European Commission

Study to support the impact assessment of a possible revision of the lists of pollutants affecting surface and groundwaters and the corresponding regulatory standards in the EU Environmental Quality Standards, Groundwater and Water Framework Directives

Contract ENV/F1/FRA/2019/0001

June 2023

Luxembourg: Publications Office of the European Union, 2023

EN PDF	KH-07-23-376-EN-N	ISBN 978-92-68-07359-9	doi:10.2779/537269

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Contract details

European Commission - DG Environment

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Specific Request Nr 24 under Framework Service Contract No ENV/F1/FRA/2019/0001
Economic analysis of environmental policies and analytical support in the context of Better Regulation

Presented by

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Date

Rotterdam, 29 June 2023

Trinomics

Rotterdam, 29 June 2023

Client: European Commission, DG Environment

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In association with:

wsp

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GLOSSARY

Abbreviation	Meaning
AC	Associated Countries
BAT	Best Available Techniques
BPR	Biocidal Products Regulation
BREF	Best Available Techniques Reference
CAS	Chemical Abstracts Service
CIS	Common Implementation Strategy
CMR	Carcinogenic, Mutagenic and Reprotoxic
DSD	The Directive on Dangerous Substances
DWD	Drinking Water Directive
ECHA	European Chemicals Agency
EEA	European Economic Area/European Environment Agency (context specific)
EFSA	European Food Safety Authority
EGD	European Green Deal
EINECS/EC numbers	European Inventory of Existing Commercial Chemical Substances number/European Community number
EMA	European Medicines Agency
EQS	Environmental Quality Standards
EQSD	Environmental Quality Standards Directive
FC	Fitness Check
FD	Floods Directive
GES	Generic Exposure Scenarios
GWAAE	Groundwater Associated Aquatic Ecosystems
GWB	Groundwater Body
GWD	Groundwater Directive
GWDTE	Groundwater Dependent Terrestrial Ecosystems
GWQS	Groundwater Quality Standards
GWWL	Voluntary Groundwater Watch List
HRT	Hormone Replacement Therapy
IA	Impact Assessment
IED	Industrial Emissions Directive
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
LFR	List Facilitating the 6 yearly review of GWD Annex I and II
MAC	Maximum Allowable Concentration
MEC	Measured Environmental Concentration
MS	Member State
MSFD	Marine Strategy Framework Directive
NGO	Non-Governmental Organisation

Abbreviation	Meaning
nrMs	Non-relevant Metabolite
OPC	Open/Online Public Consultation
PACT	Public Activities Coordination Tool
PAH	Polyaromatic Hydrocarbon
PBDE	Polybrominated diphenyl ethers
(u)PBT	(ubiquitous) Persistent, Bioaccumulative and Toxic
PC	Participating Countries
P.E.	Population Equivalent
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
PFCA	Perfluorinated carboxylic acids
PFOS	Perfluorooctane sulfonate
PMT	Persistent, Mobile and Toxic
PoMs	Programs of Measures
POP	Persistent Organic Pollutant
PS	Priority Substance
RBMP	River Basin Management Plan
RBSP	River Basin Specific Pollutants
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Risk of Hazardous Substances
SCCS	Scientific Committee on Consumer Safety
SCHEER	Scientific Committee on Health and Emerging Environmental Risks
SDG	Sustainable Development Goal
SSD	Sewage Sludge Directive
SUP Directive	Single-Use Plastics Directive
SVHC	Substances of Very High Concern
SW WL	Surface Water Watch List
ToR	Terms of Reference
TV	Threshold Value
UWWTD	Urban Waste Water Treatment Directive
vPvM	very Persistent and very Mobile
WHO	World Health Organisation
WISE	Water Information System for Europe
WFD	Water Framework Directive
WG	Working Group
WG GW	Working Group for Groundwater
WL	Watch List
WWTP	Wastewater Treatment Plant

1 This report

1.1 Purpose of the report

This report is the impact assessment of policy options for the '*'Study to support the impact assessment of a possible revision of the lists of pollutants affecting surface and ground waters and the corresponding regulatory standards in the Environmental Quality Standards, Groundwater and Water Framework Directives'* contracted under the Framework Contract ENV/F1/FRA/2019/0001 on 'Economic analysis of environmental policies and analytical support in the Context of Better Regulation'. Our team consists of WSP E&IS GmbH (WSP) as lead, in collaboration with Trinomics.

This Report presents the final version of the analysis carried out, organised to follow the structure of the impact assessment report:

#This report	#SWD	Section
1		This report
2		Overview of methodology
3	1	Introduction: Political and legal context
4	2	Problem definition
5	3	Why should the EU act?
6	4	Objectives: What is to be achieved?
7	5	What are the available policy options?
8	6	What are the impacts of the policy options and who will be affected?
9	7	How do the options compare and what are the preferred options?
10	8	Preferred policy package
11	9	How will actual impacts be monitored and evaluated?

1.2 Objectives of the project

The objective of the project is to support the European Commission with an assessment of impacts of a range of options for the review and revision of lists of pollutants affecting surface and ground waters, supported by a study of the costs and benefits. This will assist the Commission in deciding on the most appropriate legislative and non-legislative action. The study includes: the definition of an impact assessment methodology; the collection of thematic information to inform the analysis of impacts; and performing the analysis of impacts, including costs and benefits (including avoided costs).

The study covers all EU Member States (MS), screening and assessing policy options based on technical reviews of the lists of surface and groundwater pollutants and the findings of the Fitness Check of the Water Framework Directive (WFD) and related legislation.

1.3 Structure of the report

The report follows the structure of an Impact Assessment report as defined in the European Commission's Better Regulation toolbox and has the following structure:

- Section 1 introduces this report.
- Section 2 presents an overview of the methodology used.
- Section 3 provides the political and legal context related to the options.
- Section 4 presents a problem definition, including an intervention logic and baseline information related to how the problem would evolve without intervention.
- Section 5 presents an overview of why the EU should act.
- Section 6 provides further detail underlying the objectives of the policy options.
- Section 7 presents an overview of various policy options.
- Section 8 provides the impacts of the policy options (economic, environmental, and societal impacts).
- Section 9 presents a comparison of options.
- Section 10 presents the preferred option.
- Section 11 provides details of how the policy options would be monitored/evaluated to demonstrate the aims have been achieved.

2 Overview of methodology

This section provides a high-level overview of the approach taken to carry out this assignment, including key steps undertaken. More detailed descriptions of the methodologies, and their potential limitations, are presented in each of the following chapters, where relevant.

The methodology was designed to meet the requirements of the Better Regulation Guidelines[1] and provide the European Commission with timely evidence collection, stakeholder engagement and analysis of information gathered. The main steps have been:

- Collection of data through an extensive literature review.
- Complementing and validating the information through consultation activities, namely:
    - Feedback to the Inception Impact Assessment.
    - An online open public consultation (OPC).
    - A targeted expert survey.
    - Workshops.
- Analysis and comparison of the policy options.

The policy options have gone through a number of analysis steps. As a first step, during the inception phase and building on the ToR, the team formulated the list of potential policy options for surface water, groundwater and complementary options related to digitalisation, administrative streamlining and better risk management. Following this, a screening report was developed in close cooperation with the Commission. The report developed a series of policy options, analysing the relevance, effectiveness, efficiency, and feasibility of each option. This was achieved through the analysis of literature and the outputs of Common Implementation Strategy (CIS) Working Group (WG) meetings.

The list of retained options has been further analysed through an additional literature review, and via stakeholder feedback through the first stakeholder workshop held on May 21st 2021, and through an open public consultation and targeted expert survey which took place between July-November 2021. The analysis presented in this report focusses on the projected environmental, economic and social impacts of each option.

2.1 Literature review

Following the screening report, a ‘master spreadsheet’ was developed, with standardised sections for different types of information to allow the efficient gathering and collation of data, which is presented in a format ready for analysis and comparison between the different substances. The master spreadsheet includes sections covering:

- **Substance identification and classification information** (including IUPAC name, CAS and EINECs/EC numbers, common names, trade names, major metabolites, and hazard classification).

[1] European Commission, Better Regulation Guidelines, swd2021_305_en.pdf (europa.eu)

- **Environmental fate parameters** including a range of physico-chemical data affecting environmental behaviour, such as solubility, volatility, log Koc, log Kow, half-life in water, sediment, and soil.
- **Manufacturing and use profile** including a breakdown of all potential uses (as a life cycle, manufacturing, use, waste, legacy hotspots), tonnages, geographic variations.
- **Pathway to environment** (based on the manufacturing and use profile, details of point sources, diffuse sources, efficacy of wastewater treatment plants, high level summary data).
- **Legislative status** (details of how the substance is managed across all relevant legislation, including restricted uses, critical concentrations/thresholds, and consideration of evolving policy).

For surface waters, this information was further supplemented by lists of river basin specific pollutants (RBSPs) including EQS from Member State Competent Authorities, Programs of Measures (PoMs) for existing PS that may also be relevant for candidate PS. For groundwaters, the method of addition (to Annex I or II), the likely exceedance above proposed groundwater quality standards (GWQS) and the number of additional GWBs which could fail to reach good status were all considered. Further consultation and data gathering was undertaken to help target data for the costs and benefits element of the impact assessment focusing on the environmental impacts and costs of measures.

The study has also gathered reported surface water monitoring data within the WISE database held by the European Environment Agency, and dashboards, which includes data from the first and second river basin management plans. The monitoring data helped inform the current state of play against the proposed EQS, and supported the cost assessment triggered by proposed legal changes. There is no EU-wide monitoring network for emerging groundwater pollutants and the study used monitoring data which had been provided for the purposes of the GW WL process.

To help populate the master sheet used in the impact assessment for policy options we have completed a literature review, which has included a combination of key EU databases alongside academic literature and industry data. This has included:

- **REACH data held by the European Chemicals Agency (ECHA).** This includes:
  - The publicly available REACH registration data on tonnages, uses, and environmental data.
  - Classification and labelling inventory for recognised hazard classifications.
  - Public Activities Coordination tool (PACT) for emerging actions under REACH and related legislation.
- **European Food Safety Agency (EFSA) database of pesticide actives.** This includes the details of approved and non-approved actives, underlying documents on decision making, and data for pesticide residues.
- **Data held by the European Medicines Agency (EMA).** This includes:
  - Official lists of approved medicines, including whether the approval covers human uses, veterinary uses, or both.

  - Article 57 database, which includes details of pharmaceutical products approved at Member State level.
- **Pubchem**. This online resource provides peer reviewed data covering hazards, physico-chemical properties and environmental fate data, major metabolites, uses, and environmental data.
- **Drugbank.com**. This online resource provides a wealth of chemical, environmental and human health data related to pharmaceuticals.
- **WISE database**. EEA database of water monitoring data provided by Member State competent authorities.
- **EEA dashboards**. The EEA dashboards provide data on priority substances (i.e. for surface water) from the first and second RBMPs. This data is primarily of interest for the existing priority substances subject to potential amendment or deselection and is not used in this assessment of impacts on groundwater.
- **Further studies** made available to the consulting team or the Commission as part of the stakeholder consultation

Note that the current study is running in parallel to the work of the Joint Research Centre (JRC), who are developing dossiers for EQS determination and obtaining the opinions of the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) on different surface and groundwater options.

2.2 Consultation activities

2.2.1 *Feedback to the Inception Impact Assessment*

The European Commission published the roadmap on 'Integrated water management – revised lists of surface and groundwater pollutants'[2] to offer the opportunity for interested parties to provide feedback on the scope of the Impact Assessment. The roadmap received 19 pieces of feedback, which were analysed in the 'Consultation Synopsis Report'.

2.2.2 *Online public consultation (OPC)*

The open public consultation included questions tailored to examine three distinctive components which outlined potential measures to be analysed:

1. Protect the aquatic environment and human health from chemical pollution through achieving good surface water chemical status by controlling emissions of PS and ceasing/phasing out emissions, discharges and losses of PHS;
2. Ensure a high and equal level of protection of groundwater resources including their connected or dependent ecosystems and their uses;
3. To continuously improve knowledge and decision-making on sufficient, correct, robust and transparent monitoring and reporting information.

The questionnaire was made available in all EU languages and uploaded to the EU Survey tool.[3] The consultation period started on 26th July 2021 and ended on 1st November 2021. The OPC received a total of 151 responses, which were analysed in the 'Consultation Synopsis Report'.

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12662-Integrated-water-management-revised-lists-of-surface-and-groundwater-pollutants_en

[3] https://ec.europa.eu/eusurvey/home/welcome

2.2.3 *Target stakeholder consultation- survey*

An online survey tailored towards stakeholders with a detailed technical knowledge of surface water and groundwater substances and current EU legislation was developed. The survey specifically targeted a broad range of stakeholder groups including public authorities responsible for implementing and/or enforcing the Directives, industry and sectoral associations representing companies concerned, monitoring organisations, environmental and consumer NGOs, universities and research institutes, and any other organisations interested in responding to the survey.

The survey was made available between 27th July 2021- 19th October 2021, building upon the more general OPC, and addressing three topic areas for which different policy options which were analysed (surface waters, groundwaters and complementary options). The targeted survey received a total of 124 responses which were analysed in the ‘Consultation Synopsis Report’.

2.2.4 *Workshops*

Two workshops were held with stakeholders throughout the duration of the project in May 2021 and March 2022. Participants for the workshops were primarily composed of members of the related CIS Working Groups. The first workshop aimed to obtain initial insights and recommendations for proposed policy options from stakeholders, in addition to receiving feedback on preliminary data of the impact assessments. Finally, the workshop gathered stakeholder comments to assist in drafting relevant content for the OPC and targeted survey. The second workshop presented draft impact assessment findings and selected policy options in order to collect feedback on selected policy options, as well as on the monitoring and evaluation strategies. The first workshop was attended by 247 participants, and the second by 222.

2.3 Analysis and comparison of options

Data from a wide range of data sources was used to populate the master spreadsheet used in the impact assessment for policy options as illustrated in section 2.1. Further consultation and data gathering from literature, in combination with data available in the master spreadsheet, enabled a long list of technical mitigation measures (source control, pathway disruption, end-of-pipe) to be developed on a substance-by-substance basis. For each measure, the typical costs were obtained from literature (while recording variables such as geographical location that might affect these values). Simultaneously, the capacity of a given measure to remove a substance (technical effectiveness) was recorded. In addition, information on environmental, economic and social benefits have been collated for different substances. This data collection enabled the costs and benefits element of the impact assessment to be performed.

Information contained in the JRC dossiers, mentioned within section 2.1, have been used to assess potential gap in status and identify substances that will be most affected by the policy changes (e.g. introduction, amendment or deselection of substances).

Further details on the analysis of options are included in the Inception Report for this study.

3 Political and legal context

The public, all economic sectors, and nature all need 'non-polluted' water, requiring the minimisation of harmful substances entering rivers, lakes, coastal and groundwaters. Despite improvements in legislation, governance and heavy investment, European waters continue to be affected by a wide range of significant pressures, including pollution, alterations to the physical landscape surrounding water bodies, water scarcity and floods. To tackle these pressures, a number of the EU cornerstone water directives and regulations[4] have been implemented and these are briefly discussed below.

3.1 At EU level

3.1.1 *Water Framework Directive*

The **Water Framework Directive (2000/60/EC)** (WFD) adopted in 2000 aimed to ensure that all surface and groundwater bodies achieve "good status" by 2015 and by 2027 when duly justified exemptions apply. For surface water to be classified in overall good status, both chemical status and ecological or quantitative status must be at least good. For a groundwater body to be classified at overall good status, both chemical status and quantitative status must be good. Deterioration of water quality is not allowed, unless in very specific cases and when the conditions set out in the Directive are met.

The Directive rationalised and consolidated several directives into a single policy instrument and introduced the requirement for the management of water bodies to be conducted at river basin level. The Water Framework Directive (WFD) provides the **main policy framework for preserving and restoring the quality of European water bodies**, laying down a common framework for all other water policies within an integrated planning approach.

Water bodies are at particular risk from certain hazardous substances which can affect ecosystems and threaten human health. Therefore, under the Water Framework Directive, complementary Directives have been adopted establishing the standards which constitute the chemical status criteria. These include **Environmental Quality Standards Directive (EQSD)** (2008/105/EC, as amended by 2013/39/EU) and Directive on the protection of **Groundwater** against pollution and deterioration (GWD) (2006/118/EC). For all of these directives there is a legal obligation for the Commission to review the lists of pollutants every 6 years.

The WFD also sits within a larger policy landscape which can broadly be termed the chemicals acquis[5], spanning approximately 50 pieces of legislation. This includes legislation which spans broad thematic topics (such as the WFD, the Industrial Emissions Directive, REACH, and the Waste Framework Directive); and legislation which covers specific applications or issues (such as the safety of toys, detergents, cosmetics, pharmaceuticals, plant protection products and biocidal products regulation). The chemicals acquis forms a

[4] The Drinking Water Directive, the Urban Waste Water Treatment Directive, the Bathing Water Directive, the Water Framework Directive, the Floods Directive, the Groundwater Directive, the Environmental Quality Standards Directive, the Marine Strategy Framework Directive, and the Water Reuse Regulation.

[5] European Commission, 2019, Staff working document for the fitness check of most relevant chemicals' legislation (excluding REACH), COM(2019)264. (see Annex 4 table 1 which lists 41 pieces of legislation, which could be further supplemented with EQSD, sewage sludge directive, groundwater directive, ambient air quality directive, national emissions ceiling directive, fluorinated gases regulation, ozone regulation, pollutant release and transfer register regulation, mercury regulation and waste electrical and electronic equipment (WEEE) directive)

legislative landscape to effectively manage the safe manufacture and use of chemicals, while still allowing the function of the internal market, competitiveness, and innovation.

3.1.2 *Environmental Quality Standards Directive*

The **Environmental Quality Standards Directive (EQSD)** aims to protect the aquatic environment from chemical pollution through achieving good surface water chemical status by setting environmental quality standards (ambient concentrations in water, sediment, and/or biota) to be achieved through the successful management of the water body and river basin, including control of releases of priority substances to complement the requirements of the WFD. For priority hazardous substances, this includes cessation of releases and ambient concentrations returning to natural background levels. The Directive establishes Environmental Quality Standards (EQS) at a level aiming to protect the aquatic environment and human health against long-term exposure (expressed as annual average (AA) concentration) and short-term exposure (expressed as maximum allowable concentration (MAC)). Where a priority substance exceeds the EQS it denotes a chemical risk warranting action through a Programme of Measures (PoM) to return the concentration back below the EQS.

The Directive covers 45 priority and priority hazardous substances (33 from the original 2008 EQS implementation and a further 12 added in 2013[6]) including heavy metals, industrial chemicals, pesticides and unintentionally formed substances. These substances have been selected for the EQSD on the basis that they represent an EU-wide risk to surface water ecosystems and human health via the environment.

The Directive requires Member States to:

- Apply the EQS (AA and/or MAC) defined in the Directive for surface water bodies (Article 3 (1)) and ensure compliance.
- Notify the European Commission on alternative EQS established for sediment and/or biota and monitoring techniques used (Article 3).
- Monitor those substances, every 3 years and carry out a long-term trend analysis for priority substances listed in Part A of Annex I (Article 3).
- Establish an inventory of emissions, keep the inventory updated and communicate it to the Commission (Article 5).

The 2013 revision of the EQSD further established a new mechanism requiring Member States to monitor substances on a Surface Water Watch List (SW WL) (first adopted in 2015 and repealed in 2018 and 2020) to gather information to support the review of the PS list. This was on the basis that sufficient information to help determine a listing (or otherwise) was absent. Generation of monitoring data via the WL will help provide the evidence base for further consideration.

3.1.3 *Groundwater Directive*

The Directive on the protection of **Groundwater** against pollution and deterioration (2006/118/EC), also referred to as the Groundwater Directive (GWD), was adopted in 2006 and amended in 2014 by Directive 2014/80/EU, and replaced the previous Council Directive

[6] Note that good chemical status should be achieved within 15 years from listing upon the EQSD annexes.

80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances.

The GWD is designed to prevent and limit groundwater pollution in the EU. It includes procedures for assessing the chemical status of groundwater and measures to reduce levels of pollutants. In addition to protecting the environment, this indirectly protects human health by preserving high quality drinking water sources. The GWD also sets out criteria to identify upward trends in groundwater pollution levels and defines starting points for reversing these trends, so that environmental objectives are achieved using the measures set out in the WFD. The GWD sets groundwater quality standards (GWQS) for pesticides and nitrates and identifies a minimum number of other substances for MS to consider setting threshold values (TVs). The GWD requires MS to:

- Use the water quality criteria for assessing good chemical status set out in Article 3 and Annex I. Annex I of the GWD provides EU-wide GWQS for nitrate and pesticides (individual and total);
- Establish threshold values (TVs) for each pollutant identified as leading to any groundwater body (GWB) being considered at risk of failing to achieve environmental objectives. Annex II provides a minimum list of substances for MS to consider when setting TVs.
- Assess the chemical status of GWBs as set out in Article 4;
- Identify significant and sustained upward trends in concentrations of pollutants and identify the point for trend reversal ("baseline level" data obtained in 2007-2008) (Article 5);
- Identify and implement measures aimed at preventing or limiting inputs of pollutants into groundwater in a timely manner so that WFD environmental objectives can be achieved as set out in Article 6.

Article 3 of the GWD describes the criteria for assessing the chemical status of a GWB, including the use of GWQS listed in Annex I and Threshold Values (TVs) established by MS in as set out in Annex II. In annex I, GWQS are listed for nitrates and pesticides (individual and total, including their relevant metabolites). Although Annex II provides a minimum list of substances to be considered by MS when setting TVs, MS may set TVs for substances that are not on this list. TVs are set by MS for individual pollutants or groups of substances that present a risk to a GWB and are a trigger for further assessment of the impact of that pollutant. The GWD indicates that TVs should focus on the protection of the GWB, including actual or potential legitimate uses, such as drinking water, or functions of groundwater and the interactions with groundwater associated aquatic ecosystems (GWAAE) and groundwater dependent terrestrial ecosystems (GWDTE).

The 2014 revision to the GWD included changes to Annex II that added common principles for the determination of natural background levels, which was previously an important factor behind the high variation in TVs between MS. In addition, nitrite, and phosphorus (total)/phosphates were added to the minimum list of pollutants in Annex II. Importantly, the revision also acknowledged in recital 4 the need to establish a voluntary watch list mechanism to increase monitoring and knowledge of substances posing a potential risk to groundwater (including emerging pollutants) for which GWQSs or TVs should be set. This process was aimed at providing an increased knowledge base on the occurrence and distribution of these substances as well as continual analytical improvements to monitoring by MS. This watch list process is beneficial for example, for assessing potential relations between disease incidence rates and an increased exposure to harmful substances and substances of emerging concern via increased concentrations in groundwater and connected surface waters.

Groundwater Watch List

The Groundwater Watch List (GWWL)[7] process was initiated on a voluntary basis for the MS/AC by the European Commission in 2014 for pollutants in groundwater. The GWWL facilitates the identification of substances, including emerging pollutants, for which GWQS or TVs should be set. The need for a GWWL process arose because several pollutants had been found in groundwater by existing monitoring programmes where improvements in analytical techniques have allowed for detection of a wider range of contaminants and at lower concentrations. Additionally, new pollutants have been identified through surveys focused on emerging contaminants and there was increased concern around the pollution they produce. This meant that there was a need to understand the extent to which new and emerging substances are present in groundwater, to better assess the risks that they pose and to consider measures to mitigate those risks, including the inclusion of some of these substances into Annex I or Annex II of the GWD.

The GWWL process was developed by the CIS Working Group for Groundwater (WG GW) during their 2016-18 mandate. One of the first steps was to develop a methodology to identify pollutants of potential concern that MS should consider adding to their groundwater monitoring programmes, which would lead to the building a body of knowledge such that risks from these substances could be understood and mitigated. The “Voluntary Groundwater Watch List Concept & Methodology” report describes how substances for inclusion on the GWWL have been identified.

The GWWL process, as reproduced in Figure 3.1, ranks substances on the basis of: i) existing knowledge around their detection in groundwater, ii) their relevant properties (mobility and persistence), iii) their sources and pathways to the environment, and iv) their toxicity/ecotoxicity considering properties and criteria such as Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB), Persistent, Mobile, Toxic (PMT), Carcinogenic, Mutagenic and Reprotoxic (CMR), Endocrine Disrupting (ED), etc, as defined by the EU REACH Regulation (EC1907/2006). At this point, substances may be added either to the GWWL or to the List Facilitating (abbreviated to LFR) the 6 yearly review of GWD Annex I and Annex II or removed from the process. The criteria for this decision are as follows:

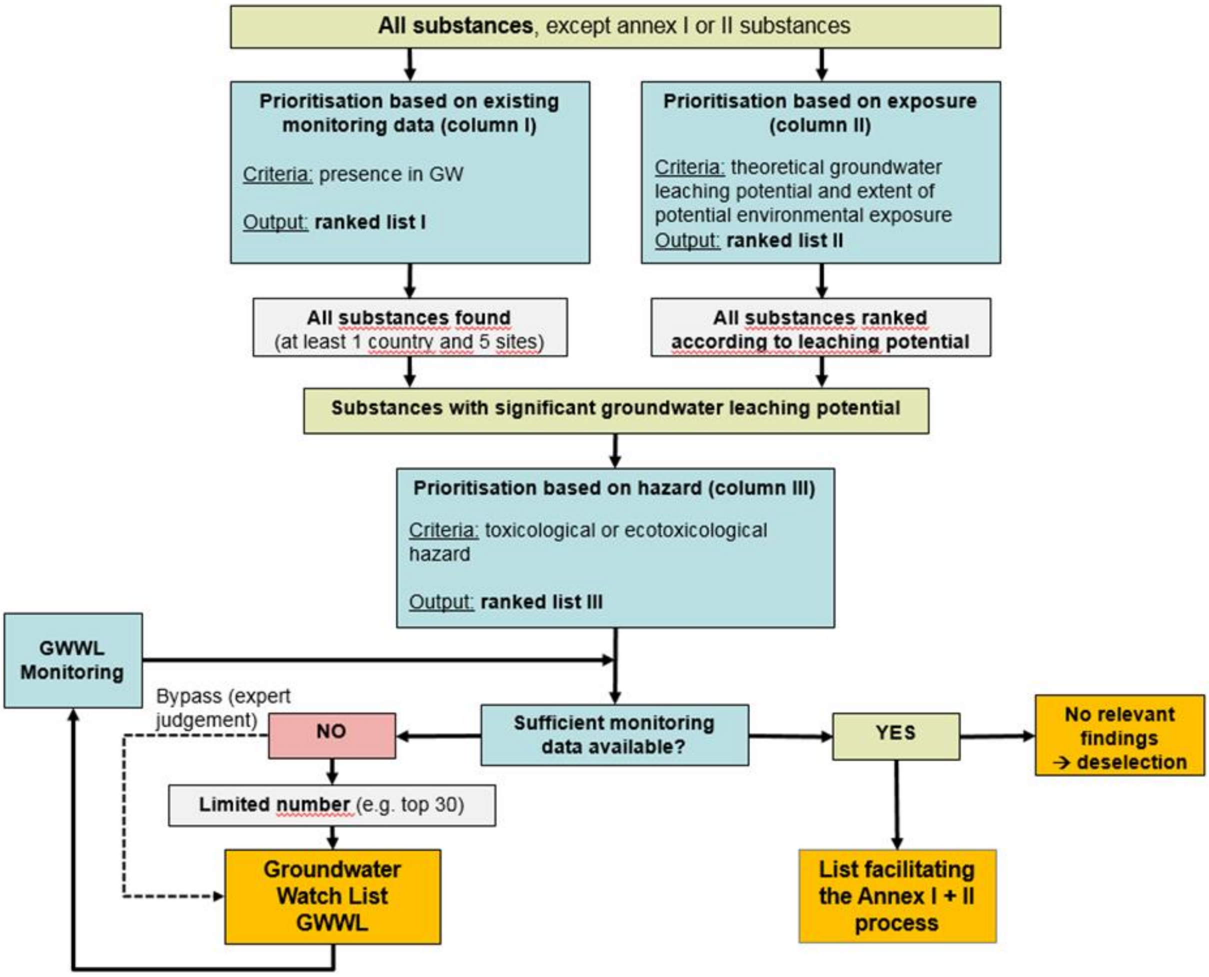
- Substances of potential EU-wide concern and with sufficient monitoring data are added to the LFR,
- Substances of potential concern with insufficient monitoring data are added to the GWWL with the requirement to collect further data.

[7] Voluntary Groundwater Watch List Concept & Methodology V 3.1 based on final draft 12.3 endorsed by CIS Working Group - Groundwater

- Substances which are not detected after widespread monitoring are defined as not of potential concern and removed from the GWWL process unless new evidence suggests otherwise.

The criteria for judging whether there is sufficient monitoring data for a substance of concern and therefore evidence of a widespread problem, is based on the number of participating countries (PC) in which they are found and the number of occurrences above the limit of quantification. Substances present in at least 4 PC and at more than 10 locations in those PC are put forward in the LFR and removed from the GWWL. Through this process it is intended that the GWWL is kept at around 30 substances. The GWWL process follows a six-year cycle in line with the legal obligation set out in Article 10 of the GWD for the Commission to regularly review the lists of pollutants in Annex I and II.

Figure 3-1 Structure of the GWWL Process (after CIS WG GW)



To date the GWWL process has been applied sequentially to three groups of pollutants starting with a pilot study on Pharmaceuticals[8]. Following this pilot study, a long-list of groups of pollutants of concern was developed by the GWWL task group within the CIS WG GW and then prioritised based on collective judgement of the whole of WG GW.

[8] European Commission DG Environment (2016). Groundwater Watch List Pharmaceuticals Pilot Study: Monitoring Data Collection and Initial Analysis

Subsequently, the GW WL process was applied to Per- and Polyfluoroalkyl substances (PFAS)[9] followed by non-relevant metabolites from pesticides (nrMs)[10]. Member States (MS) are encouraged to add the identified pollutant groups of concern to their groundwater monitoring programmes to support the collection of further data to support the GW WL process.

A detailed review of the GW WL process and recommendations are presented in Appendix A.

3.1.4 *Drinking Water Directive*

The recast Drinking Water Directive (DWD) (2020/2184) is particularly relevant to the GWWL and LFR because it sets out drinking water standards for a minimum list of 20 PFAS substances and commits the EC to developing an analytical methodology for these substances by 2024.

Following an evaluation, and impact assessment, the DWD (recast) was endorsed in December 2020. Member States will have until 2023 to transpose the Directive into national legislation. The two key changes included within the recast was greater onus on access to drinking water (particularly for vulnerable and marginalised communities) and reinforced drinking water standards to go beyond the World Health Organisation (WHO) limits. In particular, this included focus on PFAS and development of analytical methods by 2024.

3.1.5 *Other EU legislation*

Other EU legislation includes the **Urban Waste Water Treatment Directive (UWWTD)** which was adopted to protect the environment from the adverse effects of urban waste water discharges and discharges from certain industrial sectors. An impact assessment for the UWWTD has recently been performed which will lead to a proposal for revision of this legislation. All existing and candidate PS and groundwater pollutants would be affected by these changes that might entail additional treatments for larger waste water treatment plants. Tackling the impacts for pesticides may be less pronounced since other pathways to environment may be more important. The impact assessment has specific focus for pharmaceuticals, including the role of UWWT plants as a driver (or part of the driver) for anti-microbial resistance. The wastewater industry voiced concerns about the pressures they faced to manage emerging chemical risks and the greater onus being placed on wastewater companies to act as an end-of-pipe solution to chemical pressures on water.

The **Sewage Sludge Directive (SSD)** was established to protect humans, animals, plants and the environment by ensuring that heavy metals in soil and sludge do not exceed set limits. The legislation, currently under evaluation, sets limits for the concentration of seven heavy metals in sewage sludge for use in agricultural and in sludge-treated soils. The use of sewage sludge with heavy metals above these concentrations is banned.

Other EU legislation related to the protection of water bodies includes:

[9] WFD CIS 2020. Voluntary Groundwater Watch list Group. Study on Per-and Polyfluoroalkyl substances (PFAS) Monitoring data collection and initial analysis. p25

[10] WFD CIS 2020. Voluntary Groundwater Watch list Group. Study on non-relevant metabolites of pesticides (nRM) Monitoring data and collection and initial analysis. Draft Report.

- **Industrial Emissions Directive (IED) (2010/75/EU)[11]:** The overall objective of the IED is to ensure a high level of protection for human health and the environment from industrial emissions across the EU. The operator of an installation must ensure that groundwater does not deteriorate as a result of their activities. The operator of the waste incineration plant or waste co-incineration plant must take all necessary precautions to prevent pollution of surface waters and groundwaters. The IED is currently under revision.
- **Nitrates Directive (91/676/EEC):** Aims to protect water quality in the EU by preventing nitrates from agriculture from polluting ground and surface waters and by encouraging improvements in farming practices.
- **Plant Protection Products legislation:** For example, the Plant Protection Products Regulation (EC 1107/2009) ensures that the residues of plant protection products (PPP) do not have a harmful effect on groundwater. The legislation is currently under revision, as a Sustainable Use of Pesticides Regulation proposed by the Commission in June 2022.
- **Biocidal Products Regulation** (EU 528/2012): The legislation regulates the marketing and use of biocidal products while ensuring a high level of protection for human health and the environment. Active substances within the biocidal products can be considered a candidate for substitution if they are a high potential of risk to groundwater. The potential for contamination of surface and groundwater is also considered as part of authorisation processes for biocidal products.
- **REACH Regulation:** The REACH Regulation reduces the risks to the environment from high-risk chemical substances by enabling authorities to restrict the use of substances if the risks cannot be managed. The regulation applies across a wide range of chemicals and has indirect impacts on surface water and ground water quality.
- **The Single Use Plastics Directive** (SUPD) (EU 2019/904): which aims to limit the use of single-use plastic products e.g. by introducing waste management and clean-up obligations for producers (incl. Extended Producer Responsibility (EPR) schemes), and setting specific targets including; a 77% separate collection target for plastic bottles by 2025, increasing to 90% by 2029; as well as incorporating 25% of recycled plastic in PET bottles from 2025, and 30% from 2030.
- Further legislation related to metals (particularly the **Batteries Directive** (EC) no 2006/66, **Risk of Hazardous substances (RoHS)** (EU) no 2011/65; and **Regulation on mercury** (EC) no 2017/852.

3.1.6 *Other Policy Instruments and Current EU Strategies*

The need to assess options for revising the lists of pollutants affecting surface and ground waters, and their corresponding standards ties in with a number of other ongoing initiatives at the EU level. One of these is the overarching **European Green Deal**[12] which sets ambitious goals to achieve zero pollution to protect our natural environment, and has an overall objective of achieving a sustainable EU by 2050. The EU Green Deal describes a series of actions to boost the efficient use of resources by moving towards a clean, circular economy and to restore biodiversity and cut pollution.

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0075
[12] European Commission, COM(2019) 640 final, The European Green Deal

To achieve this, the EGD sets out ambitious policy initiatives including the:

- **Chemicals Strategy for Sustainability** (October 2020): Recognises that chemicals are essential for the well-being of modern society but aims to better protect citizens and the environment against them. The chemicals strategy anticipates the phasing-out use of per - and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential.
- **Zero Pollution Action Plan** (May 2021): Anticipates for air, water and soil pollution to no longer be at levels which can be considered harmful to health or the environment by 2050. A part of this is through the review of existing EU water legislation and through setting 2030 targets for 50% reduction in use of chemical pesticides, hazardous substances and antimicrobials.
- **The EU plastics strategy** (January 2018): which aims to reduce plastic waste as part of a circular economy. This includes in particular the upcoming EU microplastics initiative, which aims to help support the zero pollution action plan by targeting to reduce plastic litter at sea (by 50%) and microplastics released into the environment (by 30%) by 2030.
- **The Farm to Fork Strategy** (May 2020): Sets out, among other, the aim of reducing chemical and hazardous pesticide use in farming by 50% by 2030 and nutrient losses from soils by 20%.
- **EU Biodiversity Strategy for 2030** (May 2020): A long-term plan to protect nature and reverse the degradation of ecosystems. The Strategy contains a description of the EU's strategic approach to restoring freshwater ecosystems and reducing water pollution.
- **The Pharmaceutical Strategy for Europe** (November 2020): Environmental pollution by pharmaceuticals was already tackled by the **EU Strategic Approach to Pharmaceuticals in the Environment**[13] in 2019.**The Pharmaceuticals Strategy** is complimentary to the Green Deal and the Zero Pollution ambition through understanding the impact of pharmaceutical substances on the environment and strengthening environmental risk assessment requirements especially with regards to anti-microbial substances[14]. Furthermore, to address health issues related to pollution, the European Health Union agenda proposes measures through new initiatives such as the Pharmaceutical Strategy[15] and Europe's Beating Cancer Action Plan[16].

The **better regulation agenda**[17] (first developed in 2015) is a top-level EU strategy to ensure that legislation delivers upon its objectives in the most effective way possible. As part of the Commission's work programme EU legislation is systematically targeted for evaluation to assess whether it is fit for purpose and delivering upon its objectives. Following the evaluation further options for any required revision of the legislation are then assessed for impacts ultimately leading to revision of the legislation. Several of the related pieces of

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019DC0128&qid=1621928313442
[14] European Commission, COM(2020) 761 final, Pharmaceutical Strategy for Europe.
[15] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761
[16] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM%3A2021%3A44%3AFIN
[17] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

legislation are either currently under evaluation or follow-up steps or have been revised in the last 3 years.

