPR varies between 5,142,115 and 6,325,686 €/year, depending on the scenario. This cost is to be supported respectively by UWWTP (in orange), the entities placing products on the EU market (in grey) and the Member States (in yellow). Entities placing products on the market will bear most of the indirect costs (time to organise the EPR and declare to PROs). The WWTP will bear a small part of the indirect cost (the cost of organising EPR and arranging contracts with the PRO, depending on the scenario due to the variation of the number of costs required to implement the fourth treatment). Member States will support a negligible fraction of the cost of supervising PROs. These costs are not accounted for in EPR fees.

The direct cost represents the largest share (more than 64% for all scenarios) of the administrative cost.

Figure 17: Administrative cost distribution (€/year) per scenario and actor supporting the cost – the direct costs are displayed in blue, the indirect costs in orange, grey and yellow



Note: PROs manage the finances and reporting, and the entities placing products on the market must set up a system to declare quantities and report to the PRO, pay the fees, etc. this is the administrative cost reflected in grey.

The direct administrative cost represents between 0.5 and 3.5% of the marginal cost of the fourth treatment (using the average cost estimate).

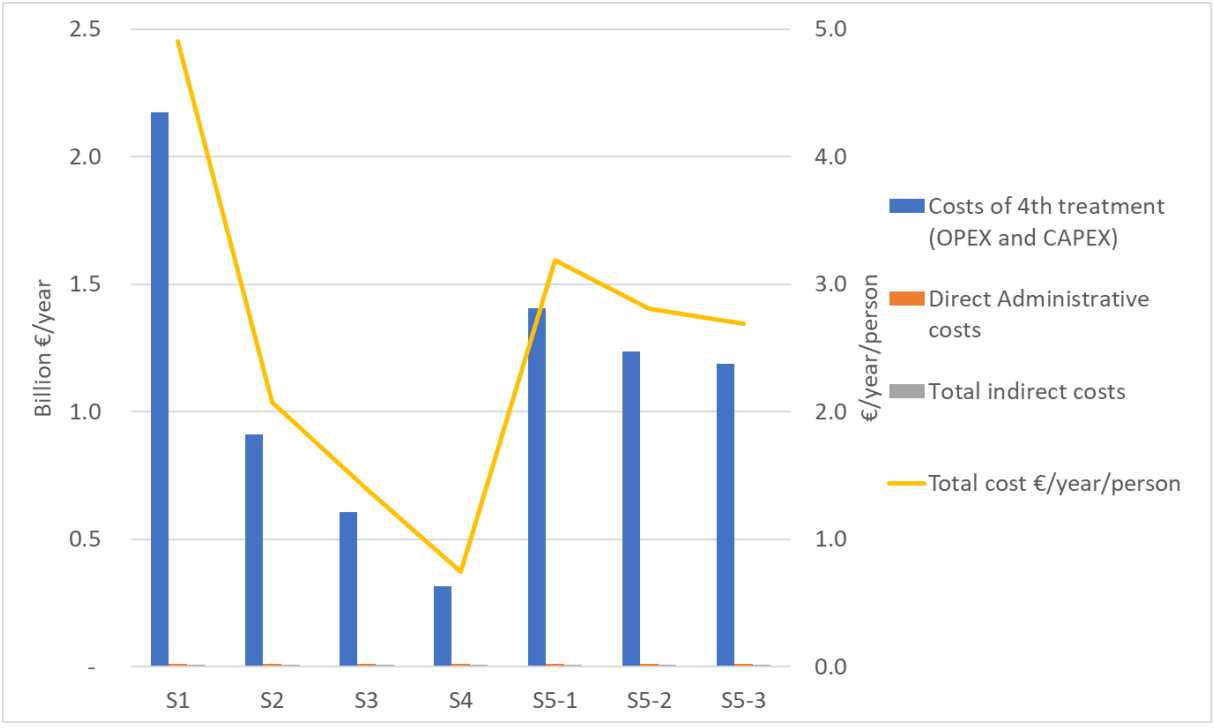
6.3. Economic impact of scenarios

6.3.1. Total impact

The total impact of each scenario includes the cost of upgrading from the third to fourth treatment and the administrative costs (direct and indirect). Compared to the upgrading cost, direct and indirect administrative costs are negligible in all seven scenarios. The economic impact of scenarios ranges between 332 million and 2,2 billion euros per year, depending on the scenario, which is equivalent to an economic impact of 0.74 to 4.90 €/year/person in the EU, depending on the scenario.

The total costs of each scenario are presented in the figure below, based on the average estimate for the cost of upgrading from the third to fourth treatment (blue bar).

Figure 18: Total costs of the scenarios



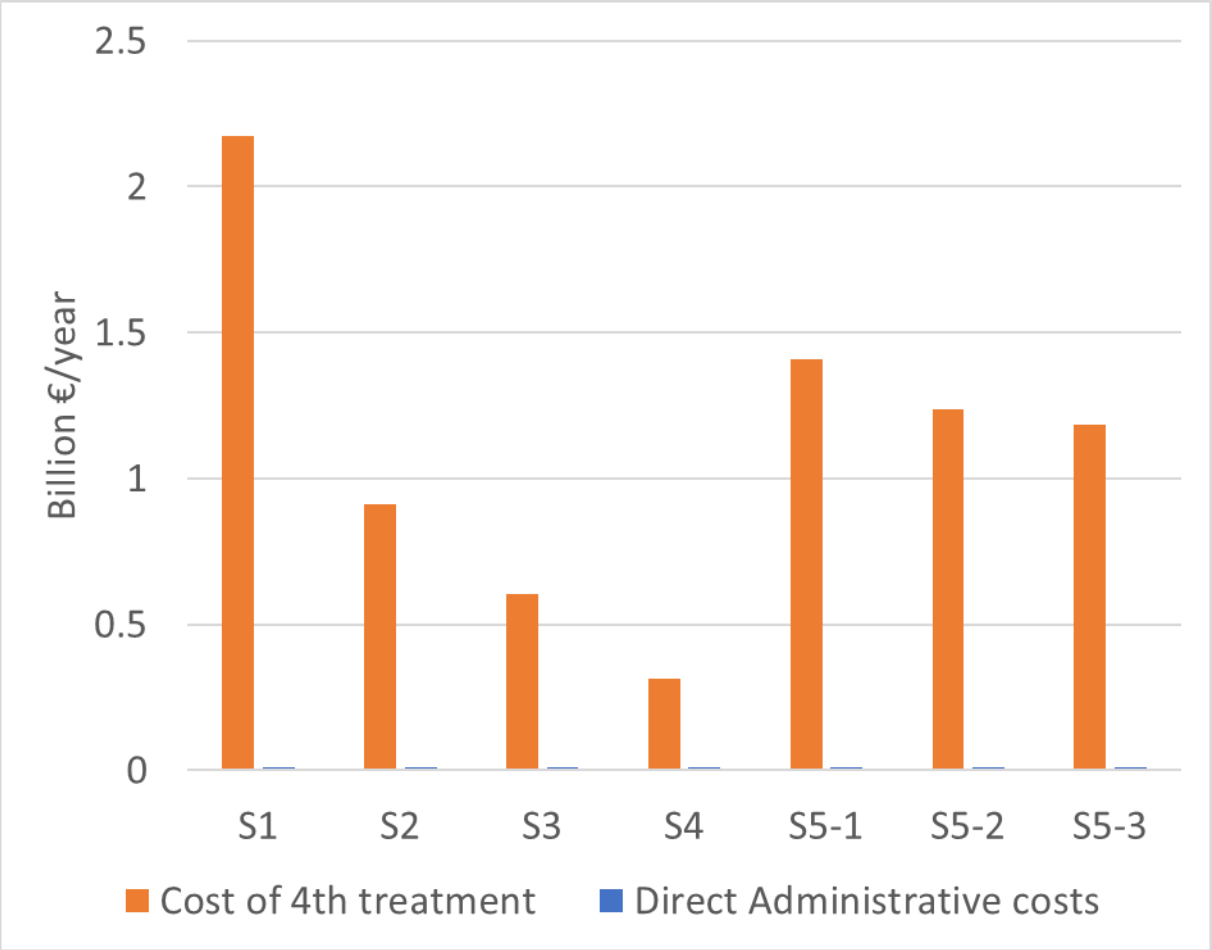
6.3.2. EPR fees

EPR fees paid by entities placing on the market to the PRO will need to cover the cost to upgrade the WWTP from tertiary to fourth treatment (CAPEX and OPEX) and direct administrative costs.

As shown in Figure 19, the direct administrative costs included in the EPR costs are negligible even in the lower bound cost estimations of the 4th treatment of the scenarios.

The average cost is presented in Figure 19 and varies between 0.31 and 2.17 billion € per year, depending on the scenario. Due to the uncertainty on the marginal cost of the fourth treatment, upper and lower bounds per scenario are also presented in Appendix.

Figure 19: Economic cost allocated to EPR (EPR fees) for different scenarios



6.4. Chosen scenario

After reviewing all 7 scenarios, scenario 5.3 is recommended. This scenario covers all plants above 100,000 PE and all plants between 10,000 and 100,000 PE with D <10, except those whose discharge is located in coastal areas.

Scenario 5.3 was chosen for its cost-efficiency:

- The focus on "WWTP above 100 000 PE" brings a high population coverage (59%) which is better than S2, S3 and S4 and similar to S5.1 and S5.3 while minimising the costs.
- The focus on "WWTP between 10 000 and 100 000 PE with D <10 except those whose discharge is located in coastal areas" prioritises sensitive areas, which was not the case for S1 and S2.

Scenario S5-3 optimized++ is used to calculate the relative impact of EPR on product price in section 7.5.

7. EPR FEES ALLOCATION

This section discusses ways to allocate EPR fees, which influence the relative impact compared to expenses for the affected products (section 7.5).

7.1. Definition and objectives

A cost allocation methodology enables to allocate the cost of an EPR scheme per sector, product category and between entities placing products on the EU market via an EPR fee scale.

The Waste Framework Directive foresees, in its article 8a §4, 3 principles that the Member States shall enforce:

- True cost: Financial contributions cover the full cost of waste collection and treatment for the products that the producer puts on the market, as well as stakeholder information, data gathering and reporting;
- Modulation: In the case of a collective EPR (it is the case here), "financial contributions are modulated, where possible, for individual products or groups of similar products, (…) taking a life-cycle approach";
- Cost-efficiency and transparency: "financial contributions do not exceed the necessary costs to provide waste management services in a cost-efficient way. Such costs shall be established in a transparent way between the actors concerned".

In existing EPR schemes for waste, financial contributions reflect the true cost of waste treatment because the fee level is defined per product category (€/kg, €/article, etc.) depending on each category's specific net treatment cost multiplied by volumes placed on the market.

In the present case, as discussed in section 6.1, the true treatment cost of micropollutants depends on the volumes of waste water treated. It does not depend on the volumes of micropollutants placed on the market and does not depend on substance characteristics. Sectors that generate micropollutants are responsible for the need to implement the fourth treatment and for its cost. Any type of allocation key between sectors or within a sector can reflect the true cost principle (by quantity, hazardousness, turnover).

Several allocation methods have been tested in this study to:

- identify how the cost could be distributed between sectors to estimate the impact on product prices and/or profit margins;
- discuss the influence of the choice of allocation key inside a sector on the impact on product prices and/or profit margins.

If an EPR for micropollutants is implemented, each PRO will define allocation, possibly under the supervision of MS if there are multiple PROs per MS (for example, one PRO per sector).

7.2. Methodology

7.2.1. Overview of allocation methods

The following cost allocation methods have been considered and are presented in **Table 17**:

- Quantity of substances placed on the market

This method is based on calculating the quantity of eligible substances placed on the market, without taking into account the proportion of substances that ultimately need to be treated by the fourth treatment.

- Quantity of substances entering the fourth treatment

  This method is based on calculating the quantity of substances found in waste water before the fourth treatment.

  In practice, if a PRO were to implement this cost allocation, the fee scale would be based first and foremost on substance weight placed on the market, and modulation criteria may be used to take into account excretion rates, potential degradability before fourth treatment or significant abatement by previous stages of WWT to reflect the quantity of substances entering fourth treatment.

- Hazardousness/environmental impact of the substances;

  This method is based on calculating the hazardous-weighted load of the substances. The hazardous load is the ratio between the concentration in waste water and a hazardousness indicator expressed as a threshold concentration.

  In practice, if a PRO were to implement this cost allocation, the fee scale would be based first and foremost on substance weight placed on the market, and modulation criteria may be used to take into account hazardousness indicators to reflect hazardous load.

Note that these cost allocation methods can be applied to allocate costs between sectors or product categories within a sector.

Table 17: Overview of the pros and cons of the cost allocation methods

Allocation method	Pros	Cons
Quantities of substances placed on the market	• Very easy to implement once PROs have collected declarations on product quantities placed on the market and product composition (feasibility)	• Does not take into account differences in emission pathways (excretion rates, biodegradability) – (true cost) • Does not take the specific hazardousness/environmental impacts into account (polluter-pays principle, incentive to substitute)
Quantity of substances entering 4th treatment	• Relatively easy to implement based on quantities placed on the market and fate factors • Substances degraded before the fourth treatment are not asked to pay (true cost)	• Information about excretion rates and substance behaviour is not consistently available today and requires producing new data (feasibility) • Does not take the specific hazardousness/environmental impacts into account (polluter-pays principle, incentive to substitute)
Hazardousness-weighted input load to 4th treatment	• Take into account the specific hazardousness/environmental impacts (polluter-pays principle, incentive to substitute)	• Limited data on the hazardousness of individual substances (feasibility in the short and medium-term)

Hazardous-weighted load entering the fourth treatment

Several hazardousness indicators can be considered. As part of this study, chronic and PNEC were favoured over acute toxicity, considering that the exposure to micropollutants via the environment is chronic. PROs could also envisage additional modulation criteria that were not computed as part of this feasibility study:

- Substitution potential: The EPR fee would be higher for substances that can be easily substituted.
- Share of substance quantity/toxic-weighted quantity that is not abated by fourth treatment: Substances that are not abated by existing technologies would pay more, encouraging substitution and research.

7.2.2. List of micropollutants considered

The allocation was based on the list of about 1,350 substances established by JRC as a proxy of the universe of chemical substances of concern to waste water. Firstly, it was necessary to refine the list to match it with the concept of micropollutants.

The list included some substances, such as ammonium or phosphate, which are out of the scope of the present study as they are treated by tertiary treatment. Some substances in the list are also found in concentrations higher than 100 µg/L in waste water which questions their place under the context of micropollutants (e.g. magnesium, iron, zinc, manganese).

Thus, all metals and inorganic substances (59 substances) were excluded from the list of substances to allocate costs.

7.2.3. Information about substance quantities

Because there is no consistent dataset yet on substance quantities placed on the market for cosmetic products, quantities entering WWTP were used as a proxy for quantities placed on the market to compute allocation between sectors. This neglects the influence of excretion rates and degradation in the sewer network. Allocation within the pharmaceuticals sector is tested based on information on quantities placed on the market.

JRC provides estimates of input concentration to UWWTP.

- For most substances, data is an average of different input concentration measurements to WWTPs. This estimate is assumed to represent an EU average, which is a limit of the exercise, considering the limited number of available measurements.
- For some substances, reported concentrations originate from the UFZ dataset and are based on output concentrations from WWTPs. Input concentration has been recalculated by considering data collected by JRC on the efficiency of existing UWWTP to treat micropollutants, i.e. output concentration is approximately 2/3 of input concentration[111].
- Substances concentrations are considered proportional to substance quantities. In other terms, the influence of variations of waste water volumes at the point of measurement is also disregarded.

For 76 substances whose concentration was missing in the JRC database, data gaps were filled by calculating the theoretical concentration of active pharmaceutical ingredients (API) in the waste water. This was estimated on the basis of the used mass of API in kg and JRC

[111] which reflects the poor removal efficiency of existing treatment processes on micropollutants

estimations of waste water volume at the EU level (73 m^3/PE/year). In order to connect quantitative estimates with hazardousness indicators from the JRC database and group of substances, ATC codes were mapped against CAS numbers of API and metabolites using the WHO database[112] and specific literature research. Often, one substance has multiple ATC codes, which reflect multiple therapeutical functions. In that case, the used masses corresponding to all ATC codes for which market data was available were summed to estimate the total mass of the active substance used. 100% of the used mass was considered as excreted API in waste water (100% excretion rate), which is consistent with market research. The concentration of 21 metabolites was corrected to 0 to ensure the consistency of the approach.

Allocation by quantities entering the fourth treatment is computed by applying treatment efficiencies after nitrogen removal (tertiary treatment) to concentrations entering WWTP. JRC has also provided treatment efficiencies.

7.3. Validation of the choice of priority sectors – contribution of pharma and cosmetic product vs other sectors

The choice of pharmaceuticals and cosmetic products as priority sectors for an EPR is supported by data on the distribution of concentration and toxic loads among different sectors emitting micropollutants. Indeed, the two sectors are the ones contributing the most to the chronic and PNEC total toxic-weighted loads: together, they account for 73% of micropollutant quantities entering WWTP, 72% of micropollutant quantities entering the fourth treatment, 65% of the total chronic toxicity load and more than 90% of the total PNEC toxicity load.

Table 18: Contribution of the sectors to concentration and toxic loads of organic substances

Sector	% of input load to WWTP	% of input load to fourth treatment	%of total hazardous load (chronic)	% of total hazardous load (PNEC)
Pharma	59%	63%[113]	48%	66%
Cosmetic products	14%	9%	17%	26%
Pesticide	7%	8%	0%	2%
Household product	0%	0%	0%	0%
Food product	7%	4%	5%	1%
Plastic additive	4%	4%	28%	3%
Tobacco	0%	0%	0%	0%
Other	6%	6%	1%	0%
Uncategorized	3%	5%	0%	1%
Total	100%	100%	100%	100%

7.4. Cost allocation by sector

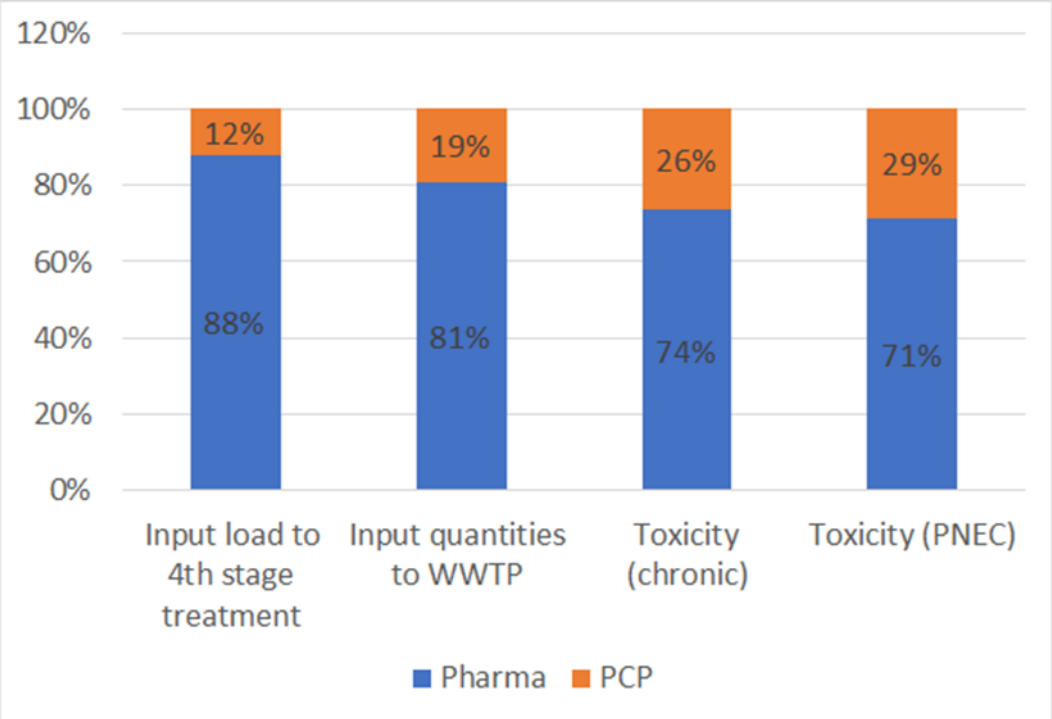
Considering that the cost of the fourth treatment is distributed between eligible sectors, the pharmaceutical sector will support 74% to 81% of the total EPR cost. In comparison,

[112] https://www.whocc.no/atc_ddd_index/ This database connects substance name with multiple ATC codes.

[113] This is a proportion out of 100% of the type of load described on the top row in order to allocate the cost. The total load is indeed lower after the first stages of treatment.

the cosmetic product sector will support 19% to 26% of the costs, depending on the selected cost allocation method.

Figure 20: Cost allocation per sector per allocation method



7.5. Limits of presented figures

Figures shown to illustrate the results of different allocation keys (quantity or hazardousness) should be refined once an EPR is in place because of:

- Data gaps (information used in this study was the best available information)
    - Depending on the sector, no information on concentrations could be identified for 25-56% of micropollutants.
    - No information on either chronic toxicity or concentration necessary to calculate the chronic toxic load used for cost allocation could be identified for 65-73% of substances, depending on the sector.
    - No information on either PNEC or concentration necessary to calculate the chronic toxic load used for cost allocation could be identified for 37%-60% of substances.
    - We did not consider the data gaps, i.e. no cost is allocated to substances with data gaps. It is impossible to assess whether this assumption underestimates or overestimates the share of cost allocated to cosmetic products or pharmaceuticals as both groups of substances have data gaps.

Table 19: Missing value rates for micropollutants substances by sector and indicator

	% of missing value		
Sector	Concentration	Chronic toxic load	PNEC toxic load
Pharmaceuticals	25%	73%	37%
cosmetic product	56%	65%	60%

- Assumption of representativeness
    - The concentration data compiled in the JRC database is the best available data, but it may not be deemed representative of average concentration in the EU. This limitation affects both the allocation by substance quantity in waste water and the allocation by hazardousness.
    - The reference waste water volume taken to calculate substance quantity based on substance concentration is 73 m^3/PE/year. It may not be representative of waste water volume at the point of measurement of individual substance concentrations depending on water consumption patterns inside the EU which could lead to overestimating or underestimating some substance quantities. This limitation affects both allocations by substance quantity in waste water and allocation by hazardousness.

Despite these limits, figures are presented to be able to give an estimate of the relative impact of EPR on profit margins or prices in the context of the impact assessment.

7.6. Discussion

Data gaps are typical of EPR prefiguration studies and do not compromise as such, the potential to set up an EPR scheme if they are complemented by PROs when setting up the EPR.

We have to distinguish two types of feasibility limits:

- Short-term limits reduce the reliability of figures presented in this report but not the intrinsic feasibility when rolling out the EPR

  Concentration data gaps are short-term limits. Micropollutant concentrations could be monitored at WWTP, and the robustness of the quantity cost allocation based on input concentration to WWTP or fourth treatment could thus be improved.

- Medium-term limits remain a challenge when rolling out the EPR

  For example, 73% of the substances for pharmaceutical products and 65% for cosmetic products do not have a chronic toxicity estimation. This data gap may not be resolved in the short term and alters the feasibility of using hazardousness indicators as modulation criteria comprehensively over the scope of substances. The modulation could instead be based on the volume of the substances/products placed on the market.

8. RELATIVE IMPACT ON PRICES AND MARGINS

The cost of EPR has been allocated between sectors based on the four different allocation keys presented in section 0.

The sectorial cost is then compared with expenses and margins to discuss the potential impact on consumers and the industry depending on the decision of the industry to pass the cost on to the consumer or reduce its margin.

For the pharma sector, the cost is also compared to

- product price by substance, which is not feasible for the cosmetic product sector due to a lack of data;
- expenses for social security

8.1. Methodology

8.1.1. Expenses by sector

To estimate relative EPR fees, i.e. EPR fees compared to the spending for covered products (pharmaceutical products and cosmetic products), we used household expenditure survey data[114]. The last household expenditure survey of Eurostat was completed in 2015, and the purchasing power parity expenditure per household for EU27 was:

- 276 € for pharmaceutical products
- 378 € for other appliances, articles and products for cosmetic[115]

We computed the spending per person based on the average EU27 household size[116] of 2.3 and the EU27 inflation[117] between 2015 and 2020[118].

Table 20: EU-27 average household spending in € per person per year

	€/person/year
Pharmaceutical products	338
Other appliances, articles and products for cosmetics * 68 %[119]	119

Source: RDC Environment computation based on Eurostat data

[114] Eurostat Mean consumption expenditure per household by COICOP consumption purpose [hbs_exp_t121].

[115] Note that this category includes more than "chemical" personal care products.

[116] Average household size - EU-SILC survey [ilc_lvph01].

[117] HICP (2015 = 100) - monthly data (index) [prc_hicp_midx].

[118] Inflation of 7.28 %.

[119] 68 % represents the share of the household expenses of the 12132A, 12132F and 12132G COICOP categories in the 1213 COICOP category (https://unstats.un.org/unsd/classifications/unsdclassifications/COICOP_2018_-_pre-edited_white_cover_version_-_2018-12-26.pdf) for Belgium. This data was not available for other countries. Therefore, we used the Belgian % and extrapolated to the EU average household spending of the 1213 COICOP category.

Note that some of the products included in the second category may not be covered by the future EPR[120]. Their proportion was estimated to calculate the expenses for products covered by EPR.

Household spending does not take into account the social security spending for pharmaceutical products. On average, the consumer pays about 38% of the pharmaceutical product prices, and 62% are covered by social security[121]. There are substantial variations of social security coverage across MS, but these should not influence the total cost calculation since both datasets are EU averages.

The total spending (by consumers and social security) for pharmaceutical products is estimated to be about 338 € per person[122]. To compute the relative price impact of EPR, we consider the consumer and social security expenses.

8.1.2. Profit margins

A literature review was carried out for profit margins related to specific products or product categories. This data is not available at this granularity but at the company level or for the whole sector. We, therefore, compiled profit margin data at the company (publicly available income statement of listed companies) or sector level (sectoral profitability or credit risk analysis).

Note that some companies sell a wide range of products and services, including some that are outside of the scope of this study. Profit margins are only available at the company level and not at the business unit level. This limit concerns principally companies selling cosmetic products because some of these companies have a diversification strategy while pharmaceutical companies sell mainly pharmaceutical products.

The operating profit margin between 2016 and 2020 was analysed using Reuters[123] data. Table 33 and Table 34 (in the appendix) detail the analysed companies.

"Operating profit margin" and EBITDA[124] are two metrics that measure a company's profitability. Operating margin measures a company's profit after paying variable costs before paying interest or tax. On the other hand, EBITDA measures a company's overall profitability, i.e. after paying taxes, but it may not consider the cost of capital investments like property and equipment."[125]

Pharmaceuticals

The weighted[126] operating profit margin between 2016 and 2020 ranges between 15 and 22%. The 5-year average is 19.48%. The operating profit margin per year for some companies is presented in Table 35 in Appendix.

[120] We considered the 12132A, 12132F and 12132G COICOP categories (https://unstats.un.org/unsd/classifications/unsdclassifications/COICOP_2018_-_pre-edited_white_cover_version_-_2018-12-26.pdf).

[121] https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf

[122] 129*(100/38).

[123] https://www.reuters.com/

[124] Earnings Before Interest, Taxes, Depreciation, and Amortisation.

[125] https://www.investopedia.com/ask/answers/010915/what-difference-between-operating-margin-and-ebitda.asp

[126] By the company revenues.

As highlighted in the Scope rating methodology report for pharmaceuticals[127], the EBIDTA depends on the type of pharmaceutical product: innovative pharma or generics. Due to the lack of pricing power, the EBIDTA is significantly lower for generics than innovative pharma. For the same credit rating[128], the generics EBIDTA margin is 10% lower than the innovative pharma EBIDTA margin. For innovative pharma, the EBIDTA margin range is generally above 20%, while for generics, it is generally between 10 and 25%. These ratings are the opinion of Scope about the likelihood a debtor will default (AAA means a very low likelihood of default, while B and below have a higher likelihood of default).

Table 21: Mapping of EBITDA margins to indicative ratings

EBITDA margin	AAA/AA	A	BBB	BB	B and below
Innovative pharma	>35%	30-35%	25-30%	20-25%	<20%
Generics	>25%	20-25%	15-20%	10-15%	<10%

Source: Scope (2021), Rating methodology Pharmaceuticals

Cosmetic products

The weighted[129] operating profit margin between 2016 and 2020 ranges between 14 and 20%. The 5-year average is 17.42%. The operating profit margin per year for some companies is presented in Table 36 in Appendix.

8.1.3. Price by substance (pharmaceuticals)

Price information by substance was searched for three EU countries for which data was available (France, Germany and Spain[130])[131]. Expenses per person per year for those 12 substances were computed by compiling this price information with average consumption in kg/inhabitant/year derived from EU average market information. Note that there is significant variability in the price of substances between countries which is why data has been searched in several countries to present the variability of situations.

8.1.4. Social security expenses (by substances for the pharmaceutical sector)

Social security expenses for health for the EU27 was computed based on Eurostat data on total public expenses for health as an average for the years 2016 to 2019[132]. No information was identified about the share of social security expenses allocated for pharmaceutical products.

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[127] https://www.scoperatings.com/ScopeRatingsApi/api/downloadmethodology?id=e405657f-f419-497d-b67c-b33c29d7f9a8

[128] A credit rating is an evaluation of the credit risk of a prospective debtor (an individual, a business, company or a government), predicting their ability to pay back the debt, and an implicit forecast of the likelihood of the debtor defaulting. Kronwald, Christian (2009). Credit Rating and the Impact on Capital Structure. Norderstedt, Germany: Druck und Bingdung. p. 3. ISBN 978-3-640-57549-7.

[129] By the company revenues.

[130] We also used price data from Sweden when there was missing data for one of the three countries.

[131] See the websites we used to calculate the price for each substance in Appendix, Table 40.

[132] Source: https://ec.europa.eu/eurostat/databrowser/view/GOV_10A_EXP__custom_1506131/default/table?lang=en

8.2. Results

8.2.1. Impact on the product price

This section shows the maximum price impact if a producer decides to pass on 100% of EPR fees on the product price.

8.2.1.1. By sector

Table 22 below shows the impact of EPR fees on expenses for pharmaceuticals and cosmetic products depending on the allocation key.

Based on scenario 5.3 optimised ++ (average estimate of 4th treatment cost), EPR will result in a maximum price impact of 2.68 €/year/person, 1.9-2.4 €/year/person for Pharmaceuticals and 0.3-0.8 €/year/person for cosmetic products depending on allocation key.

Table 22: Maximum absolute price impact for Pharmaceuticals and cosmetic products (€/year/person)

Scenario	Sector	Unit	Allocation keys			
			Quantities entering WWTP	Quantities entering 4th treatment	Toxicity (chronic)	Toxicity (PNEC)
S5.3	**Pharma**	€/year/person	2.35	2.17	1.97	1.91
	cosmetic product		0.32	0.51	0.71	0.76
	Total		2.68	2.68	2.68	2.68

Table 23 below shows the relative impact of EPR fees on expenses for pharmaceuticals and cosmetic product depending on the allocation key.

Table 23: Maximum relative impact compared to expenses for Pharmaceuticals and cosmetic products

Scenario	Sector	Unit	Allocation keys			
			Quantities entering WWTP	Quantities entering 4th treatment	Toxicity (chronic)	Toxicity (PNEC)
S5.3	**Pharma**	% Expenses	0.70%	0.64%	0.58%	0.57%
	cosmetic product		0.27%	0.43%	0.59%	0.64%
	Both sectors		0.59%	0.59%	0.59%	0.59%

If 100% of the cost of EPR is passed on to product prices, consumers will see a price increase ranging between 0.57% and 0.70% on average for pharmaceuticals, and 0.27% and 0.64% on average for cosmetic product, depending on the allocation key.

The detailed discussions about the cost allocation results by allocation rule are provided in the Appendix.

8.2.1.2. Within a sector (pharmaceuticals)

Each PRO will decide cost allocation within a sector. This section aims to discuss potential ways it could be done and its influence on the relative price impact of pharmaceutical products.

With scenario 5.3, assuming that costs are allocated based on quantities placed on the market, the fee would reach a few dozen €/kg for pharmaceuticals and cosmetic products (further information in Appendix 12.7.2). With this simple allocation choice, most pharmaceutical substances will see a negligible impact since their selling price is a few orders of magnitude higher. However, with this allocation choice, the relative impact on prices or margins would be significant for some substances that have a relatively lower selling price, such as generic pharmaceuticals (e.g. paracetamol price ranging between 63 and 240 €/kg in Spain and France, respectively), and if that cost was fully passed on prices, it could result in a significant product price impact for these particular substances (e.g.12-45% for paracetamol). The impact on consumer prices would be limited if the industry could partially cover this cost increase from its profit margin. This example with generic pharmaceuticals shows the influence of cost allocation choices and the importance that PROs design them well.

Because the marginal cost of the fourth treatment is directly proportional to the volumes of waste water to treat, any type of allocation between substances can reflect the true cost principle. Consequently, PROs may choose an allocation by quantity and accept this significant effect on prices for some substances, considering that the total impact on consumer expenses and impact on the sector remains limited. Alternatively, they may choose to consider other criteria besides quantities to set their fee scale within a sector, such as hazardousness indicators or turnover of entities placing products on the market, in order to make sure no individual substance sees a major impact on prices (e.g. for paracetamol: 0.4 to 1.5% relative price impact using the chronic toxic-weighted load and 0.5-0.7% price impact using turnover[133]).

The influence of the allocation methodology on the relative price impact is provided in Appendix 12.7.2 for the 12 most-sold substances.

8.2.2. Impact on margins

8.2.2.1. By sector

<u>Pharmaceuticals</u>

Table 25 presents the impact of EPR fees on the profit margin of the pharmaceuticals sector if producers decide to take the full cost of EPR in their margin (scenario 5.3 optimised ++ based on the average cost estimate for the fourth treatment). Allocation between pharmaceuticals and cosmetic products is based on input to WWTP (a proxy for quantities placed on the market).

The margin was calculated based on turnover (expenses without 0 to 25% VAT depending on products and countries) and a 10-35% margin rate.

In Table 39 and Table 25., margins after EPR are presented. A worst-case situation is presented on the left when the profit margin is computed with the low margin rate (10%) and high VAT rate. A best-case scenario is presented on the right when the profit margin of the cosmetic product sector is computed with the high margin rate (35%) and low VAT rate. In both cases, the cost remains lower than the profit margin. Margin decreases by

[133] Assuming 100% EPR fees is passed on price

0.6-0.9 percentage points in best- and can reach a minimum of 9.2% in the worst-case situation.

Table 24: Impact of EPR fees (scenario 5.3) on the pharmaceuticals sector profit margin

Margin after EPR fees with 10 % as a starting point		Margin after EPR fees cost with 35 % as a starting point	
25% VAT	**0% VAT**	**25% VAT**	**0% VAT**
9.2%	9.4%	34.2%	34.4%

Cosmetic products

Table 25 presents the impact of EPR fees on the profit margin of the cosmetic product sector if producers decide to take the full cost of EPR in their margin (scenario 5.3 optimised ++ based on an average cost estimate for a fourth treatment).

The profit margin was calculated based on turnover (expenses without 20% VAT) and 14-20% margin rate.

In Table 39 and Table 25, profit margins after EPR are presented. A worst-case situation is presented on the left when the profit margin is computed with a low (14%) rate. A best-case scenario is presented on the right when the profit margin of the cosmetic product sector is computed with the high margin rate (20%). In both cases, the cost remains lower than the profit margin. The profit margin decreases by 0.5 percentage points in the worst and best-case situations.

Table 25: Impact of EPR fees on the cosmetic product sector profit margin

Scenario 5.3, impact on the margin	
Margin after EPR fees with 14 % as starting point	Margin after EPR fees cost with 20 % as starting point
13.5%	19.5%

8.2.2.2. Within a sector (pharmaceuticals)

If the cost of EPR is fully absorbed into profit margins with a cost allocation based on quantities placed on the market:

- impact on profit margins is moderate in the best-case scenario (high prices and high margins): substances with high selling prices, such as lactulose or aciclovir, see no significant effect on margins. For cheaper substances, the maximum profit margin reduction is 13 pts for paracetamol and 7 pts for other substances.
- impact on profit margins is significant in the worst-case scenario (low prices and low margins), with the cost of EPR exceeding profit margins for some of the cheapest substances (e.g. paracetamol). In such an extreme case, an impact on prices must be expected (maximum impact discussed in section 8.2.1).

These results demonstrate the drawbacks of an allocation of EPR fees by quantity.

As an alternative, if PROs decide to incorporate hazardousness indicators for fee allocation, the cost of EPR fees will be distributed very differently. The impact on the profit margin for paracetamol is reduced by 1.1 to 3.8 percentage points using the chronic toxic-weighted load as an allocation basis. For other top-sold substances for which toxicity data is available (metformin, acyclovir, amoxicillin), profit margins are not significantly affected by EPR fees.

The influence of the allocation methodology on margins is further discussed, including quantitative results for the 12 most-sold pharmaceutical substances in Appendix 12.7.2.

8.2.3. Impact on social security (pharmaceuticals)

If EPR fees were fully passed on to social security expenses as part of negotiations between pharmaceutical companies and social security, public expenses for health would increase by 0.97 billion €/year for EU 27[134], which accounts for only 0.1% of public expenses for health.

8.3. Conclusions

Using scenario 5.3, the study shows that, whoever absorbs the cost of EPR (consumer via price increase, entities placing products on the market or social security, if national schemes decide to absorb the EPR fees in social security allowances as part of negotiations with the pharma sector), impacts will be limited:

- 2.7 €/year/person in the EU 27, i.e. 0.6% of annual expenses for cosmetic products and pharmaceuticals
- For pharmaceuticals:
  - 1.9-2.4 €/year/person
  - 0.6-0.7 % price increase if 100% of EPR fees are passed on prices
  - Reduction of 0.6-0.9 percentage points[135] of profit margin if 100% of EPR fees are absorbed into the profit margin
  - <0.1% of social security expenses if 100% of EPR fees are passed on social security allowances
- For cosmetic product
  - 0.3-0.8 €/year/person
  - 0.3-0.6% impact on product prices if 100% of EPR fees are passed on prices
  - Reduction of 0.5 percentage points of margin if 100% of EPR fees are absorbed into profit margins

The impact on individual products depends on their prices compared with the sector's average and on the allocation key chosen by the PROs to allocate the cost between entities placing products on the market.

8.4. Recommendations

In terms of allocation methodology, this study recommends not to use quantities solely as a basis to establish in order to avoid introducing a significant impact on prices or profit margins of cheaper substances.

Alternatively, the study recommends future PROs to use:

[134] Cost has been allocated between pharma and PCP based on quantities entering WWTP

[135] 9 percentage points only possible when initial margin was initially in the upper range (35%)

- either allocation based on turnover, providing that information can be made available to the PRO (confidentiality may be an issue depending on the legal form and governance of the PRO); or

- a mixed approach based on combinations of turnover, quantity placed on the market and/or hazardousness. As identified in section 7.6, hazardousness indicators are not found available in a comprehensive manner for all substances. PROs could develop these hazardousness indicators or cluster substances with semi-quantitative approaches (hazardousness scoring system).

9. MECHANISMS OF BEHAVIOURAL CHANGE

This section analyses theoretical mechanisms by which implementation of EPR could result in a reduction in quantities of harmful micropollutants released in waste water (behavioural change). It also comments on what is likely to happen based on collected data.

The consequences of implementing an EPR of micropollutants and EPR fees on the behaviour of entities placing products on the EU market, medical practitioners and consumers are illustrated in the figure below. It also shows the effect of these behaviours on the final quantities of harmful micropollutants released in the waste water.

The main factors influencing behavioural change have been identified:

- the scope of EPR and the introduction of modulated fees as part of a collective scheme incentivise ecodesign;
- the feasibility of substitution;
- the decision of social security and other co-payment systems (private health insurance) to cover the fees;
- the price elasticity of demand;
- the relative impact of fees compared to product prices;
- the inclusion of communication activities towards medical practitioners and/or consumers among the missions of EPR.