The aforementioned legislation and strategies form part of the “dynamic baseline” (see Section 7) to the impact assessment.

3.2 At the international level

Several of the pieces of legislation covered by the chemical’s acquis have been developed and implemented in response to international obligations of the European Union to global treaties and Conventions.

These international policy instruments (such as the UNEP Conventions under Stockholm, Basel, Rotterdam and Minamata) continue to evolve and develop. This requires EU legislation to also evolve and develop to maintain regulatory alignment. Relevant international policies include:

- **UN Sustainable Development Goals (SDGs)[18]:** developed in 2015. The SDGs include several relevant targets such as SGD 6 on ‘Clean Water and Sanitation’. For example, SDG 6.3 aims to ‘improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials’.
- **The Stockholm Convention:** This has been transposed via the Persistent Organic Pollutants (POP) Regulation which adopts a variety of measures to reduce the risk of unintentional POP releases to the environment. Such measures include restrictions on the production, placing on the market, export, storage and disposal of substances that could lead to the release of POPs. Due to the persistent and accumulative potential of POPs in surface and groundwaters, this legislation is of high importance to the EQSD, GDW and WFD[19].
- **The Basel Convention**: was established in 1989 in the context of improper disposal of hazardous wastes by operators in other countries, including those of Eastern Europe, where the cost of disposal was lower. The Convention aims to improve the management of hazardous wastes and to restrict the transboundary movement of hazardous wastes unless environmentally sound management has been applied.
- **The Rotterdam Convention**: Aims to promote shared responsibility and cooperative efforts between all of those involved in the international trade of certain hazardous chemicals such that human health and the environment can be protected from harm. It also aims to contribute to the environmentally sound use of those hazardous chemicals.
- **The Minamata Convention**: Aims to protect human health and the environment from anthropogenic emissions of mercury.

[18] https://ec.europa.eu/eurostat/documents/4031688/14665125/KS-06-22-017-EN-N.pdf/8febd4ca-49e4-abd3-23ca-76c48eb4b4e6?t=1653033908879

[19] https://ec.europa.eu/environment/water/fitness_check_of_the_eu_water_legislation/documents/Water%20Fitness%20Check%20-%20SWD(2019)439%20-%20web.pdf

3.3 At the national level

Under the GWD, MS are able to set TVs for any substance that poses a risk to GWBs. In a review of these values, the EC found that Annex II TVs have been established for a range of substances, including those on the minimum list for consideration in Annex II and a large number of additional substances not on the minimum list.[20] The number of TVs per MS ranged from zero to 62. The substances included 39 pesticides and 62 synthetic substances.

[20] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/eb87e8fb-89e7-4ea0-92e7-6e2ceb6d934a/details

4 What is the problem and how will the problem evolve?

4.1 What is the problem?

European waters are affected by a wide range of significant pressures, including water pollution, hydromorphological alterations, water scarcity and floods (EEA, 2018[21]). Discharges of pollutants by a wide range of anthropogenic sources including agriculture, households and manufacturing industries have had detrimental effects on aquatic ecosystems and constitute a cause for concern for public health. There has been a significant progress to reduce pollution since the 1990s through implementation of the Urban Waste Water Treatment Directive (UWWTD) (91/271/EEC), Nitrates Directive (91/676/EEC) and Industrial Emissions Directive (IED) (2010/75/EU). The implementation of these directives has translated into improved wastewater collection and treatment, reduced volumes of industrial effluents and reduced nitrate pollution from agricultural sources. However, significant **groundwater and surface water quality** challenges remain.

The problem definition rests mostly on the findings of the Fitness Check (FC) of the WFD and daughter Directives published by the European Commission in 2019.[22]. It concluded that the WFD, EQSD, GWD and the Floods Directive (FD) are broadly fit for purpose, with room for improvement related to investments, implementation, integrating water into other policies, chemical pollution, administrative simplification and digitalisation. The Inception impact assessment for the 'Revision of lists of pollutants affecting surface and groundwaters' highlighted that **chemical pollution**, along with nutrient enrichment and altered habitats due to morphological changes, constitute an important cause of deteriorating ecological and chemical status of water bodies.

4.1.1 *Surface waters and groundwater*

The Water Legislation FC identified several needs that are relevant for both surface and groundwater and should be addressed to ensure a higher level of protection of the water environment.

The need for accurate assessments on the combined effects of pollutant mixtures, and actions to tackle persistent chemical substances like PFAS, pharmaceuticals, microplastics, and other (emerging) pollutants. Despite water legislation evaluating the risk to people and the environment, this is predominantly done for individual substances rather than for groups. The presence of persistent chemical substances, pharmaceuticals and micro-plastics in waters is increasing across the EU. Furthermore, none of the mentioned substances are adequately tackled, even at national level. Finally, potential environmental and health risks from emerging substances, need to be better addressed in line with the 'precautionary' and 'polluter pays' principles. This is also in line with the recommendations from the 2021 draft report of the European Court of Auditors on the inconsistent application across EU

[21] EEA (2018) Report on European waters - assessment of status and pressures. EEA Report No 7/2018. https://www.eea.europa.eu/publications/state-of-water
[22] The Commission's Fitness Check of the EU Water Legislation (SWD(2019) 439 final)

environmental policies and actions,[23] which suggested strengthening of the polluter pays principle within legislation and practice.

The need for improved harmonisation to tackle pollutants in surface and groundwaters where no standards or thresholds have been established at EU-level.
There is a large variability in the ranges of threshold values throughout the EU, and even within (transboundary) river basins – where e.g. the same River Basin Specific Pollutant can be assigned contrasting EQS. For groundwater, despite some of these variations being logical (e.g. groundwater TVs are estimated based on natural background level which are linked to the geology of the area), there is a need to further harmonise TVs to improve comparability. The 2014 revision of the GWD included amendments that sought to improve consistency in the approach to deriving TVs and, therefore, address harmonisation for Annex II substances.

The need for a swifter update (compared to the current six-year cycle of revision) of the lists of pollutants of EU-wide concern (i.e. the so called "list of Priority Substances" for surface waters as well as the list of groundwater pollutants in Annex I and Annex II of the GWD). This would allow for closer alignment with scientific developments, including the Directives' inbuilt bi-yearly cycle for regularly updating the watch list monitoring data.

The approach to listing and monitoring specific individual substances (as opposed to mixtures of substances or measuring the combined effect rather than individual concentrations) has proven to be ineffective at reflecting the **effects of combinations of chemicals** and possible substitutes for the active substance. Therefore, a more holistic effect-based approach might be needed. The Chemicals Strategy for Sustainability highlights the need to address risks from chemicals across policy areas, and the need to include horizontal proposals to enhance consistency between water and other legislation on chemicals, for example as regards risk assessment and approaches to groups of substances or data sharing between different legislative areas. It also includes actions to address certain groups of substances of very high concern, such as endocrine disruptors, persistent mobile and toxic (PMT), and very persistent and very mobile substances (vPvM), and specifically PFAS.

Surface water

In the case of **surface water pollutants**, the Fitness Check concluded in relation to chemical pollution, the legislation focuses on some less relevant older pollutants while not sufficiently addressing a number of **pollutants of emerging concern**, such as pesticides, pharmaceuticals, microplastics, metals and PFAS[24]. Further discussion on the critical categories of substance and characterisation of the problem are provided below:

Pharmaceuticals

Pharmaceuticals play a critical societal role for the wellbeing of both humans and animals (through veterinary applications). While the pharmaceuticals in use are extensively tested to

[23] ECA 2021. The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions. ECA special report pursuant to Article 287(4), second subparagraph, TFEU
[24] https://www.epa.gov/pfas and https://www.columbian.com/news/2022/jun/15/epa-forever-chemicals-pose-risk-even-at-very-low-levels/

ensure they are safe for use in their intended applications[25], the unintentional release to environment during manufacture, disposal of unused medicine, or via excreta can be problematic. The European Union Strategic approach to pharmaceuticals in the environment (PIE), 2019[26] comments that the metabolic stability of some pharmaceuticals can be as high as 90% of the active ingredient excreted or washed off into wastewater treatment. Even in cases where rates of metabolism are very high, e.g., the JRC dossier for carbamazepine[27] comments that less than 2% of the active remains unmetabolized for excreta. The efficacy of wastewater treatment works tends to be poor against pharmaceuticals, some pharmaceuticals (such as carbamazepine) can have a high environmental persistence, and importantly the rate of release is continuous allowing build up in the environment.

Where pharmaceuticals are intended for use by humans and/or animals (meaning they are extensively tested), they are less likely to have acute toxic effects for aquatic species. However, they are likely to have more subtle chronic impacts, which can build up over time having substantial ecosystem altering effects. For some of the most widely used pharmaceuticals this presents a significant challenge, given the high rate of continuous use, and ergo release, which effects the surface water environment over a protracted period.

An example of this is the use and release of estrogenic compounds, particularly the synthetic estrogen (17 Alpha ethinylestradiol (EE2)) which is more concentrated than naturally produced estrogen hormones (E1 and E2). The EQS dossier produced by the German Environment Agency[28], identifies a range of negative health effects for aquatic species, avian species and mammals. In particular related to the normal function of reproductive, immune, and endocrine systems, e.g., feminisation and intersex of fish and crustaceans[29,30], decreased sperm count, motility and morphology of sperm in mice[31], Damage to renal systems in wistar rats[32] and impaired endocrine function also in rats[33].

These longer-term systemic impacts on a chronic scale have the potential to negatively impact ecosystem stability and alter the biodiversity of surface water environments permanently. They also represent a significant concern for secondary poisoning of humans via drinking water abstraction. Where use is ongoing, and releases are continuous it means without intervention the problem is likely to persist and progressively evolve to long lasting damaging effects for the environment and potentially human health.

Pesticides

Agriculture represents a key sector for the European Union, both in terms of economic contribution but also food production and food security. The use of pesticides to help protect

[25] EFPIA, 2015, The management of pharmaceuticals in the environment – FAQ document.
[26] European Commission, 2019, EU strategic approach to pharmaceuticals in the environment, Commission communication COM(2019)128
[27] JRC, 2021, Environmental fact sheet for EQS - carbamazepine
[28] German Federal Environment Agency, 2021, EQS datasheet for 17 Alpha Ethinylestradiol (EE2)
[29] Rehberger, 2020, 'long-term exposure to low 17a ethinylestradiol (EE2) concentrations disrupts both the reproductive and immune system of juvenile rainbow trout', Environment International vol 142
[30] Marlatt et al, 2022, 'Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans', Environmental Research Vol 208
[31] Delbes et al, 2022, ' Effects of endocrine disrupting chemicals on gonad development: mechanistic insights from fish and mammals', Environmental research vol 204
[32] Zayed et al, 1998, Systemic and histopathological changes in Beagle dogs after chronic daily oral administration of synthetic (ethinyl estradiol) or natural (estradiol) estrogens, with special reference to the kidney and thyroid. Toxicological Pathology, 26, 730-741
[33] Shibutani et al, 2005, 'Down regulation of GAT-1 mRNA expression in the microdissected hypothalamic medical preoptic area of rat offspring exposed to ethinyl estradiol. Toxicology, 208, 35-48.

and maximise crop yields is well established, with the German Federal Agency for Nature Protection (UBA) along with many other national agencies highlighting that use of pesticides is continuously increasing. The concern for surface water protection is that rivers and water bodies running through agricultural lands can be impacted multiple times over long stretches of water where the main pathway to environment is from surface runoff events[34 35 36]. Babut et al (2013)[37] comments that 35 % of pesticides enter water bodies diffusely via surface runoff and only 5% via drift.

Liess et al., 2021[38], comment that the concentrations of pesticides are beyond ecologically acceptable thresholds in more than 80 % of the small water bodies within agricultural landscapes after rain events in Germany. Similarly, more than 80 % of the investigated water bodies show a reduced proportion of sensitive aquatic organisms such as dragonflies and caddisflies. Thus, pesticides are a crucial stress factor for insects in small water bodies in agricultural landscapes[39].

Regulatory monitoring for European surface water between 2007 and 2017 records exceedances of quality standards of 5–15% by herbicides, 3–8% by insecticides, and negligible exceedances for fungicides.

As a further exacerbation of these pressures, some pesticides can remain in the environment for years and accumulate in soils and water[40] . This can further increase the risk for contamination of ground-water.

The protection of economically significant aquatic species, including freshwater fish and shellfish, was included among the areas protected under the Water Framework Directive in order to protect the aquatic environment and for economic reasons. A 2000-2019 literature review identified a number of haematological and blood biochemical effects of various herbicides, insecticides, and fungicides in fish. It also noted an adverse effect of pesticides on the immune systems of fish and possible immunosuppression. Pathophysiological changes in fish induced by pesticides depend on a complex set of factors[41].

[34] Michael Neumann, Ralf Schulz, The Signficance of Entry Routes as Point and Non-Point Sources of Pesticides in Small Streams–, Water research 36-2002, https://www.researchgate.net/publication/2573014_The_Signficance_of_Entry_Routes_as_Point_and_Non-Point_Sources_of_Pesticides_in_Small_Streams
[35] Moschet C, Wittmer I, Simovic J, Junghans M, Piazzoli A, Singer H, Stamm C, Leu C, Hollender J. How a complete pesticide screening changes the assessment of surface water quality. Environ Sci Technol. 2014 May 20;48(10):5423-32. doi: 10.1021/es500371t. Epub 2014 May 12. PMID: 24821647.
[36] S. Lorenz, A. Raja Dominic, M. Heinz, A. Süß, M. Stähler, J. Strassemeyer,Effect of buffer strips on pesticide risks in freshwaters, Crop Protection, Volume 154, 2022, 105891, ISSN 0261-2194, https://doi.org/10.1016/j.cropro.2021.105891. https://www.sciencedirect.com/science/article/pii/S0261219421003616
[37] Babut et al, 2013, Pesticide risk assessment and management in a globally changing world – report from a European interdisciplinary workshop, Environmental science of pollutant research vol 20 pp 8298-8312
[38] Liess M, Liebmann L, Vormeier P, Weisner O, Altenburger R, Borchardt D, Brack W, Chatzinotas A, Escher B, Foit K, Gunold R, Henz S, Hitzfeld K L, Schmitt-Jansen M, Kamjunke N, Kaske O, Knillmann S, Krauss M, Küster E, Link M, Lück M, Möder M, Müller A, Paschke A, Schäfer R B, Schneeweiss A, Schreiner V C, Schulze T, Schüürmann G, von Tümpling W, Weitere M, Wogram J, Reemtsma T. Pesticides are the dominant stressors for vulnerable insects in lowland streams. Water Research Volume 201, 1 August 2021, 117262 https://doi.org/10.1016/j.watres.2021.117262
[39] See German Federal Agency for Nature Protection (UBA), Scientific Opinion Paper October 2022, Towards sustainable plant protection: evaluation of the draft regulation on the sustainable use of plant protection products 2022/0196 (COD) with a focus on environmental protection, page 27.
40 Sharma A, Shukla A, Attri K, Kumar M, Kumar P, Suttee A, Singh G, Barnwal RP, Singla N. Global trends in pesticides: A looming threat and viable alternatives. Ecotoxicol Environ Saf. 2020 Sep 15;201:110812. doi: 10.1016/j.ecoenv.2020.110812. Epub 2020 Jun 5. PMID: 32512419 and https://pubmed.ncbi.nlm.nih.gov/32512419/
[41] Bojarski and Witeska, 'Blood biomarkers of herbicide, insecticide, and fungicide toxicity to fish – a review', Environ Sci Pollut Res Into. 2020 June;27(16):19236-19250, https://pubmed.ncbi.nlm.nih.gov/32248419/

While there is a strong regulatory framework for protecting human health in legislation (including allowed maximum pesticide residues on food, and safe limits for drinking water), the regulation is based on a substance-by-substance approach. Although there is some degree of scientific uncertainty in relation to potential synergistic effects of simultaneous exposure in real-life conditions and concerns about prenatal exposure and health effects in children, it is also clear that cumulative exposure results from sources like food, drinking water, skin exposure resulting from spray drift to homes in rural areas etc. is often not within the main focus of scientific studies. It is therefore appropriate to restrict the use of pesticides to low-risk pesticides and biocontrol in urban areas where there is a high risk of human exposure where the risk of exposure to pesticides through contact with the skin, ingestion or inhalation is greater.

In order to improve the consistency between the quality standards for groundwater and surface water a quality standard for total pesticides in SW should also be introduced in the near future.

The pesticide-based candidate priority substances include two families of insecticides (neonicotinoids and pyrethroids), two herbicides (glyphosate and nicosulfuron), and one anti-fungal biocide (triclosan). All of these substances are known to have undesirable impacts for the environment, e.g., neonicotinoids have been identified as a significant concern for pollinators such as bees[42], and pyrethroids are acutely toxic to aquatic species even at low concentrations[43,44,45].

Industrial chemicals (including BPA and PFAS)

Industrial chemicals form a critical use for a very wide range of applications that enhance the quality of life for all EU Citizens. This includes direct uses within industrial settings for manufacturing purposes and indirect uses within mixtures and articles for a range of sectors. Pathway to environment depends on the specific use, but commonly releases to surface water via wastewater treatment works are important. For the candidate priority substances this includes:

- Bisphenol A used in the manufacture of polycarbonate and epoxy resins, with uses including water supply pipes, linings of cans, construction products, and coatings in the automotive sector (as anti-scratch protection). Releases to environment can be as bisphenol A directly, but also in the form of micro-plastics from abrasion (see section 4.1.2). In April 2023[46] EFSA published it's re-evaluation of BPA's safety assessment which included a significant reduction in the tolerable daily intake set in the previous assessment from 2015. Furthermore, the JRC dossier[47] highlights the bioaccumulation potential for bisphenol A, and detection in a wide array of matrices including water, air, biota, and sediment. Regulatory controls on Bisphenol A have already banned its use in thermal paper and plastic bottles (particularly baby bottles)[48]. In 2017 The Member State Committee unanimously agreed with the classification of Bisphenol A as an endocrine

[42] EFSA, 2018, Neonicotinoids risks to bees confirmed, https://www.efsa.europa.eu/en/press/news/180228
[43] Lu et al, 2019, Understanding the bioavailability of pyrethroids in the aquatic environment using chemical approaches, Environment International vol 129
[44] Farag et al, 2021, An overview on the potential hazards of pyrethroid insecticides in fish, with special emphasis on cypermethrin toxicity, published in the journal animals vol 11
[45] Werner et al, 2008, Effects of pyrethroid insecticides on aquatic organisms, ACS symposium series.
[46] EFSA, 2023, re-evaluation of the risk to public health from bisphenol A in foodstuffs.
[47] JRC, 2021, datasheet for EQS – Bisphenol A
[48] BPA is restricted under the EU REACH Regulation (Restriction Entry No. 66), Plastic food contact materials regulation, and Toy safety directive.

disruptor for wildlife and humans[49]. Over the years there have been several studies which reported detection of BPA in environmental compartments such as water bodies[50], soil/sediment[51] and air[52]. Bisphenol analogues (BPs) have been widely used in industry as substitutes for bisphenol A (BPA) and have been detected frequently in surface water, sediment, sewage and sludge. The presence of BPs in the natural environment could pose risks to the aquatic ecosystem and human health. Decades of peer-reviewed research clearly demonstrate significant associations between endocrine disrupting substances (EDCs) – even in low doses – and adverse health effects such as cancers, fertility problems, obesity and learning disabilities. Consequently, very small quantities have a clear effect on human health[53]. Therefore, given ongoing new use and already in place stockpiles of in-use articles and mixtures, a continuous release of bisphenol A to environment is possible. Given its endocrine disrupting classification, potential for bioaccumulation, and potential for biodiversity effects, without intervention the problem evolution is likely to see negative impacts for the surface water environment and risk to human health from secondary poisoning.

- PFAS are a group of per/poly fluorinated chemicals utilised for their high water and oil repellence, flame-retardant properties, and chemical inertness, which has valuable uses for membranes within applications where corrosion is an issue. Their unique properties have meant they are extensively used in an extremely broad range of uses. The OECD estimates around 4,700 substances exist[54] with potential applications across Europe. Potential release to environment varies depending on application, again with release to surface water via wastewater treatment works a common source. Dispersive uses, particularly fire-fighting foams and textiles are key sources for release to environment. Their unique oil and water repellence properties make them extremely stable and persistent in the environment, with PFAS often referred to as ‘forever chemicals’.

  In the US advocates have long urged action on PFAS after thousands of communities detected PFAS chemicals in their water. PFAS chemicals have also been confirmed at nearly 400 US military installations, according to the Environmental Working Group, a research and advocacy organization. EPA findings that PFAS exposure, even in small amounts over time, is linked to serious health problems including cancer, thyroid disruption and reduced vaccine response are in line with science which clearly indicates that PFAS chemicals are very toxic at extremely low doses. In response to calls for the EPA to regulate all PFAS chemicals “with enforceable standards as a single class of chemicals", non-binding health advisories were issued setting health risk thresholds for PFOA and PFOS to near zero, combined with an announcement that EPA expects to

[49] https://echa.europa.eu/-/msc-unanimously-agrees-that-bisphenol-a-is-an-endocrine-disruptor#:~:text=MSC%20unanimously%20agrees%20that%20Bisphenol%20A%20is%20an%20endocrine%20disruptor&text=The%20Member%20State%20Committee%20(MSC,serious%20effects%20to%20human%20health.
[50] Jianchao Liu, Lingyu Zhang, Guanghua Lu, Runren Jiang, Zhenhua Yan, Yiping Li, Occurrence, toxicity and ecological risk of Bisphenol A analogues in aquatic environment – A review, Ecotoxicology and Environmental Safety, Volume 208, 2021,
[51] P. Chakraborty, S. Sampath, M. Mukhopadhyay, S. Selvaraj, G.K. Bharat, L. Nizzetto. Baseline investigation on plasticizers, bisphenol A, polycyclic aromatic hydrocarbons and heavy metals in the surface soil of the informal electronic waste recycling workshops and nearby open dumpsites in Indian metropolitan cities. Environ. Pollut., 248 (2019), pp. 1036-1045, 10.1016/j.envpol.2018.11.010
[52] P. Fu, K. Kawamura, Ubiquity of bisphenol A in the atmosphere, Environ. Pollut., 158 (2010), pp. 3138-3143, 10.1016/j.envpol.2010.06.040
[53] L.N. Vandenberg, T. Colborn, T.B. Hayes, and J.P. Myers et.al. - Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3365860/
[54] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/

propose national drinking water regulations for PFOA and PFOS in 2023. Health concerns clearly justified EPA to “move much faster to reduce exposures to these toxic chemicals.” A peer reviewed study[55] of the Environmental Working Group (EWG) estimates that more than 200 million Americans are drinking water contaminated with PFAS at a concentration of 1 part per trillion, or ppt, or higher[56]. The demands for US legislation setting national drinking water standards for PFAS clearly indicate the seriousness of the problem and would also necessitate the EPA to develop discharge limits for industries suspected of releasing PFAS into the water.

In the European Union the ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration on 23 March 2022 and interested parties could submit comments and contributions by 23 September 2022. In parallel a REACH restriction dossier covering all PFAS is in preparation to be submitted to ECHA. Also 20 individual PFAS and quality standard for total PFAS were added to the drinking water in December 2020.. Given their very long lived nature, harmful chronic effects even at low concentrations, and current ongoing use, the problem already is substantial and evolution would suggest a worsening situation without urgent intervention.

Metals

Metals are naturally occurring substances with a wide range of uses in different sectors. Where they are naturally occurring, care is needed to identify and understand naturally occurring background concentrations and anthropogenic contributions to the aquatic environment. For the candidate priority substance in particular, the major anthropogenic sources of silver include mining operations, smelting, coal combustion, and production of articles that contain silver, including the use of nanoform silver in medical applications.

Information from ECHA suggests that in 2018 total EU manufacture and use of silver was between 100,000 – 1,000,000 tonnes /year[57]. The use of silver is steadily increasing (year-on-year increases vary between 5-13% in recent years)[58].

The antibacterial activity of silver has led to an increased use of silver in an ever-wider range of consumer products. The different forms of silver, including silver salts (e.g. silver nitrate), silver oxides and silver materials appear as silver wires, silver nanoparticles (Ag-NP) and others, which are used in consumer and medical products. In medical care, forms of (nano)silver are used, for example in wound dressings and catheters to reduce infections. In consumer products, forms of (nano)silver are used, for example in sports and other textiles, washing powders and deodorants, where (nano)silver should reduce odours producing bacteria.

[55] David Q. Andrews and Olga V. Naidenko, Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States https://pubs.acs.org/doi/full/10.1021/acs.estlett.0c00713
[56] Independent scientific studies have recommended a safe level for PFAS in drinking water of 1 ppt: https://www.ewg.org/news-insights/news-release/study-more-200-million-americans-could-have-toxic-pfas-their-drinking
[57] Substance Evaluation Conclusion as required by the REACH substance evaluation process (Article 48 of REACH Regulation (EC) No 1907/2006) and evaluation report for Silver: EC No 231-131-3
[58] https://www.silverinstitute.org/silver-supply-demand/

According to ECHA information based on REACH dossiers, and tests performed with the smallest nanoform with the highest specific surface area, have indicated that silver nitrate (ionic silver) is more toxic than the nanoform of silver (toxicity to algae and long-term toxicity to aquatic invertebrates) and that silver nitrate is equally or more toxic than the nanoform of silver (toxicity to soil microorganisms).

Silver exhibits bactericidal activity at concentrations that are not cytotoxic to human cells, they are important for medical use especially in the context of treatments of multi-resistant bacteria. Also, silver strongly enhances the antibacterial activity of conventional antibiotics even against multi-resistant bacteria through synergistic effects[59]. Consequently, they are important as a 'last' resort for treating infections with multi-resistant bacteria[60].

Currently, silver still has proven bactericidal activity towards this bacterium even against strains that display multi-drug resistance. Therefore, it is of utmost importance to avoid /limit silver resistance in bacteria to avoid limiting its effectiveness in treatments for infectious diseases. With the rise of antibiotic resistant bacteria, there are also serious concerns of pathogens developing resistance to silver.

The widespread use of (nano)silver has already led to the release and accumulation of silver in water and sediment, in soil and even in wastewater treatment plants (WWTPs) and is thus impacting microbial communities in different environmental settings. The resistance mechanism is also linked to the increasing pools of many antibiotic resistance genes already detected in samples from different environmental media, which will likely find their ways to animals and humans. This is worrisome, as the increasingly indiscriminate over-use of silver in non-essential consumer products further promotes the development of silver resistance in bacteria. Therefore, there is a clear need to minimise water related silver-emissions[61].

Consequently, the problem as presented is that anthropogenic sources of metallic emissions boost concentrations within surface water above natural background concentrations. For silver in particular it has a key anti-bacterial role and fight against bacterial species resistant to some forms of anti-biotics. Without intervention the effectiveness of silver is likely to weaken, and development of silver-resistant bacteria are likely to form which may exacerbate or speed anti-microbial resistance. Furthermore, where silver is able to create anti-bacteria effects it has the capacity to alter the aquatic biome, and this has knock-on consequences for biodiversity and aquatic health of other species that may be susceptible to bacterial ecosystems altered by exposure to elevated silver concentrations.

Surface water summary

Based on the specific issues detailed for each category of substance (above), it can be demonstrated that as a result, the aquatic environment could be better protected, and it is therefore necessary to consider revising the lists of pollutants in the light of scientific

[59] Bacterial resistance to silver nanoparticles and how to overcome it; Aleš Panáček, Libor Kvítek, Monika Smékalová, Nature nanoparticles, 2018, volume 13 p.65-71: https://www.nature.com/articles/s41565-017-0013-y

[60] Effect of Graphene Oxide and Silver Nanoparticles Hybrid Composite on P. aeruginosa Strains with Acquired Resistance Genes; Povila Lozovskis et.al., International Journal of Nanomedicine, 17 July 2020, p. 5147-5163: https://pubmed.ncbi.nlm.nih.gov/32764942/

[61] The impact of silver nanoparticles on microbial communities and antibiotic resistance determinants in the environment, Kevin Yonathan et.al. Environmental Pollution 15 January 2022, p.293-

developments. Indeed, data obtained from monitoring substances on the surface water watch list and the voluntary monitoring, confirm that some of those substances pose a risk to, or via, the aquatic environment.

These findings are consistent with the findings of the evaluation of the UWWTD, which also identified contaminants of emerging concern as an increasingly important problem. Wastewater treatment reduces the amount of some contaminants of emerging concern entering the aquatic environment, but upstream and downstream additional solutions are essential, particularly for diffuse source pollutants.

Furthermore, the FC noted that a limited number of ubiquitous substances, such as mercury and other persistent pollutants, are largely responsible for good chemical status not being achieved in surface waters. While significant progress is being made in addressing both European and (to some extent) global sources, concentrations are expected to reduce only very slowly over time.

Finally, there is now new information on some of the **existing substances** which are already in the EQSD and GWD lists. Developments under other sectoral legislation, has come to light since the last reviews of the lists, prompting a reconsideration of those substances and/or their standards or designation as priority hazardous substances. As such it is important to ensure coherence between legislation and also that the legislation is up to date with latest technological developments.

A range of new information has been reviewed during CIS working group dicussions and by the JRC, including data on ecotoxicity, environmental concentrations, production and use, and assessments of persistence, bioaccumulation, carcinogenicity, mutagenicity, reprotoxicity and endocrine disrupting potential. This information pointed to concerns regarding a number of substances not yet identified as PS, and to a need to review the status and/or EQS of some existing PS. It also pointed to the need to consider deriving EQS for the identified substances in a specific matrix[62].

The selection of possible new candidate PS was conducted using the approaches outlined in WFD Article 16(2). The prioritisation exercise resulted in 24 possible new PS including PFAS as group (of potentially 24 substances). Alongside this, 15 substances were identified as candidates for EQS amendment, 5 considered as candidates for potential deselection from the PS list and 8 substances requiring review for potential status change. The substances and their status under this revision process are summarised in the table below.

Table 4-1 Overview for substances of concern in surface water covered by the current study

Options	Substance
Additions	17 alpha-ethinylestradiol (EE2)
Additions	17 beta-estradiol (E2)
Additions	Estrone (E1)
Additions	Azithromycin
Additions	Clarithromycin
Additions	Erythromycin

62 Matrix refers to water, sediment, or biota, the three compartments of the aquatic environment in which contaminants can be measured.

Options	Substance
Additions	Diclofenac
Additions	Carbamazepine
Additions	Ibuprofen
Additions	Nicosulfuron
Additions	Acetamiprid
Additions	Clothianidin
Additions	Imidacloprid
Additions	Thiacloprid
Additions	Thiamethoxam
Additions	Bifenthrin
Additions	Deltamethrin
Additions	Esfenvalerate
Additions	Permethrin
Additions	Glyphosate
Additions	Triclosan
Additions	PFAS
Additions	Bisphenol A
Additions	Microplastics
Additions	Silver
Amendment to EQS	Chlorpyrifos
Amendment to EQS	Cypermethrin
Amendment to EQS	Dioxins
Amendment to EQS	Diuron
Amendment to EQS	Fluoranthene
Amendment to EQS	PAHs
Amendment to EQS	Heptachlor/Heptachlor oxide
Amendment to EQS	Hexachlorobenzene
Amendment to EQS	Hexachlorobutadiene
Amendment to EQS	Mercury
Amendment to EQS	Nickel
Amendment to EQS	Nonyl phenol
Amendment to EQS	PBDEs
Amendment to EQS	Tributyltin
Amendment to EQS	Dicofol
Amendment to EQS	Hexabromocyclododecane
Deselection	Alachlor
Deselection	Chlorfenvinphos
Deselection	Simazine
Deselection	Trichlorobenzenes
Deselection/ Change of status	Carbon tetrachloride
Change of status	Aldrin
Change of status	Dieldrin
Change of status	Endrin
Change of status	Isodrin

Options	Substance
Change of status	DDT
Change of status	Tetrachloroethylene
Change of status	Trichloroethylene

See Appendix C for the details of each substance, uses and reasons for concern and Appendix D for monitoring data.

Groundwater

In the case of **groundwater pollutants**, the Fitness Check concluded that "*overall, the GWD has been successful in setting specific objectives, protecting groundwater resources, and avoiding their deterioration. Although groundwater presents a slow onset of impacts, and measures require time to take effect, groundwater bodies are generally in better status than surface waters at EU level.*[…]

Annex I to the GWD requires that all Member States assess the status of groundwater bodies using groundwater quality standards set out for nitrates and pesticides and their relevant metabolites.

Annex II to the GWD sets a minimum list of pollutants which Members States should consider during their assessment of the risk that groundwater bodies will not achieve good status. Where these pollutants and any other substances not listed in Annex I or II, are identified through monitoring and pressure information as also posing a risk to achieving good status then threshold values must be set by Member States. There is, however, very large variability in the ranges of threshold values across the EU. This in part could be due to the flexibility the Directive allows when it comes to setting the values, taking several factors into consideration (e.g. receptors, risks, pollutants, natural background levels). However, the wide numerical range of threshold values is much larger than that which could be explained by local differences. The process of keeping up with science (on emerging pollutants) has largely occurred as part of the voluntary engagement of Member States and stakeholders who supported the Commission. The potential for more secure long-term technical and scientific support to carry out such updates should be explored, as should the potential for a more efficient approach for updating the annexes."

Since the adoption of the WFD in 2000, the chemical and quantitative status of groundwater bodies (GWBs) has been assessed as part of the six-year river basin management planning (RBMP) cycles[63].

By the 2nd RBMP groundwater, the EU (EU27 countries) was still under significant pollution and abstraction pressure. Although 75% of the GWBs, covering 76% of the GWB area in the EU

[63] The chemical status of GWBs is assessed through the reviewing the evidence for: i) pollution of the groundwater body as a whole (general chemical test); ii) impacts on drinking water protected areas; iii) evidence of saline intrusion; iv) impacts on groundwater associated aquatic ecosystems; v) impacts on groundwater dependant terrestrial ecosystems tests; and vi) statistically and environmentally significant upward trends in pollutant concentrations. The general chemical test is most commonly used and involves an assessment of how widespread pollution is within a GWB. If concentrations are above the TV for a substance of concern over a minimum area, typically one third or 20% of the GWB, then the status is poor. The results of status assessment are reported in RBMPs.

were at good chemical status, 12% of GWBs did not achieve good status and 13% were at unknown status.
Out of the nearly 160 synthetic and naturally occurring substances leading to poor chemical status, the main pollutant was nitrate which affected 9% of GWBs covering 18% of the GWB area. In 2019, the amount of nitrate in groundwater had increased by 2.7% since 2014.[64] The second main groundwater pollutant was the **pesticides** group (including relevant metabolites). Between 2013 and 2020, exceedances of one or more pesticides were detected between 4% and 11% of groundwater monitoring sites.[65] For groundwater, these exceedances of quality standards were directly attributable to herbicides in 7% of cases and to insecticides in around 1% of cases, whilst being lower for fungicides[66]. Aquatic biodiversity is a vital resource and there is an important feedback loop between terrestrial and aquatic ecosystems[67]. Scientific studies have also shown that insecticides may be responsible for more than half, and herbicides for more than one-quarter, of acute risks to aquatic life in the EU.[68] In 2016, around 90% of groundwaters in EU-27 countries had achieved good quantitative and chemical status.

Other commonly reported parameters leading to poor status were ammonium, chloride, sulphate, lead, nickel and arsenic[69]. The main drivers and pressures acting on GWBs and leading to poor status include agriculture with 20% of the EU 27 GWB area being affected by agricultural diffuse pollution and 7% by agricultural abstraction; the supply of water to the public (7%); discharges from scattered isolated dwellings not connected to sewerage networks (5%); point source pollution from abandoned industrial or contaminated sites (4%); and point source pollution from industrial plants regulated under the Industrial Emissions Directive (4%)[70].

Under the GW WL process monitoring data was collected from MS and PC for PFAS, pharmaceuticals and nrMs along with any TVs set for PFAS and nrMs by MS and Associated Countries (AC)[71][72]. The GW WL process has identified the likely risk to groundwater from these substances and the need to expand monitoring and assessment of this risk at the EU level.