The behaviour of each stakeholder group, as well as each of these factors, are further detailed in the following sub-sections.

9.1. Behavioural change for producers

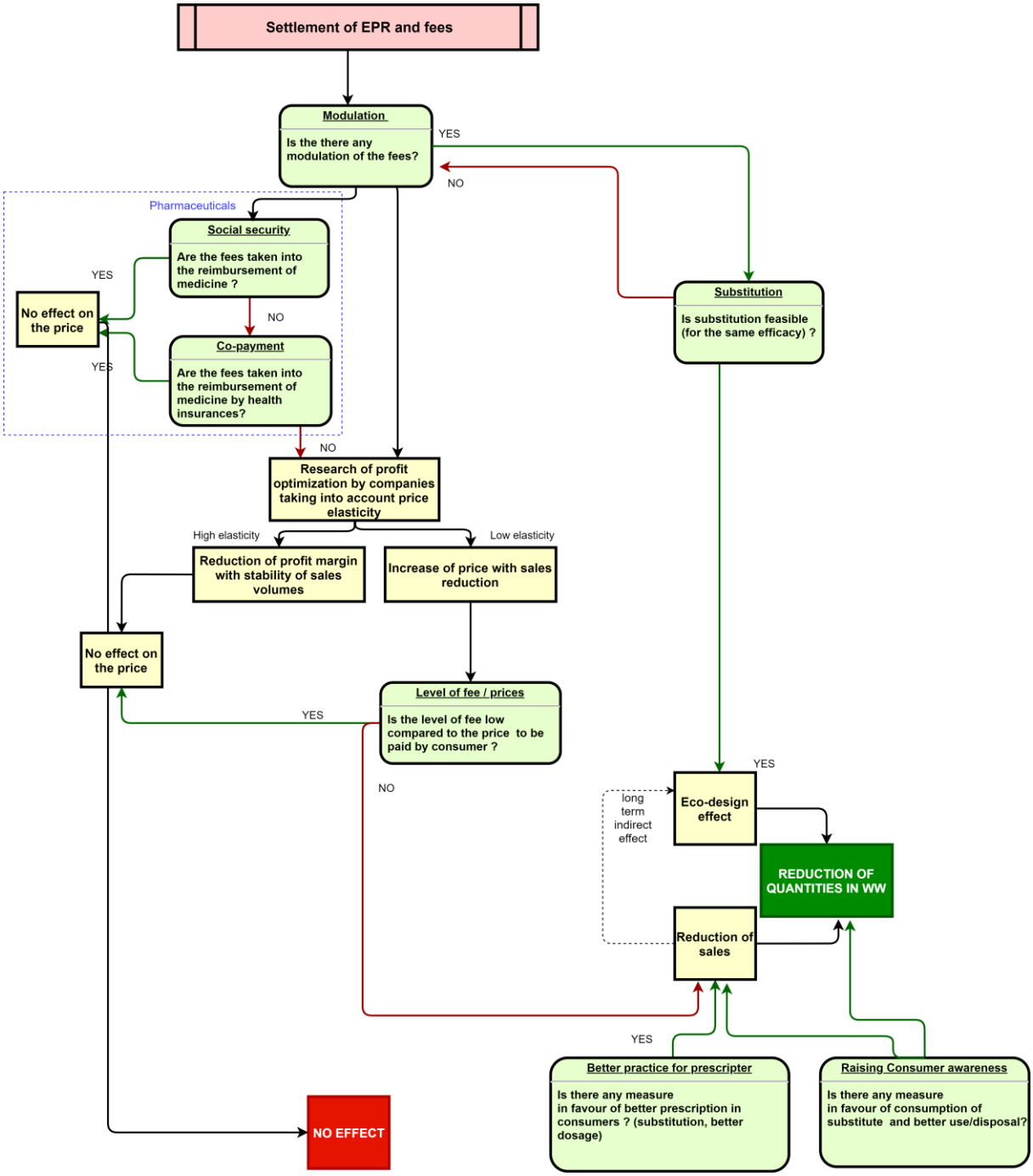
EPR can cause two main changes in producers' behaviour, which can lead to a reduction in the release of harmful micropollutants to waste water:

- increase in the uptake of ecodesign measures, including the substitution of harmful substances;
- increase in price, which may lead to a behavioural change for consumers (reduction of sales of harmful substances).

However, if entities placing products on the market decide to take the cost of EPR from their profit margin, there will be no price impact, and demand will remain unaffected, so no influence is expected on micropollutants quantities released to waste water.

In the real world, these changes can combine depending on substances and for a given substance.

Figure 21: EPR impact on micropollutant quantities and toxicity



9.1.1. Increase ecodesign

The fees to be paid (through EPR) by those placing products on the EU market will incentivise ecodesign, i.e. developing less hazardous products. However, the extent of such impact would depend on the expected cost increase because of EPR (which is not expected to be significant); it will nevertheless give the right signal to the market leading to innovation. This cannot be generalised and depends on each sector. For example, in the case of pharmaceuticals, it depends on the type of medication, its R&D cycle and whether it is possible to replace the molecules with more sustainable ones. Overall, for a number of products, there is no "green" alternative, but EPR will at least encourage innovation for products where a green alternative exists.

Different factors can influence the way EPR stimulates the behaviour of producers towards more ecodesign and more sustainable products. These factors are discussed in the following sections.

EPR will significantly stimulate ecodesign if the uptake of ecodesign practices by producers directly affects a reduction of the amount of EPR fees.

9.1.1.1. Individual vs collective schemes

In an individual system where each producer would be responsible for financing the management of its own micropollutants, the incentive would be automatic: the more a producer designs its products to ease the waste management stage, the lower the financial contribution.

An individual system is not feasible for micropollutants since all micropollutants stemming from different products are mixed and treated by the same WWTPs.

However, in a standard collective system, the benefit of individual investments in product improvements will not only be given to the company making the investment but will be partly shared with other producers[136]. In such an organisation, the incentive to ecodesign is limited: Producer Responsibility Organisations can finance R&D together to find common ways to reduce their waste management costs. However, because ecodesign is also about gaining a competitive edge and is linked to proprietary innovation, there are limited areas of ecodesign that can be financed collectively.

To further stimulate ecodesign, several collective EPR schemes organised via Producers Responsibility Organisations have introduced modulated fee scales: the amount of EPR fees depends on targeted product characteristics likely to affect the waste management cost and environmental impacts.

Modulation of fees can be defined at two different levels: the scope of EPR and specific incentivisation of ecodesign and substitution.

9.1.1.2. Fee Modulation

<u>Scope of EPR</u>

If the cost of EPR is distributed on a large number of products / active substances or entire sectors (e.g. all pharmaceuticals and cosmetic products), many producers will be affected. In a collective organisation, the more producers and substances are subject to EPR, the lower individual fees are, and the lower the relative impact on product price and profit margins. This organisation is simple to implement and control but deviates from the polluter pays principle because producers that do not pollute still have to pay. Some EPR schemes have adopted it in the waste sector, e.g. lubricants that do not generate waste oils must still pay an EPR fee in Greece and Spain. However, it must be noted that in these examples, the relative impact of EPR fees is limited compared to product price (<1%)[137].

On the other hand, if substances that do not require the fourth treatment (i.e. biodegradable or harmless substances) are exempted from paying a fee, the ones that do pay will see a higher impact. This could lead to a more significant behavioural change for

[136] Lindhqvist T, Lifset R, Can We Take the Concept of Individual Producer Responsibility from Theory to Practice? Journal of Idusrial Ecology, 2003

[137] ADEME (2021) Bilan européen des filières REP pour les lubrifiants

affected producers. It is a minimum condition to ensure EPR can influence ecodesign, and it ensures that EPR is well connected to the polluter pays principle.

Incentivization of ecodesign action

A system of EPR fee modulation, which grants a bonus (lower fee) to more environmentally friendly products, pushes for ecodesign.

In an EPR for micropollutants, a standard fee scale without modulation of fees would only consider volumes of products or substances placed on the market.

On the other hand, a modulated fee scale could account for substance-specific factors such as excretion rate or hazardousness or impact on treatment cost.

Several packaging EPR schemes, such as the Green dot in Germany, Fost Plus in Belgium, and CITEO in France, have implemented modulated fees based on various criteria (weight, easiness for recycling, refillable packaging) to help producers identify options for ecodesign. The ratio EPR fee/total amount of sales can be an indicator used by producers to decide to push for ecodesign[138].

Some studies have shown that in order to give efficient support to ecodesign, the EPR system would need to be designed product by product[139], especially when an EPR covers very different products (which is the case, for instance, of Electrical and Electronic Equipment and also of the different micropollutants concerned). However, a too-specific approach could lead to less cost-effective EPR management, as the fees would be almost product specific. PROs will have to find a compromise between feasibility and incentivisation.

9.1.1.3. Feasibility of substitution

Once there is sufficient incentive to substitute, substitution must still be feasible. The feasibility of substitution is company and sector-specific.

Sectors do not have the same drivers for substitution

- **Pharmaceuticals**
  This sector is mainly focused on the efficiency and cost-effectiveness of treatments. Moreover, the time required for research and innovation is generally several years (5.5 years on average), and the number of substances to be tested before making the final selection is significant (between 5,000 to 10,000 medicinal candidates for a selection of 10 to 20 final candidates).[140] Finally, the sector has a complex value chain. All of these elements make substitution a complex process.

[138] Favot M, Veit R, Massaruttio A, The ratio of EPR compliance fees on sales revenues of electrical and electronic equipment in Italy. A circular economy Perspective (Resources, Conservation and Recycling, 2016) https://www.researchgate.net/publication/318124312_The_ratio_of_EPR_compliance_fees_on_sales_revenues_of_electrical_and_electronic_equipment_in_Italy_A_circular_economy_perspective

[139] Sachs N, Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States, Harvard Environmental Law Review, vol 30, 2006

[140] Drug development: the journey of a medicine from lab to shelf (The pharmaceutical journal, May 2015) https://pharmaceutical-journal.com/article/feature/drug-development-the-journey-of-a-medicine-from-lab-to-shelf and Bayer : « Between 5,000 and 10,000 compounds are rigorously studied in numerous laboratory tests and the best ones further optimized. out of four or five drug candidates that are then tested on humans in clinical studies often only one substance is approved and becomes available to physicians and patients. » https://www.bayer.com/sites/default/files/110713-bayerpharma-brosch-en-web.pdf

- **Cosmetic Products**
  This sector is used to develop substitution of substances as part of the REACH Regulation: indeed, every application for authorisation for a PBT, vPBT or CMR substance must include an analysis of possible substitute substances. Moreover, some voluntary substitutions have occurred at a large scale in this industry, e.g. for microbeads[141]. Therefore, ecodesign through substitution might be easier to achieve for this sector.

  Moreover, it appears that consumer demand for more environmentally friendly products has been growing in this sector. For instance, the global market value for natural cosmetics and cosmetics is expected an increase from almost 34.5 billion dollars in 2018 to roughly 54.5 billion dollars expected for the year 2027. This data suggests the growing importance of the natural and organic cosmetic product market. In fact, the awareness of consumers on the type of products purchased is growing over time. This is especially the case when it comes to personal consumer goods. [142]

Specificity of companies

A similar cost can affect producers quite differently, depending on their turnover, the specificity of their products, the temporality of their innovation cycles etc.

The cost of behavioural change (substitution, adaptation of doses, ecodesign) can generally be amortised more easily in case of high turnover, thanks to economies of scale. On the other hand, small companies can be more agile than big companies in the way they can innovate even in case of significant changes in the organisation.

Moreover, a company decides to invest in substitution according to its competitive environment.

9.1.2. Reduction of sales of harmful substances through the price policy

Ultimately, fees are supported either by consumers or producers or both[143]. This depends on the decision of producers to either pass on the fees in the prices or absorb them in the profit margin.

This decision depends on the elasticity of the demand for goods:

- No elasticity of consumer demand: if producers can transfer all the costs to the consumers without affecting their demand substantially, they will increase their product prices. In that situation, there will be little incentive for them to innovate and ecodesign and little effect on the volumes sold.
- If the elasticity of demand is significant, meaning that changes in prices are likely to affect volumes sold and thus profitability, two cases can be described:

[141] In 2018, 97.6% of plastic microbeads used for exfoliating and cleansing purposes in wash-off cosmetic and personal care products were phased out between 2012 and 2017 (Source : CosmeticsEurope https://cosmeticseurope.eu/how-we-take-action/leading-voluntary-actions/all-about-plastic-microbeads/)

[142] Global market value for natural and organic cosmetics and personal care from 2018 to 2027, Statista https://www.statista.com/statistics/673641/global-market-value-for-natural-cosmetics/

[143] Gottberg A, Morris J, Pollard S, Mark Herbert C, Producer responsibility, waste minimisation and the WEEE Directive: case studies in ecodesign from the European lighting sector, Science of the Total Environment, 2008 (vol 359 1-3)

- If producers reduce their profit margin, there will be no effect on the final price for the consumer and, therefore, no effect on the volumes sold.
- If producers pass on the fees in their prices, the effects on sales will depend on the level of fees compared to the price to be paid by consumers and the price elasticity of demand.

Depending on the level of fees compared to the prices and the profit margin, the impact of EPR will be quite different.

9.1.2.1. Level of sales compared to prices

According to our literature analysis, no specific study analysing the share of fees that is passed on to the prices has been identified.

For EPR on electrical and electronic products in Italy, the ratio of EPR fees to product prices is rather low (between 0.36 to 0.54 %), and it tends to decrease and stands even lower than the average product price increase (2.14 %). This shows that fees are not the main factor driving up prices. Indeed, prices are based on many other parameters that can be more influential on the prices than the fees themselves. Hence, isolating the contribution of the fee is complex.

The Vernier report[144] in France also shows the low level of EPR fees in France compared to the average product price.

Table 26: Level of fee versus product price for EPR in France

Product	Fee €	Average price €	Percentage fee/price
Textile	0.007	40	0.02%
Smartphone	0.02-0.04	280	0.007%
1.5l water bottle	0.01	0.62	1.6%
Tyre	1.25	70	1.8%
Refrigerator	20	440	4.5%
Washing machine	10	370	3.2%

Source: Vernier Report, 2018

9.1.2.2. Specificity of pharmaceuticals sector: role of social security and health insurance on prices

In the EU, around two-thirds of pharmaceutical expenditure is, on average, borne by the public payers[145]. The rest is managed by other contributors, which can be voluntary health insurance, final consumers, or both.

For pharmaceuticals, the existence of a price signal for consumers and entities placing products on the market will be influenced by the way the social security system and private health insurance will consider the fee in the reimbursement of medicines.

[144] Les filières REP - Responsabilité élargie des producteurs en matière de prévention et de gestion des déchets générés par leurs produits, Jacques Vernier, Mars 2018, https://www.ecologie.gouv.fr/sites/default/files/REP_Rapport_Vernier.pdf

[145] Vogler S, Habl C, Leopold C, Rosian-Schikuta I, de Joncheere K, Lyager Thompsen T. PPRI Report. Vienna: Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG; 2008

The social security pricing and reimbursement policies are quite different from one country to another. However, in most EU Member States, there is a strong linkage between the pricing and reimbursement of medicines. Price negotiations between manufacturers and public payers often take place before or after the definition of the level of reimbursement[146].

Patients must pay for pharmaceutical expenditure that is not covered by social security. This concerns private self-medication expenses and any kind of co-payments for partially reimbursed medicines. This co-payment can be either a percentage or a fixed fee. In some countries, voluntary health insurance (VHI) can cover this complementary payment. The population share with VHI varies from one Member State to another[147].

Two parameters are important to consider for the impact of EPR on prices:

- the scope of reimbursement by social security: will it include the fee or not?
  If the fee is fully integrated into the amount to be reimbursed, then the fee will be supported by social security and not by the producer. There will be no effect on prices paid by consumers and no incentive for both producers and consumers to change their behaviour (respectively, design and consumption patterns).
  On the contrary, if the fee is excluded of the reimbursement, the price effect on consumers will depend on the fee level compared to the part that is not reimbursed or co-paid.

- the scope of reimbursement by co-payers
  If the health insurance takes into their reimbursement of medicines the EPR fees (that are not already considered by social security). In that case, there will be no effect on the final price for consumers who have health insurance.

  However, the effect of a price increase will be supported by final consumers who are used to self-medication, who pay for over-the-counter medicines or who do not have any health insurance.

Impact on sales
The non-consideration of fees in the reimbursement of pharmaceuticals results in lower reimbursement.

We have not identified studies on lower reimbursement. However, a study[148] on full de-reimbursement in France shows some immediate effects in:
- reduction of the number of prescriptions;
- increase of self-medication (patients buying without a medical prescription), but without compensation for the reduction of sales;
- increase of prices (43 % on average but with important disparities, from -25 % to + 249 %).

Error! Bookmark not defined. Vogler S, Habl C,Bogut M, Voncina L, Comparing pharmaceutical pricing and reimbursement policies in Croatia to the European Union Member States,Croat. Med, 2011 April

[147] Pharmaceutical regulation in 15 European countries, the European Observatory on Heath systems, review 2016

[148] Pichetti S, Sermet C, Le déremboursement des médicaments en France entre 2002 et 2011: éléments d'évaluation, question d'économie de la santé , juillet-août 2011

9.2. Behavioural change for medical practitioners (case of pharmaceuticals products)

Actions like exact dose prescription by the doctor and exact dose delivery (e.g. selling medicines per unit) could have major impacts on reducing the excessive use of medicines. Indeed, the fate of medicines in waste water depends on whether it is used in excess or not: most active substances are degraded when they are metabolised, whereas the proportion of substances used in excess is not metabolised and usually released as is, without biodegradation.

Different systems[149] of incentives exist in European countries (from communication to financial incentives) to maximise the efficiency of pharmaceuticals and reduce risks and costs. The change of behaviour of prescribers through guidelines, information and education prescriptions are generally oriented toward a more cost-effective health expenditure. These actions that are quite common among the EU Member States could be enlarged and co-financed by the EPR for a selection of medicines based on their final impacts on waste water.

9.3. Behavioural change for consumers

Besides the impact of price increases on sales, which has been previously discussed, EPR can influence better end-of-life management and the fulfilment of the recommended doses due to communication activities. However, these changes will be much more difficult to predict since they depend on Member States' specific implementation of EPR.

9.4. Conclusions on behavioural change

- Entities that place products on the market may decide to absorb the cost in the profit margin or to pass it on the price (or a combination). Public authorities may decide to absorb partially or fully the (potential) price impact on social security for pharmaceuticals. Mechanisms that influence these choices have been highlighted in this report.
- On average, the cost of EPR is relatively limited compared to product prices and margins (<1% of product prices for a margin between 10 and 35%, depending on product categories). Therefore, no significant impact on consumer demand or supply is expected.
- EPR is unlikely to significantly incentivise the substitution of pharmaceuticals in short- to medium-term, considering their specific innovation cycles and the priority of therapeutical activity in identifying eligible substances. However, EPR would, in any case, give a price signal to the industry, which can integrate this aspect into the innovation process, increase knowledge and potentially lead to better design or treatment solutions.
- EPR may further incentivise substitution in the cosmetic products sector by exempting biodegradable substances and requiring harmless substances to pay a fee. However, regulation and consumer pressure are already strong drivers for substitution in this sector. The added value of EPR in that regard is unclear, it would provide an additional incentive.

[149] Analysis of differences and commonalities in pricing and reimbursement systems in Europe DG Enterprise and Industry of the European Commission (2007)

10. ALTERNATIVE APPROACHES

Alternative approaches are being developed in some countries to tackle the additional costs of micropollutant treatment in urban waste water.

10.1. Fund-based solution (Germany)

The German Association of Energy and Water Industries (BDEW) has developed a concept of establishing a fund for financing the additional treatment required for micropollutants in waste water.