For **PFAS** non-legally binding TVs had been set by some MS which acted as a trigger for further investigations. Although the recast DWD includes drinking water standards for 20 PFAS, this legislation only came into force in 2020 and, therefore, was not available for the

[64] https://ec.europa.eu/eurostat/documents/4031688/14665125/KS-06-22-017-EN-N.pdf/8febd4ca-49e4-abd3-23ca-76c48eb4b4e6?t=1653033908879
[65] https://www.eea.europa.eu/ims/pesticides-in-rivers-lakes-and
[66] EEA. (2020).ETC/ICM Report 1/2020: Pesticides in European Rivers, Lakes and Groundwaters - Data Assessment. https://www.eionet.europa.eu/etcs/etc-icm/products/etc-icm-report-1-2020-pesticides-in-european-rivers-lakes-andgroundwaters-data-assessment. See also Ramboll, …, p. 73.
[67] Ramboll, …, p. 74.
68 Wolfram J, Stehle S, Bub S, Petschick LL, Schulz R. (2021). Water quality and ecological risks in European surface waters– Monitoring improves while water quality decreases. Environment International. 2021 Jul 1;152:106479.
[69] EC 2019a, SWD(2019) 30 final. European Overview RBMPs.
[70] EEA 2021, STUDY OF THE IMPACTS OF PRESSURES ON GROUNDWATER IN EUROPE. SERVICE CONTRACT No 3415/B2020/EEA.58185,Comparative study on quantitative and chemical status of groundwater bodies
[71] EC 2020, Voluntary Groundwater Watch List Process - Study on Per- and Polyfluoroalkyl substances (PFAS) Monitoring Data Collection and Initial Analysis.
[72] EC 2021, WFD CIS Voluntary Groundwater Watch List Process - non-relevant pesticide Metabolites (nrM) Groundwater Monitoring Data Collection and Initial Analysis DRAFT REPORT

most recent cycle of status assessment. Some MS may have already set TVs for these substances as an EQS has been in place for PFOS since 2015.

For **nrMs** both legally binding and guiding values had been set at a local or regional level by several MS (e.g. in Denmark, Luxembourg[73] and Belgium). In these countries all metabolites of pesticides are monitored.

The results of GWB status assessment using these TVs was not reported as part of data provision for the GW WL process. Advisory drinking water standards and EQS may have been used as criteria for setting TVs for PFAS and pharmaceuticals, and the Annex I pesticide GWQS used for setting TVs for nrMs.

Outcomes of Groundwater Watch List Process

The compounds identified by the GW WL process and added to the LFR[74] to date consist of **pharmaceuticals, PFAS and nrMs of pesticides**. The PFAS on the LFR were selected largely based on their occurrence in groundwater in MS that participated in the voluntary GW WL process. Therefore, these substances differ from the PFAS listed for surface water and in the recast of the DWD[75] as these were selected using different criteria (e.g. human health or ecotoxicity related). PFAS are a very large group of chemicals (according to the OECD, at least 4,730 distinct PFASs are known[76]) and the identified substances should therefore be regarded as representative compounds for the group. National or local TVs or guiding values reported in the GW WL for PFAS ranged from 0.06 to 10 µg/L based on drinking water and 0.1 to 3 µg/L for groundwater, with some variation for groundwater in close proximity to surface water.

The two pharmaceuticals on the LFR were selected because of occurrence in groundwater across a number of MS.[77] No TVs or guiding values were reported as part of the pilot study into occurrence in groundwater.

The consideration of nrMs from pesticides by the GW WL process resulted in the submission of a group of these substances for inclusion on the LFR[78]. Although at present there is no legally binding definition for nrMs, Guidance[79] from the Health and Food Safety Directorate of the European Commission, which is linked to the pesticide authorization regulation (EC 1107/2009), provides a definition that has been applied by several MS and AC. Some MS and AC, such as Luxembourg[80], do not differentiate between nrM and relevant metabolites and consider all pesticide metabolites as “relevant metabolites”.

[73] https://enveurope.springeropen.com/articles/10.1186/s12302-017-0123-z
[74] EC 2019, First List facilitating Annex I and II review process of the GWD V. 2.1
[75] DIRECTIVE (EU) 2020/2184 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2020 on the quality of water intended for human consumption (recast)
[76] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/
[77] Marsland, T. and Roy, S., 2016. Groundwater Watch List: Pharmaceuticals Pilot Study – Monitoring Data Collection and Initial Analysis. Report for the Groundwater watch list Voluntary Group undertaken by Amec Foster Wheeler, pp. 58.
[78] 38th CIS Groundwater Working Group (Virtual) Meeting - under Germany’s 2020 EU Council Presidency - 30 September / 1 October 2020
[79] GUIDANCE DOCUMENT ON THE ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER OF SUBSTANCES REGULATED UNDER REGULATION (EC) No 1107/2009. EUROPEAN COMMISSION HEALTH & FOOD SAFETY DIRECTORARE GENERAL. Sanco /221/2000- rev.11. 21 October 2021
[80] https://enveurope.springeropen.com/articles/10.1186/s12302-017-0123-z

All relevant metabolites of pesticides are already included in Annex I of the GWD and have a GWQS of 0.1 µg/L (individual pesticides and relevant metabolites) or 0.5 ug/L (total pesticides). The uniform nature of the 0.1 ug/l standard in groundwater is needed to ensure adequate protection but should be supplemented in the future with specific EQS for substances in groundwater. Similarly, to improve the consistency between the quality standards for groundwater and surface water a quality standard for total pesticides in surface water should also be introduced in the near future. By contrast nrMs may be defined as “a metabolite which does not meet the criteria for “relevant metabolites” and are not considered “metabolites of no concern”[81]. Some of the nrMs put forward in the LFR include metabolites from parent pesticides which are not approved for use in the EU, possibly meaning that their presence is related to historical or illegal use. Such a link to the parent pesticide is important as any programme of measures to address nrMs will need to address the use of the parent compound rather than the nrMs themselves which are formed in the environment. TVs or guiding values have been set for 47 nrM substances by several MS, having most of the reported values between 0.1 and 3 µg/L, and a maximum of 10 µg/L.

Cumulative values of 6 µg/L and 1 µg/L were reported for the sum of methyl-desphenyl-chloridazon and desphenyl-chloridazon, and for the sum of dimethenamid-P sulfonic acid, dimethenamid-ESA and dimethenamid-OXA, respectively.

The List Facilitating review process is summarised in the table below.

Table 4-2 Substances in the List Facilitating Review

Substance	Group	Acronnym
Perfluorooctane Sulfonate	PFAS	PFOS
Perfluorooctanoic Acid	PFAS	PFOA
Perfluorohexanoic Acid	PFAS	PFHxA
Perfluoroheptanoic Acid	PFAS	PFHpA
Perfluorohexane Sulfonate	PFAS	PFHxS
Perfluorobutane Sulfonate	PFAS	PFBS
Perfluorodecanoic Acid	PFAS	PFDA
Perfluorononanoic Acid	PFAS	PFNA
Perfluoropentanoic Acid	PFAS	PFPeA
Perfluorobutanoic Acid	PFAS	PFBA
Carbamazepine	Pharmaceutical	
Sulfamethoxazole	Pharmaceutical	
Desphenyl-chloridazon (Metabolite B)	nrMs of Pesticides	
Methyl-desphenyl-chloridazon (Metabolite B1)	nrMs of Pesticides	
2,6-Dichlorbenzamid (2,6-D, BAM, M01, AE C653711)	nrMs of Pesticides	

[81] [(a) CO2 or an inorganic compound, not containing a heavy metal; or (b) it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern or (c) it is a substance, which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment.

Substance	Group	Acronnym
Aminomethylphosphonic acid (AMPA)	nrMs of Pesticides	
Metazachlor-acid (OXA) (BH 479-4)	nrMs of Pesticides	
Metazachlor ESA Metazachlor-SA (BH 479- 8) (Metazachlor-sulfonic acid (ESA)	nrMs of Pesticides	
Atrazine-2-hydroxy	nrMs of Pesticides	
N,N-Dimethylsulfamid (DMS)	nrMs of Pesticides	
s-Metolachlor-acid, (OXA, CGA 51202, CGA 351916)	nrMs of Pesticides	
Chlorthalonil-SA (R417888 or VIS-01 / M12) (Chlorthalonil sulfonic acid)	nrMs of Pesticides	
Metolachlor-sulfonic acid (ESA, CGA 380168, CGA 354743)	nrMs of Pesticides	
Dimethenamid-ESA	nrMs of Pesticides	
Flufenacet-sulfonic acid (ESA) 201668-32-8	nrMs of Pesticides	
Alachlor-t-sulfonic-acid (ESA)	nrMs of Pesticides	
S-Metolachlor NOA 413173 or VIS-01 (Chlortalonilsulfone acid) Metabolite	nrMs of Pesticides	
Dimethachlor CGA 369873 1418095-08-5	nrMs of Pesticides	

See Appendix F for the details of each substance, uses and reasons for concern.

4.1.2 *Microplastics*

The widespread presence of microplastics in the environment is a source of ever increasing concern for ecosystems and human health. Due to their small size, microplastics can be easily ingested or inhaled by organisms, potentially leading to adverse health impacts on wildlife and humans. Microplastics are detected in 80% of our livestock feed, blood, milk and meat (Vrije Universiteit Amsterdam, 2022[82]), and is also present in human blood (Leslie et al, 2022[83]). Microplastic pollution spreads across borders, regions, species and ecosystems. An OECD report (OECD, 2021[84]) echoes the scale of the problem, indicating that “microplastics have been observed in all surface waters and sediments of EU lakes (Global Nature Fund, 2022[85]) and rivers, as well as in drinking water.” An additional aggravating factor is the multitude of chemical additives present in (micro)plastics[86] as well as the properties of plastics to act as chemical sink for other chemical pollutants.

The potential for long-term and irreversible risks to ecosystems and human health calls for mitigation measures to halt the accumulation of plastics and microplastics in the

[82] Vrije Universiteit Amsterdam , 2022, 'Plastic Particles in Livestock Feed, Blood, Milk, and Meat - A Pilot Study', Microsoft Word - Livestock mps study KEY messages_final_2022-07-05.docx (plasticsoupfoundation.org)
[83] Leslie et al, 2022, 'Discovery and quantification of plastic particle pollution in human blood', **Environment International** Vol 163
[84] OECD, 2021, 'Policies to Reduce Microplastics Pollution in Water - Focus on Textiles and Tyres', report published by the OECD
[85] Global nature fund, 2022, 'Blue Lakes – Micro Plastics in Lakes', https://www.globalnature.org/en/microplastic-in-lakes
[86] Hahladakis, J, Velis, C, Weber, R, Iacovidou, E, Purnell, P, (2018) An overview of chemical additives present in plastics: Migration, release, fate and environmental impact during their use, disposal and recycling. Journal of Hazardous Materials, 344, pp. 179-199. https://doi.org/10.1016/j.jhazmat.2017.10.014

environment. Microplastics are different to other substances as they are not characterized by a specific well defined molecular formula, allowing a chemical classification.

The reporting of the second RBMPs showed that although the presence of microplastics in water in the EU is a known problem, litter was only identified as a significant pressure for a very small number of surface water bodies in only a few MS. The process by which microplastics enter surface water is primarily understood to be:

- The discharge of untreated wastewater from the waste infrastructure which can contain high levels of plastics. This is linked to storm water runoff which can cause domestic and industrial waste to be discharged directly into receiving waters during periods of heavy rainfall in combined sewer systems.
- Precipitation can have another impact with regards road runoff with flows from road surfaces that can emit pollutants including microplastics into the wastewater system. Estimates show that final release of microplastics from tyre wear is 15% in fresh water (majority in soil).
- Artificial grass on sports and football pitches all over Europe are a source of microplastic presence in the environment as they are usually covered with a layer of synthetic rubber granules – a form of microplastic -with a fraction of these materials flowing into surface waters. The release of these synthetic granules are thus a significant source of microplastic pollution. The problem is growing because artificial fields are becoming increasingly popular as a durable, year-round alternative to traditional grass sports fields.
  Pitch owners add between 1-5 tonnes of granules to the average sports field each year, in order to replace lost granulate. This means that each pitch loses between 1 and 4 per cent of their granules every year. The most commonly-used type of rubber granulate is made from a synthetic polymer called Styrene Butadiene Rubber (SBR) which consists of old tyres fragmentised into particulate granules. The production of granulates as infill for artificial turf is estimated to process around 21% of the end-of-life tyres in Europe, approximately 600 kilo tonnes per year[87].
  Studies show that zinc, in particular, leaches out from the granulate in sufficiently high concentrations to harm soil biota and aquatic life. Reports estimate that a total of 51,616 pitches exist in Europe with an installed area of 112 million square metres. Using the infill density of 16.1 kg/m2 the total infill estimated to be installed in Europe is 1.8 million tonnes. Estimated granulate emissions from artificial grass pitches amount to between 18,000 and 72,000 tonnes annually in Europe[88]. Also, polymeric infill from artificial sports turf can be inadvertently removed by players (when attached to their clothing or footwear), and also through maintenance activities such as snow clearance in some countries[89]. Consequently, it may then enter drains, soil, or surface water, or be removed as part of waste collection.

[87] Verschoor, Anja & Gelderen, Alex & Hofstra, Ulbert. (2021). Fate of recycled tyre granulate used on artificial turf. Environmental Sciences Europe. 33. 10.1186/s12302-021-00459-1 https://www.researchgate.net/publication/349833422_Fate_of_recycled_tyre_granulate_used_on_artificial_turf.
[88] Hann S, Sherrington C, Jamieson O, Hickman M, Kershaw P, Bapasola A, Cole G (2018) Investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products (European Commission) https://bmbf-plastik.de/sites/default/files/2018-04/microplastics_final_report_v5_full.pdf
[89] Report 7021 Microplastic from cast rubber granulate and granulate-free artificial grass surfaces https://www.naturvardsverket.se/48ec62/globalassets/media/publikationer-pdf/7000/978-91-620-7021-2.pdf

- Furthermore, personal care products, transportation, plastic pellets, and textile fibres also constitute importance sources of microplastics. A multitude of personal care products still contain plastic microbeads that are intentionally added to such products. This represents an important source of primary microplastics. With more than 500 microplastics ingredients identified in personal care products, an approximate 4,130 tonnes of microbeads are emitted annually due to the use of cosmetic and exfoliant products in the EU.
  Transportation, particularly road transportation, has been highlighted as a significant source of microplastics by many research centres, particularly associated to the wear and tear of tyres and to the friction caused by acceleration and braking. Current models predict annual tyre wear emissions per capita to range between 0.23 and 1.9 kg per country, with Europe generating 1.3 million tonnes of tyre wear waste annually[90]
- Plastic pellets, also known as pre-production pellets or beads, are the most widely used raw material to produce plastic products, having a diameter that ranges between 1 and 5 mm, with a regular round shape. EU production ranges between 58 and 70.6 million tonnes annually. In 2015, an estimated 16,888 to 167,431 tonnes of pellets are lost to the environment as a result of inadequate handling practices or accidental spillage during production, storage, and transportation, making plastic producers, handlers, and converters one of the largest sources of primary microplastic pollution today (ECOS, 2020). [91]

In general, groundwater resources are well protected from contamination and drinking water treatment removes most microplastics, however further research is required to assess potential routes of microplastics contamination of drinking water (e.g. the distribution stage) and the potential for human health risks. The process by which microplastics enter groundwater is understood to be:

- Decomposition of landfilled plastic waste creating leachate, issue at both active and closed landfills. Microplastics in the leachate can enter soil and ground water.

Studies from 2016 on the annual amounts of plastics entering surface and groundwater report numbers between 1.15-2.41 million metric tons (Lebreton, 2017[92]), whereas recent studies from 2021 already rate the global annual plastic input at between 9-23 million metric tons (WWF, 2022[93]) (UNEP, 2021[94]) (Pew Trust, 2020[95]). In the absence of action, the amount of plastic waste entering aquatic ecosystems could triple (OECD, 2022) to around 53 million tonnes per year by 2030 (UNEP, 2021) and quadruple by 2050. Recent research showed that

[90] Stothra Bhashyam, S., Nash, R., Deegan, M., Pagter, E., Frias., J., (2021). Microplastics in the marine environment: sources, impacts and recommendations: https://research.thea.ie/handle/20.500.12065/3593
[91] Polyester Textiles as a Source of Microplastics from Households: A Mechanistic Study to Understand Microfiber Release During Washing. E. Hernandez, B. Nowack and D.M. Mitrano, Environ. Sci. Technol. 2017, 51, 7036–7046 https://pubs.acs.org/doi/pdf/10.1021/acs.est.7b01750?rand=xcjelxp2
[92] Lebreton, 2017, 'River plastic emissions to the world's oceans', Nature Communications, vol 8 https://pubmed.ncbi.nlm.nih.gov/28589961/
[93] WWF, 2022, 'Impacts of plastic pollution in the oceans on marine species, biodiversity and ecosystems', Report published by WWF
[94] UNEP, 2021, 'From Pollution to Solution: a global assessment of marine litter and plastic pollution', UN report
[95] Pew Trust, 2020, 'Breaking the Plastic Wave: A Comprehensive Assessment of Pathways Towards Stopping Ocean Plastic Pollution', Report

between 31,000 and 42,000 tons of microplastics (or 86–710 trillion microplastic particles) are spread on EU farmlands every year by the use of sewage sludges in agriculture. Consequently, an average plot of farmland likely mirrors the microplastic levels of ocean surface waters (Micru, 2022[96]). Once in the environment, plastic particles break down to nano-plastics. As a result, concentrations of microplastics will continue to rise for decades even if all plastic emissions cease now (WWF, 2022). Combined with the continuous degradation of plastics already in the environment to micro and nano-plastics, this will result in a 50-fold increase of surface water and ocean (micro) plastic concentrations by 2100. Although EU initiatives like the Single Use Plastics Directive, the proposed restriction of intentionally added microplastics (ECHA, 2020[97]), the upcoming initiatives on unintentional releases, the Textile Strategy and other planned EU actions will reduce microplastics at source, their anticipated effect will only result in an expected reduction of emissions by 10% to 30% at best. Projected increases in plastic production, road transport volumes and synthetic textile production in the next decades also predict an exponential growth in plastic emission levels under the business-as-usual scenario.

There are inherent challenges in tackling pollution from microplastics, however the revision of the Directives should consider the extent to which microplastics can be addressed. Introducing a harmonized measurement methodology, in combination with a monitoring obligation for MS on microplastics, would be a crucial first step to help define microplastics and collect harmonized monitoring data. Those data could then be used to quantify the problem, characterize the kind of plastics and validate results for modelling exercises for microplastics and set environmental quality standards for maximum concentrations in surface and groundwater.

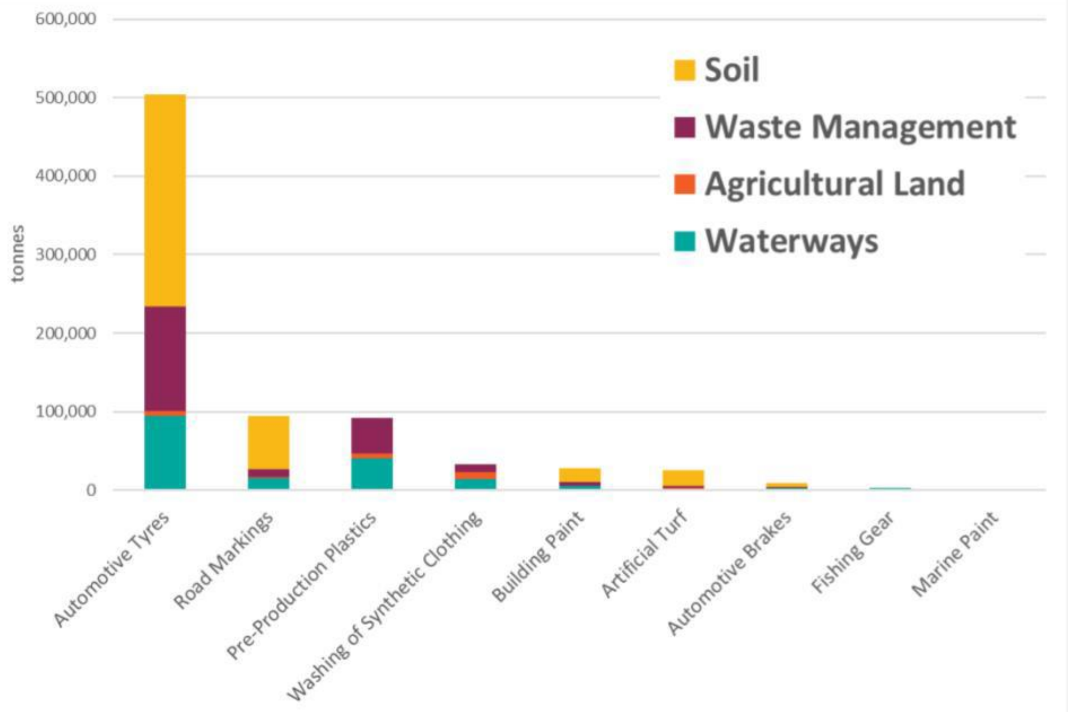
[96] Micru, 2022, 'Farmlands in Europe may be the single largest reservoir of microplastics in the world', [Farmlands in Europe may be the single largest reservoir of microplastics in the world (zmescience.com)]

[97] ECHA, 2020, 'Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics', ECHA/RAC/RES-O-0000006790-71-01/F; ECHA/SEAC/RES-O-0000006901-74-01/F

Box 1. Micro-plastics

The European Commission (2018) investigated options for reducing releases in the aquatic environment of microplastics emitted by products. As part of this study, the quantified sources and fates of a variety of microplastics (from wear and tear) were estimated and the primary source of microplastics from wear and tear is from automotive tyres and the microplastics produced from each source are divided into four fate categories. As it can be seen, waterways are an important sink for microplastics, entering through storm water or directly.

Figure 4-1. Estimated generation of microplastics by sources and environmental fates



Source: Eunomia

OECD (2021) report on microplastics confirms these findings, indicating that "microplastics have now been observed in the surface waters and sediment of lakes and rivers, as well as in drinking water".[98] Under a business-as-usual scenario, global plastics use, waste and related environmental damages are projected to triple by 2060. With around half of the produced plastics ending up in landfill and less than a fifth recycled, the remaining 30% leak into the environment[99]. Inadequate disposal of plastic waste is the main driver of global plastic leakage, but microplastics, littering and losses from marine activities are also key concerns timely and ambitious policies can drastically reduce future environmental damages and in particular plastic leakage to the environment. The level of ambition of the policies and of international engagement will determine the extent to which plastic pollution is reduced.

[98] OECD, 2021

[99] Source: OECD (2022), Global Plastics Outlook: Economic drivers, Environmental Impacts and Policy Options: https://www.oecd.org/environment/plastics/ and https://www.oecd-ilibrary.org/sites/de747aef-en/index.html?itemId=/content/publication/de747aef-en

The main challenge is that monitoring methods are currently not harmonised among the EU and it is therefore very difficult to compare data if they are available at all. Additionally, microplastics are not a unique substance, and the terminology is an umbrella that gathers a number of different polymers and size under the same appellation. This definition issue, meaning that there is currently no common understanding of a harmonized definition of microplastics and how to measure and analyse them. In the marine environment, the small plastic particles are not included in the counting of beach litter, therefore it is important to achieve a common definition of microplastics as well.

Microplastics can have adverse effects on the environment through physical toxicity of the particles, through chemical toxicity or pathogen toxicity (i.e. microplastics as vector for pathogens). Regarding the effects of microplastics on human health and the environment, there is very little information on harmfulness or (eco)toxicity of the microplastics to human health. Regarding the effects of microplastics on the environment, there are some data and publications related to hot spot locations indicating that there are effects on environment. From ecotoxicological point of view, microplastics are persistent substances that also act as a sink for other forms of chemical pollution due to absorption. As a result, the combined effect of microplastics and the accumulated harmful substances, microplastics pose a risk to the environment and humans alike. To minimize potential risks the precautionary principle and the polluter pays principles need to be applied.

Also, there are still many unsolved questions on how microplastics interact with chemical substances in the environment, and how this can be monitored. Therefore, deriving a harmonized methodology for monitoring of microplastics in itself already poses a challenge, as it is difficult to measure microplastics in different types of water (surface water, groundwater, or other). As a result, a future harmonized methodology for drinking water cannot be used directly to measure microplastics in other waters for example.

The water legislation FC found that the WFD is flexible enough to reinforce its implementation with regards to emerging concerns from microplastics, however microplastics are not explicitly mentioned. The mechanism whereby management plans are periodically revised based on an analysis of drivers and pressures can therefore deal with these newly identified pressures. However, integration of these pollutants of emerging concern in RBMPs has been quite limited so far and will require far greater attention in the future.

Furthermore, the value and efficiency of reducing pollution at source as promoted by the WFD and EQSD is important because the SSD and UWWTD can impact microplastic concentrations where sludge is applied on soil.

4.1.3 *Digitalisation, administrative streamlining and better risk management practices*

The water legislation FC noted a number of limitations of EU water legislation which have hindered implementation. These are outlined below:

A need for new monitoring approaches. There is a requirement to adapt current pollutant monitoring processes more swiftly considering the significant pressures stemming from emerging pollutants (such as microplastics) and possible cumulative effects of pollutant mixtures. Currently, monitoring practices focus only on individual substances or groups of substances, yet it is estimated that hundreds of chemical mixture combinations cumulatively occur in freshwater bodies throughout the EU[100]. Consequently, there is a clear mismatch between quality standards for individual substances and actual real-life exposure to cocktail of chemical substances consisting of a multitude of ever varying chemical substances.

Chemical mixtures in waters are derived from a multitude of sources, occurring at different times, locations, and concentrations. The interactions of pollutants and their biological effects are challenging to predict, with three broad interactions occurring: 1) the chemicals may act individually- with individual toxicity demonstrated; 2) combine with each other and become more toxic; 3) interfere with the toxicity mechanisms of each other and become less toxic. As such, due to the lack of monitoring of these interactions, it is plausible that Priority Substance concentrations monitored individually may be below EQSs, yet when combined with other substances their impact could be harmful. Developing mixture assessment approaches, and corresponding guidelines, can therefore be regarded as a key step to understanding chemical-ecological status interactions in water bodies in more detail.

A need for improved monitoring approaches. The WFD establishes minimum monitoring frequencies for biological, hydromorphological and physico-chemical quality elements. The occurrence of certain pollutants, such as pesticides, within water bodies can vary significantly dependent on (for example) economic activities. In order to obtain more reliable spatial and temporal pollutant trend data, increased monitoring frequencies could be desirable. The same logic also applies to the Watch List mechanism, where MSs are required to monitor a range of substances only once annually (this only applies to the surface water watch list, for the groundwater watch list this is voluntary).

In addition to the above, the Fitness Check identified a range of monitoring techniques, which have been implemented by MSs, particularly regarding satellite data, automated sensing technologies, citizen science, and smartphone applications. However, the uptake of these monitoring approaches is often limited. Producing practical guidance on how to implement such monitoring approaches, and the benefits of doing so, was noted as a pathway to their adoption. As such, the majority of the options presented in section 8 are directed towards this aim.

A need for improved risk assessment and the translation into risk management. A key risk assessment component of EU water legislation is the Surface Water Watch List mechanism.

[100] EEA (2018) Chemicals in European Waters- Knowledge Developments

This mechanism is aimed at emerging substances where current monitoring does not allow sufficient data to ascertain the risk the substance in question. The Watch List monitors these substances at selected EU representative monitoring stations for at least 12 months, and up to 4 years. Substances which are therefore identified as having a significant EU-wide risk are then considered as candidate Priority Substances for the next review of the PS list. However, the noted time lag between revisions and simultaneous delay in obtaining conclusive data was noted as a weakness in the Fitness Check, in addition to addressing only a limited number of substances. It has been noted by stakeholders that it is challenging to use the mechanism as an early-warning system.

Another risk assessment component under EU water legislation is included under Annex V of the WFD. Here, MSs are required to identify pollutants of regional or local importance (River Basin Specific Pollutants- RBSPs) and set corresponding EQS, monitoring schemes and regulatory measures. The Fitness Check identified some discrepancies in RBSP between MS-where significant differences exist in the number of identified substances and their EQS for the same substances. Furthermore, as MSs use contrasting methodologies to select RBSPs, there can be a lack of consistency in identifying relevant substances. As such, RBSP values may not be comparable between MSs, which could undermine the coherence of EU water legislation.

In relation to **reporting and data sharing**, the Fitness Check noted the need for reporting to be further simplified and automated as the current system is resource intensive. While progress has been made in some member states towards digitisation of reporting and visualisation of results (e.g. moving from reporting to harvesting of data, allowing re-use of data), the potential is far from complete. Many MSs still have problems reporting even basic data in electronic format. There is a **need to improve data management transparency and utilisation.** The Fitness Check noted that significant strides have been taken in making monitoring and reporting data in digital formats, yet there is significant unexploited potential. By further digitalisation of monitoring and reporting, it is likely that the administrative burden of MSs would be reduced in the future, with costs also likely to reduce in the medium-long term. In addition, through digitalisation the comparability of MS data can be more closely aligned, ultimately increasing the transparency of data and metadata through publishing them on an online, centralised platform. This would also be beneficial for an increase in the lacking compliance of MSs with provisions of the EU INSPIRE Directive, e.g. by using the INSPIRE Geoportal for this purpose. Digitalisation also helps to be independently of reporting timeframes, thus making data available more often and closer to real time and would thus also be beneficial for policy makers to demonstrate progress and the results of their efforts at national scale in the Member States.

In summary, six key problems have been defined in relation to the digitalisation, administrative streamlining and better risk management :

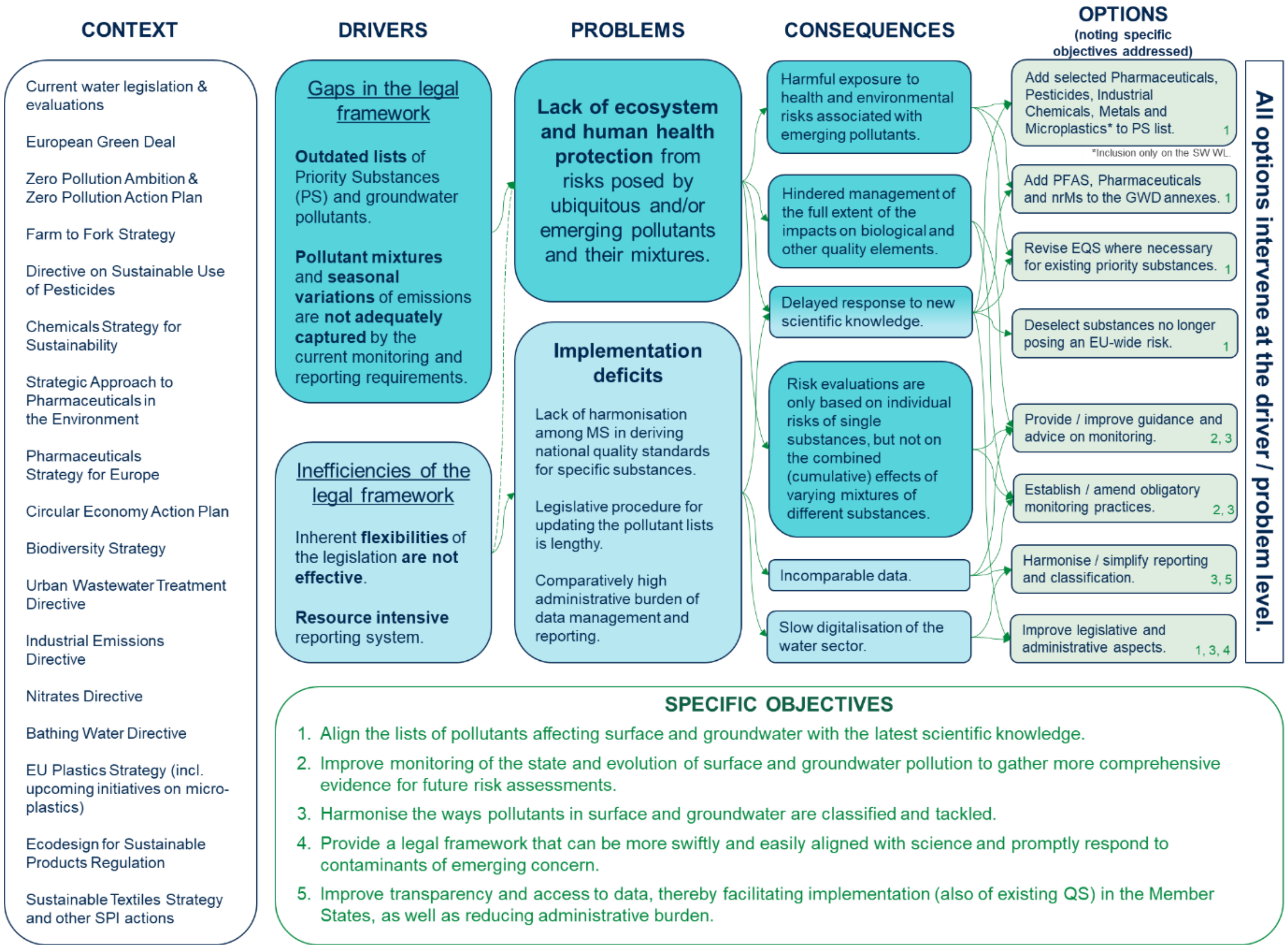
1) Pollutant mixtures are not adequately captured in WFD monitoring and reporting. Therefore, the full extent of the impacts this has on biological and other quality elements is not appropriately managed;
2) Current monitoring may not adequately capture the impacts of economic activities with variable time periods. Modernised monitoring approaches should be able to limit the

burden associated with increased monitoring frequencies in the medium to long term. They include, inter alia, the introduction of new fluid monitoring sensors that allow multiple parameters to be measured simultaneously in one sample, and the automatic transmission of data. If this is carefully done the overall monitoring efforts can be lowered, while at the same time more detailed monitoring results can be obtained;
3) The Surface Water Watch List mechanism addresses a limited number of emerging pollutants, and reports on these with a frequency which can hinder the responsiveness of legislative actions. For substances noted as emerging within water bodies, the required monitoring frequencies do not sufficiently allow for comprehensive trend analyses. Furthermore, it can be challenging for the Watch List mechanism to keep pace with new scientific knowledge; the Groundwater Watchlist is established on a voluntary basis only and therefore yields less information.
4) The legislative procedure for updating the list of priority substances (and the list of substances in Annex I to the GWD) is long, and thus delays reaction to newly identified pollutants.
5) Considerable variation exists in the designation of EQS for RBSPs, resulting in incomparable data. This is largely due to the lack of harmonised approaches to deriving EQSs;
6) The administrative burden of data management remains high, whilst a lack of standardised, comprehensive data limits the robustness of reporting. A lack of standardisation in data monitoring and reporting is also slowing the digitalisation of the sector.

4.1.4 *Intervention logic*

An Intervention logic for the WFD, EQSD and GWD is presented in the Figure below, highlighting the interactions between the Directives, and the needs and problems they are aimed at addressing.

Figure 4-1 Intervention logic



4.2 Who is affected by these problems?

The problems identified impact multiple sectors and stakeholders, in addition to also directly impacting the environment (surface and ground water bodies, and their surrounding ecosystems). This includes MSs and particularly the competent authorities tasked with implementing EU water legislation, as well as citizens in general.

Environment	Currently, data on the causal links between chemical status and the ecological status of surface water bodies is lacking. The pollutants impact the health of local ecosystem, yet due to the flow regimes of EU waterways, and their transboundary nature, impacts can also occur at much greater spatial scales. This issue is made even more complex by the range of possible chemical mixtures present in waters, and the impacts that these mixtures have on the environment and health of citizens. The response-rate of EU and MS interventions to tackle pollutants ultimately determines the extent to which pollutants negatively impact the environment. The duration between identifying pollutants under the WL mechanisms and adding these pollutants to the regulatory lists impacts the exposure of the environment to these pollutants. Similarly, the contrasting values established by MSs for pollutants of regional concern results in varying environmental exposure to such pollutants within the Union. Slow or mal-informed risk management can therefore have severe negative environmental impacts.
Economic sectors	A range of economic actors are highly dependent on clean water quality. These actors include, inter alia, agriculture which relies on water for irrigation, tourism and the recreational sector (which rely upon clean water to attract tourism), industries (which require clean water for their industrial processes) and water companies (required to provide drinking water of an adequate quality). Poor water quality due to the existence of pollutants can negatively affect these sectors and can increase costs, for instance, if agricultural and drinking water has to be sought from different sources, or due to high treatment costs required to be able to safely utilise the water resources.
Competent authorities	Authorities can be impacted by the aforementioned problems through ensuring the adequate monitoring of pollutants are undertaken and through effectively enforcing actions. Competent authorities will be required to provide administrative and resource capacities.
EU society (and neighbouring countries)	The inefficiencies in tackling surface and groundwater pollutants can result in direct negative impact on the EU economy. Environmental protection and clean water are essential aspects of human health and wellbeing, ultimately contributing both social and economic benefits to EU citizens. Due to the transboundary nature of EU waters with neighbouring countries, tackling water quality issues also directly impacts citizens of countries sharing river basins with an EU MS.

4.3 How would the problem evolve?

4.3.1 *Introduction*

In order to help inform the impact assessment for revision of the EQSD and GWD, it is important to understand the existing state of play.

In developing a baseline for the study, it is important to recognise that the EU policy landscape continues to evolve and change at a rapid rate. These policy changes are likely to drive innovation and technical knowledge, delivering changes in industrial processes. Therefore, it is possible that in a business as usual / do nothing scenario, that the emissions of candidate PS, existing PS (EQSD) and Annex I/II (GWD) substances would change due to other legislation/initiatives and thus environmental concentrations would change. It could even mean that 'good chemical status' could still be achieved even without listing the substance/s as a priority substance (i.e., environmental concentrations of substance would be below the proposed EQS without any additional effort from the EQSD specifically) or as an Annex I substance with a groundwater quality standard or an Annex II substance (GWD).

A dynamic baseline, which reflects the likely changes to emissions and by-proxy environmental concentrations in a business as usual / do nothing scenario has been developed. This is assumed to cover the short-to-medium term picture (next 2-5 years). One caveat is that as the policy landscape continues to evolve, and there are likely to be further changes in decision making, and implementation, it is hard to quantitatively predict the impacts of the dynamic baseline. Instead, a qualitative analysis is presented in the following sub-sections which first provide an overview of the relevant legislation and the best understanding of how it is evolving. Then in section 4.3.3, an overview of how this evolution may impact the emissions of candidate and existing PS and substances proposed for listing in Annex I and Annex II of the GWD within the dynamic baseline is provided (assuming the business as usual/do nothing scenario).

4.3.2 *Legislative overview*

As noted in Section 3, there are a number of the EU cornerstone water directives and regulations which address pollution as well as a wider range of water related issues. Table 4-3 and 4-4 provide an overview of the regulatory evolution for the most relevant legislation and potential impacts for the substances under review for surface waters and groundwater respectively. Each legislation has its own drivers and agenda to maintain, but there are three major overlying themes that affect all of the legislation listed:

- **European Green Deal**[101] (published in 2019) represents the EU's concerted efforts to tackle climate change challenges, but also includes several strategies related to chemicals. In particular these include:
  - **The farm to fork strategy (May 2020)**[102]
  - **The biodiversity strategy for 2030 (May 2020)**[103]

[101] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[102] https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en

[103] https://ec.europa.eu/environment/strategy/biodiversity-strategy-2030_en

  - **The strategy for sustainable use of chemicals towards a toxic-free environment (October 2020)[104]; and**
  - **The strategy for pharmaceuticals (November 2020)[105]**
- **Better Regulation Agenda[106].** The better regulation agenda (first developed in 2015) is a top-level EU strategy to ensure that legislation delivers upon its objectives in the most effective way possible. As part of the Commission's work programme EU legislation is systematically targeted for evaluation to assess whether it is fit for purpose and delivering upon its objectives. Following the evaluation further options for any required revision of the legislation are then assessed for impacts ultimately leading to revision of the legislation. Several of the related pieces of legislation are either currently under evaluation or follow-up steps or have been revised in the last 3 years.
- **International developments.** Some of the legislation covered by the chemical's acquis have been developed and implemented in response to international obligations of the European Union to global treaties and Conventions. These international policy instruments (such as the UNEP Conventions under Stockholm, Basel, Rotterdam and Minamata) continue to evolve and develop. This requires EU legislation to also evolve and develop to maintain regulatory alignment.

Surface Water

Table 4-3 provides an overview of the regulations relevant to surface water.

Table 4-3 Overview of regulatory evolution for most relevant chemicals' legislation directly linked to surface waters

Legislation	General implications for substances	Relevant substances
WFD (2000/60/EC) and its Programmes of Measures in MS	The MS are currently in the process of adopting the third river basin management plans (RBMPs) due end of 2021. These will include the chemical status of priority substances added in 2013 for the first time. MS will also include PoMs to address the main issues identified and achieve environmental objectives. Based on discussions with multiple MS authorities there are concerns for widespread chemical status failures within water bodies.	All existing PS, including those added to Annex I in 2013. The second RBMPs indicated that the majority of chemical status failures were linked to a small number of substances, particularly mercury and PAHs. The third RBMPs will provide an update on this situation and relevant context for the further review on EQS amendment for those substances. Additionally, PFOS added to EQSD Annex I in 2013, will be reported for the first time. There are concerns that there may well be widespread EQS exceedances.

[104] https://ec.europa.eu/environment/strategy/chemicals-strategy_en

[105] https://ec.europa.eu/health/human-use/strategy_en

[106] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

Legislation	General implications for substances	Relevant substances
Drinking water directive (recast) (EU 2020/2184)	Following an evaluation, and impact assessment, the DWD (recast) was endorsed in December 2020. Member States will have until 2023 to transpose the directive into national legislation. The two key changes included within the recast was greater onus on access to drinking water (particularly for vulnerable and marginalised communities) and reinforced drinking water standards to go beyond the WHO limits. In particular, this included focus on PFAS and development of analytical methods by 2024.	All existing PS, and candidate PS, with the possible lower focus on pesticides. The directive specifically mentions pharmaceuticals, pesticides, PFAS endocrine disruptors and micro-plastics. This includes the development of analytical methods for PFAS to help support improved monitoring and control.
Urban wastewater treatment directive (91/271/EEC)	The Urban wastewater treatment directive (UWWTD) is currently undergoing an impact assessment following an evaluation study. Following the conclusion of this work the subsequent steps will focus on the revision of the UWWTD. Key themes within the IA include[107]: • The need to tackle micropollutants and pharmaceuticals. This could include greater onus on monitoring, reporting and treatment, including a wide-spread upgrade of UWWT plants to tertiary treatment. • The role of extended producer responsibility (EPR) to help support the financial burden of upgrades. • Improved management of industrial and storm flows, including losses from combined sewer overflows (CSOs) during peak events.	All existing and candidate PS would be covered by these changes. Tackling the impacts for pesticides may be less pronounced, since other pathways to environment may be more important. The impact assessment has specific focus for pharmaceuticals, including the role of UWWT plants as a driver (or part of the driver) for anti-microbial resistance. The evaluation results concluded that the existing UWWT directive only loosely covers the chemical quality elements. The wastewater industry voiced concerns about the pressures they faced to manage emerging chemical risks and the greater onus being placed on wastewater companies to act as an end-of-pipe solution to chemical pressures on water.
Sewage sludge directive (86/278/EEC)	The SSD is currently undergoing an evaluation to assess its effectiveness. It is too early to comment on any potential changes to the SSD. However, one of the concerns that has been raised, is that the rather limited number of substances included within the SSD for quality standards, whereas several Member States have more comprehensive lists of substances. The evaluation will look in particularly whether the SSD should include	This directive will likely impact the candidate pharmaceutical substances (particularly antibiotics). It could also be foreseen that emerging pollutants such as bisphenol A and PFAS would also be included. Regarding PFAS, the quality standards work by requiring an analysis of concentrations in both the receiving soil and the sludge, with the quality

[107] Revision of the Urban Waste Water Treatment Directive – Inception Impact Assessment, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12405-Water-pollution-EU-rules-on-urban-wastewater-treatment-update-_en

Legislation	General implications for substances	Relevant substances
	new substances within the directive such as micro-pollutants, and in particular the role of the SSD to combat anti-microbial resistance.	threshold applied at the cumulative level. PFAS create negative effects at very low concentrations and are already widely present in the nature environment, including the terrestrial environment. The inclusion of PFAS within the SSD could present several practical issues and have consequences more widely for how sewage sludge is managed within the European Union.
Plant Protection Products (PPP) (EC no 1107/2009) Regulation, including the Sustainable Use of Pesticides (SUP) Directive (EC) No 2009/128 **Also including the developments of the new EU Green Deal and Farm to Fork Strategy[108].**	Under PPP pesticide active substances have to renew approvals on a periodic basis. Equally, plant protection products (containing an active substance) have to be authorised at MS level with further periodic review. A wider concern has been the use of emergency authorisations for pesticides which are not approved. In particular neonicotinoids, where one source quotes '67 emergency authorisation granted across EU MS in the two years since approval was removed in 2018[109]' Under the SUP Directive MS are required to develop National Action Plans, these have been largely updated between 2018 and 2020, with some remaining updates ongoing (expected to be completed before the end of 2021). An evaluation of PPP was completed in 2018, which highlighted that the function of this legislation was good overall, but needed greater transparency, stricter control of product authorisations and greater use of precautionary principle for safer alternatives and consideration of undesirable impacts. The SUP is currently undergoing an evaluation with study findings in Spring 2022 which includes findings related to the currently available pesticide statistics	The following candidate priority substances have pesticide approvals as follows. Expiry dates are for the current approval not withstanding any renewal process. • Neonicotinoids: • Acetamiprid: approved until 2033 • Clothianidin: not approved since Jan 2019 • Imidacloprid: not approved since Dec 2020 • Thiacloprid: not approved since Aug 2020 • Thiamethoxam: not approved since 2018 • Pyrethroids: • Bifenthrin: not approved since Jul 2019 • Deltamethrin: approved until Oct 2021 • Esfenvalerate: approved until Dec 2022 • Permethrin: not approved since 2000 Other pesticides • Nicosulfuron: approved until Dec 2021 • Glyphosate: approved until Dec 2022 • Chlorpyrifos: not approved since Jan 2020 • Dicofol: not approved since Sept 2008 • Diuron: not approved since Sept 2020 • Tributyltin: not approved since 2002

108 https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en

109 https://unearthed.greenpeace.org/2020/07/08/bees-neonicotinoids-bayer-syngenta-eu-ban-loophole/

Legislation	General implications for substances	Relevant substances
	being insufficient to effectively monitor progress on the sustainable use of pesticides in MS and at farm level. As part of the EU's new green deal, the Farm to Fork strategy was published in May 2020, with the ambition to be less reliant on pesticides. This includes targets to reduce the use and risk of chemical pesticides by 50% by 2030, particularly including pesticides with high hazard profiles and reduce fertilizer use by at least 20% by 2030. It also includes the target of reducing by 50% the sales of antimicrobials for farmed animals and in aquaculture by 2030.	• Alachlor: not approved since 2006 • Chlorfenvinphos: not approved since 2006 Based on the findings of the PPP evaluation the number of pesticidal substances in use with high hazard profiles is now low (at 2%), while pesticides with fewer problematic hazards has grown, now at (37%)[110]. This is due in part to more rigorous scrutiny of actives and removal / non-renewal of actives which demonstrate high hazard issues. Note the potential implications for the above substances. Note that pesticides identified as persistent organic pollutants (POPs) are not approved for use in the EU and will be covered under the POPs Regulation: hexachlorobenzene, heptachlor, aldrin, dieldrin, endrin, isodrin, DDT,
Biocidal Products Regulation (BPR) EU/528/2012	The BPR works in a similar fashion to PPP with two tiers of regulation, approval of active substances at EU level and authorisation of biocidal products at MS level. ECHA commenced the review programme for all existing approved biocidal substances in 2014 which is due to complete in 2024. This review is intended to assess the reported hazard profile against any new data and assess risks that use of biocidal products may present. As part of the strategy for the non-toxic environment, this would include targets for substitution where hazards of high concern are identified.	Triclosan: the approval under BPR was reviewed in 2014, noting that triclosan had uses as a disinfectant and preservative for fibres, leather, rubber, and other polymerised materials. The decision of the review by ECHA determined unacceptable risks for environment and thus the approval was revoked. This meant all products containing triclosan for the above use were banned as of the beginning of 2017. Triclosan also has uses as biocidal preservative in cosmetic products. Following review by the scientific committee on consumer safety (SCCS) in 2014 use was permitted in toothpaste, soap, deodorants, face powders, and blemish concealers, nail polish, and systems used to clean fingernails and toenails provided concentrations did not exceed 0.3% w.w. Use in mouthwash was permitted provided concentrations did not exceed 0.2% w.w. Silver: Currently under review within the BPR processes. This has partly

[110] EC, 2020, 'staff working document for the evaluation of plant protection products regulation and maximum residues levels in pesticides', COM(2020)208.

Legislation	General implications for substances	Relevant substances
		concluded that the approval for silver (nanomaterial form) use in several biocidal applications primarily related to drinking water and food was removed in Spring 2021[111]. The review of endocrine disrupting properties is ongoing.
REACH Regulation (EC) No 1907/2006, and Regulation on Classification, Labelling and Packaging (CLP) (SC) No 1272/2008	The REACH Regulation is the EU's central piece of regulation governing the safe manufacture, import and use of chemicals, including procedures to apply further regulatory control through identification of substances of very high concern (SVHC) and management under Authorisation or Restriction. The REACH regulation is currently undergoing a far-ranging evaluation and options appraisal for revision of the regulation. In particular, This includes additional focus on several areas including mixture assessments, definition of essential use, further information requirements for lower tonnages (below 10 tonnes per annum), and control requirements for specific hazard classes (particularly endocrine disruption) as well as categories of chemicals, including consideration for addition of polymers to REACH.	PFAS: Five EU MS have notified ECHA of an intention to submit a nomination dossier for restriction of all PFAS substances by July 2022. This approach is based on a basic definition of PFAS covering 6,000 substances. Regulatory control of the first two PFAS substances (PFOS, and PFOA) have been transferred under the POPs Regulation. Subsequent PFAS substances (PFHxS, PFHxA, and C9-C14 PFCAs) are undergoing the process to be restricted. Bisphenol A: REACH restriction in place for use in thermal paper, also listed as an SVHC based on its endocrine disrupting properties. Silver: assessment for endocrine disrupting properties is ongoing (carried out under BPR – see previous row) Mercury: REACH restriction in place for use in thermometers and measuring devices. See also the Mercury Regulation relating to dental amalgam, as well as RoHS (electrical equipment), batteries directive (which bans the use of mercury) and safe concentration limits for mercury under Toy safety and food safety legislation. Nickel: Registered under REACH no ongoing actions. Nonylphenol: REACH restriction in place for use in textiles, also listed as an SVHC based on its endocrine disrupting properties. PBDEs: the commercial mixtures based on the lower-order homologues (Penta and Octa) were already banned in Europe as of 2004. The deca homologue of PBDEs was added to the REACH restriction list in March 2019 with a 0.1% w.w. maximum concentration limit

[111] https://echa.europa.eu/-/biocides-committee-proposes-not-to-approve-four-silver-containing-active-substances

Legislation	General implications for substances	Relevant substances
		for all mixtures and articles placed on the market. It has subsequently been moved under the POPs Regulation to align with the listing in the UNEP Stockholm Convention.
Single use plastics directive (EU 2019/904); this includes the wider EU plastics strategy and upcoming initiative on microplastics pollution.	The single use plastics directive sits within the remit of the circular economy. This recognises that while plastics are a valuable material which has enhanced technology and the quality of life for EU citizens markedly, the waste aspects and environmental pollution represents a significant concern. The Directive aims to address issues with environmental pollution, in particular marine litter as part of the UN Sustainable Development Goal 14. This includes the aim to reduce marine plastic litter by 50% and all environmental releases by 30% by 2030.	Microplastics represent a significant environmental pollutant. Broadly, the sources of microplastic can be categorised into primary sources, where microplastics are used intentionally (e.g. in personal care products). They can also come from secondary sources as a result of environmental and mechanical actions on larger plastic articles degrading them into microplastics, this is particularly important for uses in textiles, as well as automotive applications (brake and tyre wear). Single use plastics could act as an important source of secondary microplastics, and therefore limiting their use and release to environment would have beneficial impacts for reducing microplastics in the environment.
Further legislation related to metals (particularly the Batteries Directive (EC) no 2006/66, Risk of Hazardous substances (RoHS) (EU) no 2011/65; and Regulation on mercury (EC) no 2017/852	There are several additional legislation related to the non-ferrous metals covered by the current study: • Mercury regulation restricts the import and export of certain mixtures of mercury. It also includes measures for mercury use in dental amalgam, and greater control of mercury containing waste. The regulation helps transpose the EU’s commitment to the UN Minamata Convention which entered into force in August 2017. • The third iteration of RoHS(III) expands the list of substances from six to 10 and restricts their use in electrical equipment. This includes mercury and PBDEs). The Batteries Directive aims to protect the environment by limiting the use of certain hazardous materials (including mercury).Following an evaluation of the directive, a proposal to amend it was	• Mercury (Mercury regulation, RoHS, and batteries directive) • Nickel (batteries directive) • PBDEs (RoHS) Mercury is one of the key issues for good chemical status, being part of a small set of substances that cause widespread EQS failures across Europe. Further reductions in emissions would help this situation, but due to the existing mercury already in the environment, achieving good status may have a considerable lag time between emissions and environmental concentrations.

Legislation	General implications for substances	Relevant substances
	published in December 2020[112]. The proposed amendment is intended to improve waste management and recycling of materials (such as nickel) to avoid waste and loss to environment. Further, RoHS and related legislation such as the Batteries Directive help feed in to the EU's sustainable use of chemicals and non-toxic environment strategy.	
Pharmaceutical legislation	Within Europe several strategies have been published in the last two years to address the manufacture and use of pharmaceuticals. This includes as part of the green deal: • The pharmaceuticals strategy for Europe. • The sustainable use of chemicals strategy leading to a toxic-free environment. Additionally, in 2019 the EU launched its Strategic Approach to Pharmaceuticals in the Environment. This included a set of actions to be completed with the latest progress update published in November 2020[113]. In regulatory terms the strategy calls for a set of implementing decisions and delegated acts to strengthen environmental and human protections. As an example of this in November 2020, the Commission published its implementing decision (EU) no 2020/1729) on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. Additional delegated acts are currently being drafted for veterinary products (again linked to antimicrobials), as well as a study to determine whether a central EU-wide review system is needed for pharmaceutical ingredients to support environmental risk assessment.	All pharmaceutical candidate priority substances, including the oestrogenic compounds (estrone, 17-beta-estradiol, and Ethylestradiol EE2), antibiotics (azithromycin, clarithromycin, and erythromycin), diclofenac, carbamazepine, and ibuprofen. A considerable body of work is developing under the strategies mentioned in the cell to the left. In particular, the Strategic Approach for Pharmaceuticals in the Environment states that a full lifecycle approach should be taken with measures implemented not only at the end of pipe, but also much earlier in the lifecycle following polluter pays principles. The body of work identified should have a positive effect for emissions of pharmaceuticals to surface water, although there may be a lag between ongoing work, implementation, and reductions in releases. The issue also remains highly sensitive and therefore, implementation of measures to reduce releases could still be problematic yet.

112 https://ec.europa.eu/environment/pdf/waste/batteries/Proposal_for_a_Regulation_on_batteries_and_waste_batteries.pdf

113 https://ec.europa.eu/environment/water/water-dangersub/pdf/Progress_Overview%20PiE_KH0320727ENN.pdf

Legislation	General implications for substances	Relevant substances
Industrial emissions Directive 2010/75/EC (IED)	Over the course of 2018 to 2020 an evaluation of the IED was completed through multiple studies. This included a study to assess the contribution of IED to water policy targets[114]. The study concluded that only 17% of Best Available Techniques (BAT) conclusions (leading to emission limit values) related to water. While specific sectors such as wastewater and chlor-alkali production were well covered, others were far less so and there as a lack of systematic coverage for water quality issues. A recommendation of the study is greater coherence with related legislation (such as REACH) which would extend to water legislation also. An options appraisal for the revision of the IED is ongoing with the study expected to conclude by the end of 2021. This encompasses a measure to systematically include data from related legislation into the update of BAT reference documents (BREFs) and BAT conclusion processes. BREF documents (which lead to BAT conclusions) are updated approximately once every 10 years. The latest update, which is for ceramics (commenced in February 2021), has included a more significant role for ECHA, including greater identification and consideration of SVHCs. The JRC are taking a similar role to identify chemicals of concern for industrial sectors and helping to guide data collection. The revision of IED does have the potential for greater control of substances and releases to surface water, but a significant lag may be expected between implementation and further reductions in releases to water.	All candidate pharmaceutical substances – these are largely covered by the BREF document on the manufacture of organic fine chemicals. All metals (candidate priority substances, and substances for review of EQS amendment). Mercury, nickel, and silver will be covered by the BREF on non-ferrous metals. Dioxins, hexachlorobenzene, and PAHs appear under several IED regulated sectors, but most notably waste incineration and large combustion plants. PFAS is not directly covered by the IED but manufacture would likely appear under either the organic fine chemicals or large volume organic manufacture. Pesticides are not directly covered by the IED but manufacture of intermediate chemicals may be captured by one of the BREFs on organic chemicals (organic fine chemicals or large volume organic chemicals). PBDEs are not directly covered by the IED but may be relevant for waste incineration as end-of-life processes. Tetrachloroethylene, trichloroethylene, and carbon tetrachloride would all be covered by large volume organic chemicals.

[114] https://circabc.europa.eu/ui/group/06f33a94-9829-4eee-b187-21bb783a0fbf/library/af2ff560-431b-4b61-b318-4543a9b176ff/details

Legislation	General implications for substances	Relevant substances
Persistent Organic Pollutants (POP) legislation, including the POPs Regulation (EU) no 2019/1021; UNECE CLRTAP protocol[115]; and UNEP Stockholm Convention[116]	The POPs regulation was recast in June 2019, this gave ECHA a more central role to align with ongoing processes under REACH. The process for nomination of candidate POPs was amended for greater transparency and input from a wider range of stakeholders. The other major change was update to the sections on POPs contaminated waste to improve traceability and audit trail of wastes that contain POPs.	The PFAS substances PFOS and PFOA sit under the POPs regulation requirements. In due course PFHxS will also be moved from REACH to the POPs regulation to align with the Stockholm Convention. Dioxins, hexachlorobenzene, hexachlorobutadiene, hexabromocyclododecane, PAHs, PBDEs, aldrin, dieldrin, endrin, DDT, and heptachlor. The POPs regulation already places requirements for national implementation plans, which include action plans for Annex C substances such as dioxins and PAHs. These plans should help identify sources and minimise emissions to all vectors, including water. The POPs regulation would also align to the toxic-free environment, with potentially greater onus on waste management in the future.
Waste legislation - several acts and decisions	The EU adopted four revised sets of waste legislation in 2018 (to be implemented by 2020) as part of the drive towards a circular economy, which includes greater control over waste and potential losses to the environment. This includes revisions to: • Waste Framework Directive (EU 2018/849) • Landfill Directive (EU 2018/850) • Directive on Waste (EU 2018/851) • Packaging and Packaging Waste Directive (EU 2018/852) Key to the success of all four directives is more rigorous monitoring and reporting at Member State level. In particular it includes aims to significantly reduce the use of landfill, and adoption of waste management systems to identify where material can be recycled. It also includes the creation of the SCIP (Substances of Concern in complex objects (Products) database[117] to identify high concern chemicals within articles and	Several substances affected, particularly where substances are used within articles entering the waste stream (e.g. PFAS, Bisphenol A, Silver, mercury, nickel, PBDEs, and nonylphenol). Disposal of pesticide/biocide wastes would already be treated as controlled waste due to its hazardous properties, but the revision of waste legislation may strengthen controls. See also management under the IED (BREFs and BAT conclusions, particularly for waste and waste incineration). Pharmaceutical wastes may be something of gap although will be broadly covered by the waste framework directive. Greater controls over unused pharmaceuticals / pharmaceutical waste may be addressed more directly by the Strategic Approach to Pharmaceuticals in the Environment.

[115] https://unece.org/environment-policyair/protocol-persistent-organic-pollutants-pops

[116] http://www.pops.int/

[117] https://echa.europa.eu/scip

Legislation	General implications for substances	Relevant substances
	remove them safely for destruction prior to recycling.	These initiatives are all likely to help reduce the releases to environment, however how successful they may be is hard to determine at this stage.
Other legislation (e.g. toy safety, cosmetics, food safety, food contact materials, Chemical Agents' Directive, prior informed consent, Ambient Air Quality Directive, Montreal protocol, and fertiliser regulations	The European Union chemical acquis includes additional legislation. Under these different approaches is the adoption of what are termed 'generic exposure scenarios' (GES), where the hazards of a given substance trigger immediate action. This largely relates to where the substance is identified as CMR or PBT[118] (e.g. use of CMR substances is banned from toys, cosmetics, and food contact materials). The current review of the REACH regulation is exploring expanding these hazard classes to also include endocrine disrupting chemicals, which in the wider context could see these hazards adopted more widely into GES for other related vertical legislation. Additional legislation make use of named lists of substances (e.g. prior informed consent, fertiliser regulations, detergents regulation etc) with specific obligations. As knowledge on chemicals of emerging concern develops these legislation can be updated to include new substances. At a parent level there is also the EU chemicals strategy for sustainability towards a toxic-free environment, which sets the agenda for greater protection of the environment and human health.	Broadly this would cover the majority of both the candidate priority substances, and those existing priority substances where the study is providing an impact assessment for amendment of EQS or deselection of substances respectively. Many of the legislation identified have already been in use for several years and already provide protections for the environment and human health. The greater change may relate to the ongoing work under the sustainable use of chemicals and toxic-free environment which could have positive benefits for releases of all substances under review. This would utilise the existing legislative framework under the chemical's acquis to further target specific issues.

Beyond the wider chemicals' acquis, the problems presented can also continue to evolve under the WFD itself. For the candidate priority substances this includes RBSPs lists (where they have already been added to RBSP list or are in the process of being proposed and added).

It is possible to already state that where RBSPs are determined at a national level, the substances selected will vary among Member States as will the assigned EQS. The use of RBSP lists provides a critical role under the WFD to allow sufficient flexibility to address more localised issues that may only affect one or a smaller number of MS and do not necessarily represent an EU-wide risk. For the candidate priority substances, it can be assumed that the wider impacts and risks may be more significant (i.e., there is an EU-wide risk). This means

[118] Carcinogenic, Mutagenic, or toxic for reproduction. Persistent, bioaccumulative and toxic.

for the baseline using the RBSP list represents an uneven mode of management given the varying quality standards in use and more scattered coverage. This would suggest the impacts from the candidate priority substances would affect EU surface waters in an uneven fashion, which has consequences for comprehensive protections (via PoMs) and level playing field.

Groundwater

For the LFR pollutants there are already measures in place which will be impacting on concentrations in groundwater, e.g. the banning of use of parent compounds of some PFAS and nrMs means that the most stringent mitigation available has already been implemented. It will be important to understand how the policy landscape will change the baseline situation against which the impact of the options are assessed. Confounding factors such as the groundwater lagtime for recovery, population growth and increase in emissions, and the potential for pollutant substitution (where one substance is banned but it is replaced by a chemically similar compound with similar harmful properties that has not been banned) will also change the baseline situation. The timescale for mitigation measures for groundwater to have an impact on persistent pollutants can take decades in some aquifers, whilst the target dates for some initiatives (e.g. reduce pesticide use by 50% by 2030) allow accumulation of pollutants in aquifers in the interim.

In addition to changes in policy and legislation there will be advances in technical knowledge, changes in industrial processes, development of alternative substances, advances in analytical techniques and improved understanding of the environmental fate of substances that may affect the use and emissions of groundwater pollutants.

Table 4-4 provides an overview of the regulations relevant to groundwater. The table presents the main existing regulatory measures which are applicable to prevent groundwater pollution from the substances put forward on the LFR. For each measure the general implications and specific impact on relevant substances are identified. In the final column of the table, the likely impact of these measures on the dynamic baseline for groundwater are qualitatively assessed. This assessment is given in terms of a positive (i.e. reduces observed concentrations in groundwater) or negative impact (may lead to increased concentrations or even deterioration of status).

Table 4-4 Overview of regulatory evolution for most relevant chemicals' legislation directly linked to groundwater

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Groundwater Directive (GWD)[119] [1]	In some MS nrMs are considered as relevant metabolites and applied Annex I GWQS.	Some MS and AC have defined TVs for some of the pollutants under consideration in particular for nrMs and PFAS.	Positive: -for nrMs based on measures to address pesticides through Annex I listing and TVs in some MS, -for PFAS based on prevent and limit requirements and TVs in some MS.

119 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Regulation No 1107/2009 concerning the placing of plant protection products on the market[120] [1]	Active substances can only be approved for use in plant protection products if they fulfil the approval criteria. Authorisation of individual active substances is subject to periodic review (10 years); new information could change authorisation	Parent compounds of nrMs fall into a number of categories: approved; not approved, banned, not registered.	Positive for nrMs with banned parent compounds. Where a permitted parent compound is reviewed in light of LFR evidence on concentrations of nrMs in groundwater there may be a ban in use.
Directive 2009/128/EC, establishing a framework for community action to achieve the sustainable use of pesticides	Measures under this directive: • Include instructions on safety, storage and disposal of pesticides with sales; • Improve public awareness of possible risks from the use of pesticides; • Promote research programmes aimed at determining impacts of pesticide use on human health and the environment; • Provide systems for regular inspection of pesticide application equipment; • Generally prohibit the use of aerial spraying of pesticides; • Take measures to avoid pollution of the aquatic environment, such as using the most efficient application techniques, establishing buffer strips, planting hedges along waterbodies, and reducing or eliminating use in areas with a high likelihood of runoff of surface water or sewers; • Promote low-pesticide pest management methods (including integrated pest management and organic farming); • Minimising or prohibiting use of pesticides in sensitive areas. All of these measures must be implemented in National Action Plans	Parent compounds of nrMs are pesticides which must be used in compliance with the requirements of this directive. The SUD supports delivery of the EU's Farm to Fork initiative, which aims to reduce hazardous pesticide use by 50% by 2030. The 2020 DG SANTE impact assessment suggests slow implementation of the SUD although most MS had developed action plans by 2017. Achievement of the 2030 target is uncertain.	Positive for nrMs - although speed of implementation may hamper reduction

120 REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Biocidal Products Regulation[1] 121	A biocidal product consisting of, containing, or generating a relevant substance, cannot be made available on the EU market if the substance supplier or product supplier is not included in the Article 95 list for the product type to which the product belongs. The regulations may require manufacturers to consider environmental risks depending on use.	Two of the 16 nrMs parent compounds (Tolylfluanid and Dichlofluanid) are on the Article 95 list.	Postive for relevant nrMs
REACH Regulation 122[1]	Registration process may bring new information and potential action, on substances. In addition, substances may be added to SVHC candidate list and then Annex XIV (the authorisation list) with a sunset date but possible exemptions for specified uses. REACH cannot affect emissions from existing products.	PFAS: A number of PFAS are on the REACH Candidate List of substances of very high concern (SVHC). These are: • 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (HFPO-DA), a short-chain PFAS substitute for PFOA in fluoropolymer production. Its ammonium salt is commonly known as GenX. • perfluorobutane sulfonic acid (PFBS) and its salts, a replacement for PFOS	Positive for relevant PFAS for future manufacturing, but existing products will still provide a source
Persistent Organic Pollutants (POPs) Regulations 123: Stockholm Convention 124, [1] **Directive 79/117/EEC**	Under the Stockholm Convention, for existing and new POPs, measures must be taken to either eliminate production and use (some exemptions possible) (Annex A), restrict production and use (Annex B), or reduce unintentional releases with the goal of eliminating them altogether (Annex C). Measures and/or exemptions could change.	PFAS and parent compounds for nrMs Since 2009, perfluorooctane sulfonic acid and its derivatives (PFOS) have been included in the Stockholm Convention to eliminate their use. PFOS has already been restricted in the EU for more than 10 years, under POPS	Positive for relevant PFAS for future manufacturing, but existing products will still provide a source Positive for nrMs derived from POPs parent compounds
Food Contact Materials Regulation (EC) No 1935/2004; and	Food Contact Materials Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food; and Commission	Several PFAS (incl. PFOA, PFECA and ADONA) are not permitted for use in food contact materials. EFSA has set a new safety threshold for	Positive for some PFAS - reducing the amount of waste food packaging materials in

121 REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products

122 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

123 REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants and amending Dir

124 http://chm.pops.int/Convention/ThePOPs/tabid/673/language/en-GB/Default.aspx;

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Commission Regulation (EU) No 10/2011	Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	the main perfluoroalkyl substances, or PFAS, that accumulate in the body. The threshold – a group tolerable weekly intake (TWI) of 4.4 nanograms per kilogram of body weight per week – is part of a scientific opinion on the risks to human health arising from the presence of these substances in food[125].	landfill which could leach to groundwater
Industrial emissions Directive126(IED)	Regulates industrial emissions to water and other environmental media for a wide range of industrial sectors, with emission controls based on Best Available Techniques (BAT).	Manufacturing sites for PFAS and pharmaceuticals	Positive for PFAS (environmental levels have been demonstrably high close to manufacturing sites) Positive impact on the release of residues in wastewater from pharmaceutical manufacturing sites which can significantly impact surface water(and groundwater via leakage) and landfills. Emissions from manufacturing sites will be tightly controlled through permitting under this regulatory regime.
Drinking Water Directive (DWD)127 recast **MS drinking water standards**	The DWD sets drinking water standards for a range of pollutants. Under the DWD recast PFAS have been assigned Drinking Water Standards. It establishes a requirement for testing of the sum of PFAS that identifies a minimum list of 20 PFAS compounds that shall be included. MS shall define a guidance value to manage the presence of non-relevant metabolites of pesticides in water intended for human consumption. MS have already assigned drinking water standards to a number of the pollutants under consideration	DWD sets standards for PFAS compounds as PFAS (total) and / or PFAS (sum) and will provide an analytical method by 2024 Requires monitoring of drinking water for PFAS MS standards could apply to any of the substances listed. The PFAS standard will affect the General Chemical test and Drinking Water Protected Area test and could lead to poor GWB status. Requirement for MS to manage the presence of nrMs could lead to action at source through review of authorisations	Positive for PFAS in the long term (based on persistence and GW lagtime) but likely to lead to deterioation in status in the short to medium term due to increased monitoring identifying presence of PFAS Positive for nrMs if MS take action to manage the levels of nrMs at source rather than increased treatment.

[125] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D,Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR,Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Vleminckx C, Wallace H, Barregard L,Ceccatelli S, Cravedi J-P, Halldorsson TI, Haug LS, Johansson N, Knutsen HK, Rose M, Roudot A-C, VanLoveren H, Vollmer G, Mackay K, Riolo F and Schwerdtle T, 2020. Scientific Opinion on the risk to humanhealth related to the presence of perfluoroalkyl substances in food. EFSA Journal 2020;18(9):6223, 391pp.https://doi.org/10.2903/j.efsa.2020.6223

126 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast)

127 RECTIVE (EU) 2020/2184 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2020 on the quality of water intended for human consumption

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Pharmaceutical legislation: **The Veterinary Medicinal Products Directive 2001/82/EC sets out the controls on the manufacture, authorisation, marketing, distribution and post-authorisation surveillance of veterinary medicines** **Directive 2001/83/EC — Community code relating to medicinal products for human use.** **Guideline on the Environmental Risk Assessment (ERA) of medicinal products for human use**[128] **Guideline on assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater**[129] **Environmental impact assessment (EIAS) for veterinary medicinal products**[130]	Assessment of the environmental impact of medicinal / veterinary products is a legal obligation and must be performed to evaluate and limit potential adverse effects of medicines on the environment. However, this only applies to medicines brought to market after 2005. In addition, information on environmental impacts of pharmaceuticals is not available to the public or authorities. Accessibility is generally limited to risk assessors only. Environmental Risk Assessment (ERA) results are not considered for the decision on granting market authorisations of human pharmaceuticals, and proposed risk mitigation measures are not binding. An ERA assessment is mandatory for all applications for a marketing authorisation for human and veterinary medicinal products; it is considered in the benefit-risk assessment for the latter.	Pharmaceuticals / veterinary medicines on the GWWL and List Facilitating that were licensed after 2005. Environmental risk assessment process may be too weak to have an impact on wider groundwater pollution. Control on veterinary medicinal use is much stronger than for human use in response to the drive to reduce anti-microbial resistance in the environment.	Positive impact on pharmaceuticals but may be limited depending on conflict with human health needs. Control of vetinary uses likely to have a greater impact.

128 GUIDELINE ON THE ENVIRONMENTAL RISK ASSESSMENT OF MEDICINAL PRODUCTS FOR HUMAN USE European Medicines Agency Doc. Ref. EMEA/CHMP/SWP/4447/00 corr 21

129 Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater. European Medicines Agency Doc. EMA/CVMP/ERA/103555/2015: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-assessing-environmental-human-health-risks-veterinary-medicinal-products-groundwater_en.pdf.

130 Environmental impact assessment (EIAS) for veterinary medicinal products — Phase I & II European Medicines Agency CVMP/VICH/592/1998 - CVMP/VICH/790/2003.

Legislation	General implications for substances	Relevant substances	Impact of measure on baseline
Environmental Quality Standards Directive[131]	Sets out environmental quality standards (EQSs) concerning the presence in surface water of certain substances or groups of substances identified as priority pollutants (PS) because of the significant risk they pose to or via the aquatic environment. Proposals to add 22 PFAS to Priority Substance list with PFOA equivalent EQS of 4.4 ng/l.	PFOS is a Priority Substance (PS) with an EQS of 0.00065 µg/l (since 2011). Carbamazapine, PFAS and glyphosate (parent compound of some nrMs) are under consideration as PS (see surface water sections of this report). Under the surface water test failure of a dependent surface water body will reuslt in a GWB being at poor chemical status. Note that groundwater ecosystems are not considered in status assessment.	Positive for PFAS, pharmaceuticals and nrMs in long term for GWBs connected to SWBs but could lead to poor GWB status in short term due to increased monitoring identifying presence of PFAS
EC pharmaceutical strategic approach[132] Article 8c of the Priority Substances Directive (2008/105/EC as amended by Directive 2013/39/EU133) requires the EC to propose a strategic approach to the pollution of water by pharmaceutical substances.	The main objectives are to: identify actions to be taken or further investigated to address the potential risks from pharmaceutical residues in the environment; encourage innovation where it can help to address the risks, and promote the circular economy by facilitating the recycling of resources such as water, sewage sludge and manure; identify remaining knowledge gaps, and present possible solutions for filling them; ensure that actions to address the risk do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals.	Pharmaceuticals strategy does not highlight any specific implications for groundwater.	Low positive to neutral change for groundwater (limited to GWBs linked to SWBs and there may be a conflict with human health / quality of life)

4.3.3 Development of a dynamic baseline

The appraisal of the most relevant chemicals legislation and initiatives within the chemical acquis has allowed to assess the impact of future emissions to surface water, and therefore by-proxy the ambient concentrations.