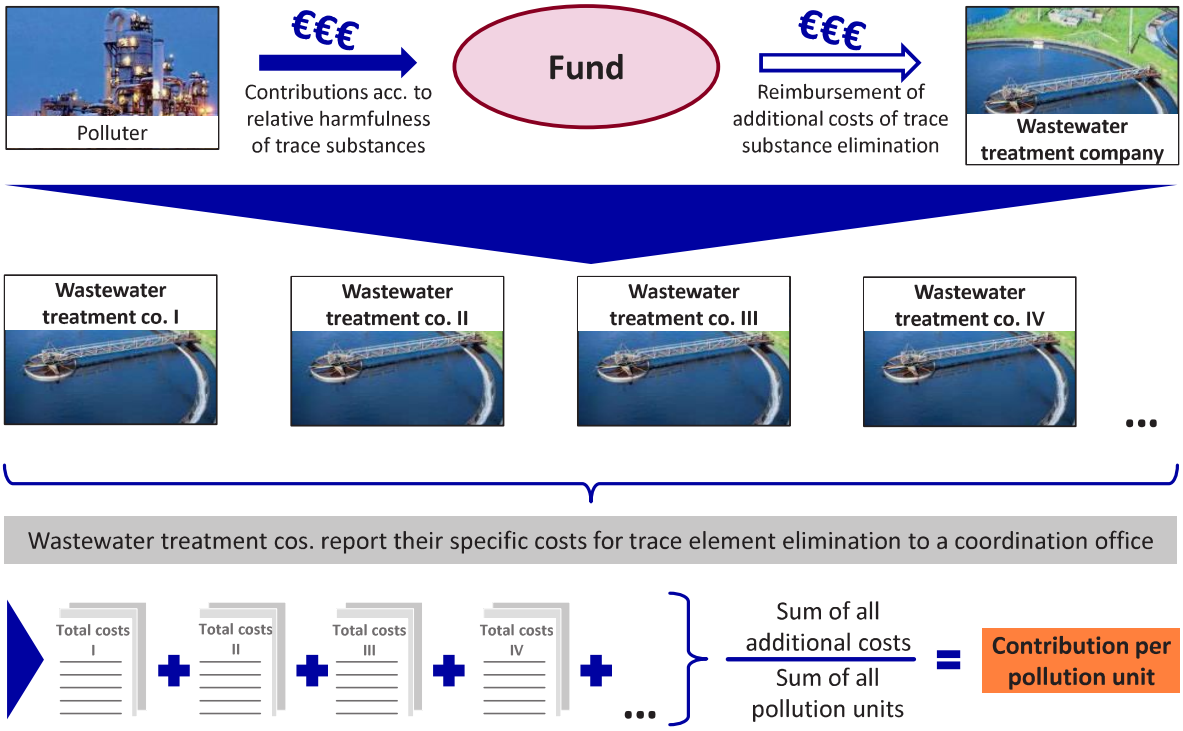


Figure 22: Fund-based solution (source: BDEW)

In this approach, a fund has to be established where all polluters will make contributions for products containing micropollutants. A polluter is a manufacturer or importer that places micropollutant-containing products on the market, irrespective of whether the environmental quality standard is exceeded in the catchment area where the polluter is based. The contributions to the fund are calculated according to the relative harmfulness of the micropollutants, which is calculated by multiplying the pollution load with the respective EQS.

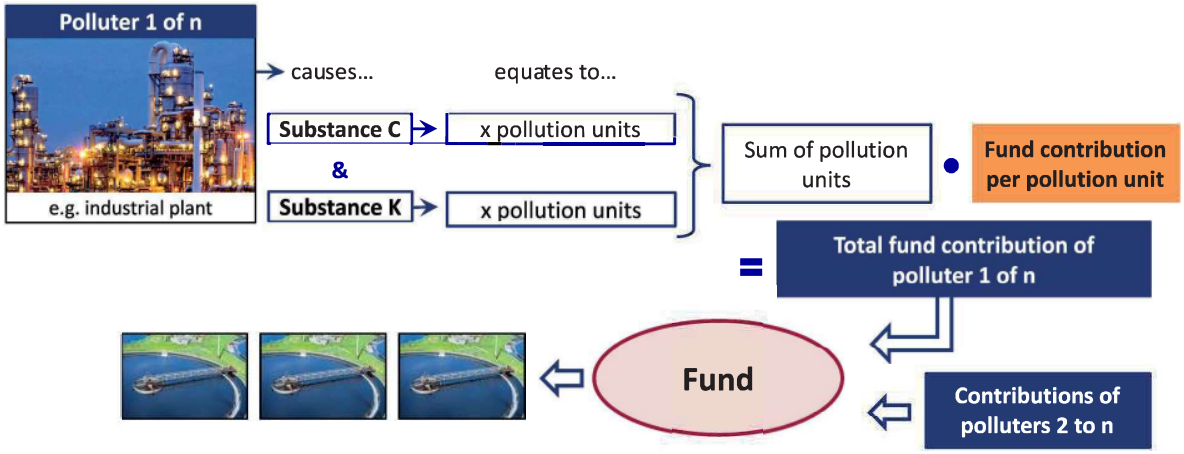


Figure 23: Determination of the fund contribution of a polluter (source: BDEW)

Based on water quality monitoring, the payments will be dynamically adjusted according to the changing levels of trace substance inputs - both about currently detectable and relevant micropollutants and about new micropollutants that may be identified in the future (further development of EQS).

The fund-based solution is technology-neutral; hence polluters can decide independently which measures they wish to take to reduce micropollutants in their products.

The costs incurred by the wastewater treatment companies for the waste water treatment to eliminate micropollutants are reimbursed by the fund. Likewise, the fund will cover the costs of practical measures whose central objective is to raise awareness among professional and private users of the micropollutant issue to induce them to handle the substances and products in question in a manner to minimize contamination.

With the fund-based solution, all substances' costs per pollution unit are identical. This may initially be unexpected; however, it is logical since the relative harmfulness of a substance is taken into account when calculating its pollution units because the EQS value is used as the "degree of harmfulness". Accordingly, two substances at the same load will cause different levels of pollution units (and therefore require different levels of contribution to the fund) if their EQS values and, thus, the harmfulness coefficients differ.

The contribution to the polluter's fund to pay for a substance is calculated by multiplying the number of pollution units the polluter causes by the cost per pollution unit. If a polluter (manufacturer or importer) is responsible for the emission of several different substances, its total contribution to the fund will be calculated by adding together the individual contributions due for each of the substances involved. The sum of all contributions will, by definition, correspond to the total costs of all wastewater treatment companies for eliminating micropollutants. Payments into and out of the fund are balanced using the contribution per pollution unit. If the total number of all pollution units nationwide increases (decreases), under the presumption of a fixed level of total costs, then the contribution per pollution unit will fall (rise). The coordination office will decide the adjustment of the amount of the contribution per pollution unit. The context is illustrated in the figure above (Figure 23).

As this approach has not yet been implemented, its effectiveness and efficiency are difficult to assess.

10.2. Generalised tax approach (Switzerland)

Switzerland applies the polluter pays principle through a range of taxes using a three-stage concept (see Figure 24).

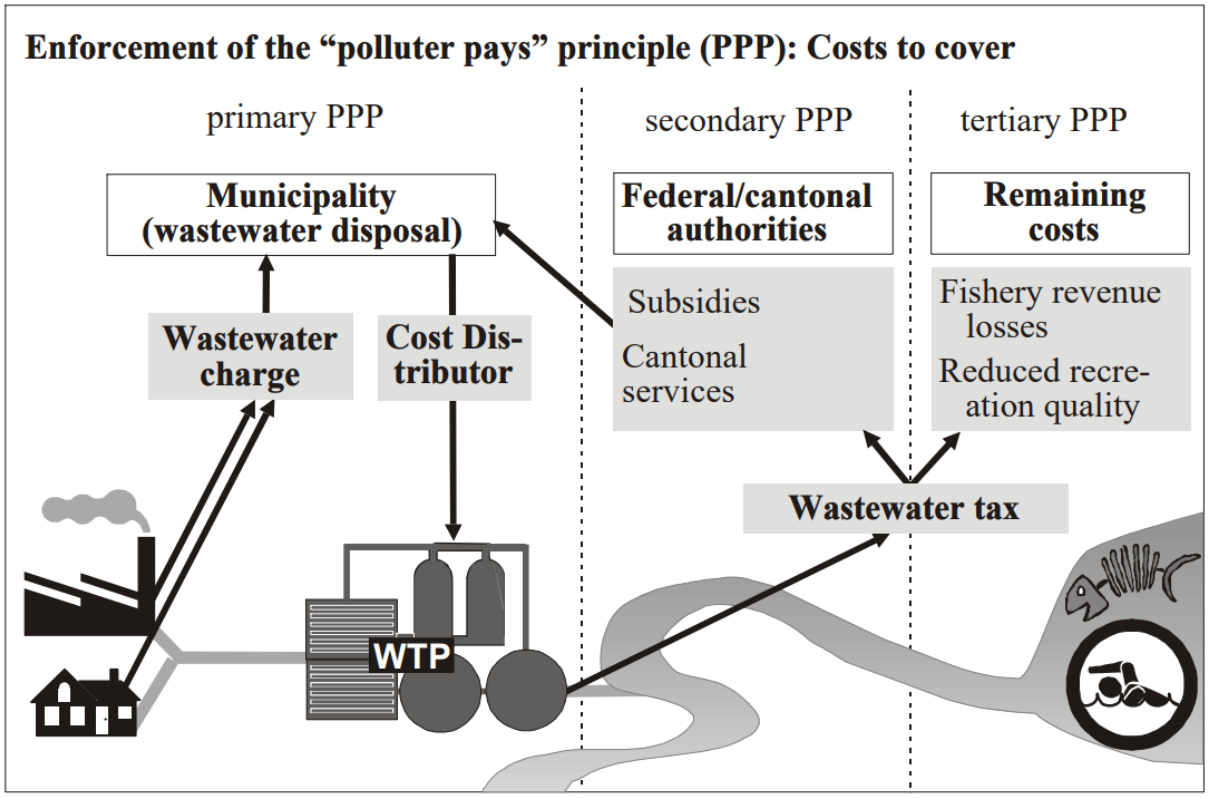


Figure 24: Swiss approach to financing waste water treatment

Source: Ecoplan (Economic Instruments for Wastewater Disposal, André Müller and David Kramer)

The Ecoplan article distinguishes between three levels of PPP in the Swiss context.

Primary PPP: It covers the direct costs of waste water disposal and the CAPEX and OPEX are to be paid by households and businesses in the form of wastewater charges.

Secondary PPP: Costs incurred by the State through subsidies, expenditure for the development of WWTPs etc. However, subsidies lower wastewater disposal costs and are inconsistent with PPP.

Tertiary PPP: Coverage of consequential costs for environmental protection (external costs) caused by actual water pollution. The external costs are covered by wastewater taxes to be paid by the polluters and are levied at the WWTP according to the volumes disposed of into rivers and lakes.

Regarding micropollutants, Switzerland has adopted a different approach and a 20 years plan (to be implemented by 2040) for upgrading its sewage treatment plants to help cut the release of micropollutants to the aquatic environment by 80% using either or both technologies: powdered active charcoal and ozonation.

Switzerland's Water Protection Ordinance was revised to require additional treatment at large or critical sewage treatment plants, i.e. the fourth treatment to be provided at all waste water plants serving more than 80,000 inhabitants, at all treatment plants serving more than 24,000 inhabitants and discharging into lakes, and at treatment plants serving

more than 8000 inhabitants and discharging into rivers if the discharge represents more than 10% of the minimum flow. This would mean about 130 WWTPs (out of 700) will be upgraded at the cost of CHF 1.2 billion. A tax of 9 CHF (about 8 EUR)[150] is paid by the plant per connected resident (in turn recovered from the resident) per year to the federal government to finance the upgradation of waste water treatment plants. While 75% of the investment costs (CAPEX) of upgrading a WWTP will be covered through the revenue generated by this tax, the WWTP operators will have to bear the increase in the OPEX but will benefit from exemption from waste water tax. This strategy has a goal of 80% elimination of 12 micropollutants. This approach is simple in principle but doesn't follow the polluter pays principle, as all citizens will have to bear the additional costs of micropollutant treatment.

A cost-benefit analysis[151] indicates that the average willingness to pay per household is there to reduce the potential environmental risk of micropollutants. The benefits, aggregated over households in the catchment of the WWTPs to be upgraded, justify the investment decision from an economic point of view. However, it doesn't exactly follow the polluter pays principle.

10.3. Comparison of alternatives with the EPR

The relative advantages and disadvantages of the three approaches are presented in the table below.

	EPR	Swiss approach	BDEW approach (fund)
Polluter Pays Principle	Full in line with PPP	The whole society bears the burden and not just the polluters. However, it incentivises users to buy sustainable products (especially cosmetics) and use them responsibly.	In line with the PPP but doesn't take into account the differences between different polluters and the risks related to different substances.
Technical feasibility	Technically feasible, the complexity lies in the burden-sharing approach.	Simple in concept but potentially willingness to pay will be low in some MS.	Technology neutral, so easy to understand as a concept; the difficulty would be in engaging the producers and agreeing on a collective cost sharing if very different micropollutant emission potentials.
Legal feasibility	Waste Framework Directive provides a framework from which it can be inspired	Fiscal rules are governed by the Member States and thus difficult for the EU to implement.	Managing such a fund at the EU level would not be legally feasible.

[150] This tax will be removed when the upgradation of WWTPs is complete

[151] Ivana Logar, Roy Brouwer, Max Maurer, and Christoph Ort (2014) Cost-Benefit Analysis of the Swiss National Policy on Reducing Micropollutants in Treated Wastewater. Environmental Science & Technology 2014 48 (21), 12500-12508 DOI: 10.1021/es502338j

	EPR	Swiss approach	BDEW approach (fund)
Effectiveness	Already been proven in the case of solid waste, but different pathways in the case of micropollutants add to the complexity. Also, the possibility of free-riders for the products sold online.	Currently being applied in Switzerland, it may not be very effective for the diverse socio-economic and environmental conditions of Member states.	It is still at a concept level, so its effectiveness has not been proven. The feasibility of creating a fund in the context of environmental liability was considered low by a previous study.[152]
Efficiency	An efficient economic instrument.	A cost-benefit analysis shows it to be cost-effective but for a small and relatively homogeneous country.	Not enough information assesses its efficiency, but there is a risk of uneven cost impacts on different sectors and even companies within the same sector.
Proportionality	It can be easily adapted to national specificities, as seen in existing EPR systems	Not adapted as the fiscal systems very different in MS	Not adapted as the fiscal systems very different in MS
Coherence	Coherent with existing legislation	N/A	N/A
Relevance	Very relevant to tackle the issue	Relevant to tackle the issue	Potentially relevant to tackle the issue
EU added value	High EU added value in defining the governing principles	Low EU added value; such approaches can be taken by MS	EU could bring added value as relevant businesses operate at the EU level.

11. CONCLUSIONS

EPR for micropollutants is feasible if it is organised as a financial EPR, where entities placing on the market finance WWTP operators for the marginal cost of the fourth treatment.

The scope of EPR should focus on priority sectors contributing to the discharge of micropollutants to municipal waste water. Data on substances found in waste water and toxic-weighted loads have demonstrated that pharmaceuticals and cosmetic products are the top two contributing sectors.

Entities placing products on the market should be asked to pay as function of the type of substances they place on the market, based on a list of criteria defining the scope of micropollutants. Inorganic substances, harmless substances and substances that biodegrade in a few hours before reaching WWTP may be exempted to pay.

152 https://ec.europa.eu/environment/archives/liability/eld/eldfund/pdf/Final%20report%20ELD%20Fund%20BIO%20for%20web2.pdf

Responsibilities of different stakeholders involved in the EPR are highlighted in this report: EU, Member States, entities placing products on the market, PRO, and WWTP operators. This will be helpful for the EC to draft the UWWTD and help MS and PROs implement the scheme nationally.

Different scenarios requiring more or less WWTP to implement the fourth treatment have been investigated, with more or less focus on priority WWTP of concern for micropollutants based on size, sensitivity or risk indicators. Scenario 5.3 was ultimately chosen, imposing all WWTP above 100,000 Person Equivalent and all WWTP between 10,000 and 100,000 PE with dilution factor at discharge below 10, unless they are in coastal areas, to implement the fourth treatment.

This scenario leads to an annual cost of 1.2 billion EUR for EU 27, of which only approximately 11 million € is the administrative cost, most of the cost being allocated to upgrading WWTP to the fourth treatment (CAPEX and OPEX).

Considering scenario 5.3, the financial impact of EPR is moderate: 2.7 €/year/person in the EU 27, i.e. 0.6% of annual expenses for cosmetic products and pharmaceuticals. Impacts on product price, margin and social security have been computed considering extreme scenarios where 100% of EPR fees would be allocated to a given stakeholder. Factors affecting the decision to take EPR fees inside profit margins are discussed qualitatively. Even if 100% is passed on to product price, the impact is limited; therefore, no significant impact on consumer demand or supply is to be expected.

EPR is unlikely to significantly incentivise the substitution of pharmaceuticals, considering their specific innovation cycles and the priority of therapeutical activity in identifying eligible substances. EPR may further incentivise substitution in the cosmetic products sector by excluding biodegradable and harmless substances to pay a fee. However, regulation and consumer pressure are already strong drivers for substitution in this sector. The added value of EPR in this regard is unclear.

The cost of the fourth treatment is due to the need to treat the hazardous effluent and therefore is due to the presence of micropollutants. However, the marginal cost of 4th treatment is only proportional to the volumes of water to be treated and is not proportional to quantities of micropollutants found in waste water (due to the properties of the influent). Consequently, applying the true cost principle, any allocation method can be used by PROs to distribute the costs between entities placing products on the market: based on turnover, quantities, hazardousness or mixed approaches. This report recommends that PROs should not use quantities solely as a basis to establish the fee but favour turnover or a mixed approach (turnover, quantity and/or hazardousness) to avoid introducing a significant impact on the prices of cheaper substances.

Information from the registration and authorisation process can be used to verify product declarations and to collect useful information to define relevant hazardousness indicators that the PROs could use to allocate the costs between entities placing products on the market.