This assessment has been completed using expert judgement and in a two-step process. First, it was assessed if an effect of changes to existing and/or the adoption of new legislation are likely to sort an effect. If yes, the magnitude of the effects was assessed by using a scale as follows:

+ + which indicates a significant emissions reduction against current rates (assumed to be ≥30%)

131 Directive 2008/105/EC setting environmental quality standards in the field of water policy

132 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE European Union Strategic Approach to Pharmaceuticals in the Environment

133 DIRECTIVE 2013/39/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy

+ Which indicates some emissions reduction against current rates (assumed to be ≤30%)
0 Which indicates that the legislation / initiative will have no impact, and emission rates will grow/shrink/remain the same organically due to other factors.
- Which indicates some emission increase against the current rates (≤30%). Effectively meaning the existing legislation / initiative fails to manage the issue effectively.
- - Which indicates a significant increase in emissions against current rates (≥30%).

It is also possible for some legislation with specific focus to only be relevant to some of the candidate PS, and therefore 'n/a' has been used to indicate where a specific piece of legislation or initiative is not applicable.

Surface water

Table 4-5 provides the high-level summary rankings for the candidate PS substances, grouped for brevity. The rationale behind the ranking for specific substances against specific legislation/initiatives is further provided in Appendix E.

Table 4-5 illustrates that for many of the candidate PS there are already efforts being made under other legislation which might have a beneficial impact for the aquatic environment. The most significant of these is for PFAS. The issues surrounding PFAS has been a core focus within the EU Green Deal and are reflected across a basket of legislation. This is most notably for REACH where five Member State competent authorities are tabling a REACH restriction for all PFAS substances to submit to the Commission before the end of 2021.

Conversely, the only substance identified where emissions may increase is ibuprofen. The pharmaceutical strategy puts in place requirements to better understand the environmental impact of pharmaceuticals and to put in place measures to target the issues identified. However, based on analysis of the strategy it seemed apparent that controls for non-prescription medications, along with data on material flows are likely key weaknesses. Where the EU has an ageing population, and medications like ibuprofen continue to become more widely available, it is possible to foresee that use will continue to grow and that the existing approaches will have minimal impact at limiting those emissions.

One further caveat is that Table 4-5 reflects emission rates to surface water and does not take into account persistence or residence time in different environmental compartments, which would have a further impact on ambient concentrations within surface water. Physical properties and environmental fate will vary substance by substance, adding uncertainty to this analysis. However, as a high-level approach, consideration of emissions and emission control is a reasonable proxy to help understand whether we could expect the ambient concentrations in surface water to go up, down, or remain broadly similar against the existing policy interventions.

For existing priority substances that have been proposed for review of EQS and deselection, there are a variety of underlying issues. For the set identified for review of EQS, some stakeholders had concerns highlighted around selection of the EQS (i.e., too high/low) at the time of implementation (such as mercury and nickel), while for others the EQS was either adopted in the predecessor to the EQSD (the Dangerous Substances Directive) and has not been reviewed since or has been in use for a considerable time (such as heptachlor and hexachlorobenzene). This recognises that the scientific understanding will have advanced considerably since the adoption of the EQS . Therefore, as a baseline (assuming no changes to EQSD). Where a significant amount of time has passed since the EQS was developed, the evolving scientific knowledge may suggest that either the EQS is too high and therefore the risk is underplayed, or because the EQS is too low overplaying the risk and potentially meaning that limited resources for PoMs are addressing the wrong substances.

For the existing priority substances targeted for deselection, dependent on the outcome of the impact assessment it may mean that these substances could be removed from the PS list (notwithstanding the need for possible transition to RBSPs). As a baseline, the scale of the problem for specific PS needs to determine that an EU-wide risk remains. If the issues can be handled more effectively at national level (i.e., through RBSP lists), it could help reduce the burden on MS overall and allow reallocation of focus to newly added PS.

Table 4-5 Overview of dynamic baseline for candidate PS*

	Pharmaceuticals			Pesticides			Silver	PFAS	Bisphenol A	Microplastics
	Oestrogenic substances	Macrolide antibiotics	Other pharmaceuticals	Neonicotinoids	Pyrethroids	Other pesticides				
WFD - PoMs	0	0	0	+	+	+	0	+	0	+
Drinking Water Directive (recast)	0	0	0	0	0	0	0	+	+	0
Plant Protection Products Regulation	N/A	N/A	N/A	0	0	0	N/A	N/A	N/A	N/A
Biocidal Products Regulation	N/A	N/A	N/A	0	+	0	+	N/A	N/A	N/A
REACH	N/A	N/A	N/A	N/A	N/A	N/A	0	++	+	N/A
CLP	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Further legislation related to metals	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Pharmaceutical legislation	0	0	0 (Diclofenac, carbamazepine) - (ibuprofen)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Industrial emissions directive	+	+	+	0	0	0	0	+	+	0
Persistent Organic	N/A	N/A	N/A	N/A	N/A	N/A	N/A	+	0	N/A

	Pharmaceuticals			Pesticides			Silver	PFAS	Bisphenol A	Microplastics
	Oestrogenic substances	Macrolide antibiotics	Other pharmaceuticals	Neonicotinoids	Pyrethroids	Other pesticides				
Pollutants Regulation										
Waste legislation	0	0	0	0	0	0	+	+	0	+
European Green deal:										
Farm to fork strategy	N/A	+	N/A	0	+	0	N/A	N/A	N/A	N/A
Biodiversity to 2030 strategy	+	+	+	+	+	+	0	+	+	N/A
Strategy for sustainable use of chemicals	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Pharmaceutical strategy	+	++	+ (Diclofenac, carbamazepine) 0 (ibuprofen)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Overall summary	+	++	+ (Diclofenac and carbamazepine) - (ibuprofen)	+	+	+ (nicosulfuron) 0 (Triclosan and glyphosate)	0	++	+	+
Comments	The pharmaceutical strategy provides an opportunity to limit releases with IED as a possible vehicle alongside the update to UWWTD	There are concerns surrounding AMR under multiple policy elements which should further control release of macrolide antibiotics in	The pharmaceutical strategy should address issues with the other pharmaceuticals. However, for non-prescription medicines like ibuprofen data gaps and controls look weaker, suggesting	Some of measures within PoMs for other pesticides could have synergistic benefits, equally the target under fark to fork to limit use of hazardous pesticides will likely reduce releases to the	Same comments for pyrethroids as neonicotinoids. One possible difference is that the use of pyrethroids generally is longer standing than neonicotinoids and they	Similar issues here for the other remaining candidate PS that are pesticides. For triclosan, the rating is assumed as 'no impact', on the basis that use was as a biocide which is	The only policy currently aiming to further address silver is the biocidal products regulation. This is looking at EDC properties of	Wide tranche of activities targeting PFAS at all stages of the life-cycle, additionally PFAS as a core commitment in the EU Green Deal. There is	There are several steps being taken to address BPA. Addition to the drinking water directive, added to the IED as a KEI under the	The EU plastics strategy and parts of waste legislation (e.g. single use plastics directive) could have some beneficial impacts towards reducing emissions. However, the scale

	Pharmaceuticals			Pesticides			Silver	PFAS	Bisphenol A	Microplastics
	Oestrogenic substances	Macrolide antibiotics	Other pharmaceuticals	Neonicotinoids	Pyrethroids	Other pesticides				
		the dynamic baseline	emissions will continue to grow in line with affluence, availability, and an ageing population.	environment.	represent one of the most used set of pesticides. Unclear how fully the farm to fork strategy will impact.	now prohibited. No live use identified, suggesting difficult to see how releases could be lowered.	nanoform silver. Which is a very specific issue. More generally policy impacts on releases identified.	sustained effort to reduce use, and emissions across the whole chemical acquis, which will impact in the next few years.	BREFs. Possible further reduction in amendment of the UWWTD. But overall could expect reductions in releases within dynamic baseline.	of the issue and continued demand for plastics meaning overall impacts may be more limited.

*Revisions of the urban wastewater treatment directive and sewage sludge directive have been excluded from the ranking as they are at earlier stages of the better regulation process. For context further commentary has been provided within Appendix E.

Key: + + significant reduction in emissions // + some emission minimisation // **0** no impact // **-** some emission increase // **- -** significant emission increase // N/A not applicable

Groundwater

Summary results

It is clearly important to understand this dynamic baseline as part of the impact assessment process. However, the emergent nature of the pollutants being assessed means that there is limited information available on their current impact on groundwater (status and trends) and the current effectiveness of mitigation measures. This makes it difficult to accurately quantify the impact of existing legislation and strategies on the future evolution of the problem, before even considering the options for adding the LFR pollutants to the GWD Annexes. A qualitative assessment of the dynamic baseline is made with respect to the three pollutant groups under consideration in terms of:

- their current and historical production and use in the EU;
- the current regulatory framework and EU strategies under which their use is controlled or limited; and
- the extent of knowledge of their groundwater pollution potential.

A similar evaluation method has been used for groundwater and the results are provided in Table 4-4. And Figure 4-1 which provide high-level summary rankings for the groups of substances considered for addition to the GWD annexes. The assessment illustrates that for many of the LFR groups of substances there are already efforts being made under other legislation which might have a beneficial impact for groundwater. The most significant of these is for PFAS. Conversely, the only substance identified where emissions may increase are the pharmaceuticals. The pharmaceutical strategy puts in place requirements to better understand the environmental impact of pharmaceuticals and to put in place measures to target the issues identified. However, based on analysis of the strategy it seemed apparent that controls for already permitted medications is likely a key weakness. Where the EU has an ageing population, and availability of pharmaceuticals continue to be widely available, it is possible that use will grow and that the existing approaches will have minimal impact at limiting those emissions.

The analysis in Table 4-4 does not consider persistence or the long residence time in some groundwater. Physical properties and environmental fate will vary substance by substance, adding uncertainty to this analysis. However, as a high-level approach, consideration of emissions and emission control is a reasonable proxy to help understand whether we could expect the ambient concentrations in groundwater to go up, down, or remain broadly similar against the existing policy interventions.

The groups of substances identified to date through the GW WL process and added to the LFR have not been part of routine monitoring across all MS, precisely because they are considered 'emerging pollutants' for which we require additional knowledge and data at EU level. Where national monitoring exists, it is likely to be restricted to past 5-10 years and any earlier data using outdated analytical techniques may be unreliable (e.g. for PFAS). This means that there is limited information on the spatial distribution (only in some MS) and insufficient data to identify significant trends in concentrations. The GW WL processing of aggregated data indicates the extent to which pollutants are found across PC and the inclusion of pollutants on the LFR in groundwater across several PC is indicative of their:

- widespread presence;
- leaching potential (or mobility); and
- persistence in groundwater.

The changing baseline situation for groundwater status over the next 10 to 20 years during which the identified options will have an impact is affected by:

- **Continued emissions** of some compounds and parent compounds (e.g. PFAS already in products, which will be disposed of in future).
- Reduction in concentrations of pollutants entering groundwater driven by **legislation and environmental strategies**.
- The **time lag in groundwater** systems for recovery from pollution.
- **External factors** such as population growth or climate change.

Figure 4-1 Dynamic baseline schematic for PFAS, nrMs and pharmaceuticals in groundwater (trends shown are illustrative of direction only not magnitude)

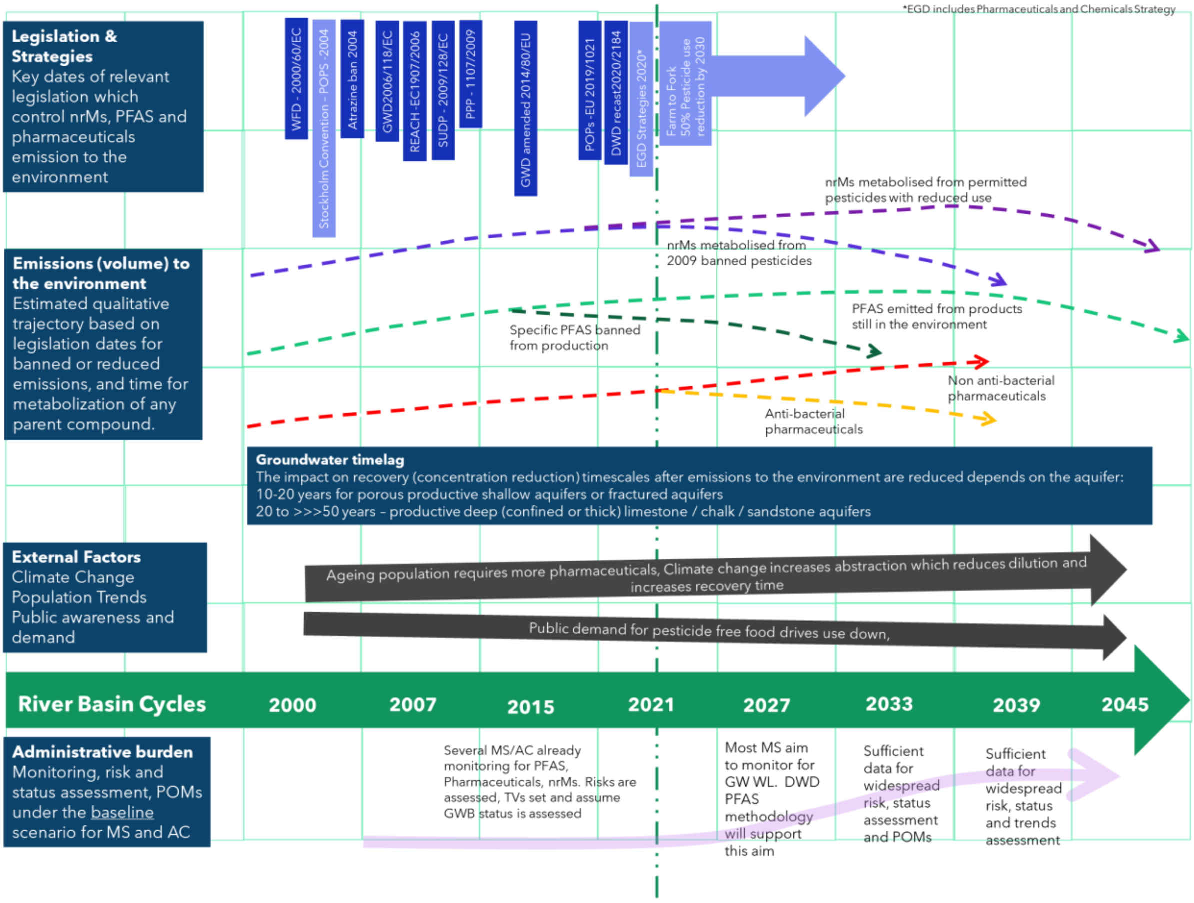


Table 4-6 Overview of dynamic baseline for candidate Annex I and Annex II substances (groundwater)

	Pharmaceuticals	nRMs	PFAS
GWD	0	+	+
Plant Protection Products Regulation	0	+	+
Sustainable use of pesticides	N/A	+	N/A
Biocidal Products Regulation	N/A	+	N/A
REACH	N/A	N/A	++
Persistent Organic Pollutants Regulation		+	+
Food contact materials Regulation	N/A	N/A	+
IED	N/A	N/A	+
DWD recast	N/A	+	+
Pharmaceutical legislation	+	N/A	N/A
EQSD	+	+	+
European Green deal:			
Farm to fork strategy	N/A	+	N/A
Pharmaceutical strategy	+	N/A	N/A
Overall summary	+	+	++

	Pharmaceuticals	nRMs	PFAS
Comments	The pharmaceutical strategy provides an opportunity to limit releases with IED as a possible vehicle	Some of measures within PoMs for other pesticides could have synergistic benefits, equally the target under fark to fork to limit use of hazardous pesticides will likely reduce releases to the environment.	Wide tranche of activities targeting PFAS at all stages of the life-cycle, additionally PFAS as a core commitment in the EU Green Deal. There is sustained effort to reduce use, and emissions across the whole chemical acquis, which will impact in the next few years.

*Revisions of the urban wastewater treatment directive and sewage sludge directive have been excluded from the ranking as they are at earlier stages of the better regulation process. For context further commentary has been provided within Appendix ??

Key: + + significant reduction in emissions // + some emission minimisation // **0** no impact // - some emission increase // - - significant emission increase // N/A not applicable

Legislative and strategic controls under the baseline scenario

The qualitative assessment of the impact of legislation on the LFR substance groups in Table 4-4 and supporting information in Appendix F shows that some nrMs and PFAS already have the most stringent measure in place i.e. their widespread use or manufacture is banned. There are a number of other measures in Table 4-4 also focused on reducing the use of the remaining LFR nrM and the multitude of unregulated PFAS substances, or their parent compounds. The key measures are also shown at the top of Figure 4-1 along with their implementation date. The Pharmaceuticals Strategy appears relatively weak with respect to the protection of groundwater. The strategy aims to compile environmental risk assessments for substances detected in the environment, suggests that these will be retrospective where the current risk assessment is not adequate, but only for vetinery medicines and those used in aquaculture. Actions unde the Pharmaceuticals Strategy focus on reducing anti-bacterial resistance may help to reduce emissions of relevant anti-bacterial substances on the GW WL and Sulfamethoxazole. There may also be conflict between human and animal health requirements versus environmental protection in the case of pharmaceuticals[134].

Emissions under the baseline scenario

Without intervention, the mass of pollutants present in groundwater will increase with continued emissions and their persistence. This will lead to wider distribution and increased concentrations (rising trends) within GWBs across MS and potentially an increased number of GWBs at poor status. Existing and planned measures, including those identified in Table 4-4 will limit, and in some cases, prevent further emissions of some of the substances (or parent substances), notably those that are not approved for use or that have restricted use. However, for those substances whose emissions are not restricted or ceased through such controls, additional measures may be required.

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[134] One of the Pharmaceuticals Strategy objectives is to "ensure that actions to address the risk [from pharmaceutical residues in the environment] do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals"

The timing of changes in emissions of PFAS, nrMs parent compounds and pharmaceuticals to the environment (not the concentration in groundwater) depends on timing or focus of legislation or strategies. Figure 4-1 shows the estimated timing of reductions in emissions, taking into account the implementation of controlling legislation and strategies as well as the continued release of substances. Therefore, for PFAS which are banned and no longer used for specific purposes (e.g. fire fighting foams) the trend decreases sooner than for PFAS which exist in products such as textiles where they will continue to be released to the environment even on disposal. For nrMs with a banned parent compound, their formation and release to the environment will depend on the rate of degradation (metabolisation) of the parent compound which is a function of environmental factors such as temperature, sunlight, moisture content, presence of co-metabolites and micro-organisms capable of breaking down the parent compund. The decrease in emissions will be faster than for those whose parent compounds are not banned. The Farm to Fork Strategy aimed reduction of 50% pesticide use by 2030 will help to reduce the emissions of these nrMs and this reduction will support the aims of the Biodivesity Strategy[135]. The Pharmaceuticals Strategy aims to reduce anti-bacterial resistance may mean that the emissions of relevant anti-bacterial substances on the GW WL and for Sulfamethoxazole are also reduced compared to others.

Future changes to other legislation may introduce further measures that control of the use and emissions of polluting substances. These may arise from the strategic approach to the pollution of water by pharmaceutical substances and from changes to the EQSD for some PFAS and pharmaceuticals.

Groundwater recovery

The lag time in groundwater systems for recovery from pollution will see trends in concentrations of especially persistent pollutants increase before they decrease (post measures) potentially leading to future deterioration even after measures have been implemented. This is especially compounded for nrMs (and some PFAS) where the timeline for groundwater recovery includes the time for the parent compound to metabolize and for the resultant metabolites concentration to attenuate. An example of studies and modelling of nitrate trend reversal in aquifers across the EU is useful. Nitrate is a persistent and typically diffuse pollutant in aerobic aquifers. Therefore, the observation or prediction of timescale for trend reversal gives an estimate of timescale for other similarly persistent pollutants such as nrMs and PFAS. Timescales for reversal of trends in nitrate in groundwater can range from 5 to over 50 years[136]. A similar timescale for recovery may be likely for other persistent pollutants as suggested in Figure 4-1

[135] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU Biodiversity Strategy for 2030 Bringing nature back into our lives COM/2020/380 final

[136] CIS 2017, Annex - Compilation of Indicative case studies in relation to WFD Article 4(4) exemptions on grounds of natural conditions

External controls

Some external trends may result in increased use and emissions of the LFR substances. For instance, demographic changes (in relation to population size and age) may affect the use of pharmaceutical products. In particular, identification and analysis of key trends in the area of urban wastewater noted the following trends:

- Ageing population - projected proportional increase in populations aged 65 or older in the majority of the MSs between 2015-2030;
- (Increased) population size - the effects of population growth differ between MSs. Malta, Luxembourg and Cyprus saw the largest population growth during 2019 whilst Romania, Latvia and Bulgaria saw a decrease;
- Migration - 24% of the EU population benefitted from net migration of a working age population within the EU to offset ageing.

Climate change may negatively impact on the emissions of permitted parent compounds of nrMs or where crop management practises change. Climate change is predicted to increase groundwater abstraction[137] (primarily for irrigation) and reduce recharge rates which will lead to increased concentrations / longer groundwater recovery lag-times due in part to less dilution in aquifers. Existing measures used to deal with nutrient pollution, could also lead to increased use of some nrM parent compounds. For example, a popular measure to prevent nutrient leaching from bare soils over winter is the growing cover or catch crops. Typically, this requires the use of glyphosate (parent of nrM Aminomethylphosphonic acid) to destroy the cover crop prior to main crop sowing.
Public demand may drive positive change e.g. raised awareness of pesticide residues and PFAS in the food-chain will increase the demand for food without these chemicals.

4.4 Monitoring, data management and other complementary practices

The current situation relating to the different problem areas followed by a description of the qualitative factors that are relevant in the definition of the baseline and its evolution in relation to monitoring, data management and other complementary issues are presented in the sections below.

Current practices for characterising and assessing mixtures of pollutants

To meet the requirements of the WFD, MSs need to establish tools and techniques for monitoring the ecological and chemical status of surface waters, enabling the identification of ecological impacts, pollutants and their sources. To be fully effective, monitoring and measures need to tackle chemical mixtures. These are also one of the main areas of the Chemicals Strategy for Sustainability.

In 2000 the Common Implementation Strategy (CIS) guidance document[138] No. 7, on "Monitoring under the WFD", was published. It is focused on monitoring of inland waters, transnational water bodies, coastal water bodies and groundwater, based on the criteria

[137] https://circabc.europa.eu/d/a/workspace/SpacesStore/119820b6-5a27-4f1b-a99d-503b49ebe43d/4.2-CC-GW.pdf

[138] WFD Guidance Documents accessible here: **https://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm**

provided in Annex V of the WFD. Since then, several other guidance documents[139] have been published focusing on specific monitoring issues. They include No. 15 on groundwater monitoring, No. 19 on surface water chemical monitoring to clarify the monitoring of priority substances, No. 25 on chemical monitoring of sediment and biota, No. 32 on biota monitoring and No. 33 on analytical methods for biota monitoring. Complementing the guidance documents there are a number of ISO documents that provide principles and standards for the sampling and processing of samples from surface and groundwater (e.g. ISO 5667-11 (2009)). These guidelines are living documents that should evolve with time and increasing knowledge and understanding of processes and technology. A large range of knowledge regarding monitoring techniques and how best to apply them is therefore already covered in these documents.
Information available, including watch list monitoring data from the Member States, indicates that suitable analytical methods for all substances included in this assessment are either already available or will be with high certainty before the revised limit values take effect (after the subsequent agreement by the co-legislators, the entry into force and the subsequent transposition into national law of legislation). To facilitate this process, the Commission is advised, as in the past, to make efforts to facilitate the sharing of experience and best practices between Member States on the use of adequately sensitive methods.

Effect-based methods (EBM) can detect the effects of mixtures of compounds in water and demonstrate the potential of these mixtures to affect aquatic organisms and human health. EBM can assist in the diagnosis of whether complex mixtures are impacting water quality without the need to immediately identify individual substances. At the same time, the screening role which EBM can play, may assist in identifying additional priority substances. Scientific research has successfully applied a wide range of EBMs for both diagnostic and monitoring purposes to assess the likelihood of impacts of chemical pollution[140]. The 2014 technical report on aquatic effect-based monitoring tools[141] elaborates on different standards and guidance available for the application of EBMs. A follow-up report[142] goes into more detail. EBMs are now available for several effect categories, but it is still difficult to set appropriate trigger values. It will also be necessary to harmonise implementation of the methods, possibly through the development of Standard Operating Procedures (SOPs). It may also be necessary to develop an EBM-specific CIS guidance document, explaining i.a. how to incorporate EBM tools into the design of monitoring programmes.

An additional monitoring tool to be further supported through, for instance, the development of a guidance document, is passive sampling. Passive sampling is an easy to implement and

[139] The guidance documents are technical documents intended to facilitate the implementation of Directive 2000/60/EC and are not legally binding. Any authoritative reading of the law should only be derived from Directive 2000/60/EC itself and other applicable legal texts or principles. Only the Court of Justice of the European Union is competent to authoritatively interpret Union legislation.

[140] Brack et al (2019). Effect-based methods are key. The European collaborative projects SOLUTIONS recommends integrating effect based methods for diagnosis and monitoring of water quality, Environmental Science Europe, 31.
[141] EC (2014). Technical report on aquatic effect-based monitoring tools, Annex. Technical Report 2014-077. Luxembourg: Office for Official Publications of the European Communities, https://circabc.europa.eu/sd/a/161d57fc-5557-4e9f-95fc-85883c32508d/Effect-based%20tools%20CMEP%20report%20annex%2028%20April%202014.pdf
[142] CIS WG Chemicals Sub-Group 2021 Technical Proposal for Effect-Based Monitoring and Assessment under the Water Framework Directive https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/5b2f9e69-e078-429f-94b7-b361d123e072/details

run methodology, that records contaminant exposure over time. The time-integrated data from passive sampling devices can be used to complement the grab-sampling methods often used for chemical monitoring, and in particular to replace biota monitoring because of their integrative action. Although passive samplers can quantify low concentrations in water, they have the disadvantage that they measure average concentration over time and cannot reveal fluctuations. Hence, they work best in combination with other monitoring measures, including as components of some EBMs.

Current monitoring practices unsuitable for adequate temporal resolutions

The WFD does not dictate the spatial or temporal monitoring resolutions necessary for a good assessment of water quality, but does recommend minimum monitoring frequencies (Annex V). Deriving optimal sampling frequencies largely depends on the sampling location (such as the existence of anthropogenic effluents, hydromorphological conditions, etc.), the variable being measured and its variability within the environment[143]. A significant proportion of surface water monitoring is disproportionately directed towards 'surveillance monitoring' to inform the design of monitoring programmes, to assess long-term trends in water status (ecological and chemical) and to assess the overall water status within each catchment. It is to be carried out for a period of one year within each RBMP cycle. Operational monitoring of surface waters aims to determine the status of water bodies identified as being at risk of failing the good status objectives; it assesses the magnitude of pressures and the effectiveness of management measures. MS can decide the frequency of operational monitoring but for PS the guideline is a minimum of once per month. For groundwater monitoring, the approach is similar but covers quantitative and chemical status, and must be able to detect any significant and sustained upward trend in pollutants. Operational monitoring of chemical status should be carried out at least once per year between the surveillance monitoring periods. Given the freedom that exists for MS to determine their monitoring programmes, it is difficult to estimate the exact level of monitoring. Within the targeted survey consultations as part of this project, stakeholders were asked to provide an estimation (between 1-5, with 1=not at all and 5= extensively applied) of the extent of monitoring of substances in the voluntary groundwater watch list. When excluding 'I don't know' responses, the largest proportion of responses indicated that the monitoring of these substances was extensively applied (i.e. answer number '5') at national level (n=4, 12%). At local and regional level, the extent of monitoring is less clear, with the majority of respondents indicating answer '3' (local: n= 3, 9%; regional: n=4, 11%) implying that improvements to monitoring could be made.

In relation to monitoring techniques, a range of guidance documents are available, as mentioned at the beginning of this section. In addition to the CIS and ISO documents, there are also guidelines from the OSPAR Convention for the Joint Assessment and Monitoring Programme (JAMP) and from HELCOM (the COMBINE manual). However, some aspects of monitoring under the WFD could be better prescribed, and it would be helpful to have an overview of the extent to which MSs have implemented recommended best-practice techniques, including the requirements of Directive 2009/90/EC.

[143] Vilman et al., (2018) Estimation of the water quality of a large urbanized river as defined by the European WFD: what is the optimal sampling frequency?. Environmental Science and Pollution Research, 25(24)

Current practices for risk assessment and the translation into risk management

Within the surface water and groundwater watch list mechanisms, EU monitoring data is gathered to inform future prioritisation exercises (surface waters) or to identify substances for which quality standards or threshold values should be established (groundwaters). The monitoring and reporting obligations for MSs are mandatory for surface waters, whilst voluntary for groundwaters. The monitoring data received is used to assess risk from these substances across the EU.

There is some concern that the frequency of surface water watch list monitoring does not adequately capture peak concentrations, in particular of plant protection products; and that the cycle for establishing the watch list, monitoring the substances and reviewing the data is not optimal. In particular, it takes a long time for substances to be assessed for inclusion in the priority substances list. In the targeted stakeholder consultation…..

Because the GW WL mechanism for groundwater is voluntary, the assessment of new/emerging pollutants in groundwater may not be as consistent across the EU as that of pollutants in surface and drinking water. In the targeted consultation, stakeholders were asked to outline the value of additional guidance documentation. The majority of responses indicated that guidelines on the monitoring of substances in the voluntary groundwater watch list were required (on a scale of 1 (not at all) to 5 (very useful); when excluding 'I don't know' responses, the majority of stakeholders (n=13; 42%) indicated that such guidance would be 'very useful'). Furthermore, stakeholders outlined in the OPC that there is a need to improve the collection of data on new pollutants via a common implementation platform (the majority of respondents (n=80; 54%) answered '5' i.e. there is very much a need to improve data collection).

For identifying RBSPs and the setting of respective EQS, the WFD has maintained a fairly flexible approach that allows MSs to account for specific local conditions. Information on best practices for the setting of EQS for chemical pollutants, including RBSPs, in surface waters has been made available in CIS guidance document No. 27[144]. The monitoring and reporting of RBSPs mostly follows the same approach as for PS. The flexibility allowed in EQS setting and RBSP identification has resulted in highly variable identification of substances as RBSPs, and in a wide range of EQSs for the same substances, across MS. The Fitness Check noted that the RBSP variability is higher and more significant than could be explained by any location-specific conditions. In the second reporting cycle of the RBMPs, the variability in setting EQS increased compared to the first. If no approaches are taken to harmonise the EQS applied for RBSPs, and thus the identification of substances as RBSPs across the EU, the assessment of status across the MS will remain difficult to compare, and some MS will fail to take measures against a number of problematic substances.

In relation to that, there has long been puzzlement about why the RBSPs are included in the assessment of ecological rather than chemical status. They include many pesticides, metals and other substances of types also found in the priority substances list, although the latter was established to cover the substances posing the highest risk across the EU. Even for the PS

[144] WFD Guidance Document: No. 27 – Deriving Environmental Quality Standards version 2018

there is still some flexibility in the monitoring obligations, according to whether relevant pressures are identified in the MS. In addition to harmonising the EQS applicable for RBSPs, consideration could be given to incorporating the assessment of risk from RBSPs into the chemical status assessment for surface waters. Other physico-chemical parameters, such as nitrates, might also be considered in that assessment, as they are in the assessment of groundwater chemical status.

Current status of data management transparency and utilisation

Several of the CIS guidance documents cover best practice for data monitoring and reporting under the WFD and its daughter directives: in particular No.s 7, 15, 19, 31, 32, 35, and No.22 on the use of GIS. These help towards ensuring standardised monitoring and reporting. However, as identified in the Fitness Check, there is still some incoherence between MSs, which has led to some difficulty in comparing the status of water bodies. In particular, since MS are only required to report exceedances rather than absolute concentrations of pollutants, it is hard to judge how close MS are to meeting the good status objective, and hard to make use of the data on RBSPs to assess risk across the EU. Therefore, it would be helpful if MS could report absolute concentrations.

In addition, there is a strong interest in using innovative technologies to improve data and reduce costs, but as mentioned above, not all innovative monitoring methods are yet completely ready to be applied. There is also a need for additional guidance, e.g. on the practical application of EBMs/trigger values and passive sampling, and on use of satellite data[145].

Innovation and digitalisation should aim to improve access to coherent and comparable data through data portals. The primary web portal for water-related data in Europe is the WISE database developed by the European Environment Agency. As indicated in the Fitness Check of EU water legislation, the database is fit-for-purpose, but efforts are required to enhance its user-friendliness and shared usage across sectors, by different stakeholders. As noted in the Fitness Check- the WFD Reporting Guidance Document[146], which explains how MS should report their data into the database, is very complex although a range of WISE data viewers are available and being added to. It could be useful to increase awareness of the database, and how to use it, among stakeholders by preparing simple guidance-in close collaboration with the EEA.

At the same time, consideration must be given to how the EEA could harvest water-quality data directly from MS databases on a continuous basis. This would require revision of the Reporting Guidance, in particular to ensure the compatibility of MS databases with the EEA data-harvesting system.

[145] Remote sensing data can provide important contextual information, e.g. in relation to detecting algae blooms in surface waters. This data can provide additional important information on the nutrient status of surface waters. These data can in turn be used to cross-check the coherence, consistency, comparability and thus the overall data quality of data reported by the Member States on N and P concentrations in surface waters. This can then also be linked to possible KTMs identified in the corresponding PoM.
The Copernicus-funded remote-sensing data from the European Tropomi satellite-based measurement instrument are important in this context as they can be made available quite fast.
[146] Available at: https://cdr.eionet.europa.eu/help/WFD/WFD_521_2016/Guidance/WFD_ReportingGuidance.pdf

On the subject of transparency, improved (public) communication via the publication at regular intervals of information on water quality could be beneficial. The costs and benefits of publishing ‘monitoring’ data according to an INSPIRE compliant format to provide regular information to the public on local water quality could be examined in more detail.

4.4.1 *Trends that may affect current baselines*

Climate change

Climate change is leading to more unpredictable weather events with greater extremes including both increased rainfall (intensity) and increased duration and frequency of dry seasons and droughts. Increased rainfall can increase urban run-off and stormwater overflows from sewer systems, thus placing additional pollutant-load pressure on water bodies; an increase in the duration and frequency of dry seasons and droughts can result in reduced dilution of pollutants in surface waters. Both can significantly affect the status of water bodies. Dry periods often translate into increased abstraction for many uses of both surface and groundwaters which can put at risk chemical status. In addition, droughts can also cause additional stress on freshwaters used as drinking water sources, in particular groundwater aquifers. The impacts of climate change can thus be expected to make existing pollution-related problems worse.

Growth in urbanisation and ageing populations

Trends in the current development of society are likely to have an impact on water resources, primarily through increased pressures. Two particularly important social developments that may impact surface and ground water resources are urbanisation and the aging of populations.

Urbanisation is defined as the process by which natural or semi-natural land is converted into urban uses[147]. The urban environment is largely impervious to water, resulting in the water transport having to occur through artificial means (e.g. sewer networks) [148]. Due to the impermeability of urban areas, water retained and collected, often to reduce flood risk, can contain several pollutants from different sources, and therefore present a risk to water bodies when discharge. As a result, an increasing degree of urbanisation will have a direct impact on the quantity of contaminants entering the environment. Studies have projected that between 2015 and 2030, built-up areas within the EU will grow to occupy 7% of EU territory and by 2050 it is estimated that 83.7% of the EU population will be living in urban areas[149].

In addition, demographic changes (in relation to population size and age) may also have an impact on contaminant release and therefore increase the pressure on water treatment facilities. For instance, projected population trends that show an increase in the share of elderly people, relative to the total population, may have an impact on the consumption of pharmaceuticals in the future. The consequent release of pharmaceutical compounds into waste water collection and treatment facilities is likely to increase the pressure on those facilities, as well as on the environment as pollutant loads increase.

[147] SETO LAB (Yale University), (n.d.), Environmental Impacts of Urban Growth
[148] McGrane, (2016), Impacts of urbanisation on hydrological and water quality dynamics, and urban water management: a review
[149] European Commission, (n.d.), Developments and Forecasts on Continuing Urbanisation

Innovation and digitalisation

Innovation and digitalisation are key priorities for the water sector in order to align the sector with EU ambitions such as those set out in the European Green Deal. In the context of water management, the metering of water supply/consumption, and the monitoring and reporting of water quality, are increasingly modernising by automation processes, remote sensing and remote data transmission. For example, the fitting of waste water treatment plants with smart remote monitoring technologies that allow telemetric reporting of data can reduce operating costs, improve plant lifetimes and facilitate the switching of plant operations depending on different conditions[150]. The increased use of multi-parameter (fluid) sensor technologies is another example (see Annex I (Chapter 11)). Furthermore, technologies are evolving rapidly that could facilitate data processing and information sharing in the water sector.