12. APPENDIX

12.1. Substance classification

A.1. Norman suspect list exchange databases

Name of the database	Source link
S2	http://doi.org/10.5281/zenodo.3900133
S8	http://doi.org/10.5281/zenodo.2621980
S9	http://doi.org/10.5281/zenodo.2621989
S11	http://doi.org/10.5281/zenodo.2623741
S13	http://doi.org/10.5281/zenodo.3959386
S14	http://doi.org/10.5281/zenodo.3544805
S16	http://doi.org/10.5281/zenodo.2624325
S20	http://doi.org/10.5281/zenodo.3779854
S23	http://doi.org/10.5281/zenodo.2648765
S25	http://doi.org/10.5281/zenodo.3653165
S26	http://doi.org/10.5281/zenodo.2648816
S28	http://doi.org/10.5281/zenodo.3542001
S29	http://doi.org/10.5281/zenodo.3548844
S39	http://doi.org/10.5281/zenodo.3541665
S47	http://doi.org/10.5281/zenodo.2658140
S48	http://doi.org/10.5281/zenodo.2658144
S49	http://doi.org/10.5281/zenodo.2658153
S56	http://doi.org/10.5281/zenodo.3248838
S57	http://doi.org/10.5281/zenodo.3248884
S58	http://doi.org/10.5281/zenodo.3247724
S60	http://doi.org/10.5281/zenodo.3766352
S66	http://doi.org/10.5281/zenodo.3829088
S67	http://doi.org/10.5281/zenodo.3779849
S69	http://doi.org/10.5281/zenodo.3862689
S69	http://doi.org/10.5281/zenodo.3862689

Name of the database	Source link
S10	http://doi.org/10.5281/zenodo.2623485
S18	http://doi.org/10.5281/zenodo.3542115
S52	http://doi.org/10.5281/zenodo.2669467
S62	http://doi.org/10.5281/zenodo.3634963
S64	http://doi.org/10.5281/zenodo.3695174
S73	http://doi.org/10.5281/zenodo.4247792
S59	http://doi.org/10.5281/zenodo.3547224
S2	http://doi.org/10.5281/zenodo.3900133

A.2. UBA database

Name of the database	Source link
UBA	https://www.umweltbundesamt.de/en/database-pharmaceuticals-in-the-environment-1

A.3. COMPTOX databases

Name of the database	Source link
Amino acids	CompTox Chemicals Dashboard | AMINOACIDS Chemicals (epa.gov)
antibiotics	CompTox Chemicals Dashboard | ANTIBIOTICS Chemicals (epa.gov)
Antifungal Wiki	CompTox Chemicals Dashboard | WIKIANTIFUNGALS Chemicals (epa.gov)
Antimicrobial wiki	CompTox Chemicals Dashboard | ANTIMICROBIALS Chemicals (epa.gov)
Antiseptic wiki	CompTox Chemicals Dashboard | WIKIANTISEPTICS Chemicals (epa.gov)
Antiviral wiki	CompTox Chemicals Dashboard | WIKIANTIVIRALS Chemicals (epa.gov)
Flavornet	CompTox Chemicals Dashboard | FLAVORNET Chemicals (epa.gov)
Color index and dyes	CompTox Chemicals Dashboard | CIDYES Chemicals (epa.gov)
Cosmetics	CompTox Chemicals Dashboard | COSMOSDB Chemicals (epa.gov)
Drugbank	CompTox Chemicals Dashboard | DRUGBANK Chemicals (epa.gov)
Flame retardant	CompTox Chemicals Dashboard | FLAMERETARD Chemicals (epa.gov)
Flavorants wiki	CompTox Chemicals Dashboard | WIKIFLAVORS Chemicals (epa.gov)
Food additive	CompTox Chemicals Dashboard | FDAFOODSUBS Chemicals (epa.gov)

Name of the database	Source link
Herbicide wiki	CompTox Chemicals Dashboard | WIKIHERBICIDES Chemicals (epa.gov)
Human hormone	CompTox Chemicals Dashboard | HUMANHORMONES Chemicals (epa.gov)
Insecticide wiki	CompTox Chemicals Dashboard | WIKIINSECTICIDES Chemicals (epa.gov)
Non-steroidal anti-inflammatory drug wiki	CompTox Chemicals Dashboard | WIKINSAIDS Chemicals (epa.gov)
PAH	CompTox Chemicals Dashboard | PAHLIST Chemicals (epa.gov)
PCB	CompTox Chemicals Dashboard | PCBCHEMICALS Chemicals (epa.gov)
Pesticide	CompTox Chemicals Dashboard | INERTNONFOOD Chemicals (epa.gov)
Pesticides	CompTox Chemicals Dashboard | OPPIN Chemicals (epa.gov)
PFA	CompTox Chemicals Dashboard | EPAPFASCAT Chemicals
pyrethroids (household insecticide)	CompTox Chemicals Dashboard | PYRETHROIDS Chemicals (epa.gov)
Refrigerants	CompTox Chemicals Dashboard | REFRIGERANTS Chemicals (epa.gov)
Rodenticide wiki	CompTox Chemicals Dashboard | WIKIRODENTICIDES Chemicals (epa.gov)
Solvents wiki	CompTox Chemicals Dashboard | WIKISOLVENTS Chemicals (epa.gov)
Surfactants	CompTox Chemicals Dashboard | ALLSURFACTANTS Chemicals (epa.gov)
Vitamin	CompTox Chemicals Dashboard | VITAMINS Chemicals (epa.gov)
Opioids	CompTox Chemicals Dashboard | OPIOIDS Chemicals (epa.gov)
Hepatic metabolites phase 1	CompTox Chemicals Dashboard | WETMORE2012 Chemicals (epa.gov)
hepatic metabolites phase 2	CompTox Chemicals Dashboard | WETMORE2015 Chemicals (epa.gov)
elegans metabolites	CompTox Chemicals Dashboard | WORMJAM Chemicals (epa.gov)
chemicals in blood	CompTox Chemicals Dashboard | HUMANBLOOD Chemicals (epa.gov)

A.4 CosIng database

Name of the database	Source link
CosIng	Cosmetic ingredient database (Cosing) - Ingredients and Fragrance inventory - Ingredients / Fragrance Inventory | European Union Open Data Portal (europa.eu)

12.2. Registration and reporting processes

Table 27: Detailed description of registration process of pharmaceuticals and cosmetic product

	Pharmaceuticals	Cosmetic Products	
Legal acts & scope	**Directive 2001/83/EC** (on medicinal products for human use) **Regulation (EC) No 726/2004** Substances used in a medicinal product within the scope of the 2 previous acts are exempted from registration in REACH	**Regulation (EC) No 1223/2009 (on cosmetic products)** **REACH Regulation (EC) No 1907/2006** Note**: The regulation No 528/2012** concerning the making available on the market and use of **biocidal products <u>does not apply</u> to** biocidal products or treated articles that are within the scope of the regulation No 1223/2009**.**[153]	
Registration process		Cosmetic products regulation	Reach
Scope	**The medicine** is registered to get a marketing authorization.	The **cosmetic product** is registered.	**Every substance** contained in the product is registered individually, provided that they are imported or manufactured in quantities **> 1 tonne / year.** Data requirements vary according to the tonnage placed on the market per year: • 1-10 tonnes • 10-100 tonnes • 100-1000 tonnes • > 1000 tonnes
Competent authority in charge of registration	1) Centralized (European Medicines Agency) **for some specific products**[154] or 2) National (Member state competent bodies) for others	• EU Commission • Member States competent authorities (which are registered by the EU Commission)	ECHA (European Chemicals Agency)
Result of the registration	1) Authorization in whole EU	Notification of the product marketing in EU	Notification of the product marketing in EU

[153] Regulation No 528/2012, article 2, 2(i)

[154] products developed through biotechnology processes (DNA, genes coding for proteins, monoclonal antibodies), treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorders, diabetes, auto-immune diseases, viral diseases, orphan medicinal products, optional: new active substance, significant therapeutic innovation, great interest for patients, generic medicinal of a centrally authorized medicinal (source : Article 3 Regulation 726/2004)

		Pharmaceuticals	Cosmetic Products	
		2) Authorization in one single MS[155]	The address of the responsible person is indicated on the product label	Notification of the substance manufacturing or import in the EU
Registration tools (databases)				
Name / website		1) Community Register of Medicinal Products 2) national registers[156]	Cosmetic Product Notification Portal (CPNP)	• REACH-IT (ECHA) • SIEF: Substance Information Exchange Forum (for registrants for the same substance)[157]
Level		1) EU 2) MS[158]	EU	EU
Publicly available		Partly (public assessment report): SPC (summary of Product characteristics)	No The portal is available to competent authorities, European poison centres, cosmetic products responsible persons and distributors	Publication on the ECHA website: list of the registrants, parts of the registered dossier[159]
Registration requirements				
Scope for registration	Active substance, finished product or both?	The product is registered: one single strength, one pharmaceutical form one presentation The qualitative and quantitative composition in terms of active substance(s) and excipients must be detailed.	The product is registered. According to Reach, all substances (active substance, preservatives, etc.) must be detailed	All substances manufactured, imported or contained in an article / a mixture. To each substance (for one use) is associated a single file in REACH to which all the companies contribute. Every potential registrant must inquire from ECHA whether a valid registration has already been submitted for the same substance. ECHA then

[155] When a company wants to authorise a medicine in several Member States, two other procedures can complement the national procedure:
- the mutual-recognition procedure: companies that have a medicine authorised in one EU Member States can apply for this authorisation to be recognised in other EU countries. This process allows Member States to rely on each other's scientific assessments. The reference member state provides either the assessment report for the medicine or an update of this assessment report.
- the decentralised procedure: companies can apply for the simultaneous authorisation of a medicine in more than one EU Member State if it has not yet been authorised in any EU country and does not fall within the scope of the centralised procedure.

[156] https://www.ema.europa.eu/en/medicines/national-registers-authorised-medicines

[157] This SIEF organization aims to facilitate the exchange of available data between co-registrants and agree on classification and labelling. It also helps them to deliver a joint submission (with a leader). (Source: https://echa.europa.eu/documents/10162/13631/data_sharing_fact_sheet_en.pdf)

[158] If the medicine is present in different countries, then each MS database will include it.

[159] Registrants have the possibility to flag as confidential certain sections in the registration dossier.

		Pharmaceuticals	Cosmetic Products	
				provides the potential registrant with access to the contact details of the existing registrants
	Exceptions		Specific requirements for some restricted / prohibited substances nanomaterials, carcinogenic, mutagenic substances (CMR cat 1A or 1B)[160] may be authorized by exception provided a specific agreement of the commission or a SCCS assessment:	Specific requirements for nanomaterials. Exemptions of registration for substances: - with minimum risk because of their intrinsic properties (e.g. water, nitrogen...) - for which registration is inappropriate or unnecessary (e.g. occurring in nature like minerals, ores and ores concentrates if they are not chemically modified) - polymers [161]
	Level of the companies in the value chain?	End of the chain (manufacturer of the final product)	The downstream chain actor who puts the product on the market: • Manufacturer of the product (itself or its EU based representative if outside the EU) • Importer of the product • Distributor if cosmetic product under his name or trademark or modified product	A part of the value chain[162] : • EU manufacturers and importers of substances on their own or in mixtures • EU producers and importers of articles (if the article contains a substance in quantities > 1 tonne per year) • EU representative if outside the EU
Codification		INN ATC codes[163] 164	INCI Chemical name CAS EINECS ELINCS CPNP classification	IUCLID (international uniform chemical information database)
Requirements that may be useful for the EPR scoping	Excretion rate	**Pharmacokinetics:** • Absorption: extent and rate of absorption in vivo and in situ studies ; kinetics	No information on the fraction emitted to waste water requested	No information on the fraction emitted to waste water requested

[160] Article 15 and 16

[161] Monomers or any other substances they consist of must be registered provided certain conditions are fulfilled REACH, Guidance on registration, 2.2.3

[162] The formulator mixes the individual substances to produce the mixture, does not have registration obligations under REACH unless he is at the same time a manufacturer or importer of the individual substances contained in the mixture or an importer of the mixture itself. It is the same for a distributor.

[163] 3rd or 4th level – i.e. pharmacological subgroup or chemical group

[164] https://www.whocc.no/atc_ddd_index/?code=J01CR02&showdescription=yes

		Pharmaceuticals	Cosmetic Products	
		parameters and bioavailability (serum/ plasma/ blood) • Excretion: routes and extent of excretion		
	Metabolites	**Pharmacokinetics:** metabolism: chemical structure of metabolites and possible metabolic pathway	Not relevant	Not relevant
	Data about quantities put on the market, forecast sales	Upon request of pharmacovigilance: volume of sales and volume of prescription at EU level and broken down per MS	No data asked	Calculation of total annual volume (tonnes per year) of the substance[165] intended to be manufactured and imported to define a tonnage band
	Sanitary risks	**Toxicology focused on use** Single dose and repeat dose toxicity genotoxicity Carcinogenicity Reproductive and developmental toxicity local tolerance	**Toxicological profile of the substances** with a particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and photo-induced toxicity in case of UV absorption. Particular consideration shall be given to any possible impacts on the toxicological profile due to particle sizes (nanoparticles), impurities or interaction of substances. Undesirable effects and serious undesirable effects Restriction or prohibition of certain substances (including some colorants and preservatives)[166]	The cosmetic products are exempted to report on the toxicology issue to REACH since these aspects are already covered by the regulation for cosmetics.
	Environmental risks	**Environmental Risk Assessment**[167] needs to be provided (except for medicine containing GMO for which specific guidelines are provided). It aims at providing data on toxicity, persistence and bioaccumulation through different methods (from the simplest to the most complex and	/	• If 1 to 10 tonnes / year: information on exposure • If > 10 tonnes / year[168] - Environmental fate properties of a substance

[165] aggregation of the substance on its own, in a mixture or in an article. Volumes manufactured or imported as intermediates need to be counted separately.

[166] Annex II, III, IV, V, VI of Regulation 1223/2009

[167] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-environmental-risk-assessment-medicinal-products-human-use-first-version_en.pdf

[168] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

	Pharmaceuticals	Cosmetic Products	
	detailed one). If the simplest method concludes that there is no risk, the next method has not to be applied.		- Environmental hazard assessment (including the determination of a predicted no-effect concentration) - toxicity, persistence and bioaccumulation (PBT and vPvB) assessment - Exposure assessment (dose / concentrations of the substance to which the environment is or may be exposed - Risk characterisation
Documentation needed	**Common Technical Document (CTD).** Applicable for all types of marketing authorisation applications irrespective of the procedure to be applied (i.e. centralised, mutual recognition or national)	**Product information file** In which a ***Cosmetic product Safety report*** is provided Available to the EC and the Member States in which the product is made available (including a description of the method of manufacturing)	**For substances: Technical dossier** In which a Chemical Safety Report (CSR) for 10 tonnes or more per year

Table 28: Detailed description of registration process for pharmaceuticals and cosmetic product companies

		Pharmaceuticals	Cosmetic Products
Regulations & scope		**Directive 2001/83/EC** (on medicinal products for human use) **Regulation (EC) No 726/2004**	**Regulation (EC) No 1223/2009 (on cosmetic products)** **Reference to ISO 22716 for good manufacturing practices**
Registration process			
Scope		Manufacturers, importers and distributors of medicines	Manufacturers of cosmetics
Competent authority in charge of registration		MS authority	MS authority
Result of the registration		1) Manufacturer in and outside the EU: Manufacture and importation authorization (MAI) 2) Distributor: Wholesale distribution authorization (WSA)	No registration of the manufacturing company is required. The ISO 22716 standard provides guidance to check compliance of the company. An internal audit is required to check this compliance and an internal ISO 22716 certificate is to be added to the product information file.
Registration tools (databases)			
Name / website		Centralized EUDRA GMDP	-
Level		EU	-
Publicly available		public	-
Registration requirements			
Scope for registration	Active substance, finished product or both?	- Active substance: compliance to Good manufacturing practice (GMP)/Good distribution practice and ensure that the suppliers do the same along the value chain through audits [169] - Excipient: follow the Commission guidelines on the risk assessment for excipient to ascertain GMP [170]	-
	Exceptions		-
	Level of the companies in the value chain?	All the companies from the product manufacturing authorization backward to the active substance manufacturer and importers	-

[169] Article 46(f) Directive 2001/83

[170] article 47 Directive 2001/83

	Pharmaceuticals	Cosmetic Products
Codification	Reference number	-
Requirements that may be useful for the EPR scoping	- Quality management system - typology of medicinal product	-
Document needed	GMP Master file	-
Publicly available	Partly (public assessment report)	-

Table 29: Description of reporting process of pharmaceuticals and cosmetic product products

		Pharmaceuticals	Cosmetic Products	
Reporting (supervision) requirements			Cosmetic products regulation	REACH
Competent authority in charge of supervision		The competent authority for authorization (EU or MS)	MS competent authority	ECHA
Information to provide	Adverse effects	**Suspected adverse reactions must be reported**, including unexpected reactions within 15 days [171]	• **Serious undesirable effects** of product must be reported by the responsible person without delay (effect, name and corrective measures • In case of serious doubts regarding the safety of any substance contained in cosmetic products: submit a list of all cosmetic products for which he is responsible and which contain this substance (incl. concentration of the substance in the product)	Any new relevant available information concerning their registration without undue delay (such as new tonnage band)
	Production quantities	/	-	
-	Sales quantities	All data on sales and any data on volumes of prescriptions must be provided in PSUR [172]	-	new tonnage band

[171] by marketing authorization holder (art 107)

[172] Article 107 b Directive 2001/83

Note: Moreover, the distribution authorization holder must keep record for 5 years (art 80) in the form of purchase,/sales invoices giving for any transaction in medicinal products received, dispatched or brokered at least the following information:

- date,

Documentation needed	• Periodic safety update reports (PSURs) 173[174] : benefits and risks data and evaluation + sales • Post authorisation safety (and/or efficacy) studies and / or document any suspected adverse reaction.		
Frequency at which the info is to be provided	Specified in the marketing authorization[175]		
Reporting (supervision) tool (databases)			
Name / website	• Eudravigilence for adverse effects PSUR repository for PSUR (from 2016)	CPNP	REACH-IT
Level	EU	EU	EU
Publicly available	no	No	Yes

- name of the medicinal product,
- quantity received, supplied or brokered,
- name and address of the supplier or consignee, as appropriate,
- batch number of the medicinal products

The competent national authority can carry out Inspections of the manufacturers and importers based on a risk assessment.

[173] While Directive 726/2004 seem to mean this information may be asked upon request, the guidance document seem to mean this information is mandatory

[174] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/periodic-safety-update-reports-psurs

[175] Article 107c Directive 2001/83. For marketing authorizations granted before July 2012: PSUR shall be submitted at least every 6 months during the first 2 years following the initial placing on the market, once a year for the following 2 years and at three-yearly intervals thereafter until a new frequency is written

Table 30: Description of reporting process for pharmaceuticals and cosmetic product companies

	Pharmaceuticals	Cosmetic Products
Regulations & scope	**Directive 2001/83/EC** (on medicinal products for human use) **Regulation (EC) No 726/2004**	**Regulation (EC) No 1223/2009 (on cosmetic products)** **Reference to ISO 22716 for good manufacturing practices**
Reporting process		
Scope	Manufacturers, importers and distributors of medicines	Manufacturers of cosmetics
Competent authority in charge of reporting	MS authority	MS authority
Result of the reporting	• Good Manufacturing practice GMP Masterfile (active substance for manufacturer in or outside the EU)) • Good Distribution Practice GDP	Statement on compliance with good manufacturing practice (in the Product information file)[176]
Frequency		Compliance monitoring with the principles of good manufacturing practices at least every 4 years[177]
Reporting tools (databases)		
Name / website	Centralized EUDRA GMDP	-
Level	EU	-
Publicly available	Public: inspection reports	-

[176] Regulation No 1223/2009, Article 11

[177] Regulation No 1223/2009, Article 22

Table 31: Detailed costs of different treatment technologies in WWTPs

Project	Country	Technology	Size (p.e.)	€/m3		
				min	average	max
NEPTUNE	-	Ozone + sandfilter	30 000	0.15	0.18	0.2
NEPTUNE	-	Ozone + sandfilter	500 000	0.05	0.06	0.07
NEPTUNE	-	Powder AC + filter	30 000	0.25	0.28	0.3
NEPTUNE	-	Powder AC + filter	500 000	0.09	0.10	0.11
TREATREC	-	Ozone + sandfilter	20 000		0.22	
TREATREC	-	Ozone + sandfilter	100 000		0.18	
TREATREC	-	Ozone + sandfilter	300 000		0.16	
STOWA	Netherlands	Ozone + sandfilter	20 000	0.21	0.26	0.31
STOWA	Netherlands	Ozone + sandfilter	100 000	0.18	0.22	0.26
STOWA	Netherlands	Ozone + sandfilter	300 000	0.16	0.19	0.22
STOWA	Netherlands	PAC + sandfilter	20 000	0.26	0.3	0.34
STOWA	Netherlands	PAC + sandfilter	100 000	0.19	0.23	0.27
STOWA	Netherlands	PAC + sandfilter	300 000	0.18	0.21	0.24
STOWA	Netherlands	GAC	20 000	0.28	0.33	0.38
STOWA	Netherlands	GAC	100 000	0.27	0.31	0.35
STOWA	Netherlands	GAC	300 000	0.26	0.3	0.34
-	Finland	GAC + ozonation	< 10 000	0.56	0.74	0.91
-	Finland	GAC + ozonation	10 000 - 100 000	0.46	0.60	0.73
-	Finland	GAC + ozonation	> 100 000	0.4	0.50	0.6
Tekniska Verken, Linköping	Sweden	Ozone	235 000		0.03	
Knivsta	Sweden	Ozone	100 000		0.07	
Knivsta	Sweden	Ozone	12 000		0.09	
Knivsta	Sweden	GAC	100 000		0.11	

Sources: RDC Environment elaboration based on EurEau (2019), Treating micropollutants at waste water treatment plants and Swedish Agency for Marine and Water Management (2018), Treatment techniques for pharmaceuticals and micropollutants in waste water.