The implementation of the INSPIRE Directive 2007/2/EC may also have further impacts on monitoring and reporting. The Directive lays down the rules establishing the infrastructure for spatial information in the European Union in support of Union environmental policies and policies or activities that may have an impact on the environment (Art. 1(1)). The aim is to deliver useful, standardised and high quality data in order to formulate, implement, monitor and evaluate European, national and local policy. The Directive does not set requirements for the collection of new data, or for reporting to the Commission but, rather, lays down a number of rights and obligations regarding the sharing of spatial data sets. Annex I to the Directive lists 34 data themes which are covered under INSPIRE, including data that is commonly reported under the Water Information System for Europe (WISE). The set-up of INSPIRE is aimed at facilitating data-harvesting and reaping benefits of technological developments, reducing burdens of environmental monitoring and reporting while enabling information to be collected and utilized. In addition to the Implementing Rules, non-binding Technical Guidance documents describe detailed implementation aspects and relations with existing standards, technologies, and practices[151]. As such, the INSPIRE Directive not only requires MSs to disclose their national data that must be collected on the bases of other environmental policy frameworks (including the WFD), but also sets a standard for reporting data and making it publicly accessible. The INSPIRE Directive was set to come into full force by 2021.

In the context of the Chemicals Strategy for Sustainability, and building on the Information Platform for Chemical Monitoring (IPCheM) the European Commission is looking at establishing a data-harvesting system for chemical monitoring and toxicity data. This could introduce provisions for a harmonised approach to data harvesting across a range of chemicals-related policy sectors.

[150] https://ec.europa.eu/environment/ecoap/sites/default/files/eio5_eco-innovation_and_digitalisation_nov2020.pdf
[151] Technical guidelines for the INSPIRE Directive; https://inspire.ec.europa.eu/Technical-guidelines3

4.5 Gap Assessment

4.5.1 *Process for developing a gap assessment for EQSD*

The next step in the analysis is to define the size of 'gap' between current situation (monitoring data) and the proposed EQS (as annual average/maximum allowable concentration for water; sediment; and biota). This issue has two facets to it. Firstly, the scale of the problem on a geographic basis (how many water bodies fail chemical status / how many MS may be obligated to develop and apply PoMs); and secondly the magnitude of the problem (how far above the thresholds do concentrations rise).

The JRC and WG Chemicals have developed dossiers for candidate PS and those PS targeted for amendment. The dossiers include the proposed new EQS and an assessment of the available monitoring data. The dossiers are publicly available on the CIRCABC website, accompanied by spreadsheets containing the monitoring / measured environmental concentration (MEC) data[152]. The distance to target assessment has been based on these EQS dossiers and MEC data.

4.5.2 *Methodology for Candidate Priority Substances*

The assessment has been made using a combination of the monitoring data gathered (as MEC spreadsheets) and the assessment already taken and reported within the EQS dossier.

Based on these data, criteria have been developed to help judge the 'distance to target'. To allow additional flexibility (recognising that the quantity and quality of monitoring data is variable), the criteria makes use of a decision tree with two pathways: pathway 1 (data rich) or pathway 2 (data poor). The criteria effectively judge the two metrics (**scale** and **magnitude**) to help assign each substance into a category defining the distance to target, as relatively large, medium, or small. As a caveat this approach is not meant to define the scale of the problem in detailed quantitative terms, but rather provides a strong indication for the orders of magnitude and helps identify which substances are likely to prove the most challenging in terms of achieving good chemical status against the proposed EQS.

To determine the distance to target, the methodology has been applied as a two-stage process. Firstly, based on the selection criteria and expert judgement all substances have been assigned to a group to denote the distance to target against proposed EQS (large / medium / small). This process has been based on the criteria shown in Table 4-7.

Table 4-7 Criteria used to assess the size of the gap in EQS compliance

Size of gap	Decision tree pt 1. Monitoring data exists for ≥14 MS (assumed to include EU27+NO). Use these criteria.	Decision tree pt 2. Monitoring data exists for ≤14 MS (assumed to include EU27+NO). Use these criteria.
Small	**Scale:** Predicted exceedances in ≤33% of MS based on the monitoring data available. **Magnitude:** Based on AA & MAC exceedances compared to predicted EQS + scale of non-detects as a measure of how widespread the problem is	Predicted exceedance is infrequent over the temporal trend demonstrating a 'patchy' picture. Additionally, there are a high level of non-detects in the sample set (>50%), and scale of the exceedance for any one year for AA or MAC is ≤50% of the predicted threshold. (i.e., maximum AA /MAC is 1.5 x the EQS)

[152] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/73b2d635-4cb1-4d7d-975c-da1b5db594d8

Size of gap	Decision tree pt 1. Monitoring data exists for ≥14 MS (assumed to include EU27+NO). Use these criteria.	Decision tree pt 2. Monitoring data exists for ≤14 MS (assumed to include EU27+NO). Use these criteria.
	nationally and how significant the scale of the exceedances.	
Medium	**Scale:** Predicted exceedances in ≥33% but ≤66% of MS based on monitoring data available.	Predicted exceedances occur consistently year on year across the temporal trend for available monitoring data. Volume of non-detects in the sample is below 30%, scale of the exceedance for AA and/or MAC is up to 30% for all years.
	Magnitude: Based on AA & MAC exceedances compared to predicted EQS + scale of non-detects as a measure of how widespread the problem is nationally and how significant the scale of the exceedances.	
Large	**Scale:** Predicted exceedances in ≥66% of MS based on monitoring data available.	Predicted exceedances occur consistently year on year across the temporal trend for available monitoring data. Volume of non-detects in the sample is below 30%, scale of the exceedance for AA and/or MAC is above 50% for all years. (i.e, maximum AA/MAC is 1.5 x EQS for all years).
	Magnitude: Based on AA & MAC exceedances compared to predicted EQS + scale of non-detects as a measure of how widespread the problem is nationally and how significant the scale of the exceedances.	

Secondly, following the preliminary assignment to distance to target groups (large / medium / small), a comparison process has been completed against the dynamic baseline to assess whether any evolution in policy would affect the groupings and mean that some substances need to be re-assigned. The completion of this process did identify a small number of substances, where as a result of emission reduction under the dynamic baseline the distance to target could be expected to shrink in the coming years, meaning that substances could be demoted to a lower group. No substances were identified against the dynamic baseline where they needed to be promoted up a group in terms of the gap increasing.

The assessment against the dynamic baseline assumes, based on evolving policy, there will be an emission reduction of up to 50% depending on the existing policies. As a clarifying point, the EQS is based on ambient concentrations and while an emission reduction would have a positive impact on ambient concentration, the physico-chemical properties and persistence of the specific chemical are likely to have a direct impact on how much of a benefit will be seen within a short period (e.g. the immediate few months). Therefore, these aspects have also been reviewed on a substance-by-substance basis when taking into consideration the possible changes under the dynamic baseline.

Further explanatory notes for specific substances are provided in the footnotes[153].

[153] This footnote provides some further explanatory notes for specific substances detail decision making and specific issues encountered:

Carbamazepine. The data provided by the MEC spreadsheet against the proposed EQS shows that for all M S based on the monitoring data provided there would be exceedances of the AA threshold. i.e., all MS show exceedances with a 100% failure rate to reach compliance. The dossier comments in Table 6.1.8 that as part of the risk assessment only one out of 15 Member States would fail achieve good chemical status based on the proposed AA threshold. The assignment to group is based on the MEC data.

Ibuprofen. No MEC data was available for this substance the assessment is based solely on the EQS dossier.

Acetamiprid. The MEC data for this file suggests that a 'medium' grouping should be assigned. However, based on the wider conclusions of the EQS dossier, dynamic baseline and expert judgement. It was assessed that the size of the gap is more likely to be small. This substance was re-assigned based on expert judgement and the supporting evidence outlined.

Nicosulfuron. The EQS dossier assessment suggests that based on the monitoring data provided all MS would fail against the proposed AA threshold. However, the MEC data identifies (in corroboration with the EQS dossier) that limited monitoring data is available from different MS. Two MS in particular dominate more than 98% of all samples. For these two M S based on nearly 90,000 samples over the period 2006 – 2019, there were 80% of samples below the limits of detection. This suggests that the magnitude of the issue may be overstated. The dynamic baseline further

4.5.3 Methodology for Amendment of existing EQS

The assessment for the amended EQS has largely been completed using a qualitative approach. Data from the EEA dashboards provides details around the current rate of exceedances for named substances, based on number of water bodies and Member States (noting that a total of 137,000 surface water bodies are identified in the EEA data). Based on the EQS dossiers (where available) and communication with the Joint Research Centre, a two-stage process has been followed.

Firstly, the data from the EEA dashboard for the number of waterbodies with exceedance and number of MS states with an exceedance has been used to assess the magnitude and scale of the issue in order to assign an existing ‘size of the problem’ (see Table 4-8, below). Then as a second step based on the proposed EQS (where available) and guidance from the Joint Research Centre, an assessment has been made as to whether the size of the gap would be worse, better, or the same following amendment of the EQS.

Table 4-8 Assessment for current scale of the size of the gap for existing PS targeted for EQS amendment.

Substance	Number of water bodies with EQS exceedance	Number of MS with at least 1 WB in exceedance	Assumed current size of the gap
Chlorpyrifos	523	9	Small
Cypermethrin	Unknown	Unknown	-
Dioxins and furans	Unknown	Unknown	-
Diuron	1509	11	Small
Fluoranthene	2367	17	Medium
Heptachlor	Unknown	Unknown	-
Hexachlorobenzene	868	14	Small
Hexachlorobutadiene	811	11	Small
Mercury	46,780	25	Large
Nickel	1840	22	Medium
Nonylphenol	986	11	Small
PAHs	3926	19	Medium
PBDEs	23,800	9	Large
Tributyltin	1988	18	Medium
Dicofol	No data	No data	Small*
Hexabromocyclododecane	No data	No data	Medium**

* No monitoring and compliance data available from EEA dashboard. Based on the fact that permitted use of dicofol in the EU ceased in 2008, and use was in decline prior to this date, assume distance to target is small.

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indicates emission reductions are expected. Based on the combination of these things nicosulfuron has been reassigned from ‘medium’ to ‘small’.
Triclosan. The temporal trend provided in the EQS dossier shows highly variable fluctuations around the proposed EQS. The MEC data suggests that based on the monitoring data that the substance should be assigned to the “small” group. However, based on further comments and assessment within the EQS dossier it is suggested that addressing the concentrations may be more problematic, and therefore this substance has been assigned to the “medium” group.
Silver. EQS dossier does not provide any comment about monitoring data, potential rates of exceedance or risk assessment for exceedance. Assignment has been based on MEC data only.

** No monitoring and compliance data available from EEA dashboard. Based on the EU implementation plan for POPs, considerable quantities were used in the EU prior to the REACH Authorisation in 2017. This may pose a more significant issue for sediment and biota. Based on the supporting evidence assume distance to target is 'medium'.

4.5.4 *Process for developing a gap assessment for GWD*

Groundwater status is assessed on the basis of evidence of widespread pollution from Annex I substances and substances identified a putting groundwater at risk of deterioration (i.e. environmental significant trends); or harm to receptors including protected areas and ecosystems. Therefore, understanding the gap between the current groundwater status situation and that following the inclusion of PFAS, pharmaceuticals and nrMs in Annex I or Annex II would require knowledge of the number of GWBs at risk of failing to meet good chemical status, MS reporting a failure and the level of exceedance in groundwater.

Unlike the surface water situation, however, there is no EU-wide monitoring network for emerging groundwater pollutants. In the absence of monitoring evidence of the impact of PFAS, pharmaceuticals and nrMs on groundwater receptors or trends in concentrations, only the baseline scale of pollution can be estimated (Section 4.3.3). It was assumed that TVs would be set using drinking water standards under Annex II and that the GCA test would be the primary test used. Emissions, pathways, detection in groundwater and benchmarking against the GWB status due to substances with similar patterns of emissions, environmental fate and persistence which are already listed in the GWD Annexes were all considered.

In order to assess the gap between the baseline position and the impact of the proposed policy options for groundwater, the method of addition (to Annex I or II), the likely exceedance above proposed groundwater quality standards (GWQS) and the number of additional GWBs which could fail to reach good status were considered in the context of monitoring data which had been provided for the purposes of the GW WL process. The detail of the gap assessment method is expanded further in Section 8.3.1.

5 Why should the EU act?

The legal basis of the Directives is Article 192(1) of the Treaty on the Functioning of the European Union and the following specific review clauses in the water legislation:

- Water Framework Directive Article 16(4) and 16(7).
- Environmental Quality Standards Directive Article 8.
- Groundwater Directive Article 10.

5.1 Treaty on the Functioning of the EU

Article 192(1) of the Treaty on the Functioning of the European Union states that the “Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay”.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union. Article 192 (1) states that “the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall decide what action is to be taken by the Union in order to achieve the objectives referred to in Article 191’ and Article 21(2.f) that requires the Union to help develop international measures to preserve and improve the quality of the environment and the sustainable management of global natural resources, in order to ensure sustainable development” .

5.2 Review clauses in the water legislation

The European water legislation includes review clauses that require the revision of the relevant annexes of the directives to follow technical progress and ensure the level of ambition of the legislation is maintained. The WFD Article 16(4) stipulates the Commission’s obligation to review, every 6 years, the list of priority substances (WFD Annex X) that pose a risk to or via the aquatic environment.

The EQSD Article 8 elaborates on this obligation by referring also to review of the environmental quality standards EQS in Annex I to the EQSD. Article 10 of the GWD requires review of the lists of pollutants and standards in groundwater in Annexes I and II to the GWD. Moreover, Article 8b includes an obligation for the European Commission to establish a watch list of substances for which Union-wide monitoring data are to be gathered for the purpose of supporting future prioritisation exercises and which shall be updated every 24 months.

5.3 Subsidiarity principle

The Fitness Check of EU water legislation confirmed that the subsidiarity principle was respected by the Directives (i.e. leaving sufficient flexibility to MS to adapt water management to local conditions), and that EU-level action is necessary to tackle the issue of water quality. The FC also found that MS were not likely to have achieved the same results individually; in particular, the river basin scale and therefore transboundary cooperation (and consistency) facilitated by the EU water legislation have had a positive effect.

The flexibility left to Member States to adapt water management to local conditions has however also resulted in inconsistencies and incomparability particularly in relation to River Basin Specific Pollutants.

In order to increase the comparability between Member States RBSPs could be converted from 'physico-chemical' quality elements supporting the assessment of ecological status into contributors to the chemical-status assessment. The inclusion of RBSPs in the chemical status assessment does not change the overall status assessment (determined by the chemical and ecological status assessments), but it would ensure that similar approaches are taken to all chemical pollutants (whose effects on human health as well as ecosystems should be considered in all cases). Making the RBSPs an integral part of the chemical status would increase understanding of the reasons for failure and thus of the measures to be enforced.

Irrespective of whether RBSPs are considered part of ecological or of chemical status, the chemical status of a water body will be mainly determined by compliance with or exceedance of the EQSs that have been set, whether at national or Union level. Harmonisation of the EQS applied for RBSPs, for example by setting them at EU level, would be expected to contribute to better comparability between Member States.

The non-inclusion of RBSPs in the 'ecological status' assessment could result in many water bodies being assessed as having improved ecological status, as some RBSPs are currently responsible for failure.

Considering that 60% of EU river basins are transboundary, and that pollutants also cross borders, there is clear EU added value in transboundary management of water pollution. The WFD and daughter Directives have triggered or reinforced action to address the transboundary pressures on water resources at river basin level, both nationally and internationally. These Directives have as goal of tackling water quality protection across the EU at the same level and with a coordinated EU-wide approach, which ensures that downstream action to protect EU surface and ground waters is not jeopardised by upstream inaction.

5.4 Precautionary principle

The need to apply the 'precautionary principle' and the "polluter pays principle" is embedded in points (11) and 44 of the recitals/ preamble of the WFD which state the following:

"As set out in Article 174 of the Treaty, the Community policy on the environment is to contribute to pursuit of the objectives of preserving, protecting, and improving the quality of the environment, in prudent and rational utilisation of natural resources, and to be based

on the precautionary principle and on the principles that preventive action should be taken, environmental damage should, as a priority, be rectified at source and that the polluter should pay.

In identifying priority hazardous substances, account should be taken of the precautionary principle, relying in particular on the determination of any potentially adverse effects of the product and on a scientific assessment of the risk."

The European Court of Auditors noted that the polluter pays principle was not consistently applied in the EU, with the polluter not bearing the full costs of water pollution and with EU funds being used at times to cover the costs. This finding justifies further action at EU level to ensure the water environment as a whole is protected and that pollution is addressed at source.

The potential for long-term and irreversible risks to transboundary ecosystems and human health from emerging contaminants necessitates EU measures to halt the bioaccumulation and limit health risks. While some of these pollutants can in part be addressed through end-of-pipe measures (such as the UWWTD), upstream solutions are also essential to limit pollutant emissions and to avoid passing the bill for treatment to the end-user. This is particularly important considering that Article 7(3) of the WFD (protection of areas used for the abstraction of drinking water), is 'under-implemented' and necessitates drinking water and urban waste water treatment plant operators to deploy costly treatment methods.

Article 7(3) of the WFD states: *'Member States shall ensure the necessary protection for the bodies of water identified with the aim of avoiding deterioration in their quality in order to reduce the level of purification treatment required in the production of drinking water. Member States may establish safeguard zones for those bodies of water'*.

An additional aspect, identified in the problem definition, relate to the state of knowledge and pollutants of emerging concerns including microplastics. Within the current context, the science and understanding of emerging chemical issues for surface and groundwater has advanced beyond the current policy position. This means that a range of substances potentially representing an EU-wide risk have been identified but are not currently managed by the EQSD or GWD, meaning that the approach will vary Member State to Member State, with no intervention in some cases.

Additionally, Annex I point (3) of the GWD gives Member States the right to set stricter GWQS values: "*Where, for a given body of groundwater, it is considered that the groundwater quality standards could result in failure to achieve the environmental objectives for associated bodies of surface water, or in any significant diminution of the ecological or chemical quality of such bodies, or in any significant damage to terrestrial ecosystems which depend directly on the body of groundwater, more stringent threshold values will be established*".

Finally, there is a legislative framework in place which requires the EU to act (see section 5.2) and through the FC has demonstrated the benefits of an EU level approach for substances that present an EU-wide risk.

5.5 Role of the EU

In addition to the points made above, EU water legislation has also led to improved levels of protection for human health in Europe, and allowed for water policy to be mainstreamed within other policy domains where objectives may conflict with water policy objectives, notably agriculture, transport, chemicals and energy. Furthermore, The 2019 Fitness Check (FC) of EU water legislation confirmed the added value of the WFD, EQSD and GWD. The Directives have triggered or reinforced action at European level to address the transboundary pressures on water resources at river basin level, both nationally and internationally. In addition, EU legislation has been instrumental in the development of a strong, resilient and globally competitive EU water industry. Without this EU water legislation, only few MSs would have achieved the level of protection we have today and the outlined common benefits would have not been attained.

6 Objectives: What is to be achieved?

The overarching objective of the review of the lists of pollutants affecting surface and ground waters and the corresponding regulatory standards in the Environmental Quality Standards, Groundwater and Water Framework Directives is to **strengthen existing EU legislation for the protection of the environment and human health** from the adverse effects of water pollution and to contribute to the achievements of the objectives of the WFD. Also, there is an accelerated need to reduce the presence of toxic chemicals both individual and cumulative in water in light of the on-going triple planetary crisis (climate change, biodiversity and pollution). The review will consider how to align the lists of pollutants affecting surface water and groundwater with the latest scientific knowledge whilst contributing towards the protection of European citizens and natural ecosystems and contributing to the EU Green Deal zero pollution ambition by reducing the risks to or via the aquatic environment posed by certain substances, and how to increase effectiveness and streamline the administrative burden of the legislation, hence facilitating a quicker response to emerging risks.

The planned EU intervention would have the following objectives:

1. Align the lists of pollutants affecting surface and groundwater with the latest scientific knowledge.
2. Improve monitoring of the state and evolution of surface and groundwater pollution to gather more comprehensive evidence for future risk assessments.
3. Harmonise the ways pollutants in surface and groundwater are classified and tackled.
4. Provide a legal framework that can be more swiftly and easily aligned with science and promptly respond to contaminants of emerging concern.
5. Improve transparency and access to data, thereby facilitating implementation (also of existing quality standards) in the MS, as well as reducing administrative burden.

The general and more specific objectives for surface water and groundwater pollutants are summarised in the table below.

Table 6-1 General and specific policy objectives

	General objectives	Specific objectives
Surface water pollutants	Protect aquatic environment and human health from chemical pollution through achieving good surface water chemical status by controlling emissions of priority substances and ceasing or phasing out emissions, discharges, and losses of priority hazardous substances.	• To identify new PS/ PHS and set EQS for them and amend those of listed Priority / Priority Hazardous Substances based on consideration of the latest scientific knowledge • To reduce water pollution, preferably at source, from pollutants such as industrial chemicals, pesticides, pharmaceuticals, and metals. • To mitigate the potential environmental and (human) health impact(s) of pollutants of emerging concern, like PFAS, pharmaceuticals etc.

	General objectives	Specific objectives
Groundwater pollutants	Ensure a high and equal level of protection of groundwater resources including their connected or dependent ecosystems and their uses. Indirectly, ensure a higher level of human health protection.	• To identify new substances for addition to the lists of groundwater pollutants (Annexes I and II to the GWD), with corresponding quality standards in the case of Annex I based on consideration of the latest scientific and technical knowledge. • To reverse pollution trends to enable environmental objectives set out in the WFD be achieved. • To promote a uniform and transparent procedure for establishing TVs in MS. • To enhance the comparability of the assessment of groundwater chemical status throughout the EU by setting additional common pollutants (and their corresponding quality standards). • To mitigate the potential environmental and (human) health impact(s) of pollutants of emerging concern, like PFAS, pharmaceuticals and non-relevant metabolites from pesticides (nrMs) etc.
Complementary objectives	Strengthen existing EU legislation for the protection of the environment and human health from the adverse effects of water pollution and to contribute to the achievements of the overall objectives of the WFD. Improve knowledge through improved data collection and use of data on monitoring of the state and evolution of surface and groundwater pollution to gather more comprehensive evidence for future risk assessments. Provide a legal framework that can be more swiftly and easily aligned with science and promptly respond to contaminants of emerging concern. Ensuring a more effective and coherent decision-making process by promoting the 'one-substance-one-assessment approach' Improve transparency and access to data, thereby facilitating implementation (also of existing	• To provide clear guidelines to MSs; • To ensure **improved knowledge** through better monitoring of pollutants including through the use of modern methods and consideration of microplastics; • To properly address the actual risks posed to the aquatic environment by improving the timeliness of regulatory action and the consistency of action across the EU, and considering mixtures of pollutants; • Harmonise the ways pollutants in surface and groundwater are classified and tackled; • To provide a mechanism to **improve the knowledge** base and make future identification of substances of concern more effective including through an effective and optimal watch list process; • To improve data collection (methods), in particular by introducing modern data collection techniques; • To progress streamlined reporting regarding data accessibility, data completeness and coherence, reporting frequency, timely data availability and data quality. The latter could e.g. be achieved by (simply) replacing the current 'pass/fail' reporting, be reporting the measured concentrations (these data are already available), as to ensure a better assessment of the 'distance to target' and the possible additional efforts needed ; • To promote data reuse and data sharing in line with the principle "collect once – use many times", and move towards a "data harvesting" model and a better integration of data flows reported to the EEA under EU (water) legislation in particular for the inventories of emissions;

	General objectives	Specific objectives
	quality standards) in the MS, as well as streamlining reporting in view of reducing administrative burden.	• Provide a **legal framework** that can be more swiftly and easily aligned with science and promptly respond to contaminants of emerging concern through the use of Delegated Acts limited to updating technical issues like revising the lists of pollutants and associated quality standards; • Improve the safeguards to a level playing field and allowing comparability of water body status between Member States by harmonising national threshold values set out in in a repository for River Basin Specific Pollutants and some groundwater pollutants (those for which MS set national standards) and ensuring a swifter update to technical and scientific progress of the pollutants included in the repository of harmonised threshold values. • Through the "one substance-one-assessment" approach, synergies with related EU legislation, e.g. in the area of chemicals, can be increased.

These objectives are compatible with the overarching EU objective, reinforced in the Treaty of Lisbon, that the EU will work for the sustainable development of Europe based, in particular, on a high level of protection and improvement of the quality of the environment.

7 What are the available policy options?

7.1 Overview

A range of policy options have been identified aiming to tackle the aforementioned problem areas and to address the identified specific objectives. The options for surface water and groundwater include the following:

- **Addition of substances** and/or groups of substances to the list of Priority Substances (PS) in surface waters and the setting of corresponding Environmental Quality Standards (EQS) in Annex I of the Environmental Quality Standards Directive (EQSD).
- Possible **amendment of EQS** of named listed PS in Annex I of the EQSD.
- Possible **deselection** of named listed PS from Annex I of the EQSD.
- **Designation/re-designation** of some PS as PHS in Annex II to the EQSD; re-designation of the eight "other pollutants" in Annex I of the EQSD: conversion to full PS, deselection, or retainment as "other pollutants".
- **Addition of substances to the lists of groundwater pollutants** (Annexes I and II to the GWD), with corresponding quality standards in the case of Annex I[154].
- '**Complementary options**'- such as changes to monitoring procedures, the development of guidance documents, and implementation of improved data management.

7.2 Options for surface water pollutants

Following analysis of the problem definition for surface water, a total of five[155] policy options were identified (listed in the table below). These options incorporate the work completed by the JRC and the CIS Working Group Chemicals to identify named lists of substances, and broadly cover the three thematic areas: additions, amendments, deselection. When looking at possible policy measures to address substances that are included in the substance lists under the Directive, it is important to differentiate between PS and PHS since the regime of possible measures is different. Measures for PS to be selected and taken by Member States are mainly aimed at reducing emissions in view of complying with the EQS, whereas measures for PHS must be aimed at phasing out emissions entirely.

The first and second policy options are similar with the main difference being whether a wider grouping strategy for certain chemicals could be used. This option was included on the basis that some listed priority substances already concern groups (e.g. dioxins and furans, polyaromatic hydrocarbons, and polybrominated diphenyl ethers), and while it would not preclude the need to complete analysis separately it could limit burden as well as ensure that listing one substance does not prompt greater use of another similarly hazardous one in the same group. This covered the possible grouping of the three estrogenic substances, three macrolide antibiotics, five neonicotinoid pesticides, four pyrethroid pesticides and 24 PFAS[156]

[154] The analysis of the GWD Annex II Parts A and C are beyond the scope of the impact assessment, since they were reviewed in 2014, and their implementation still needs to be assessed (including introduced data reporting changes).
[155] In the SWD 540/2 the Policy option 5 - Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of priority substances is considered under Monitoring, reporting and administrative streamlining option 4b
[156] For PFAS, the use of a relative potency factor (RPF) approach was considered for setting a group EQS but the scientific justification for that is still too uncertain to be introduced in the legislation. Consequently, a sum of all PFAS approach analogous to the DWD was seen as a more appropriate way forward.

substances. Additionally, further consideration has been given to including pesticides as a group in surface waters, with a group standard of 0.5 µg/l, i.e. corresponding to that in the GWD and the DWD. Group (total or sum of) EQS were identified as a potentially useful tool for "future proofing" legislation for large substance groups (including PFAS and Bisphenols) where there is rapidly changing information on the scale of impact whilst coherence with other legislation such as the GWD and DWD would be supported but would require some additional effort to collect the necessary (scientific) data. This would also fit under Policy Option 2.

Table 7-1 Surface water policy options

Policy option	Description	List of substances
Policy option 1:	***Additions***. Based on the named list of candidate priority substances from the work completed by the JRC and WG Chemicals, include all substances individually in the priority substances list, and set corresponding individual EQS.	***Pharmaceuticals:*** 17-alpha-ethinyl-estradiol (EE2), 17-beta-estradiol (E2), estrone (E1), Azithromycin, Erythromycin, Clarithromycin, Diclofenac, Carbamazepine, Ibuprofen ***Pesticides:*** Nicosulfuron, Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam, Bifenthrin, Esfenvalerate, Deltamethrin, Permethrin, Glyphosate, Triclosan ***Industrial chemicals:*** PFAS, Bisphenol A (BPA) **Metals**: Silver and its compounds **Other**: microplastics* *Note: only PFAS and BPA meet the criteria for designation as PHS*
Policy option 2:	***Additions***. Based on the named list of candidate priority substances from the work completed by the JRC and WG Chemicals, include all substances using groups of substances where appropriate in the priority substances list, and set corresponding EQS, using markers or the sum of substance concentrations in the case of groups.	
Policy option 3:	***Amendments***. Revise EQS where necessary based on new scientific data for existing priority substances	Chlorpyrifos, Cypermethrin, Dioxins, Diuron, Fluoranthene, PAHs, Hexachlorobenzene, Hexachlorobutadiene, Mercury, Nonyl phenol, PBDEs, Tributyltin, Heptachlor/Heptachlor oxide, Nickel, Dicofol, Hexabromocyclododecane
Policy Option 4:	***Deselection***. Deselect substances shortlisted following agreed deselection criteria.	Alachlor, Chlorfenvinphos, Simazine, Carbon tetrachloride, Trichlorobenzenes**
Policy Option 5:	***Amendments***. Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of priority substances.	Carbon tetrachloride, Aldrin, Dieldrin, Endrin, Isodrin, DDT, Tetrachloroethylene, Trichloroethylene

* Microplastics related options are included in Complementary options (harmonised methodology, monitoring etc.); ** New candidate (March 2022)

It is also important to note that the options 3-5 are not mutually exclusive and can be implemented in combination. Policy options 1 and 2 focus on the listing of new candidate substances, i.e. if and how (e.g. individually or as groups) they should be listed, therefore constituting an "either-or" selection as they represent different approaches for the same candidate substances.

7.3 Options for groundwater pollutants

A range of policy options for groundwater have been identified to address the pollution of groundwater by three groups of emerging contaminants: PFAS, pharmaceuticals and nrMs as identified through the voluntary groundwater watchlist (GWWL) process.
The list of policy options for groundwater is presented in the table below with a link to SWD (2022) 540 Final policy option arrangement.[157]

Table 7-2 Groundwater policy options

Policy option	Description	
Policy Option 1	**Add PFAS to the GWD annexes**	**Cross-reference to the GW Option numbering used in SWD (2022) 540/2**
1a	PFAS (Group of 10)[158] included in Annex I and assigned a GWQS of 0.10 µg/l (based on the drinking water standard for 20 identified PFAS – the 10 PFAS would be a subset of the 20)	Other options considered (Option 1)
1b	All PFAS added as group to Annex I with a GWQS for "PFAS total" of 0.5 µg/l (again following the drinking water standard for PFAS total);	Option 2
1c	All PFAS added as a group to Annex II for MS to consider for the development of a TV for specific substances posing a risk to GWBs.	Option 3
1d (SCHEER recommended)	PFAS (Group of 24 proposed as for the surface water Priority Substance list)[159] included in Annex I and assigned a GWQS of 4.4 ng/l PFOA equivalent[160]; For PFAS substances not included on the PS list, the PFOA relevant potency factor (RPF) could be used to calculate the GWQS. If no RPF exists, then the RPF of PFOA could be assumed and a GWQS of 4.4 ng/l applied.	Option 1
Policy Option 2	**Add Pharmaceuticals to the GWD Annexes**	

[157] SWD (2022) 540 final where the same policy options for groundwater are arranged based on addition to Annex I of the GWD as groups or individual substances or by addition to Annex II.
[158] Perfluorobutanoic Acid, Perfluorobutane Sulfonate, Perfluorodecanoic Acid, Perfluoroheptanoic Acid, Perfluorohexanoic Acid, Perfluorohexane Sulfonate, Perfluorononanoic Acid, Perfluorooctanoic Acid, Perfluorooctane Sulfonate, Perfluoropentanoic Acid.
[159] 6:2 Fluortelomer phosphate diester; 8:2 Fluortelomer phosphate diester; Perfluorobutanoic Acid; Perfluorobutane Sulfonate; Perfluorodecanoic Acid; Perfluorododecanoic Acid; Perfluorodecane Sulfonate; Perfluoroheptanoic Acid; Perfluoroheptane Sulfonate (sulfonic acid); Perfluorohexanoic Acid; Perfluorohexadecanoic Acid; Perfluorohexane Sulfonate; Perfluorononanoic Acid; Perfluorooctanoic Acid; Perfluorooctadecanoic Acid; Perfluorooctane Sulfonate; Perfluoropentanoic Acid; Perfluorotetradecanoic Acid; Perfluorotridecanoic Acid; Perfluoroundecanoic Acid; Perfluorodecane sulfonic acid; Ammonium 4,8-dioxa-3H-perfluorononanoate; Hexafluoropropylene oxide-dimer; Perfluoro ([5-methoxy-1,3-dioxolan-4-yl]oxy) acetic acid.
[160] Wieneke et al. (2020) derives relevant potency factors for individual PFAS compared to PFOA for use in risk assessment for oral exposure through food and drinking water.

Policy option	Description	
2a (SCHEER endorsed)	Pharmaceuticals Carbamazepine and Sulfamethoxazole added to Annex I and assigned GWQS of 0.5 and 0.1µg/l respectively (protective of human health).	Option 1
2b	All pharmaceuticals added as a group to Annex I and assigned a GWQS of 0.5 µg/l	Option 2
2c	All pharmaceuticals added as a group to Annex II for MS to consider setting a TV for substances that pose a risk to their GWBs. The specific pharmaceuticals on the LFR are included in the minimum list for consideration, with a guideline to include Primidone[161]	Option 3
Policy Option 3	**Add Non-Relevant Metabolites of Pesticides[162] to the GWD Annexes**	
3a	nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 1 µg/l. This based on reported TVs used by MS of 0.1 µg/l - 1 µg/l (with an exceptional case of 4.5 µg/l for one particular nrM) and a uniform value of 1 µg/l is proposed by analogy with the existing uniform value for individual "pesticides" in Annex I of the GWD.[163]	Other options considered (Option 1)
3b	All nrMs added to Annex I as a group and assigned a group GWQS of 10 µg/l (analogous with the existing group value for "pesticides")	Option 2
3c	All nrMs added to Annex II for MS to consider a TV for substances that pose a risk to their GWBs	Option 3
3d SCHEER recommended	nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 0.1 µg/l (protective of human health and groundwater biota)	Other options considered (Option 1)
3e SCHEER recommended plus future proofing	All nrMs added to Annex I as individual substances with a GWQS of 0.1 µg/l (protective of human health and groundwater biota)	Option 1

[161] Based on sufficient evidence collected through the GW WL process for Primidone to be added to the LFR. This was discussed at WG GW Plenary in March 2022 and also in the 2nd Stakeholder Workshop in March 2022. This was after it had been included as a possible substance for Annex II in the Commission's mandate to the SCHEER in early 2021. In addition, the original proposed Option 2c included adding 8 further pharmaceuticals from the GW WL to Annex II for consideration by MS. This was not accepted by stakeholders at these two meetings on the basis that there was not enough evidence to support this action for those 8 except for Primidone.

[162] Desphenyl-chloridazon (Metabolite B); Methyl-desphenyl-chloridazon (Metabolite B1); 2,6-Dichlorbenzamid (2,6-D, BAM, M01, AE C653711); Aminomethylphosphonic acid (AMPA); Metazachlor-acid (OXA) (BH 479-4); Metazachlor ESA Metazachlor-SA (BH 479- 8) (Metazachlor-sulfonic acid (ESA); Atrazine-2-hydroxy; N,N-Dimethylsulfamid (DMS); s-Metolachlor-acid, (OXA, CGA 51202, CGA 351916); Chlorthalonil-SA (R417888 or VIS-01 / M12) (Chlorthalonil sulfonic acid); Metolachlor-sulfonic acid (ESA, CGA 380168, CGA 354743); Dimethenamid-ESA; Flufenacet-sulfonic acid (ESA) 201668-32-8; Alachlor-t-sulfonic-acid (ESA); S-Metolachlor NOA 413173 or VIS-01 (Chlortalonilsulfone acid) Metabolite; Dimethachlor CGA 369873 1418095-08-5.

[163] The SANCO guidance (2003 and 2021) suggests a case-by-case assessment but with an (individual) upper limit of 10 µg/l and a value of 0.75 µg/l if a risk assessment has been performed but is incomplete.

7.3.1 *Design of the options*

There is one option per chemical group with different sub-options which consider how to add these substances to the GWD Annexes, i.e. to which annex, as groups and/or individual substances, and with which quality standards or threshold-value (TV) requirement.

The design of the options considers the opinions of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)[164]. The SCHEER endorsed quality standards based on available (eco)toxicological data, harmonisation with surface water quality standards in several cases, and application of the precautionary principle. Group (total or sum of) GWQS were identified as a useful tool for "future proofing" legislation for large substance groups (including PFAS and Bisphenols) with rapidly changing information on the scale of impact whilst coherence with other legislation such as the EQSD and DWD was supported. However, this also requires consideration of the range of chemicals in the group and variability in environmental fate and transport. The options also consider views of the groundwater expert community (workshop held in 2021 and targeted questionnaire).