Table 32: Waste water production volumes per Member State

Country	Produced municipal waste water (km^3/year)	Population (2017)	Produced municipal waste water (m^3/capita/year)
Austria	1.054	8 772 865	120
Belgium	0.871	11 351 727	77
Bulgaria	0.428	7 101 859	60
Croatia	0.312	4 154 213	75
Cyprus	0.024	854 802	28
Czechia	1.299	10 578 820	123
Denmark	0.5	5 748 769	87
Estonia	0.289	1 315 635	220
Finland	0.4	5 503 297	73
France	4	66 809 816	60
Germany	5.287	82 521 653	64
Greece		10 768 193	
Hungary	0.2167	9 797 561	22
Ireland	0.783	4 784 383	164
Italy	3.926	60 589 445	65
Latvia	0.1764	1 950 116	90
Lithuania	0.1764	2 847 904	62
Luxembourg	0.2466	590 667	417
Malta	0.0208	460 297	45
Netherlands	0.0233	17 081 507	1
Poland	1.921	37 972 964	51
Portugal	2.168	10 309 573	210
Romania	0.577	19 643 949	29
Slovakia	0.56	5 435 343	103
Slovenia	0.2177	2 065 895	105
Spain	5.206	46 528 024	112
Sweden	1	9 995 153	100

Source: FAO (2017), Aquastat database[178].

Table 33: Analysed pharmaceutical companies

Companies
AbbVie
Abbott laboratories
Astellas
AstraZeneca
Bayer
Biogen
Bristol Myers Squibb
Eli Lilly
Gilead Sciences
GlaxoSmithKline
Johnson & Johnson
Medtronic
Merck
Novartis
Novo Nordisk
Pfizer
Roche
Sanofi
Takeda
Teva
Thermo Fisher Scientific
UCB

[178] http://www.fao.org/aquastat/statistics/query/index.html

Table 34: Analysed cosmetic product companies

Companies
AmorePacific
Beiersdorf
Colgate-Palmolive
Coty
Estee Lauder
Henkel
Johnson & Johnson
Kao
Kosé
L'Oréal
LVMH
Natura & Co
P&G
Reckitt Benckiser
Revlon
Shiseido
Unilever

Table 35: Operating profit margins of pharmaceutical companies

	2020	2019	2018	2017	2016
AbbVie	25%	39%	19%	34%	37%
Abbott laboratories	16%	14%	11%	6%	15%
Astellas	19%	19%	16%	20%	18%
AstraZeneca	19%	12%	15%	16%	21%
Bayer	-39%	10%	9%	17%	16%
Biogen	34%	49%	44%	44%	45%
Bristol Myers Squibb	-20%	26%	28%	25%	31%
Eli Lilly	25%	23%	16%	10%	16%
Gilead Sciences	16%	19%	37%	54%	58%
GlaxoSmithKline	23%	21%	18%	14%	9%
Johnson & Johnson	20%	21%	22%	23%	28%
Medtronic	15%	19%	22%	18%	19%

	2020	2019	2018	2017	2016
Merck	16%	25%	20%	15%	12%
Novartis	20%	19%	31%	20%	17%
Novo Nordisk	43%	43%	42%	44%	43%
Pfizer	20%	30%	10%	25%	17%
Roche	32%	29%	26%	24%	28%
Sanofi	38%	8%	13%	16%	19%
Takeda	3%	11%	14%	8%	7%
Teva	-21%	-3%	-9%	-78%	6%
Thermo Fisher Scientific	24%	17%	16%	14%	13%
UCB	18%	22%	24%	24%	21%

Source: Reuters.

Table 36: Operating profit margins of cosmetic product companies

	2020	2019	2018	2017	2016
AmorePacific	2%	7%	9%	12%	15%
Beiersdorf	12%	13%	15%	15%	15%
Colgate-Palmolive	24%	23%	24%	24%	26%
Coty	-26%	-59%	-2%	-6%	6%
Estee Lauder	4%	16%	15%	14%	14%
Henkel	10%	14%	16%	15%	15%
Johnson & Johnson	20%	21%	22%	23%	28%
Kao	13%	14%	14%	14%	13%
Kosé	12%	16%	16%	15%	14%
L'Oréal	16%	17%	18%	17%	16%
LVMH	18%	21%	21%	19%	18%
Natura & Co	2%	8%	9%	14%	14%
P&G	22%	9%	20%	21%	21%
Reckitt Benckiser	15%	-15%	24%	24%	24%
Revlon	-10%	3%	-3%	-1%	6%
Shiseido	0%	10%	9%	0%	4%
Unilever	16%	17%	25%	16%	15%

Source: Reuters.

12.3. Correspondence between chosen scenarios and the TOR

According to the terms of reference, four scenarios were foreseen in view of the quantitative impact assessment:

A. All WWTPs use fourth treatment.

B. Only large WWTPs use fourth treatment.

C. Selected WWTP discharging in specific sensitive areas.

The initial idea was to identify areas particularly vulnerable to micropollutants. However, JRC concluded there is no quality data to identify such areas.

JRC uses thus two indicators as proxy to reflect the sensitivity of the area :

- the dilution rate D (effluent load/load of the receiving water body, the less discharge is diluted in receiving water body, the more potential impact it has on the environment)
- discharge in coastal areas (discharge in coastal areas will be diluted even if dilution is weak at the point of discharge, and has potentially less impact on the environment).

D. Risk-based approach (based on monitoring data)

The initial idea reflected in the ToR was to assume that 4th stage treatment is applied depending on the concentration of given micropollutants or depending on the measured toxic load in receiving water bodies. However, this approach cannot be applied in practice because there is no consistent dataset to assess the risk associated with each WWTP in the EU with a meaningful indicator.

Considering these limitations, instead of the four scenarios initially envisaged, 7 scenarios were computed.

- S1 approximately corresponds to SA. Unlike the TOR, not all WWTP are covered, because this would have resulted in disproportionate implementation cost. Such a scenario appeared unlikely to be adopted at EU level and therefore not relevant to present in this report. However, very small WWTP are covered by fourth treatment which is the spirit of SA.
    - A threshold of 5000 PE was considered necessary to avoid disproportionate treatment cost to cover very small WWTP (CAPEX and OPEX).
    - Note that the dilution factor D=100 is high but still excludes 18% of WWTPs >5000 PE. This assumption could be revised to take into account an infinite dilution factor.
- S2, S3 and S4 relate to SB by introducing a criterion of WWTP size, with two relevant thresholds at 50 000 PE or 100 000 PE.
  An alternative fully in line with SB would have been to select 100 000 PE with an infinite dilution factor. In order to have more contrasted scenarios overall, a smaller dilution factor has been selected.
- S3, S4, S5.1 et S5.3 relate to scenario SC by introducing contrasted combinations of sensitivity indicators (D and discharge in coastal areas) and WWTP size. Dilution factors and discharge in coastal areas reflect the sensitivity of the receiving areas: if the effluent flow rate is high compared with the receiving water body capacity and not discharged in coastal areas, dilution of effluent in the environment is low.

Therefore the risk is high to significantly increase concentrations of micropollutants in the environment. It is for instance the case if the effluent is discharged in a lake or in a small river compared to WWTP size. However, the sensitivity of the ecosystems or of downstream water use (drinking water catchment areas, fishing areas, etc.) is not reflected by the dilution factor criterion. These other criteria are discussed qualitatively in section 12.4.

- S5.2 relate to scenario SD with a risk assessment indicator of 70% of WWTP likely to exceed toxicity thresholds. 70% is an estimation of the number of WWTP whose effluent would be classified as at risk for MP if local risk assessments were conducted. This value is based on surveys on European WWTPs, analysed by JRC, suggesting that approximately 70% of WWTPs could have an effluent close to or above toxicity threshold.

12.4. Discussion on risk-based approach

Switzerland and the Netherlands have adopted a risk-based approach to treat trace organic compounds in water. The principle of a risk-based approach is not only to reduce the total micropollutant load or toxic-weighted load but to prioritise the reduction of the load in areas at higher risks for the ecosystems or human health. This can be based on the following:

- The existence of a pathway to human exposition, e.g. drinking water catchment;
- The sensitivity of ecosystems in the receiving areas, e.g. Natura 2000 zone, area of specific ecological interest, etc.;
- The dilution rate: the more treated water is diluted in the receiving water body, the lower the risk that relevant toxicity thresholds to humans or ecosystems are exceeded (PNEC, chronic toxicity thresholds, etc.).

In Switzerland, the Water Protection Ordinance of 28 October 1998, reviewed on 1 January 2020, targets the WWTP discharging water in the most sensitive areas to implement quaternary treatment. The more sensitive the area, the stricter the PE criteria. Following this logic, all the treatment plants with 80 000 or more connected residents must implement a quaternary treatment (criteria 1). Then, in more sensitive areas, the obligation of treatment is extended to smaller treatment plants.

The different categories of sensitive areas are listed below by increasing sensitivity:

- Criteria 2: Catchment area of lakes;

- Criteria 3: Watercourses containing more than 10% waste water untreated for trace organic compounds;

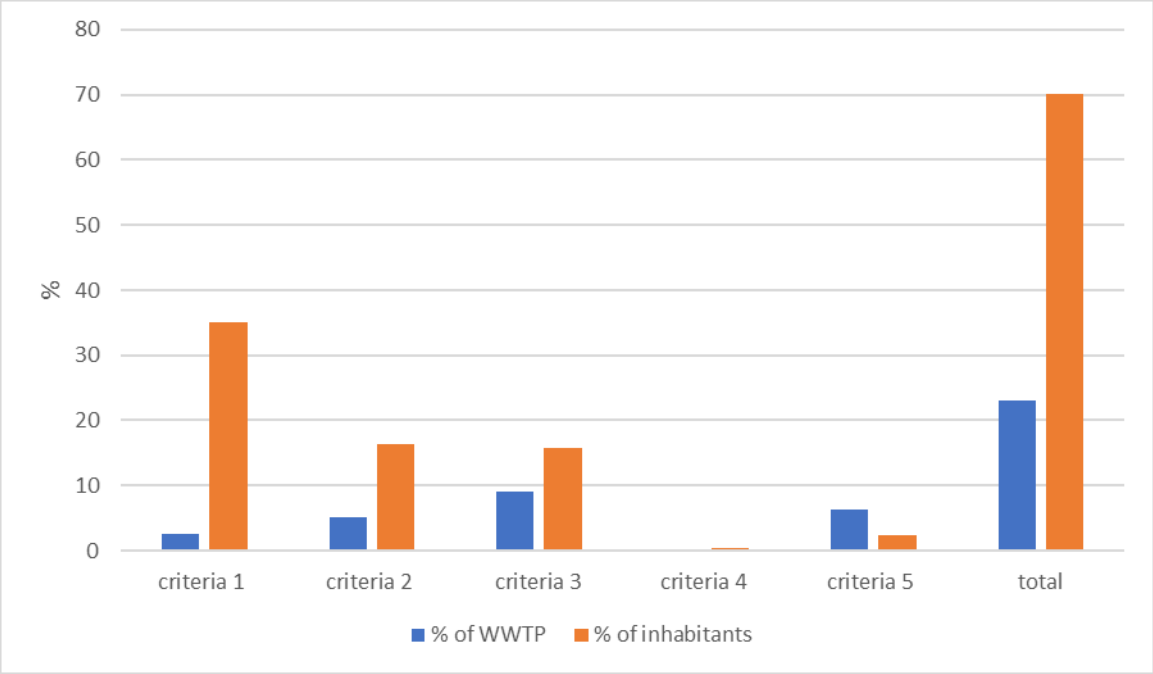
- Criteria 4: Areas with specific hydrogeological conditions, such as calcareous soils, since the discharge of polluted water in porous rocks creates a high risk of drinking water contamination;

- Criteria 5: Water bodies containing more than 20% waste water untreated for trace organic compounds located in ecologically sensitive perimeters such as natural parks[179].

The number of UWWTP and PE concerned by each criterion are represented in the figure below.

[179] This criteria will only enter in force in 2028.

Figure 25: % UWWTP and inhabitants concerned by each criteria in Switzerland



Comparison with quantitative scenarios and perspectives at EU level

The Swiss approach cumulates two types of scenarios.

A similar approach that could be implemented at EU level based on dilution factor as a sensitivity criterion (less complete and risk-based than the Swiss criteria but available at EU-level) would be to select:

- all WWTP bigger than 80 000 PE (dilution factor infinite): e.g. at EU level 46% of PE are covered by WWTP above 80 000 PE at EU level with D= 100
- +a criterion reflecting sensitivity, as an arbitrary example we could use for correspondence all WWTP below a very small dilution factor (whatever the size), in this example. 5% of WWTP below 80 000 PE have a dilution factor below 2.

Compared with quantitative scenarios established as PE = 80 000 and D= 2, the Swiss approach is more analogous to a scenario defined as PE= 80 000 or D=2.

The Swiss approach leads to PE coverage of 70%.At EU level, the illustrative approach developed by similarity would only result in a PE coverage of 51%. This difference is due to differences in the distribution of PE size in both areas and the limited part of the population located in sensitive areas considering the criterion D=2 only.

The Netherlands has adopted a different approach based on the identification of the "hotspot" UWWTP, which are the plants having the greatest impact on the concentration increase of trace organic compounds in water at three different levels[180]:

- At the discharge point;

[180] Vissers, M., L. Vergouwen en S. Witteveen (2017). Landelijke hotspotanalyse geneesmiddelen RWZI's. Stowa-rapport 2017-42. Amersfoort

- On downstream water and on the surface affected by the UWWTP (considering current and stagnant waters, the latter being more sensitive because of the potential accumulation of pollutants);

- On drinking water sources.

"Hotspot" WWTP contributing to the top 50%, 70% and 100% of the concentration increase of trace organic compounds on at least one of the levels described above were identified. Several scenarios imposing a quaternary treatment in these WWTP contributing to 50%, 70% and 100% are still under study. Detailed assumptions are confidential at this stage as they are still being discussed. According to current discussions, the treatment would be implemented in 80 to 100 WWTP (appr. 33% of WWTPs).

The impact on drinking water sources was not considered because in the Netherlands, drinking water catchments depend greatly on foreign water sources.

Comparison with quantitative scenarios and perspectives at EU level

In the Dutch approach, with concentration increase at the discharge point, only takes into account the contribution to concentration increase (without consideration of quantities involved). This would correspond to taking D (dilution factor) as the sole criterion for selecting obligating WWTP.

Other approaches adopted by the Netherlands on downstream water and affected surfaces and on drinking water sources are more complex and could not be replicated at EU level for lack of data.

Information on population coverage with the Dutch approach is not available to compare approaches at that level.

Table 37 below sums up the main characteristics of the approaches adopted in the two countries.

Table 37: Main characteristics of the risk-based approaches

	Switzerland	Netherlands
Start date	2016	2016
Status	14 UWWTP equipped	Pilot UWWTP to be launched in September Ongoing discussions on different scenarios
Type of criteria	Sensitivity of the area	"Hotspot" UWWTP
Number of WWTP to be equipped with a quaternary treatment	185	80-100
Percentage of WWTP equipped or to be equipped with a 4th treatment	20%	Around 33%

	Switzerland	Netherlands
Number of PE covered or to be covered by a quaternary treatment	6 016 011	NA
Percentage of the total population covered or to be covered by a quaternary treatment	70%	NA

In terms of quantities abated (correlated with PE), the Swiss approach is as ambitious as S1 but is more relevant than S1 to reduce risk due to the chosen criteria. It is also likely to be more cost-efficient because there is a selection of priority smaller WWTPs that should be covered by fourth treatment based on sensitive areas (which is not the case for S1).

The Dutch approach is not yet finalised; therefore, detailed data is confidential to compare ambition levels. However, the first results have demonstrated that the hotspot approach is cost-efficient because 50% of the concentration increase (taken as an impact indicator) can be tackled with only 30% of the cost compared with the cost of upgrading all WWTPs with fourth treatment[181].

[181] Cost estimations are currently rising, as a result of the experiences when building additional treatment in real life

12.5. Marginal cost

Figure 26: Marginal cost of 4th treatment (average, lower and higher bounds)

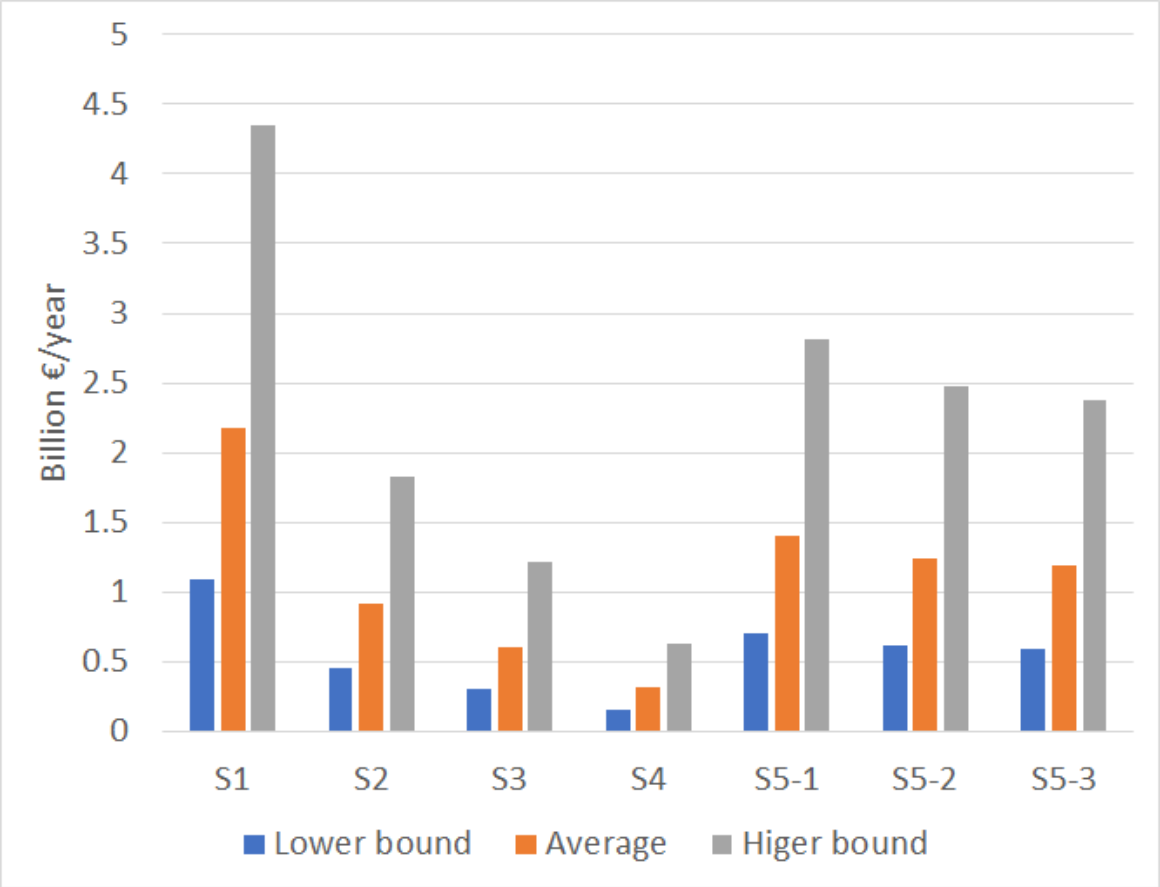


Table 32: Marginal cost of 4th treatment – results average, higher and lower bounds (billion €/year)

	PE	D	Lower bound	Average	Higer bound
S1	5000	100	1.09	2.17	4.35
S2	50000	50	0.46	0.91	1.82
S3	50000	10	0.30	0.61	1.21
S4	100000	5	0.16	0.32	0.63
S5-1	100000	10	0.70	1.41	2.81
S5-2	100000	10	0.62	1.24	2.47
S5-3	100000	10	0.59	1.19	2.37

12.6. Administrative cost

Number of FTE for the EPR

The number of FTE per PRO reported in the survey was divided by the number of product references falling into the associated EPR's scope. The average of the values obtained – excluding outliers - was multiplied by 27 to represent all countries in the EU and by the estimated number of product references for pharmaceuticals[182] and cosmetic products[183] per country.