The options may also be ordered by the proposed GWD Annex to which substances are added as this reflects the extent of the problem and influences the gap to meet the environmental objectives for groundwater as follows:

- **Annex I** of the GWD lists substances with Europe wide GWQS that is used during the assessment of risk and status of GWBs and provides for establishing more stringent standards if necessary. Listing under Annex I is appropriate for substances of Europe-wide concern such as those related to more diffuse pollution.
- **Annex II** sets out the process to be used by MS in setting TVs for pollutants that put GWBs at risk of not achieving or maintaining good status. It sets out the minimum list of pollutants which MS must consider establishing TVs for[165]. Background concentrations of naturally occurring pollutants should be considered when setting TVs and some MS use safety margins to protect receptors. Therefore, TVs may be set at a wide range of scales from national to river basin to individual GWBs. Listing under Annex II is appropriate for more localised pollution (i.e. in small number of GWBs, RBDs or MS).

7.3.2 *Use of relative potency factors (RPFs) for PFAS GW QS*

A number of governmental bodies in the EU (EFSA) and the United States have proposed health-based standards or guidelines for PFAS in water and/or food based on relating the toxicity of for example the relatively well studied PFOA or PFOS to the sum of concentration of a small number of less well studied PFAS which are thought to have similar pharmacokinetic and toxicological properties. This summing approach is concentration additive[166]. The current system of summing a comparatively small number of PFAS for which

[164] Groundwater quality standards for proposed additional pollutants in the annexes to the Groundwater Directive (2006/118/EC) (europa.eu)

[165] https://circabc.europa.eu/sd/a/ff303ad4-8783-43d3-989a-55b65ca03afc/Guidance_document_N%C2%B018.pdf

[166] Concentration addition (CA) is based on the idea that compounds "work together" to bring about a biological effect. The simplest form of CA is RPFs in which all compounds in the system are assumed to have the same

there are most detailed data appears to be a reasonable first step. While one can think of this procedure as assuming the same RPF of one for all compounds, it makes the uncertainty behind this assumption explicit. One challenge with this approach is that it can omit other PFAS. To limit the risks of that an additional uncertainty factor to take this into account is considered.

7.3.3 *Use of evidence-based GW QS for nrMs*

Feedback from technical experts indicated that the evidence for the chronic or acute effects on sensitive biota in groundwater ecosystems was in some cases limited. The proposed GW QS could be made more stringent for nrMs where there less experimental data available on chronic or acute effects on sensitive taxonomic groups, categorising nrM substances as:

- 'data-poor' for which no reliable data on chronic or acute effects of the nrM are available;
- 'data-fair' for which reliable experimental data on chronic or acute effects of the nrM are available on the taxonomic group confidently predicted to be the most sensitive, but where the data are insufficient to qualify the substances as 'data-rich'.
- 'data-rich' where there is reliable data available on chronic or acute effects of the nrM on a wider range of aquatic species of which the most-sensitive taxonomic group is confidently confirmed.

For the purposes of this impact assessment the SCHEER options listed in Table 7.2 have been carried forward.

7.4 Monitoring, reporting and administrative streamlining options (Complementary policy options)

Based on the problem definition highlighted above, and the objectives 2 to 5, a total of 13 actions categorized into three different types of policy options determined by thematic areas have been identified. The policy options can be broadly categorised into three thematic areas: improving monitoring approaches, improving data management and transparency and improving risk assessment and the translation to risk management. The options are not mutually exclusive, and can be combined and applied at the same time, in order to achieve a more effective, efficient, responsive, coherent and flexible legislation.

Improving monitoring approaches, including wider application of Effect Based Methods (EBMs), modern instruments, digital techniques etc., are necessary to address the significant pressures stemming from emerging pollutants (such as microplastics) and possible cumulative effects of pollutant mixtures. Currently, monitoring practices focus on individual substances or groups of substances, yet it is estimated that hundreds of chemical mixture combinations occur in freshwater bodies throughout the EU[167], for which EBMs could be useful. In addition, there are a range of innovative monitoring techniques, including satellite techniques and

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concentration-response curve differing only in potency. The concentrations of compounds are multiplied by their potency relative to a reference compound - generally the one best studied - and summed. The sum is then inserted into the concentration-response function of the reference compound.

[167] EEA (2018) Chemicals in European Waters- Knowledge Developments

automated sensing technologies, which could provide important insights into pollutant levels, but which have yet to be commonly adopted.
Developing and improving existing obligatory monitoring practices relates primarily to improved sharing of knowledge, best-practices and data itself. Significant data gaps exist on the effects and evolution of pollution, including the combined effects of substances, emerging pollutants, seasonal variations and river basin specific pollutants. Improving monitoring practices will close significant data gaps and help improve the risk assessment and the translation to risk management.

Harmonising and simplifying reporting mechanisms focuses on improving transparency and accessibility of reported data. By further digitalisation of monitoring and reporting, it is likely that the administrative burden of MSs would be reduced, with costs also likely to reduce in the medium to long term.

Finally, we propose a set of *administrative and legal actions* that can help improve the responsiveness and relevance of the legislation.

Table 7-3 Policy options relating to monitoring, reporting and administrative streamlining

Thematic area	Options
1. Improving monitoring approaches	Policy option 1a: Develop guidelines on applying innovative methods in monitoring procedures, including remote (satellite), continuous/automated monitoring techniques
	Policy option 1b: Follow-up to improve existing guidelines in view of setting application 'trigger values' in practice to improve monitoring of groups/mixtures of pollutants by using effect-based methods (EBMs), and trigger values
	Policy option 1c: Develop a harmonised measurement and monitoring methodology and guidance for microplastics, as a basis for mandatory MS reporting on microplastics and a future listing under EQSD/GWD.
	Policy option 1d: Develop guidelines on sampling frequency for PS and RBSPs.
	Policy option 1e: Provide a repository for sharing best practices from MS regarding available monitoring techniques, and foster cooperation to implement these.
2. Developing and improving existing obligatory monitoring practices	Policy option 2a: Include an obligation in the EQSD to use EBMs to monitor estrogens.
	Policy option 2b: Establish an obligatory GW WL mechanism analogous to that for surface waters[41] and drinking water, and provide guidance as necessary on the monitoring of the listed substances.
	Policy option 2c: Improve the monitoring and review cycle of the SW WL so that there is more time to process the data before revising the list.
3. Harmonising and simplifying reporting mechanisms	Policy option 3a: Establish an automated data delivery mechanism for the EQSD and the WFD to ensure easy access at short intervals to monitoring/status data to streamline and reduce efforts associated with current reporting, and to allow access to raw monitoring data.

Thematic area	Options
	Policy option 3b: Introduce a reference list (repository of standards) of EQS for RBSPs as an annex to the EQSD and modify Annex V of WFD section 1.2.6 (*Procedure for the setting of chemical quality standards by MS*) accordingly, and incorporate RBSPs into the assessment of chemical status for surface waters
4. Legislative and administrative aspects	Policy option 4a: Use an annex in the EQSD instead of Annex X to the WFD to define the list of PS, and update the lists of SW and GW substances by Comitology or delegated acts.
	Policy option 4b: Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of PS/PHS. ***Pesticides:*** *Aldrin, Dieldrin, Endrin, Isodrin, DDT (all to PHS);* ***Industrial chemicals:*** *Tetrachloroethylene, Trichloroethylene (to PHS), Carbon tetrachloride*
	Policy option 4c: Change the status of some existing PS to that of PHS where it fulfils the criteria of the POP Regulation and/or Article 57 of REACH Regulation. ***Industrial chemicals:*** 1,2-Dichloroethane, Fluoranthene, Octylphenol, Pentachlorophenol; ***Metals:*** Lead

These options are not mutually exclusive within this group, and they complement the surface and groundwater-specific options. Some of them would be mandatory (e.g. EBM for monitoring estrogens and measuring microplastics). Having established that these 13 options are feasible and can be implemented in combination with one another, the following sections assess the nature and possible extent of their economic, social and environmental impact.

8 What are the impacts of the policy options and who will be affected?

8.1 General considerations for all Surface water and Groundwater options

8.1.1 *Introduction*

The Treaty on the functioning of the European Union establishes the pillars of EU environmental policy and refers to the control of pollution at source and to the polluter pays principle. The control at source principle gives priority to upstream controls on the assumption that, in general, rectification at source is more cost-effective than end-of-pipe solutions. The importance of considering upstream measures was highlighted by MS and stakeholders during the workshops. Similarly, the polluter pays principle states 'that the polluter should bear the expenses of carrying out the pollution prevention and control measures introduced by public authorities, to ensure that the environment is in an acceptable state'. By applying it, polluters are incentivised to avoid environmental damage and are held responsible for the pollution that they cause. This could for example be done by introducing an Extended Producer Responsibility but this was not part of this IA support study and would require additional work similar to that done in the context of the Impact Assessment support study for the revision of the Urban Wastewater Treatment Directive. It is also the polluter, and not the taxpayer, who should cover the costs created by pollution. A recent publication from the European Court of Auditors [168] notes that progress has been made to address specific pollutants, in many cases the price of water does not cover the full costs imposed by the pollutants released into environment. Agriculture, the sector which exerts the most pressures while benefitting the most from on clean freshwater resources, contributes the least.

8.1.2 *General benefits*

Since the options do not specify the exact measures to be taken to attain a set EQS, the assessment of the potential benefits of measures themselves (as compared with the benefits of additional guidance or monitoring) can only be based on the potential measures that might be taken at EU or MS level as a result of the proposal. In addition, realisation of some of the benefits would be in the long-term. Benefits to health are extremely difficult to quantify, being dependent on many factors including exposure and intrinsic hazard of the substances themsleves. Positive impacts specific to each policy option are presented in the following sections.

Environmental benefits

- The most significant environmental benefit from amending the PS list (under option 1 (add individually), 2 (add as groups), 3 (amend existing PS/PHS), 4 (deselect)), 5 (change in status) or the groundwater pollutant list under GWD Annex I or Annex II is that it promotes action across the EU, in particular bilateral co-operation for Member States

[168] Special Report 12/2021: The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions (europa.eu)

with shared rivers and water bodies (60% of EU waters are transboundary). The use of standardised EQS, GWQS or an approach to derivation of threshold values at EU-level provides a foundation for MS to work collectively towards protection of the aquatic environment. Efforts deployed this way are more effective and efficient at managing chemical risks than MS working in isolation.

- Building upon the point above, regular monitoring of additional PS (under surface water options 1,2,3 and 5) and Annex I and II substances in groundwater has the added benefit of increased knowledge of the extent of water pollution across the EU and allows for a better prioritisation of actions and measures to address sources of pollution and pressures on water bodies. This allows an improved assessment of the effectiveness of the measures taken under the WFD and other sectoral legislation to limit substance emissions and trigger action if measures are insufficent; this benefit would not be achieved under the other sectoral legislation alone. It should be noted that monitoring of the substances in surface water option 3 and 4 already occurs, and that EQS for them already exist, but that changes in the EQS for some of those substances could act as a driver for continued improvement of monitoring and analytical standards and approaches. For surface water option 4, further data and knowledge on environmental concentrations would not be collected on these substances if removed from the PS list.
- Measures subsequently employed to deal with new or amended PS and related EQSs and with GWD Annex I and Annex II substances and to limit further chemical emissions, will have consequent improvements in biodiversity (even beyond the immediate aquatic ecosystem) that will result in a more resilient aquatic ecosystem, enhancing its capacity to deliver ecosystem services such as the processing of excess nutrients (Cardinale 2011[169]). Indirectly, this will also translate into better human health protection through a cleaner aquatic environment and cleaner drinking water.
- Cleaner sediments meaning less potential for re-dissolution in the water column and reduced uptake of harmful substances by plants and animals.

Economic benefits

- The EQSD and GWD provide a mechanism for monitoring and managing substances that represent an EU-wide risk. The addition of substances to the PS list / Annex I list provides a standardised level playing field with which to manage the issue. This is important for surface water and groundwater bodies that cross political boundaries and provides impetus for neighbouring MS to tackle issues in a consolidated fashion, which has economic benefits for all parties.
- Where a given substance/s is identified as a PS, or Annex I or Annex II substance it promotes the need for innovative measures to address the issues presented. If the substance is presented as an issue at EU-wide scale, there are potential economic benefits for MS authorities, water companies, chemical manufacturers and other relevant stakeholders to pool resources. This would equate to a cost saving compared to the same stakeholders working in isolation at national level.

[169] Cardinale, Bradley & Matulich, Kristin & Hooper, David & Byrnes, Jarrett & Duffy, J. & Gamfeldt, Lars & Balvanera, Patricia & O'Connor, Mary & Gonzalez, Andrew. (2011). The functional role of producer diversity in ecosystems. American journal of botany. 98. 572-92. 10.3732/ajb.1000364. https://www.researchgate.net/publication/51165789_The_functional_role_of_producer_diversity_in_ecosystems

- Cleaner sediment negating the need for costly remediation or dredging. This recognises that a number of the candidate substances are less soluble and likely to concentrate within suspended solids, and then within sediments and biota in the natural environment.
- Promotion of advancements in treatment technologies and innovation within the EU to deal with new PS and Annex I / Annex II substances.

Social and public health benefits

- Additional information will be available to the public on the PS/PHS, Annex I and Annex II substances and the quality of the aquatic environment;
- Reduced bioaccumulation of hazardous chemicals in humans, reduced exposure (occupational and other) if less hazardous substitutes are used;
- Potential improvements in quality of fish and shellfish from commercial fisheries, aquaculture and recreational fishing (which would confer economic benefits in managing resources more sustainably).
- Improved amenity value of water bodies (tourism, angling, etc), and reduced exposure for humans using them for bathing, surfing and other water sports;
- Cleaner water for livestock where surface water or groundwater is used directly, resulting in reduced accumulation of chemicals in meat and milk, hence reduced human exposure to hazardous substances, likewise, less accumulation in drinking surface waters;
- Reduced potential for accumulation of hazardous substances in crops when untreated water is used for irrigation.

8.1.3 *General Costs*

The majority of costs are economic, described below based on the relevant impacted actors, which would include:

- To MS Competent Authorities responsible for meeting the obligations set out in the EQSD (i.e., monitoring and analysis[170], reporting, development of PoMs, and overseeing implementation of PoMs) and GWD.
- To companies, following polluter pays principles and need for greater emission control or substitution of substances.
- To water company operators, assuming that managing some of the issues associated with PS/PHS, GWD Annex I and Annex II substances will fall upon water companies to an extent (monitoring and analysis, reporting, treatment, etc.)
- To users, including both within industrial and professional settings. Again, this could follow the polluter pays principle, as well as transition to alternatives/ changes in process etc.
- To consumers, assuming that there could also be the need to share the burden of costs associated with treatment with consumers (i.e., through water bills, willingness to pay, etc) or through impacts associated with substitution (i.e., more expensive alternatives, more expensive food, loss of products from the market etc).

[170] The polluter pays principle could ideally also be applied to recover part of the monitoring and analysis costs, incurred by Member States, from the producers of the substances. This could be done by applying ‘Extended Producer Responsibility’ provisions, but a more detailed investigation to this extend was not part of this impact assessment support study.

8.2 Surface water

8.2.1 *"Distance to Target" Assessment*

Before the impacts of different policy options could be assessed, it was necessary to determine the magnitude of the problem in terms of the difference between the current situation and the proposed EQS. This assessment for the 'distance to target' was then used as a basis for determining the kinds of measures that might be needed to achieve good chemical status, and which sectors and stakeholders might be impacted by the implementation of such measures. Following this analysis, the costs of intervention using a range of measures and the benefits of intervening could be derived, which allowed the impacts of each policy option to be determined.

Methodology for Candidate Priority Substances

Table 8-1 (below) shows the combined groupings for substances (additions and amendments). The substances in bold indicate where a change in group has taken place. For the candidate substances, these are demotions (e.g. large moved to medium) following comparison of the substance against the likely evolution under the dynamic baseline. For those substances with proposed EQS amendments, the bold indicates a change of group against the existing distance to target. Which can be either an increase or decrease in the size of the gap.

One stakeholder from the workshop indicated that for hormones EE2 and E2, the dossiers show that large majority of samples in MS (watch list monitoring) are 'non-quantified'. They argued that the distance to target would therefore be "small" in their opinion. This is incorrect since many Member States measure the 'presence' of substances (meaning measured concentrations reliably confirming exceedances of the limit of quantification (LoQ)[171], without quantifying the exact level of exceedance however). This is often due to the use of analytical methods suitable for 'quick screening' but using less precise limits of quantification. To still be able to use those 'non-quantified' sample data for risk analysis purposes, the dossiers provide the following scenario to consider the use of those so called 'censor data' (non-quantified samples)', and the scale of risk based on monitoring. The risk assessments in all substance dossiers use the same statistical approach as documented and used by EFSA and USA EPA to perform basic statistics on the concentration data derived from those data. It is based on the following data scenario which was considered as the most appropriate scenario for making a risk assessment according to the WG Chemicals / sub-group on review (SG-R) of the priority substances list. This scenario considers quantified monitoring samples and non-quantified samples only when ½ Limit of Quantification (LoQ) ≤ Predicted No-Effect Concentration (PNEC) or EQS, thus avoiding any non-confirmed exceedances. The sub-group on review (SG-R) of the priority substances list confirmed this to be the most relevant scenario to assess whether the substance poses a risk at EU-level[172]. This scenario avoids excluding data collected as non-quantified while minimising artificial exceedances. Further data on monitored concentrations in surface water is provided in Appendix D.

[171] LoQ is the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are also met. The LoQ may be equivalent to the Limit of Detection (LoD) or it could be a higher concentration. Often, the LoD defined as 3 × standard deviation of the blank, and at the LoQ defined as 10 × standard deviation of the blank.

[172] Carvalho RN, Marinov D, Loos R, Napierska D, Chirico N, Lettieri T. 2016. Monitoring-based exercise: second review of the priority substances list under the Water Framework Directive, Available at https://circabc.europa.eu/w/browse/52c8d8d3-906c-48b5-a75e-53013702b20a

Table 8-1 Distance to target assessment results

Distance to targe analysis groupings
Large
Additions: Ethylestradiol (EE2); Diclofenac; Carbamazepine; Bifenthrin, Deltamethrin, Esfenvalerate; Permethrin; Glyphosate; Bisphenol A; PFAS
Amended EQS: Mercury, PBDEs, Nickel
Medium
Additions: **Estrone (E1)**; Beta estradiol (E2); Azithromycin; Ibuprofen; **Imidacloprid**; Triclosan; **Silver****
Amended EQS: **Chlorpyrifos;** Cypermethrin, Dioxins and Furans, **Diuron**, **PAHs**, Tributyltin; **Hexabromocyclododecane**
Small
Additions: Clarithromycin; Erythromycin; **Acetamiprid**; Clothianidin; Thiacloprid; Thiamethoxam; **Nicosulfuron**.
Amended EQS: **Fluoranthene**, Hexachlorobenzene, Heptachlor/ heptachlor oxide, Hexachlorobutadiene, Nonylphenol, Dicofol

*(Additions: substances in bold demoted a group based on impacts of the dynamic baseline. Amendments: substances in bold denote a change in group based on proposed threshold change).
** Distance to target for silver is considered “medium”, based on the nanoform of silver and concerns around its contribution towards anti-microbial resistance.

8.2.2 *Identification of possible measures and impacted stakeholders*

The assessments detailed in section 8.1 help establish a state-of-play, in terms of the dynamic baseline and the distance to target for the candidate priority/priority hazardous substances (additions) and existing priority substances (amendments)[173]. Alongside the work to develop the ‘state-of-play’, an analysis has been completed based on the EQS dossiers and supplemented with further information from literature review to build up a profile for each substance. This profile includes data on physico-chemical properties, production and use, current legal status under related policy, and pathway to environment (including identification of major and minor pathways). This information, along with the analysis detailed in Section 8.1 helps identify what kinds of practical measures might be needed to achieve good chemical status, and then subsequently which stakeholders might be impacted by implementation of such measures.

Completion of this part of the impact assessment has utilised in part the steps outlined within the Better Regulation Toolbox #16[174]: This involves developing a (dynamic) baseline (for means of comparison), compiling a wide range of policy options (and underlying practical measures), screening of policy options (e.g. addition, amendment) and associated measures and then detailed analysis of the associated impacts of the screened set. On that basis the following steps have been taken:

Step 1 – Measures identification

The first step in the process was to identify all possible measures associated with different policy options (addition, amendment). This was treated as a ‘blue skies’ approach with no measure excluded from the assessment. For each substance (included under additions and

[173] The option covering deselection of existing priority substances is covered later in this section.
[174] br_toolbox_-_nov_2021_-_chapter_2.pdf (europa.eu)

amendments) based on the profile developed (including manufacture, use, and pathway to environment) all possible measures were identified that could intervene at all stages of the life-cycle to help achieve good chemical status. The measures identified included technical options such as restrictions and bans on usage, other options to limit emissions of all groups of substances and/or abatement and wastewater treatment. Additionally, for persistent chemicals or chemicals already banned presenting legacy issues, measures were considered that could be applied directly to the natural environment as a means of intervention to achieve good chemical status (e.g. contaminated site remediation).

Step 2 – Screening

Following the development of the ‘long list’ under step 1 a screening round was applied, largely using expert judgement, but again drawing upon the criteria listed under the Better Regulation Toolbox #16 (see pp114 and 115 of the toolbox). The measures were assessed based on technical, economic, and legal feasibility, and societal acceptance. For some substances a total ban might be highly effective, but if the economic costs and societal impact would be disproportionate, this would affect the suitability score of the option. In this process a number of options were screened out. This resulted in a shorter list of measures, that could be practically employed to help achieving good chemical status.

Step 3 – Identification of impacted sectors

Based on the preceding steps, using the screened list of measures, the key sectors likely to be impacted by the costs of implementing the measures from step 2 were identified.

Appendix I of this document provides a high-level matrix of the screened measures for the substances (grouped into pharmaceuticals, pesticides/biocides, industrial chemicals, and metals) side by side. This should help illustrate where the same measure could be used for multiple substances in a complimentary fashion. The measures identified can be very broadly grouped into one of four overarching categories:

- **Source control**. This means intervention at the point of manufacture and/or use. It can include technical measures such as improved abatement, on-site treatment, or other forms of emission control. It can also relate to policy measures such as restrictions/bans, or encouragement for substitution to safer alternatives.
- **Pathway disruption**. This category relates to barriers in the environment that prevent egress to surface water, which are largely covered by technical options such as buffer strips, constructed wetlands, amendment of combined sewer overflows (CSOs) etc.
- **End-of-pipe options**. This category relates to treatment at the waste phase, again, largely using technical options such as quaternary technologies for wastewater treatment, and improved landfill leachate capture systems etc.
- **Monitoring and natural attenuation**. The final category relates to a limited set of substances with long lasting legacy impacts, where the best option may be natural attenuation. This is on the basis that dredging is high cost and can potentially make water concentrations worse.

Implications of the Urban Wastewater Treatment Directive revision - quaternary treatment
The Urban Wastewater Treatment Directive has recently undergone a fitness check and options appraisal to maintain a high level of protection for water. This recognised that EU wastewater treatment works use primary and secondary treatment technologies as a minimum, and increasingly have adopted tertiary treatment technologies to manage nutrient loading for treated effluent. The further expansion to advanced technologies (quaternary treatment) for micro-pollutants is an area still under development. The JRC have undertaken an extensive **cost benefit study to complete analysis of quaternary treatment technologies**, with ozonation, granulated activated carbon (GAC), and powdered activated carbon (PAC) identified as the most cost effective, either on their own or in combination. Following this study recommendations have been included within the proposals for amendment of the UWWT directive. This follows a phased approach to implementation, including: • 2025: Update of risk registers for key micro-pollutants in treated effluents. • 2030: Upgrade to quaternary technologies for wastewater treatment plants serving population equivalents of 100,000 or greater. • 2040: Upgrade to quaternary technologies for wastewater treatment plants serving population equivalents of between 10,000 and 100,000, where risk of pollution is identified due to low dilution issues (broadly assumed to affect 70% of works). Where these implemented changes will not begin to take effect until 2030, the inclusion of the amendments and need for upgrade of wastewater treatment works has not been included in the dynamic baseline of this initiative. However, it is also key to avoid double counting of costs of further treatment within the wider impact assessment for the substances identified (either as new additions or EQS amendment). Therefore, the impact assessment has included further consideration for types of wastewater technology (per substance), including efficacy and associated indicative costs as useful contextual information. But the costs of upgrading wastewater treatment works as part of the cost-benefit analysis, has assumed that these costs will fall under the requirements of the revised UWWTD and therefore should be separate from the impact assessment conclusions derived under this study.

Based on the four major parent groupings of substances (pharmaceuticals, pesticides, industrial chemicals, and metals), the importance of the different measure categories varies. Appendix H provides a more disaggregated breakdown of the measures identified, but Table 8-2 provides a high-level quick reference for how the measure categories compare to the substance categories.

Table 8-2 Overview of measure categories and substance categories

	Pharmaceuticals	Pesticides/biocides		Industry chemicals	Metals
		Pesticides	Biocides		
Intervention at source	✓	✓	✓	✓	✓
Pathway disruption	✓*	✓		✓***	✓
End-of-pipe	✓		✓	✓	✓
Monitoring and natural attenuation		✓**		✓	

*Relates to agricultural runoff from farmed animals only **Legacy uPBT pesticides only. ***related to run-off from road only.

Based on the measures identified it was then possible to consider which stakeholders may be impacted by their implementation. Appendix I provides a disaggregated table to provide greater detail. Whereas Table 8-3, provides a high-level overview.
One further comment is that in many cases wastewater companies are identified as a key stakeholder based on upgraded end-of-pipe measures being listed as viable choices. While in some cases this may present the best practical choice (e.g. restrictions on the human use of pharmaceuticals can carry high societal costs), it is key to recognise that following polluter pays principle, the cost of such upgrades (where and if pursued) should follow extended producer responsibilities.

Table 8-3 Overview of stakeholders likely impacted by measures identified

Pharmaceuticals	Pesticides/Biocides	Industrial Chemicals	Metals
Pharmaceutical manufacturers and distributors	Pesticide/biocide manufacturers and distributors	Manufacturing (Raw chemicals) -	Mining operations sector
Healthcare sector	Healthcare sector	Manufacturing (use of chemicals) (multiple sectors)	Manufacturing industries - particularly smelting and use in electronics / automotive.
Farmers - farmed animals	Farmers (arable and pastoral)	Infrastructure and roads	Healthcare sector (biocidal applications)
Society - costs to consumers/ taxpayers	Veterinary applications - particularly biocides, farmed animals and domestic pets	Society - costs to consumers/ taxpayers	Society - costs to consumers/ taxpayers
Wastewater companies (EPR)	Society - costs to consumers / taxpayers	Wastewater companies (EPR)	Wastewater companies (EPR)
Member State Authorities - guidance and enforcement	Wastewater companies (biocides) (EPR)	Member State Authorities - guidance and permitting	Member State Authorities - mine drainage and landfill sites.
	Member State Authorities - guidance and enforcement		

8.2.3 Option 1: Review all substances (shortlisted by the COM) as individual additions

Option 1 involves adding new substances to the list of priority substances under the EQSD, alongside corresponding EQSs. The substances will be added to the PS list as individual items, or as groups where appropriate. This section provides an assessment of environmental, economic, and social impacts associated with option 1, and provides a summary in Table 8-4. Due to the large number of substances and practicalities for this report, impacts have been grouped by 'type of measure' and then relevant substances highlighted in the corresponding impact columns.

To help provide some additional context to the measure selection, Table 8-4 provides a high-level summary of the major and minor pathways to surface water for each of the candidate priority substances. In many cases the table illustrates that wastewater treatment works are a major pathway for the substance reaching surface water. The key point to recognise here is that while the wastewater treatment works is the point of release it reflects that intervention could be applied both during the manufacture/use of the substance to prevent it entering the sewer system, as well as end-of-pipe treatment. For a number of the pesticide / biocide substances the major pathways to environment are dominated by possible releases during manufacturing or run-off from field during/shortly after application. Again, this reflects that the possible intervention could act as either source control, disruption of the pathway to surface water or both.

Table 8-4 Overview of pathways to environment

<table>
<tr><th>Substance</th><th>Major Pathways</th><th>Minor Pathways</th><th>Comments</th></tr>
<tr><td>Estrone (E1)</td><td rowspan="2">Wastewater treatment works
Manufacturing (pre-treatment prior to sewer)</td><td rowspan="2">Run-off from fields</td><td rowspan="2">Naturally occurring hormones in mammals, but also used as part of HRT and some veterinary treatments (horses)</td></tr>
<tr><td>17-Beta estradiol (E2)</td></tr>
<tr><td>Ethylestradiol (EE2)</td><td>Wastewater treatment works
Manufacturing (pre-treatment prior to sewer)</td><td>Run-off from fields</td><td>Synthetic hormone, primarily human applications, but also veterinary uses.</td></tr>
<tr><td>Azithromycin</td><td>Wastewater treatment works
Manufacturing (pre-treatment prior to sewer)</td><td>Run-off from fields</td><td rowspan="3">Primarily human use. Pre-emptive use in farmed animals banned in 2019. Use for veterinary purposes now more limited.</td></tr>
<tr><td>Clarithromycin</td><td>Wastewater treatment works
Manufacturing (pre-treatment prior to sewer)</td><td>Run-off from fields</td></tr>
<tr><td>Erythromycin</td><td>Wastewater treatment works
Manufacturing (pre-treatment prior to sewer)</td><td>Run-off from fields</td></tr>
</table>

Substance	Major Pathways	Minor Pathways	Comments
Diclofenac	Wastewater treatment works Manufacturing (pre-treatment prior to sewer)	Run-off from fields. Landfill / incorrect disposal	Primarily human use, but some veterinary applications. Possible issues with expired medicines.
Carbamazepine	Wastewater treatment works Manufacturing (pre-treatment prior to sewer)	Run-off from fields	Primarily human use, but some veterinary applications.
Ibuprofen	Wastewater treatment works Manufacturing (pre-treatment prior to sewer)	Run-off from fields	Primarily human use, but some veterinary applications.
Nicosulfuron	Manufacturing Run-off from field	Spray drift	Only used as a pesticide, no biocidal uses.
Acetamiprid	Manufacturing Run-off from field Wastewater treatment works	Spray drift Landfill	Used as both a pesticide and biocide. Note use in amenity settings which could also be washed to drains.
Clothianidin	Manufacturing Wastewater treatment works	Landfill	Biocide use only. Assume potential for washed to drains
Imidacloprid	Manufacturing Wastewater treatment works	Landfill	Biocide use only. Assume potential for washed to drains
Thiacloprid	Manufacturing Run-off from field	Landfill Contaminated sites	No approval in place for pesticide or biocide. Emergency authorisation only, but used as a foliar spray.
Thiamethoxam	Manufacturing Run-off from field Wastewater treatment works	Landfill	Approved use as a biocide. Also, emergency authorisations as a pesticide. Note seed treatment only. Spray drift unlikely to be an issue.
Bifenthrin	Run-off to surface water Timber treatment	Wastewater treatment works Spray drift	Used as a biocide for timber treatment. Assume main issues are for pre-treated timbers. Direct application of existing wood could be a secondary pathway.
Deltamethrin	Wastewater treatment works Animal treatment (dipping/spraying/brushing) Manufacturing	Run-off from field. Landfill.	Indoor use as a biocide with potential loss to sewer. Also has veterinary treatment outdoor, risk of run-off, treated animals' ingress to water.

Substance	Major Pathways	Minor Pathways	Comments
Esfenvalerate	Run-off from fields Manufacturing	Spray drift Landfill/incorrect disposal	Pesticide use only, applied primarily as a spray.
Permethrin	Run-off to surface water Timber treatment	Wastewater treatment works Spray drift	Used as a biocide for timber treatment. Assume main issues are for pre-treated timbers. Direct application of existing wood could be a secondary pathway.
Glyphosate	Run-off from fields Manufacturing	Spray drift Wastewater treatment works Landfill / incorrect disposal	Herbicide use only, but amenity applications on hard surfaces could lead to washing reaching drains. Main pathway will be in agriculture.
Triclosan	Wastewater treatment works Manufacturing	Landfill / incorrect disposal	Biocidal application primarily in direct to drain applications (soaps)
PFAS	Manufacturing Wastewater treatment works	Contaminated sites landfill	Many uses, the biggest emitters to environment though will be fire-fighting foams and textiles.
Bisphenol A	Manufacturing Run-off from road Wastewater treatment works	Run-off to surface water. Landfill.	75% of all BPA is used in polycarbonate, potential run-off linked to automotive applications. Epoxy resins (17% of all uses), will be important for construction and pipes.
Microplastics	Manufacturing (plastics) Wastewater treatment works	Run-off from fields. Run-off from roads. Landfill.	Textiles are a major source of secondary micro-plastics via laundry. Primary micro-plastics have also been used in cosmetics and direct to drain applications such as personal care products. The other major sources are brake and tire wear from automotive, and sewage sludge to land spreading.
Silver	Mining operations. Manufacture (smelting)	Wastewater systems. Waste handling of electronics. Landfill. Atmospheric deposition.	Primary points of release are likely during extraction and manufacture. End-of-life processes also possible sources. Atmospheric deposition also likely a minor pathway.

Economic impacts - *Costs*

The economic costs of adding the candidate substances to the priority substance list are likely to span three different sets of categories:

- **Direct costs to sectors, companies, and Member States** (public authorities) to implement measures aiming to address any exceedance of EQS and achieve good chemical status. The actors subject to these costs may vary and in some cases the costs may fall upon the taxpayer (e.g. remediation of contaminated sites).
- **Costs to consumers** – the costs of mitigation measures implemented by different sectors (including water industry) may be passed on to consumers in the form of higher prices of products and services.
- **Indirect costs** stemming from the raised profile of the substance after addition to the priority substance list. As highlighted in Section 6, the WFD and EQSD sit within a wider chemicals acquis which forms the EU policy landscape for managing chemicals and environmental protections. Addition of substances to the priority substance list could add further weight to the need for substitution and therefore to control releases at source there may be additional costs for substitution / amendment of processes to avoid or minimise emissions. These costs are usually significant and difficult to untangle within a wider policy landscape. The dynamic baseline will be key to helping understand what costs or proportion of costs could be attributed to the PS listing to help achieve good chemical status.
- **Administrative cost burden** - costs to Member State Competent Authorities (MSCAs) and Environmental Agencies in conducting monitoring, analysis, and reporting of any new priority substances. In terms of reporting under the River Basin Management Plans, this would extend to inventory development for key pressures and planning for PoMs.

Beyond these different categories of economic costs, it is also important to stress that how and where costs manifest will depend on the extent of any exceedances of the proposed EQS (i.e. the distance to target) and the extent to which existing actions already mitigate any exceedance, i.e. it is possible that existing PoMs may already have some beneficial effects, which could be further maximised without incurring excessive costs.

Different categories of candidate substances (pharmaceuticals, pesticides/biocides, metals, and industrial chemicals) are anticipated to face different issues in terms of cost impacts. A summary of the costs which could accrue under different types of emission reduction measure are discussed further below.

Pharmaceuticals

Option 1 would apply to the following pharmaceuticals: estrone (E1), 17-beta-estradiol (E2), 17-alpha-ethinyl-estradiol (EE2), Azithromycin, Erythromycin, Clarithromycin, Diclofenac, Carbamazepine, Ibuprofen.

The distance to target for these pharmaceuticals has been assessed as:

- Large - Ethylestradiol (EE2), Diclofenac, Carbamazepine
- Medium - Estrone (E1), Beta estradiol (E2), Azithromycin, Ibuprofen
- Small – Clarithromycin, Erythromycin.

Source control:

Table 8-7 highlights that the major pathways to environment are primarily via wastewater treatment works. This can be during manufacture (assuming that production sites will have pre-treatment as part of environmental permitting) or during application. For the latter case this can be direct releases to wastewater systems from improper disposal of expired medications washed to sewer and rinsing of medicine bottles. It can also relate to releases of unmetabolized medicines in excreta.

Source control to prevent the release of these substances to the wastewater system can therefore take one of two forms or a combination of both. Firstly, a **restriction/reduction in the use** of candidate pharmaceuticals within the human population (which would subsequently lead to a reduction in production). This would have a direct impact on use and releases to sewer, and where such substances are bioavailable could have a direct impact on ambient concentrations in surface water environments within a short period of time. Secondly, **improved management of unused, expired medicines** / medicine containers to prevent the substance entering wastewater systems and/or landfills.

Restricted / reduced use of pharmaceuticals

Within the pharmaceuticals category, reduced demand or production will incur costs to manufacturers due to reduced sales, unless producers switch to manufacturing alternatives.

Reducing the demand or restricting the production of pharmaceuticals will lead to an increase in demand for alternatives that fill a similar function to the original substance. For the pharmaceuticals, an illustrative list of potential alternatives is presented in Table 8-7. Where the information was available, data on the average costs of a prescription for each pharmaceutical has been supplied. Note, it is not possible to extract information on the size of each prescription. Furthermore, there will be differences in the typical effectiveness of each substance. As a result, the total cost of treating a given condition using either the original pharmaceutical or the alternative will vary from the values given in Table 8-5.

Note that for naturally produced substances (E1 and E2) a restriction/reduction in use of synthetic hormone will have a more limited impact on releases than those oestrogenic substances (EE2) which are wholly manmade. Equally for some substances (primarily the macrolide antibiotics) there are very few alternatives (often one candidate substance being replaced by other candidate substances). This may reflect how realistic source control via reduced use is as a practical measure.