Table 38: Average, lowest and highest budget allocated to the different cost items within PROs (source: survey)

Cost item	Average budget allocated	Minimum part of the budget allocated	Maximum part of the budget allocated
Communication	38%	12%	71%
R&D	3%	0%	6%
Enforcement	5%	0%	9%
Reporting	3%	0%	9%
Performance incentive	1%	0%	5%
EPR administrative costs	38%	6%	79%
Others	12%	0%	39%

[182] 15 500, data extracted from the French public database for medicines, https://base-donnees-publique.medicaments.gouv.fr/index.php#result

[183] 15 500, RDC Environment assumption taking into account the main PCP companies

12.7. Impact relative to expenses and margins - information per allocation key and scenario

12.7.1. Impact on expenses per sector

12.7.1.1. Quantity of substances

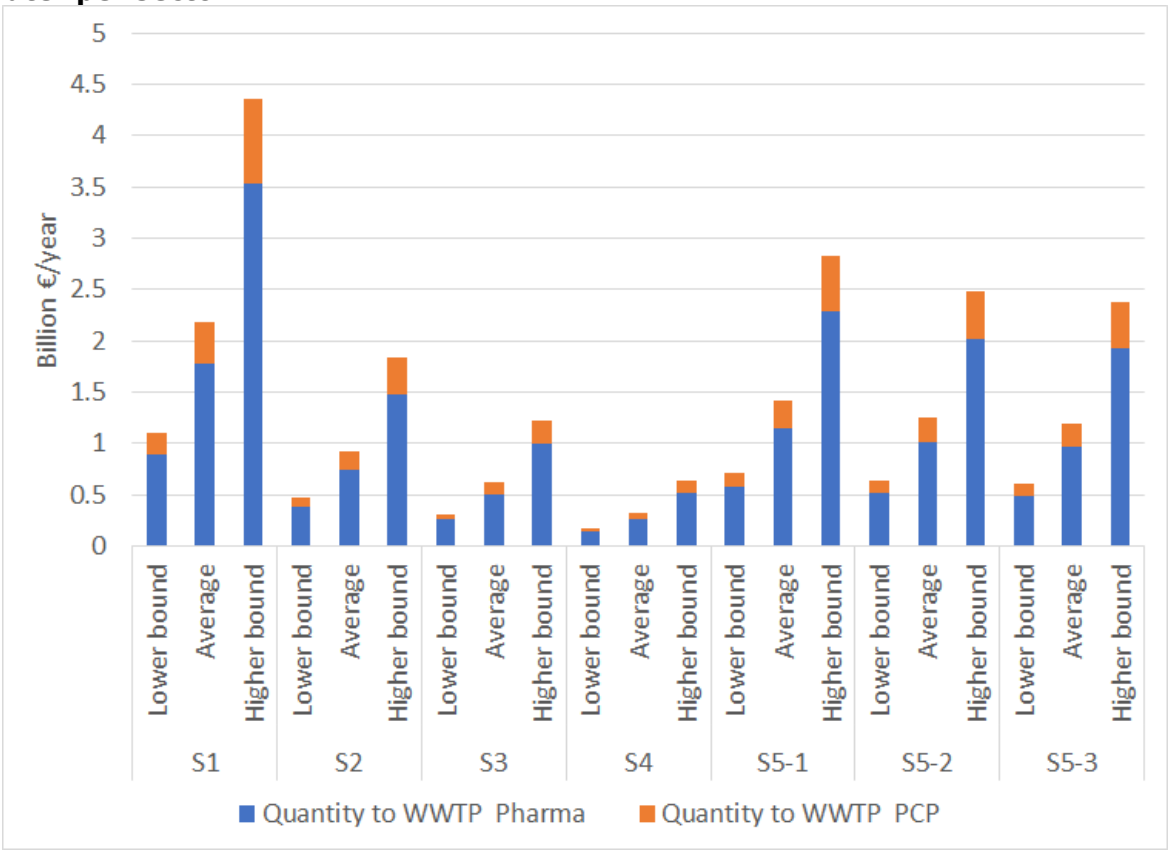
Input to WWTP

Allocating the EPR cost between sectors based on the quantity of substances found in waste water leads to attributing 19% of the total cost to the cosmetic product sector.

The average cost for the cosmetic product sector ranges from 0.06 to 0.42 billion €/year and from 0.26 to 1.77 billion €/year for the pharmaceutical sector, depending on scenario.

Figure 27 presents cost estimates per sector depending on scenario and 4th treatment cost estimate (lower, average or higher bound).

Figure 27: Cost allocation based on the quantity of substances found in waste water per sector

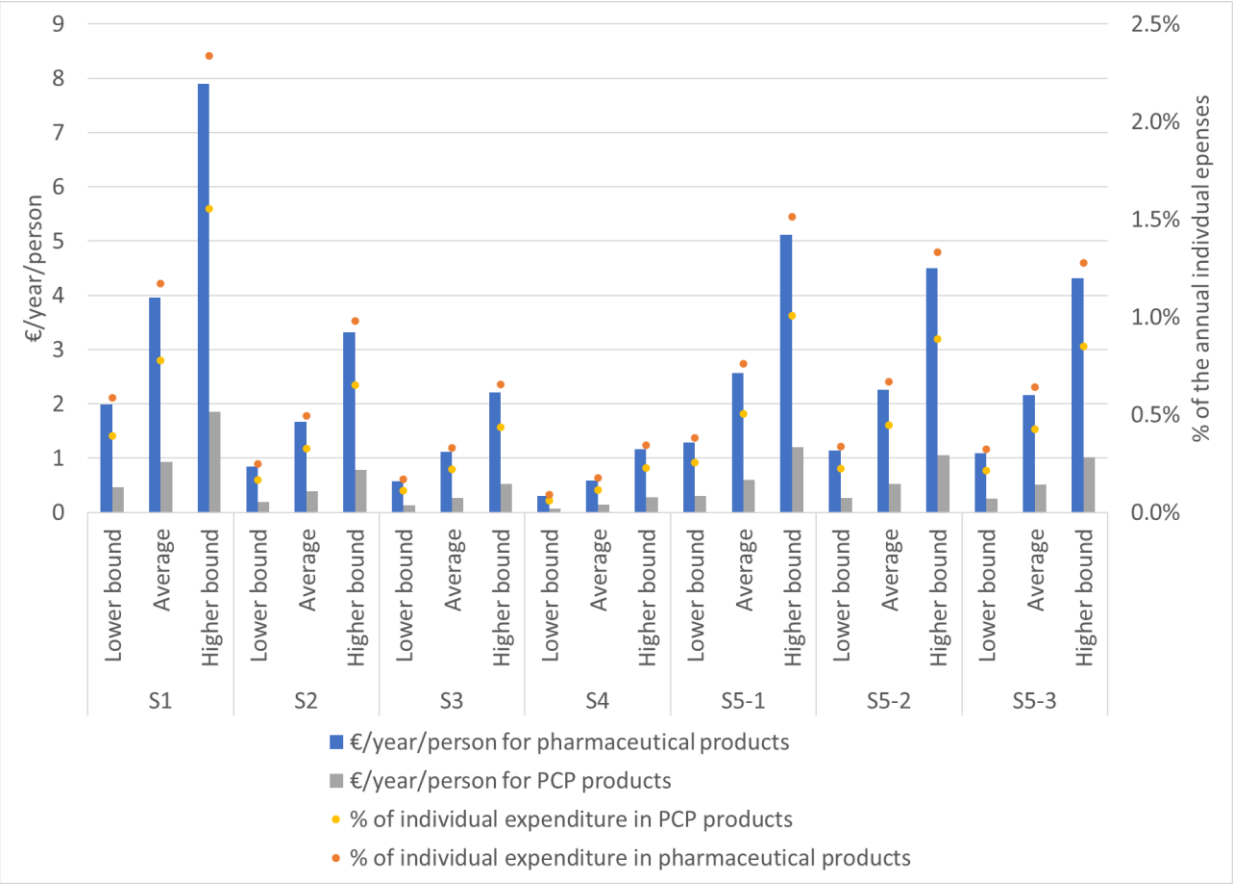


If passed on consumers through a price increase, the EPR costs could induce a relative price increase of 0.09 to 2.34% of individual expenditure in the pharmaceutical sector, and 0.06 to 1.56% in the cosmetic product sector depending on scenarios, according to average estimation of 4th treatment cost.

Figure 28 presents annual cost per capita per sector and relative impact compared to total expenses for the sector, depending on scenario and 4th treatment cost estimate (lower, average or higher bound).

Note that these estimations of relative impact compared with expenditure are averages per sector. The situation for product categories among those sectors will differ depending on prices for substances.

Figure 28: Allocation based on the quantity of substances - Variations in individual expenses per sector



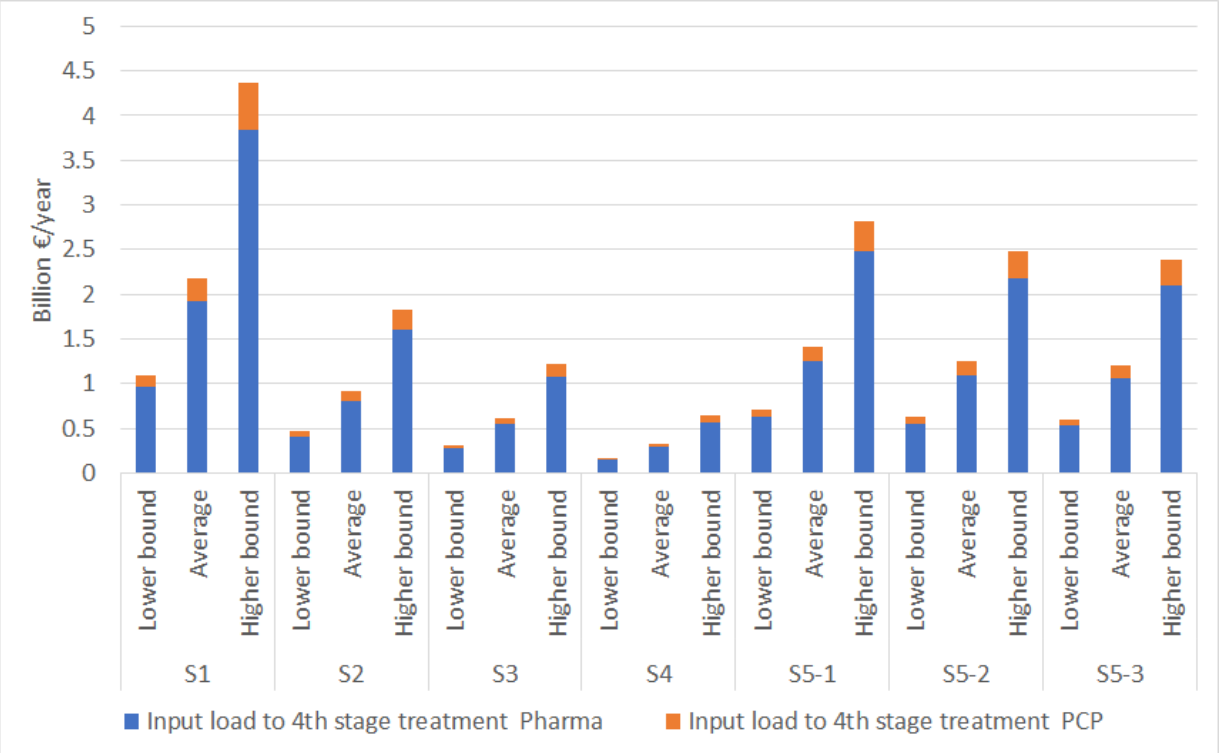
Input to 4th treatment

Allocating the EPR cost by the quantity of substances as input to the 4th treatment generated by each sector leads to attributing 12% of the total cost to the cosmetic product sector and 88% to the pharmaceutical sector.

The average cost for the cosmetic product sector ranges from 0.04 to 0.26 billion €/year and from 0.29 to 1.92 billion €/year for the pharmaceutical sector.

Figure 29 presents cost estimates per sector depending on scenario and 4th treatment cost estimate (lower, average or higher bound).

Figure 29: Cost allocation based on input to 4th treatment per sector

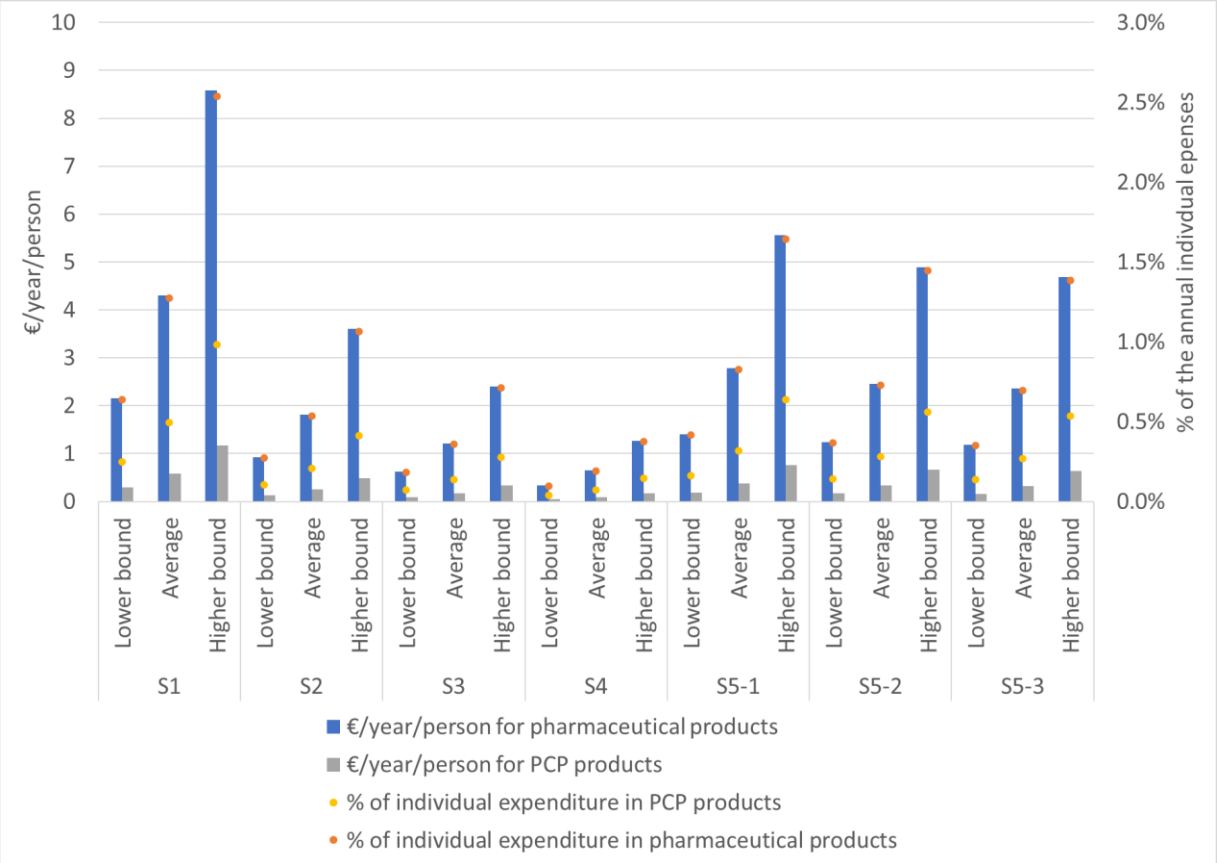


If passed on consumers through a price increase, the EPR costs could induce a relative price increase of 0.10 to 2.54% of individual expenditure in the pharmaceutical sector, and 0.04 to 0.98% in the cosmetic product sector depending on scenarios, according to average estimation of 4th treatment cost.

Figure 31 presents annual cost per capita per sector and relative impact compared to total expenses for the sector, depending on scenario and 4th treatment cost estimate (lower, average or higher bound).

Note that these estimations of relative impact compared with expenditure are averages per sector. The situation for product categories among those sectors will differ depending on prices for substances.

Figure 30: Allocation based on input to 4th treatment- Variations in individual expenses per sector



12.7.1.2. Toxicity/environmental impact of the substances

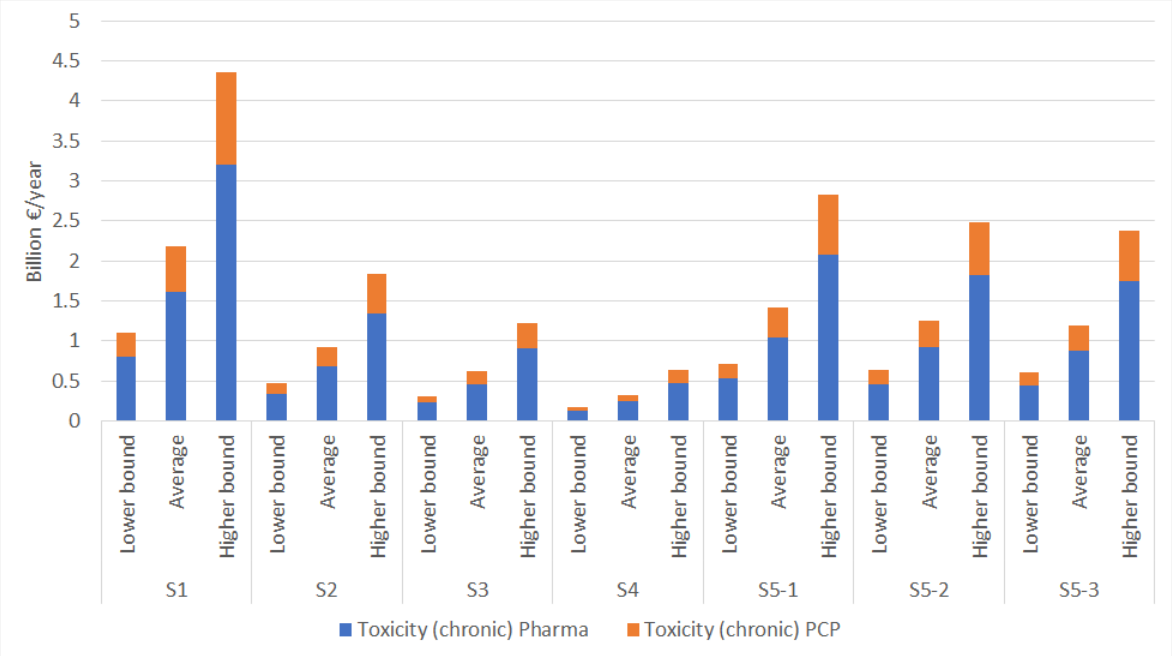
Chronic toxicity

Allocating the EPR cost between the two sectors using chronic toxic-weighted load leads to an allocation of 74% of the EPR costs to pharmaceutical products.

According to this cost allocation method, the average EPR cost estimations range from 0.24 to 1.61 billion €/year for the pharmaceutical sector and from 0.09 to 0.58 billion €/year for the cosmetic product sector, depending on scenarios.

Figure 31 presents cost estimates per sector depending on the scenario and 4th treatment cost estimate (lower, average or higher bound).

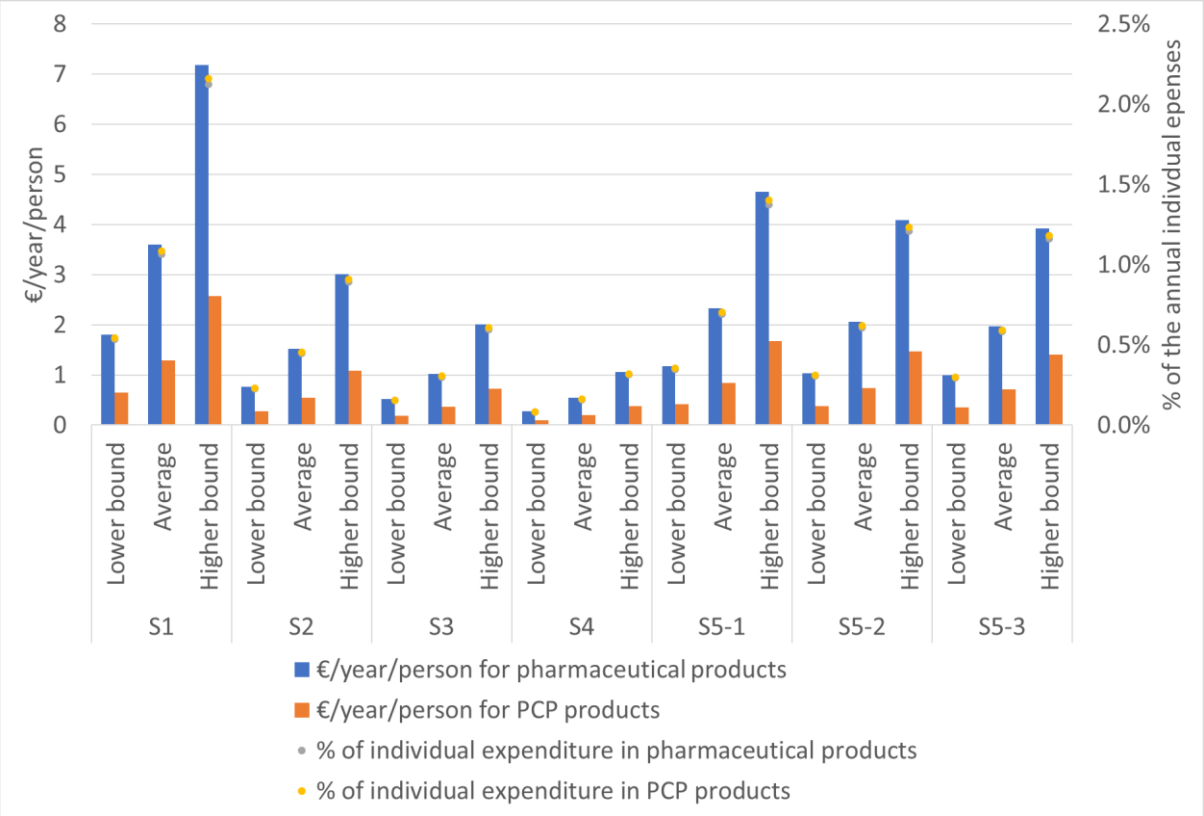
Figure 31: Cost allocation based on chronic toxicity per sector



If passed on consumers through a price increase, the EPR costs could induce a relative price increase of 0.08 to 2.12 % of individual expenditure in the pharmaceutical sector, and 0.08 to 2.16% in the cosmetic product sector depending on scenarios, according to average estimation of 4th treatment cost.

Note that these estimations are averages per sector but that the situation for product categories among those sectors could be significantly different.

Figure 32: Allocation based on chronic toxicity – Variations in individual expenses per sector



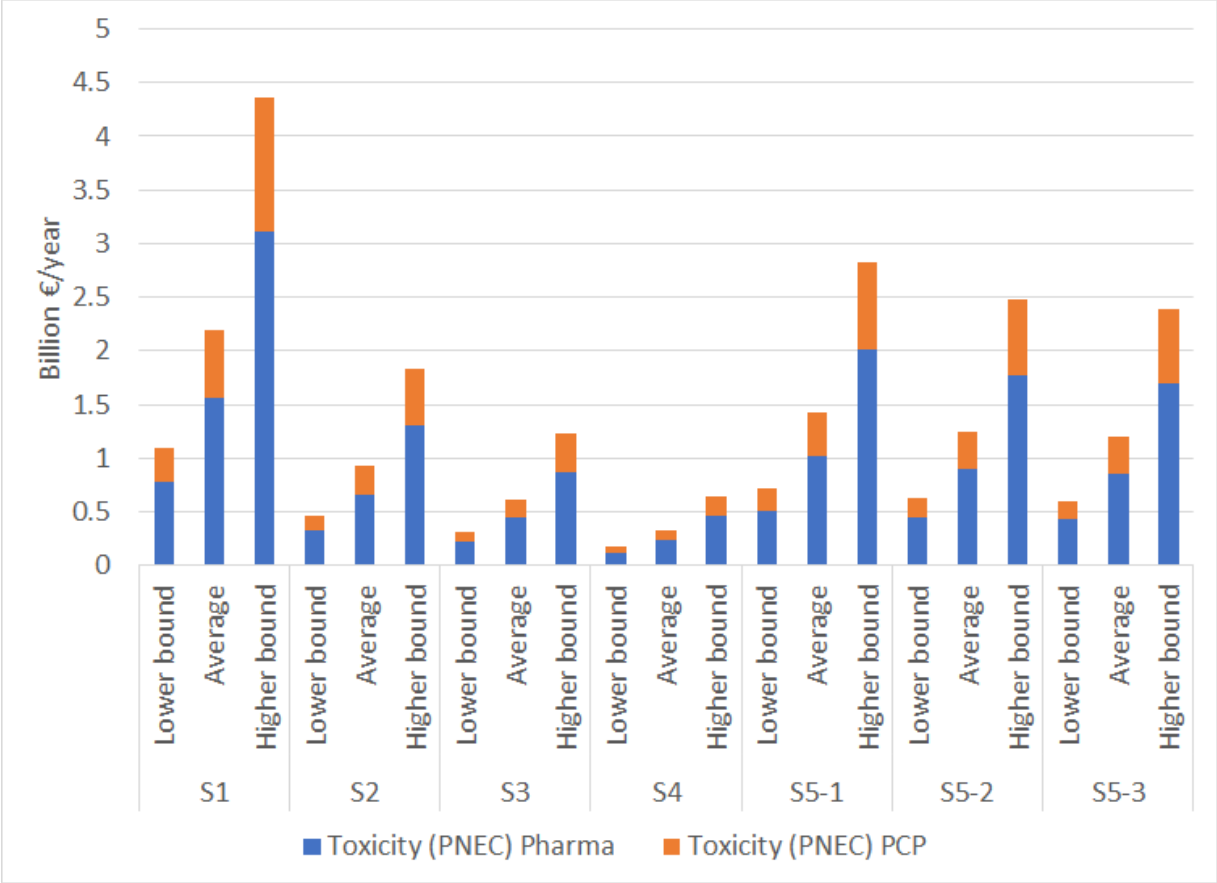
PNEC toxicity

Compared to the allocation method relying on chronic toxic-weighted load, the allocation via PNEC toxic-weight load leads to a higher share cost allocated to the pharmaceutical sector: 71%.

The average cost ranges from 0.23 to 1.56 billion €/year for the pharmaceutical sector and from 0.09 to 0624 billion €/year for the cosmetic product sector.

Figure 33 presents cost estimates per sector depending on the scenario and 4th treatment cost estimate (lower, average or higher bound).

Figure 33: Cost allocation based on PNEC toxicity per sector

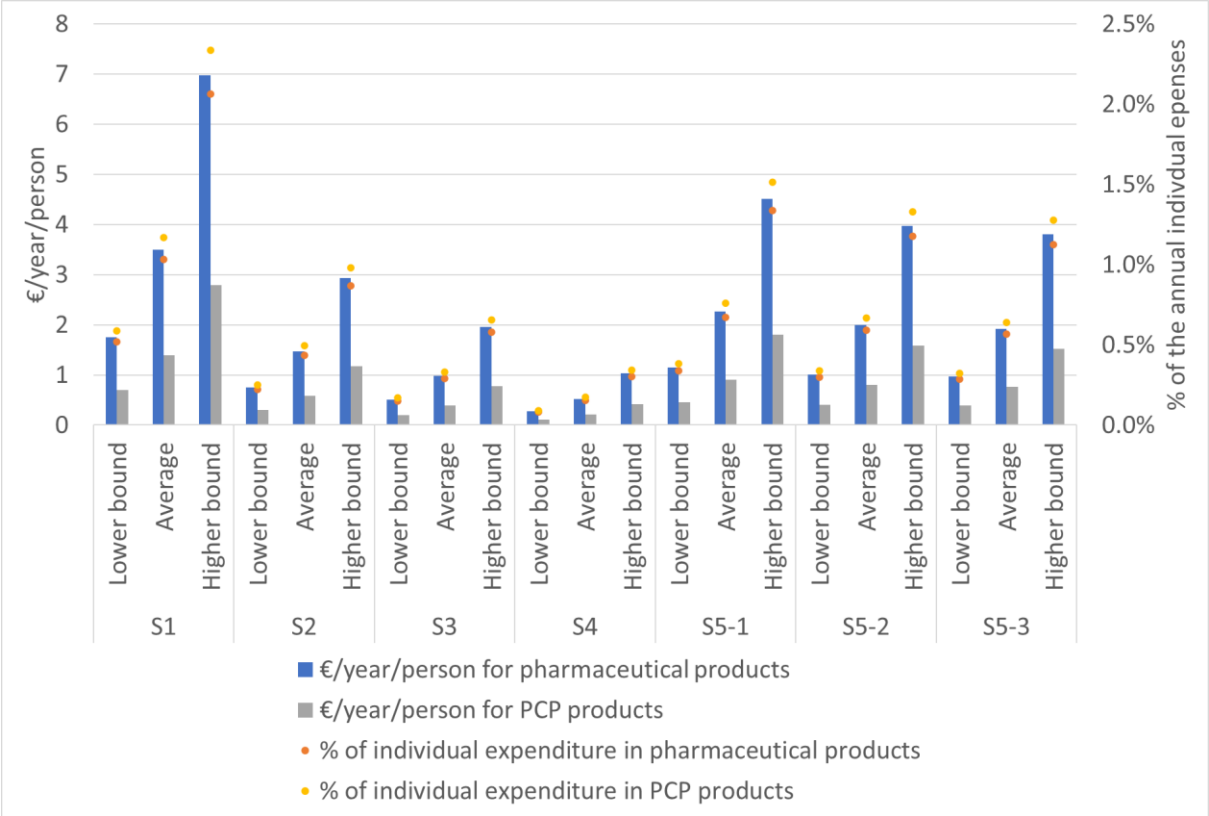


If passed on consumers through a price increase, the EPR costs could induce a relative price increase of 0.08 to 2.06 % of individual expenditure in the pharmaceutical sector, and 0.09 to 2.34% in the cosmetic product sector depending on scenarios, according to average estimation of 4th treatment cost.

Note that these estimations are averages per sector but that the situation for product categories among those sectors could be significantly different.

Figure 34 presents cost estimates per sector depending on scenario and 4th treatment cost estimate (lower, average or higher bound).

Figure 34: Allocation based on PNEC toxicity - Variations in individual expenses per sector



12.7.2. Impact per substance (pharmaceuticals)

12.7.2.1. Impact on expenses

Cost allocation within a sector will be decided by each PRO. This section aims at showing potential ways it could be done in order to compute the relative price impact by a pharmaceutical product.

With scenario 5.3, and assuming that costs are allocated based on quantities placed on the market, the fee would be in reach of a few dozen €/kg for pharmaceuticals and cosmetic product.

Information about total quantities of MP placed on the market is not available to estimate this precisely, but information about quantities measured in WWTP can be used as a proxy:

- The fee would reach 27 €/kg based on quantities of MP entering WWTP. This reflects the fee level if fees are established based on quantities placed on the market and if substances that are not excreted to wastewater or that biodegrade fast are exempted from paying.
- The fee would reach 46 €/kg based on quantities of MP entering 4th treatment. This reflects the fee level if fees are established based on quantities placed on the market and if substances that are not excreted to wastewater, that biodegrade fast or that are well treated by existing treatment stages are exempted from paying.

With such allocation choices, the relative impact on prices or margins will be higher for substances with relatively lower selling prices, such as generic pharmaceuticals (e.g. paracetamol price ranging between 63 and 240 €/kg in Spain and France, respectively).

Because the marginal cost of 4th treatment is first and foremost related to volumes of waste water to treat, any type of allocation between substances can reflect the true cost principle. As a consequence, PROs may choose an allocation by quantity and accept this significant effect on prices for some substances or may consider other criteria besides quantities to set their fee scale within a sector, such as toxicity indicators or turnover of entities placing on the market, in order to make sure that no individual substance see a major impact on prices.

To illustrate this effect, Table 3 presents the relative influence of EPR on prices, if EPR fees are fully passed on prices or if taken on the profit margin, for the 12 most-sold pharmaceutical substances, representing 80% of sold volumes of pharmaceuticals altogether. Cost was allocated between pharma and cosmetic product and between pharmaceutical substances based on two different allocation keys: quantities placed on the market (allocation between pharma and cosmetic product based on input to WWTP as a proxy) and chronic toxic-weighted load. Worst case and best case scenarios of the price impact reflect variability in price per substance depending on the country of sale. It therefore shows the extreme situations.

If the cost of EPR is fully passed on to prices with a cost allocation based on quantities placed on the market, EPR has a significant relative price impact on some of the top-sold substances with a low selling price. For instance, for paracetamol and metformin, the relative price impact varies between 12-45% and 6-48% respectively. It is important to remind that the absolute impact on expenses per year remains limited (2.4 €/year for pharmaceuticals), but an allocation by quantity focuses this impact on a few substances and gives way to a higher relative price effect for the cheapest substances compared with the average for pharmaceuticals (0.7%).

On the contrary, if PROs decide to incorporate toxicity indicators in order to allocate the fees, the cost of EPR fees will be distributed very differently. For instance, the impact on paracetamol prices would range between 1.0 and 3.7% of product prices using the chronic toxic-weighted load indicator[184].

if PROs decide to allocate the cost of EPR based on turnover, the maximum relative impact on prices will be similar between all substances within a sector (0.5-0.7% for pharmaceuticals, depending on the allocation key chosen to distribute costs between cosmetic product and pharmaceuticals sectors).

If the cost is fully taken on the profit margins there is no influence on pharmaceutical prices for most substances and cases. Cost increase may exceed profit margins in a few particular cases which would lead to a price increase (e.g. paracetamol with a quantity-based allocation and unfavourable price and margin conditions), which stresses the importance of the choice of cost allocation to be made by the PRO on the distribution of the cost within sectors.

NB: Information on the impact on product prices could not be computed by substance for the cosmetic product sector due to a lack of publicly available information on product composition and prices for individual substances.

[184] Allocation using the PNEC toxic-weighted load indicator leads to no significant on prices for the top-12 substances

Table 38: Relative influence of the EPR fees on the price of pharmaceutical substances (S5.3 optimised ++ scenario)

		100% cost passed on to prices (no impact on margins)					Cost taken on the profit margins to the maximum possible			
Name	% quantity placed on the market	Allocation based on quantities placed on the market		Allocation based on chronic toxicity		Allocation based on turnover	Allocation based on quantities placed on the market		Allocation based on chronic toxicity	
		Best case	Worst case	Best case	Worst case		Best case	Worst case	Best case	Worst case
paracetamol	41%	12%	45%	1.0%	3.7%		0%	37%	0%	0%
Metformin	12%	6%	48%	0.0%	0.0%		0%	40%	0%	0%
lactulose	7%	0%	0%	NA	NA		0%	0%	NA	NA
ibuprofen	7%	6%	8%	0.1%	0.1%		0%	0%	0%	0%
phenoxymethylpenicillin	3%	2%	5%	NA	NA		0%	0%	NA	NA
glucosamine	2%	6%	16%	NA	NA	0,5-0,7%	0%	7%	NA	NA
gabapentin	2%	2%	8%	NA	NA		0%	0%	NA	NA
mesalazine	2%	3%	3%	NA	NA		0%	0%	NA	NA
dicloxacillin	2%	2%	7%	NA	NA		0%	0%	NA	NA
piperacillin and beta-lactamase inhibitor	1%	1%	5%	NA	NA		0%	0%	NA	NA
aciclovir	1%	0%	0%	0.0%	0.0%		0%	0%	0%	0%

amoxicillin	1%	3%	15%	0.0%	0.0%	0%	5%	0%	0%

12.7.2.2. Impact on margins

Table 39 presents the impact of EPR fees on the profit margin if producers decide to take the full cost of EPR in their margin (scenario 5.3 optimised ++ based on average cost estimate for 4th treatment), for the 12 most-sold pharmaceutical substances.

Cost was allocated between pharma and cosmetic product and between pharmaceutical substances based on two different allocation keys: quantities placed on the market (allocation between pharma and cosmetic product based on input to WWTP as a proxy) and chronic toxic-weighted load.

All 12 substances are generic pharmaceuticals, whose margins typically range between 10 and 25%. These were taken as lower and higher bounds of profit margins.

In Table 39, margins after EPR are presented, assuming the cost of EPR reduces profit margins. A worst-case situation is presented on the left when pharmaceutical prices are low, and margins are low (10%). A best-case situation is presented on the right when pharmaceutical prices are high, and margins are high (25%).

If the cost of EPR is fully absorbed into profit margins with a cost allocation based on quantities placed on the market, EPR has a significant effect on margins on some of the top-sold substances with a low selling price. The conclusion is that with an allocation based on quantity, EPR fees cannot be fully absorbed by margins for some of the cheapest substances in the worst-case scenario because EPR fees exceed margins (margins shown to be negative for paracetamol, metformin, glucosamine and amoxicillin in the worst-case scenario in Table 39.). Also, the impact remains significant in the best-case scenario for some of the top substances (e.g. -13 pts margin for paracetamol), which means an impact on product price is to be expected. This shows the limit of a potential choice to allocate EPR fees exclusively based on quantities.

However, if PROs decide to incorporate hazardousness indicators in order to allocate the fees, the cost of EPR fees will be distributed very differently. Using the chronic toxic-weighted load as basis for allocation[185], the margin for paracetamol is reduced by only 1.1 to 3.8 percentage points for paracetamol. For other top-sold substances (metformin, acyclovir, amoxicillin), margins are not significantly affected by EPR fees. Data is missing for the other substances to compute the chronic toxic-weighted load.

Table 39: Impact on margins of pharmaceutical products (scenario 5.3)

Name	Allocation by quantity		Allocation by chronic toxicity	
	Worst-case: low margin (10%), low price	Best-case: high margin (25%), high price	Worst-case: low margin (10%), low price	Best-case: high margin (25%), high price
paracetamol	*-37%*	12%	6.2%	23.9%
metformin	*-40%*	18%	10%	25%
lactulose	10%	25%	NA	NA
ibuprofen	1%	18%	9.9%	24.9%

[185] Allocation using the PNEC toxic-weighted load indicator leads to no significant on prices for the top-12 substances

Name	Allocation by quantity		Allocation by chronic toxicity	
phenoxymethylpenicillin	4%	23%	NA	NA
glucosamine	-7%	19%	NA	NA
gabapentin	1%	22%	NA	NA
mesalazine	6%	22%	NA	NA
dicloxacillin	3%	23%	NA	NA
piperacillin and beta-lactamase inhibitor	5%	24%	NA	NA
aciclovir	10%	25%	10%	25%
amoxicillin	-5%	22%	10%	25%

NB: Negative margins mean there is necessarily an impact on prices, with maximum effect reflected in section 8.2.1.2, NA: Not available

The two above tables show 'extreme' cases of the potential consequences of different cost allocation systems based on the analysis of the situation in a very limited number of Member States. These extreme cases are provided for illustration but also to ensure that appropriate choices are made when it comes to the implementation of the system. In practice, to avoid such extreme cases, flexibility should be left in the legislation on the costs allocation rates between quantities and hazardousness of the products and on the way industry covers the additional costs of the EPR system (either through a reduction of their profit margins or by passing it in the price of the products or a combination).

12.8. Price of pharmaceutical substances

Table 40: Sources used to find the price of each substance

Name	Country	Price	Source
		in €/kg	
paracetamol	France	238	CEC-ZEV
	Spain	63	Murcia_Salud
	Germany	196	CEC-ZEV
Metformin	France	148	Vidal
	Spain	59	Murcia_Salud
	Germany	506	Doc_Morris

Name	Country	Price	Source
lactulose	France	20000	Pharmanity
	Spain	18797	Preciomed
	Germany	26316	Arzneiprivat
ibuprofen	France	453	Pharmanity
	Spain	371	La_informacion
	Germany	400	Homoempatia
phenoxymethylpenicillin	France	1750	Vidal
	Spain	1178	Murcia-Salud
	Germany	546	Medizinfuchs
glucosamine	France	481	Pharmanity
	Spain	174	Nomenclator
	Germany	253	doc_morris
gabapentin	France	841	Vidal
	Spain	342	Murcia_Salud
	Germany	1362	doc_morris
mesalazine	France	860	Illicopharma
	Spain	853	Murcia_Salud
	Germany	962	doc_morris
dicloxacillin	France	430	Vidal
	Spain	388	Murcia_Salud
	Sweden	1447	Apotea
piperacillin and beta-lactamase inhibitor	France	2191	Pharmanity
	Sweden	571	Apoteket
	Germany	4551	Medizinfuchs
aciclovir	France	27000	La_Sante
	Spain	36000	Farmacia
	Germany	24900	doc_morris
amoxicillin	France	773	Vidal
	Spain	191	Murcia_Salud

Name	Country	Price	Source
	Germany	1080	Medpex

[Catalogue num

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