Table 8-5 Pharmaceutical substances, potential alternatives, and the costs of each[175]

Original substance	Cost per prescription of substance (EUR)*	Alternative substance	Cost per prescription of alternative (EUR)*
Estrone (E1)		Tibolone	18.06

[175] All alternatives for E1, E2, EE2 taken from: https://www.nhs.uk/conditions/hormone-replacement-therapy-hrt/alternatives/;
All alternatives for Azithromycin, clarithromycin, and erythromycin taken from: https://bnf.nice.org.uk/treatment-summary/macrolides.html;
All Carbamazepine alternatives taken from: https://www.epilepsy.com/article/2014/3/summary-antiepileptic-drugs;
All alternatives for Diclofenac and ibuprofen taken from: https://www.nhs.uk/conditions/nsaids/;

Original substance	Cost per prescription of substance (EUR)*	Alternative substance	Cost per prescription of alternative (EUR)*
Estrone (E1)		Clonidine	23.29
Estrone (E1)		Antidepressants (to treat psychological component)	
Estrone (E1)		Lifestyle changes	
Estrone (E1)		Bioidentical or "natural" hormones	
Estrone (E1)		Complementary therapy	
17-Beta estradiol (E2)	9.87	Tibolone	18.06
17-Beta estradiol (E2)		Clonidine	23.29
17-Beta estradiol (E2)		Sertraline (example of antidepressant to treat psychological component)	10.42
17-Beta estradiol (E2)		Lifestyle changes	
17-Beta estradiol (E2)		Bioidentical or "natural" hormones	
17-Beta estradiol (E2)		Complementary therapy	
Ethylestradiol (EE2)		17-Beta estradiol (E2)	9.87
Ethylestradiol (EE2)		Contraceptive devices	13.43
Azithromycin	13.75	Clarithromycin	3.99
Azithromycin		Erythromycin	33.02
Clarithromycin	3.99	Azithromycin	13.75
Clarithromycin		Erythromycin	33.02
Erythromycin	33.02	Azithromycin	13.75
Erythromycin		Clarithromycin	3.99
Carbamazepine	7.45	Phenytoin	23.40
Carbamazepine		Phenobarbital	28.74
Carbamazepine		Oxcarbazepine	33.92
Carbamazepine		Gabapentin	6.33
Carbamazepine		Pregabalin	4.36
Carbamazepine		Lacosamide	102.18
Carbamazepine		Vigabatrin	66.65
Diclofenac	11.93	Ibuprofen	8.93
Diclofenac		Naproxen	6.81
Diclofenac		Celecoxib	4.19
Diclofenac		Mefenamic acid	41.66
Diclofenac		Etoricoxib	7.40
Diclofenac		Indometacin	5.57
Diclofenac		Aspirin	4.00

Original substance	Cost per prescription of substance (EUR)*	Alternative substance	Cost per prescription of alternative (EUR)*
Ibuprofen	8.93	Naproxen	
Ibuprofen		Diclofenac	11.93
Ibuprofen		Celecoxib	4.19
Ibuprofen		Mefenamic acid	41.66
Ibuprofen		Etoricoxib	7.40
Ibuprofen		Indomethacin	
Ibuprofen		Aspirin	4.00

* Costs are 2021 values and converted from GBP using an average of 1 GBP = 1.15 EUR over period from 2 January 2020 to 31 December 2021[176].

** All alternatives for E1, E2, EE2 taken from:

It should be noted that the cost differential between candidate pharmaceuticals and their alternatives would not be the only cost incurred during substitution of substances. There would also be technical challenges related to manufacturing and supply chains (increasing supply of alternatives), as well as technical issues related to the prescription of alternatives. The latter could occur as general practitioners might be unwilling to prescribe alternatives unless the efficacy of the alternative can be shown to be as good as the original pharmaceutical. There may also be a reluctance to shift towards alternatives for certain substances if the alternative offers a reduced possibility of generic substitution (the substitution of a branded product for an unbranded one with exactly the same chemical makeup) as this would prohibit further cost-saving steps.

It is also possible that in specific cases it may not be possible to substitute one pharmaceutical for another due to medical reasons (e.g. adverse side-effects). This reflects the need to assess each patient on an individual basis.

Improved management of unused, expired medicines / medicine containers

Table 8-4 identifies wastewater treatment works as a major pathway to surface water. Aside from releases to the wastewater system from unmetabolized pharmaceuticals in excreta, another major source is the improper disposal of expired medicines and washing of medicine bottles.

One of the most common source control measures identified for the pharmaceutical substances in this case is for improved “Take-back schemes for pharmacies/hospitals”. Take back schemes for unused/ expired medicines are required under the Directive 2004/27/EC. In France, a company known as ‘Cyclamed’ coordinates the collection of pharmaceuticals as part of an EPR scheme for pharmaceutical products. Cyclamed coordinates partnerships between more than 21,000 pharmacies, 200 distributors and 190 laboratories and collects approximately 62% of the unused medication. This corresponds with a total collected volume of unused pharmaceuticals of approximately 10,500 tonnes per year. This total cost of the system is approximately EUR 10 million which is derived from the contribution of EUR 0.0032 per medication box (VAT not included) by producers. Half of this cost comes from waste

[176] https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-gbp.en.html

disposal (250 EUR/tonne), storage and transport. This cost of waste disposal includes the cost of incineration (120 EUR/tonne). Collection boxes are given to pharmacies and the costs associated with the procurement of these boxes accounts for approximately a quarter of the total costs. Communication between Cyclamed, pharmacies, distributors, and laboratories accounts for approximately 10% of total costs and management accounts for approximately 5%. The remaining costs are associated with the establishment of studies, the conducting of research and other miscellaneous costs[177].

Pathway disruption:

Pathway disruption is the second major category of measures. While source control attempts to intervene at the point of manufacture and use, this category relates to the use of physical barriers in the environment to prevent the egress of chemicals and other materials reaching surface water.

For pharmaceuticals, Table 8-8 identifies run-off from field as a secondary more minor pathway, but it will still be important in the case of farmed animals which allowed to graze. The issue here relates to excreta reaching surface water, either from direct excretion or indirectly via run-off. This further recognises that two of the oestrogenic candidate substances are naturally produced by mammals, while the other pharmaceuticals may be present as unmetabolized substances in excreta.

Table 8-6, provides some example costs of key technologies that might be selected. While these costs are relatively low, based on the distance to target and the scale of implementation needed for individual substances the cost multipliers can be significant. For example, based on Eurostat the pastoral land in the EU27 amounts to 59 million hectares of land. Assuming possible diffuse emissions of pharmaceuticals (particularly estrogens) from excreta of farmed animals, even a low percentage of pastoral land at risk of run-off to surface water would equate to hundreds of thousands of hectares requiring some kind of physical barrier, being either buffer strips, constructed wetlands or additional fencing. Many participants in the stakeholder workshop indicated that the use of physical barriers such as buffer strips is not at saturation level across the EU and that there is a lot more than can be done.

However, issues related to training/expertise, difference in farming models, and possible lack of advisory services were raised. The respondents at the workshop also highlighted that some Member States may have a higher density of rivers and waterways adjacent to farmland than others, highlighting that the costs may be applied unevenly across the EU[178].

Table 8-6 Example costs for physical barriers[179] for pharmaceuticals

Technology	Cost
Buffer strips	€160 per hectare
Constructed wetland	€43.7 per m^3 (assume 1 metre depth)
Fencing to prevent livestock near watercourses	€6 per metre

[177] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC1106(01)&rid=2
[178] EQSD Workshop – 18 March 2022
[179] Values derived from the 2012 Impact Assessment of the review of Priority Substances and amended for inflation

The use of buffer strips was identified as being a potential measure for reducing the entry of estrone (E1) and 17-beta estradiol (E2) into the environment. Both are produced naturally by livestock and in the European Union and the United States, the annual estrogen discharge by livestock is 83,000 kg/yr which is more than double the discharge from humans[180].
Assuming as a worst case scenario that a maximum of 5% of all pastoral farmland required some form of barrier (buffer strip / additional fencing), the costs of such barriers has been calculated in Table 8-7, to provide indicative orders of magnitude for the EU27.

Table 8-7 Total estimated costs for physical barrier measures for pharmaceuticals

Measure	Cost (as € per hectare)	Total hectares (assuming maximum of 5% EU stock)	Total cost (€)
Buffer strips	160	2,950,000	472 million (per annum)
Additional fencing	€6 per m, equivalent to €2,400 per hectare	2,950,000	7 billion (one-off)

Note that aside from the economic costs of implementing such physical barriers to disrupt the pathway to surface water, there will also be societal and environmental costs. In the case of fencing, this includes impacts from sourcing and transporting timber to site. Sustainably managed forests should make the timber carbon neutral, but the processing and transport of timber will accumulate carbon emissions from use of energy and fossil fuels. Also note the need for timber treatments to protect fencing used in outdoor wet conditions, which will include the use of chemical biocides, and this in itself may present issues for protecting water quality.

End of pipe:

For pharmaceuticals end-of-pipe treatment is likely to be an important part of the overall package of measures, particularly given their clear societal and humanitarian benefit which to an extent may limit source control options. Section 8.2.2 highlighted that the recent fitness check and options appraisal for revision of the Urban Wastewater Treatment Directive has looked at the need to implement advanced (quaternary) treatment to manage micro-pollutant loads. The study completed by the JRC looked at three overall scenarios (reproduced in Table 8-8, below).

Table 8-8 Scenarios used within the options appraisal for revision of the UWWTD[181]

Options	Costs (Millions €/year)	Toxic load avoided (p.e.)
1. Low ambition – all plants >100k p.e.	841	59.2
2. All plants >100k p.e. + plants 10 k to 100k in risk areas	1,185	68.2
3. High ambition – all plants >10k p.e.	2,652	103.4

*Costs based on amortisation over 30 years.

180 Adeel et al, 2017, 'Environmental impact of estrogens on human, animal and plant life: A critical review', Environment International vol 99
181 Pistocchi et al, 2022, 'treatment of micro-pollutants in wastewater: balancing effectiveness, costs, and implications, JRC report on behalf of the European Commission.

The proposals to amend the UWWTD include a phased implementation for advanced treatment technologies which fall outside the temporal scope of the dynamic baseline. However, to maintain continuity and avoid double counting of costs the costs associated with upgrade of wastewater treatment works would fall under the purview of the urban wastewater treatment directive and are not further discussed here.

While this is the case it does not preclude further analysis for identification of treatment technologies, efficacy, or unit costs in the context of individual wastewater treatment (e.g. at manufacturing sites, hot spots such as hospitals, care homes etc.). Data on the unit cost of different advanced wastewater technologies (standardised into costs as population equivalent per annum) and efficacy against specific named technologies were collected for:

- Granulated activated carbon (GAC)
- Powdered activated carbon (PAC)
- Ozonation
- Reverse osmosis
- Nanofiltration
- UV based technologies (including UV combined with catalysts)
- Membrane bioreactors (MBR).

The following method to select the most cost-effective technology has then been applied: The cheapest option is analysed first if the efficacy of this option is at or above 75% it can be applied. If the efficacy is below 75% the next cheapest option is analysed in the same fashion until a suitable cost/efficacy combination is identified. For technologies with the same or similar unit price it is assumed that the technology with the higher efficacy is selected (i.e., the most cost-effective). Note that this analysis does not consider the site-specific situation or any local elements (e.g. existing architecture, land-space, availability of technology regionally/nationally) which might affect selection. The analysis also does not consider the possibility of combined suites of technologies. Note the JRC report comments that GAC, PAC, and ozonation looked like the best options, either as standalone or combined.
The analysis here is intended to provide steer on which substances are likely to require more labour intensive /costly technologies to suitably manage the destruction and removal of pharmaceuticals before release. Table 8-9 provides the results of this analysis, with some further commentary after the table.

Table 8-9 Most cost-effective end-of-pipe measures by pharmaceutical substance

Substance	Measure	Cost (as € per population equivalent, per annum)	Source of cost data	Efficacy (%)	Source of efficiency data
Estrone (E1)	WWTWs - Ozonation	10	[1]	90 -100	[3]
17-beta estradiol (E2)	WWTWs - Ozonation	10	[1]	90 - 100	[4]
Ethinylestradiol (EE2)	WWTWs - Reverse Osmosis	20	[2]	90 - 100	[5]
Diclofenac	WWTWs - Ozonation	10	[1]	90 - 100	[6]
Azithromycin	WWTWs - Ozonation	10	[1]	90 - 100	[7]
Clarithromycin	WWTWs - Ozonation	10	[1]	80 - 100	[7]
Erythromycin	WWTWs - Ozonation	10	[1]	80 - 100	[8]
Carbamazepine	WWTWs - Ozonation	10	[1]	90 - 100	[9]
Ibuprofen	WWTWs - Nanofiltration	20	[2]	90 - 100	[10]

* all costs are in EU27 in Euros annually - for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

Costs were converted to EUR and annualised

[1] Unpublished JRC data

[2] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/CWW_Bref_2016_published.pdf

[3] https://iwaponline.com/wst/article-abstract/70/1/70/18424/A-pilot-scale-comparison-of-advanced-oxidation?redirectedFrom=PDF

[4] https://iwaponline.com/wst/article-abstract/70/1/70/18424/A-pilot-scale-comparison-of-advanced-oxidation?redirectedFrom=PDF

https://link.springer.com/article/10.1007/s11356-016-6503-x/tables/9

[5] https://www.mdpi.com/2413-4155/3/1/11/htm

[6] https://link.springer.com/article/10.1007/s11356-016-6503-x/tables/9

https://www.hindawi.com/journals/bmri/2013/325806/tab1/

[7] https://www.eeer.org/journal/view.php?number=1273

https://www.mdpi.com/2073-4441/12/1/102/pdf

[8] https://www.mdpi.com/2073-4441/12/1/102/pdf

https://www.nature.com/articles/s41545-020-00087-x#Tab4

[9] https://www.eeer.org/journal/view.php?number=1273

https://www.mdpi.com/2073-4441/10/2/107/htm

http://randd.defra.gov.uk/Document.aspx?Document=WT02046_6995_FRP.pdf

https://jhsss.sums.ac.ir/article_46222_96b48e27608049e528607d14f5c8cad7.pdf

[10] http://randd.defra.gov.uk/Document.aspx?Document=WT02046_6995_FRP.pdf

Based on the review of technologies ozonation is the cheapest advanced wastewater technology identified and it has a high level of efficacy against the vast majority of pharmaceutical substances. The efficacy of ozonation for EE2 and ibuprofen was 60% and 50% respectively, hence why that technology was rejected, and subsequent technologies reviewed. The JRC study does make a comment that a combination of ozonation and sand filter could be a useful way to boost efficacy and therefore it could assist with these two substances in particular. However, as a more general point, ozonation appears to be an effective tool to help manage pharmaceuticals at end-of-pipe consistently as a group (see further discussion under Option 2).

While Ozonation represents the cheapest of the advanced wastewater technologies identified economically (capital costs and running costs), it is also important to consider the environmental and societal costs. Ozonation requires the manufacture of ozone (O_3) usually at site of use, which is produced through dielectric assemblies and manipulation of oxygen (O_2). Much of the costs identified relate to the high energy demands in producing ozone for use within the ozonation process. Realistically where much of the EU's energy production still relies on fossil fuels, this could represent a significant addition to CO2 emissions from energy production. Equally, Ozone is an irritant gas, which is corrosive to many metals and explosive in the right air/gas/ignition settings. This means it requires careful management and specialist equipment, with site-specific issues being key to its viable application. The technology also produces waste products that would need to be managed incurring additional costs.

Natural attenuation and monitoring (inc. dredging)

Not applicable to pharmaceuticals.

Summary

Based on the distance to target and measures identified the likely scale of the economic, environmental, and societal impacts for the candidate pharmaceutical substances has been assessed. A clear theme throughout is the clear societal and humanitarian benefits of pharmaceuticals, not only directly to human health, but the role they play within agriculture and domestic veterinary settings. Based on the feedback from the second study workshop (held in March 2022), it was clear that **mixture of source control and end-of-pipe measures** are likely to be needed as a package. The use of pathway disruption for agricultural settings is likely also to be important.

Based on the distance to target, EE2, diclofenac and carbamazepine were identified as having a large 'gap' to achieving compliance. For diclofenac and carbamazepine, a range of alternatives exist, and the end-of-pipe options look reasonably promising with ozonation effective for both. EE2 is more problematic with fewer options and more expensive end-of-pipe treatment. The loss of EE2 from the market is also likely to have societal impacts given its use in the contraceptive pill, HRT, and other hormone treatments. Therefore, this (**EE2**) **may pose the most challenging substance to manage** within the pharmaceutical set. Conversely, clarithromycin and erythromycin were identified as having a small distance to target. Options for source control are very limited, given the limited number of in-use antibiotics available. However, all of the macrolide antibiotics respond well to ozonation as an end-of-pipe treatment. Future implementation of advanced treatment under the revised UWWT Directive (baseline) would therefore be key to achieving compliance.

The remaining substances (E1, E2, Azithromycin, and Ibuprofen) all have a medium sized 'gap' to reach recommended surface water quality targets. Based on this set **ibuprofen was identified as challenging** given its increasing use and reduced controls as an 'over the counter' medicine compared to prescription medicines. However, the measures identified suggest a range of alternative medicines exist and there could be scope to manage this pharmaceutical more tightly at source, recognising the increased cost of the alternatives and societal impacts as a result. End-of-pipe options looked more challenging/costly, but site-specific issues will also affect technology selection.

Pesticides and biocides

Option 1 would apply to the following pesticides/biocides: Nicosulfuron, Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam, Bifenthrin, Esfenvalerate, Deltamethrin, Permethrin, Glyphosate, Triclosan.

The distance to target for these pesticides and biocides has been assessed as:

- Large - Bifenthrin, Esfenvalerate, Deltamethrin, Permethrin, Glyphosate
- Medium - Imidacloprid, Triclosan
- Small – Nicosulfuron, Acetamiprid, Clothianidin, Thiacloprid, Thiamethoxam.

Source control:

For pesticides and biocides, the best approach for limiting emissions to environment (and therefore environmental concentrations) is to **restrict use** in specific settings or **ban use entirely** (assuming priority hazardous substance status). This poses the question of what alternatives might be available instead. "Appendix G Possible alternatives to the candidate priority/priority hazardous substances" provides a non-exhaustive analysis of alternatives to pesticides/biocides identified as candidates for inclusion on the EQS list.

Where many alternatives exist, it should be possible to identify alternatives with similar efficacy and cost. Therefore, a restriction / ban could be used as a viable measure with the price differential affecting farmers, vets, society, and manufacturers of pesticides/biocides. In the cases where very few or no alternatives exist, a restriction or full ban would likely result in reduced crop yield or increased incidence of ill health for farmed animals and pets (due to the lack of suitable alternatives), at least in the short to medium term. This poses different questions on costs and the choice of practical measures.

Using an online marketplace[182] to establish estimates for the wholesale cost of the relevant pesticides and their alternatives, and the application rates of these substances, it was possible to derive estimates for the costs per hectare of application associated with each (able 8-10). It should be noted that the costs were obtained from estimations based on sales prices of bulk chemicals. The values provided should therefore be viewed with this in mind. In several instances it was not possible to derive a cost per hectare due to gaps in the available data. Furthermore, it was noted that application of biocides varies considerably

[182] https://www.made-in-china.com/

due to the variety of uses of the substances e.g. sprayed over specific areas, painted onto particular structures, used for spot-on treatments, or added to soaps. As a result, to ensure comparability and the application rates per hectare have been used as the basis for comparison.

Within the pesticides category, reduced demand or production will incur costs to manufacturers due to reduced sales, unless producers are able to switch to manufacturing alternatives. These costs may be of low impact, for example, neonicotinoids are already banned in the EU for use in PPP aside from emergency authorisations (e.g. at least 67 emergency authorisations for imidacloprid, clothianidin, and thiamethoxam have been issued since 2018[183]) which are being assessed by EFSA[184]. Some pyrethroids are more widely used, e.g. pesticidal products containing deltamethrin are authorised in all MS and esfenvalerate is authorised in 21 MS.

Based on Table 8-12, where alternatives exist, it can be seen that the differences in cost between the original substances and their alternatives could vary drastically. In several instances, the cost of the alternatives per hectare of treatment appears to be lower than the cost of the original pesticide/biocide. By contrast, there are instances where the cost of alternatives far exceeds the cost of the original substance e.g. etofenprox and spinosad as alternatives for acetamiprid appear to be more costly than the original, whereas-Table 8-10 are either already priority substances or candidates for addition to the priority substance list. Namely, cypermethrin, glyphosate, and pyrethroids.

[183] https://unearthed.greenpeace.org/2020/07/08/bees-neonicotinoids-bayer-syngenta-eu-ban-loophole/
[184] https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/neonicotinoids_en

Table 8-10 Pesticides, their alternatives, and the costs

Candidate priority substance (Pesticide type in brackets: H:Herbicide; F:Fungicide: I:Insecticide)	Alternative substance	**Candidate priority substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative is a priority substance or candidate priority substance (candidates noted by an asterisk)**
Acetamiprid (I)	Avermectin	3.43	4.58	
Acetamiprid (I)	Chlorantraniliprole	3.43	2403.19	
Acetamiprid (I)	Copper compounds	3.43		
Acetamiprid (I)	Diacyl-hydrazine	3.43		
Acetamiprid (I)	Diamide	3.43		
Acetamiprid (I)	Etofenprox	3.43	617.96	
Acetamiprid (I)	Flonicamid	3.43	2.75	
Acetamiprid (I)	Fludioxonil	3.43	0.03	
Acetamiprid (I)	Pyrethroids	3.43		PS*
Acetamiprid (I)	Spinosad	3.43	1669.87	
Acetamiprid (I)	Spirotetramat	3.43	0.33	
Acetamiprid (I)	Sulfur	3.43		
Acetamiprid (I)	Tebufenozide	3.43	1.54	
Clothianidin (I)	Pyriproxyfen	0.82	0.55	
Imidacloprid (I)	Pyrethroids	0.27		PS*
Thiacloprid (I)	See alternatives to acetamiprid	0.61		
Thiamethoxam (I)	No alternatives identified	0.92		
Bifenthrin (I)	Cypermethrin	0.24	0.07	PS

Candidate priority substance (Pesticide type in brackets: H:Herbicide; F:Fungicide: I:Insecticide)	Alternative substance	**Candidate priority substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative is a priority substance or candidate priority substance (candidates noted by an asterisk)**
Esfenvalerate (I)	Lambda-cyhalothrin		0.03	
Deltamethrin (I)	Lambda-cyhalothrin	0.06	0.03	
Deltamethrin (I)	Pirimicarb	0.06	0.33	
Deltamethrin (I)	Pirimiphos-methyl	0.06		
Permethrin (I)	Cypermethrin		0.07	PS
Nicosulfuron (H)	Glyphosate	0.27	1.53	PS*
Nicosulfuron (H)	Mesotrione	0.27	0.62	
Nicosulfuron (H)	Tembotrione	0.27	0.92	
Glyphosate (H)	2,4 D	1.53	16.02	
Glyphosate (H)	Bentazone	1.53	2.99	
Glyphosate (H)	Bifenox	1.53	3.43	PS
Glyphosate (H)	Caprylic acid	1.53	64.94	
Glyphosate (H)	Chlorotoluron	1.53	4.12	
Glyphosate (H)	Chlorpropham	1.53	10.99	
Glyphosate (H)	Clethodim	1.53	0.45	
Glyphosate (H)	Dicamba	1.53	0.77	
Glyphosate (H)	Diflufenican	1.53	1.65	
Glyphosate (H)	Florasulam	1.53	0.02	
Glyphosate (H)	Isoxaben	1.53		
Glyphosate (H)	MCPA	1.53	41.20	
Glyphosate (H)	Metribuzin	1.53	0.64	

Candidate priority substance (Pesticide type in brackets: H:Herbicide; F:Fungicide: I:Insecticide)	Alternative substance	**Candidate priority substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative substance** Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	**Alternative is a priority substance or candidate priority substance (candidates noted by an asterisk)**
Glyphosate (H)	Oxyfluorfen	1.53	0.27	
Glyphosate (H)	Penoxsulam	1.53	0.00	
Glyphosate (H)	Propaquizafop	1.53	0.37	
Glyphosate (H)	Propyzamide	1.53	3.07	
Triclosan (F)	Benzalkonium chloride			
Triclosan (F)	Benzethonium chloride			
Triclosan (F)	Chlorhexidine			
Triclosan (F)	Chloroxylenol			

Primarily, the analysis shows that those substances used as **herbicides and fungicides have sufficient alternatives** and restriction in use could be a viable option. Use of alternatives would be associated with a potentially higher price of the alternative, and economic impacts for pesticide manufacturers, distributors, and agronomists (assuming that producers could switch to make more of the less harmful alternative products).

For those substances that act as **insecticides / biocides with insecticide action** (primarily the neonicotinoids and pyrethroids) **more limited numbers of alternatives seem to exist**. As a further comment, approvals for most of the neonicotinoids as pesticides have already been removed, but more than 20 emergency authorisations have been granted in the last three years by Member States. EU guidance on the conditions to grant emergency authorisations and submission of applications is available[185]. Granted authorisations can be found in the EU Plant Protection Products Emergency Authorisations System (PPEAS)[186]. Also, EFSA provides technical assistance to the European Commission in examining the emergency authorisation requests from Member States for plant protection products.

Further comments raised during the second stakeholder workshop held in March 2022 also highlighted concerns that a narrowing of available pesticide options through bans/restrictions can accelerate pesticide resistance within pest species and potentially create significant environmental problems and pressures for food security.

The analysis completed and presented in Table 8-12, does however, indicate that for a number of substances there might still be some options to further reduce emissions at source, through either restrictions or encouraging substitution to alternatives (e.g. via the EU 'Sustainable Use of Pesticides' Directive). In particular, the EQS dossier highlighted the very wide use of glyphosate and concerns for potential risks to drinking water. Where a wide range of alternatives exist, it does suggest that there is scope to reduce use and subsequently emissions, with the main impacts being economic and unit price /commercial availability of the alternatives at regional/national level. For other pesticides with very few alternatives, a mixture of measures including to pathway disruption and/or end-of-pipe solutions are likely needed.

Pathway disruption

Table 8-4 indicated that for pesticides in particular a major pathway to environment is via run-off from fields. Spray-drift is identified as a minor secondary pathway. Assuming that good farming practices should already limit the risks associated with spray drift from use of pesticides in boom-sprayers, back-pack sprayers, and crop dusting.

Participants in the workshop indicated that the use of physical barriers is not at saturation level and that there is a lot more than can be done. However, issues related to training/expertise, difference in farming models, and possible lack of advisory services were raised. Calculations have been undertaken to help derive indicative (orders of magnitude) costs attributed to the application of pathway disruption for pesticides/biocides using physical barriers (see Table 8-11). The footnote to the table provides further details on how these calculations have been made, but it should be noted that there is a high level of

[185] https://ec.europa.eu/food/system/files/2021-03/pesticides_aas_guidance_wd_emergency_authorisations_article53_post-210301.pdf
[186] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home

uncertainty in the estimates, and the values in the table should be used for comparative purposes and orders of magnitude only. In line with the polluter pays principle, it is assumed that these costs would be borne by farmers either through implementation of barriers on the land (e.g. buffer strips), or through additional activities relating to biocides (capture and management of wastes contaminated with biocides).

From these estimations, it appears that the use of physical barriers for the treatment of glyphosate would come at the highest cost, but this reflects its very high usage rates across the EU. A possible compromise position could be a combination of source control (reduce use through greater application of alternatives) and reduced need for pathway disruption options.

Table 8-11 Pesticides for which a physical barrier was identified as being beneficial, and associated costs for this measure[187]

Substance	Measure	Total one off cost (€), million*
Acetamiprid	Physical barriers to surface water buffer strips (see notes to right)	1.6
Clothianidin	Physical barriers to surface water - use as biocide in chicken co-ops. Additional emission controls for farm waste (see notes to right)	162
Imidacloprid	Physical barriers to surface water - use as biocide in chicken co-ops. Additional emission controls for farm waste (see notes to right)	162
Nicosulfuron	Physical barriers - buffer strips	12.8
Deltamethrin	Physical barriers - additional controls and treatment for farmed animal use	184.6
Esfenvalerate	Physical barriers to surface water buffer strips (see notes to right)	No data
Glyphosate	Physical barriers to surface water buffer strips (see notes to right)	284.7

End of pipe:

Table 8-4 highlights that for pesticides the major pathways to environment relate to manufacture and use, including run-off during or shortly after application. For pesticides used in agricultural settings the pathway via end of pipe is less relevant, although use of pesticides in amenity areas with hard surfaces that allow wash-off/run-off to storm drains will also be important. Conversely, biocides, can be used both in outdoor settings (e.g.

[187] Cost calculations: buffer strips: data has been gathered on tonnes of pesticide used per annum as well as application rates per hectare. Based on previous section for pharmaceuticals again assume that the vast majority of arable land is away from rivers and water courses with limited risk of run-off. On that basis assume that 10% of arable land is at risk as a worst-case scenario, and then apply buffer strips at €160 per hectare. Biocidal use in farms (chicken coops and stables), data has been gathered from Eurostat for numbers of animals, and excretion rates 1,000 chickens produce 65 tonnes of litter per annum. Assume all litter and wastes will need to be retained and incinerated. All washings retained and sent for further treatment (e.g. ozonation/GAC/PAC etc) and not washed directly to drain, costs per dm^3 applied.

sheep-dips), and indoor settings (stables, coops, domestic homes, work-places, etc). Therefore, for biocidal uses, particularly within indoor settings, wash-off or rinsing to drains during cleaning and maintenance is an issue.

As indicated in the previous section, work has already been completed by the JRC to support the revision of the UWWTD and further implementation of quaternary treatment technologies, but this does not preclude analysis of technology selection, unit prices, and efficacies for specific substances. The same methodology outlined in the previous sub-section for pharmaceuticals has been used to help identify options for those substances with biocidal uses. Table 8-12 provides these results, below.

Table 8-12 Most cost-effective end-of-pipe measures by substance (biocides only)

Substance	Measure	Cost (as € per population equivalent, per annum)	Efficacy (%)
Acetamiprid	WWTWs - GAC	26.2	99
Clothianidin	WWTWs - Ozonation	10	98
Imidacloprid	WWTWs - Ozonation	10	99
Thiamethoxam	WWTWs – GAC	26.2	99
Deltamethrin	WWTWs - Ozonation	10	90
Permethrin	WWTWs - PAC	32	83
Triclosan	WWTWs - Reverse Osmosis	20.7	90-100

* all costs are in EU27 in Euros annually - for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

The results presented in Table 8-14 indicate a range of different technologies may be needed. Whereas the previous subsection highlighted that the cheapest of the advanced technologies (ozonation) was largely effective against most pharmaceutical substances, biocides appear more problematic. While ozonation still looks effective against some biocides (clothianidin, imidacloprid, and deltamethrin), it is less effective against others. For acetamiprid Ozonation has an efficacy of 57%, and for triclosan less than 75%. Data on efficacy of ozonation for thiamethoxam and permethrin was not identified. For three of the biocides (acetamiprid, thiamethoxam, and permethrin) it was necessary to use the most expensive options (GAC/PAC) in order to reach suitable levels of efficacy.

For acetamiprid a range of alternatives exist (including other biocides), suggesting more bonus could be given to source control and less reliance on end-of-pipe solutions. For thiamethoxam and permethrin, far fewer alternative chemical options exist, suggesting that a combination of measures may be needed across MSs to limit the need for (on-site) end of pipe treatment. If this is not possible, the cost impacts for end of pipe treatment are likely to be substantial.

Natural attenuation and monitoring (incl. dredging):

The final category of measures relates to natural attenuation and monitoring. As a clarifying point some of the candidate priority substances no longer have any legal commercial use but are still noted to potentially exceed the recommended EQS. This is due to high persistence and residence time in the aquatic environment (particularly sediment and biota) of some substances, but also due to legacy issues such as **contaminated sites or use of remaining stocks** (noting that new use is banned).

Where there are no ongoing uses, intervention in the life-cycle is challenging, with direct intervention in the environment itself as the only option. This can include for example dredging, although this activity has its own issues (i.e., it is very costly, re-introduces chemicals to the water column, and creates ecosystem impacts for turbidity and particulates). For remaining stocks of in-use chemicals it could be possible to introduce amnesty campaigns or take-back campaigns. For the candidate PS that are pesticides this is less likely to be relevant.

The other issue relates to contaminated sites, which are likely to be highly site-specific on a Member State by Member State basis. Remediation of individual sites for ground contamination is high cost and complex in terms of handling generated materials and logistics. The section on groundwater (see section 8.3) provides further details on this. Given that new priority substances have 15 years to achieve good chemical status under the EQSD and WFD, for legacy substances that cannot be managed in other ways the best option may be to allow the environment to heal through natural attenuation, and to closely monitor the trends.

Possible impacts and measures for drinking water pesticide group standard:

Under the Drinking Water Directive (EU 2020/2184) a group standard is used for the protection of human health, which allows a maximum of 0.5 µg/l for pesticides as a total. Drinking water abstraction can be taken from both surface water and ground water sources, and therefore further consideration of potential impacts associated with the pesticide-based candidate priority substances is prudent. To complete this analysis the measured environmental concentrations (MEC) from the JRC dossiers have been used to assess likely surface water concentrations. The MEC data provides averaged concentrations in surface water by anonymised Member State across a time-range spanning from the early 2000s to 2019. To avoid any issues with trends over the longer range skewing the data, monitoring data from 2015 – 2019 (five years) has been used to derive an average of averages per pesticide substance. The candidate pesticides have then been further aggregated to develop total pesticide concentrations for surface water per Member State and as an EU27 total.

For the EU27 the aggregation of a Europe wide average concentration (i.e., the average concentration per annum per MS, for each year between 2015-2019 was used to derive a five year average per MS, and then the average across all EU27 MS) illustrates total pesticide concentrations of 4.83 µg/l. However, glyphosate accounts for 90% of this concentration. EU27 averaged concentrations are as follows:

- Neonicotinoids (combined) 0.07 µg/l
- Pyrethroids (Combined) 0.30 µg/l
- Nicosulfuron 0.02 µg/l
- Triclosan 0.04 µg/l
- Glyphosate 4.39 µg/l (average of 13 Member States who provided monitoring data). Two Member States have very high concentrations if these are treated as outliers, the average of the remaining 11 = 0.27 µg/l.

- Combined total of all candidate pesticide-based priority substances 4.83 µg/l (adjusted total minus the high glyphosate concentrations = 0.71 µg/l)

This suggests that of the pesticide-based candidate priority substances, glyphosate is the most problematic and likely to cause exceedances. Further analysis of the Member State data illustrates that for glyphosate a broad range of concentrations exist. The lowest five- year average concentration is 0.05 µg/l and the highest is 50 µg/l. The MEC data for glyphosate was provided by 13 Member States. Based on the five-year averaged data, 5 Member States are above 0.5 µg/l and 8 are below. In particular, two Member States have very high concentrations of 8 and 50 µg/l respectively. If these are treated as outliers, the averaged concentration of 11 Member States is 0.27 µg/l.

The EU average concentrations have been used to gap fill for Member States that provide monitoring data for some but not all of the candidate substances. For glyphosate the lower 0.27 µg/l has been used to gap fill where this data was missing from specific Member States (rather than the higher average based on all glyphosate data). Using this approach full data-sets were possible for 25 Member States, with 13 of the 25 exceeding the 0.5 µg/l limit.

The analysis presented here has been conducted in isolation for the pesticide-based candidate substances only. This notes that a number of other pesticides are already recognised priority substances. Data available from the European Environment Agency dashboards provides details of chemical status (i.e., good/poor) but not specific concentration data which is held at Member State level (often not in the public domain). This has meant a total analysis for all pesticides (existing and candidate) has not been possible.

A further comment is that where abstraction for drinking water takes place, further processing can be applied (such as carbon filtration, settling, boiling etc) which would reduce concentrations within drinking water. However, despite this being the case glyphosate in particular, and to a secondary degree pyrethroids would be the main causes for exceeding the drinking water standard. This would require further measures to help support compliance. The measures already detailed within this section should have significant impact for reduction of surface water concentrations. Additional measures may include tighter control on the use of glyphosate and pyrethroids in vulnerable zones, and potentially additional treatment of water post-abstraction. In particular carbon filtration, it is unclear to what extent this measure is already in use thereby avoiding additional costs.

Summary

The following substances were identified as having a relatively large distance to target, all of the pyrethroids (bifenthrin, esfenvalerate, deltamethrin, and permethrin) and glyphosate. For the **pyrethroid substances**, in particular, the highly toxic nature of the substance and therefore low EQS indicate issues in terms of both scale and magnitude of the gap, with the latter being critical. This would suggest **a full basket of measures at source control, pathway disruption and end-of-pipe may be needed**. The use of chemical alternatives for pyrethroids also looked very limited (often other pyrethroids), including cypermethrin (which is already a priority substance). In this case the issues may be both economic and societal. Workshop delegates already highlighted that restrictions / bans and narrowing available pesticide options may lead to increased pest resistance and potential impacts for crop yields, food security and food prices. The pyrethroid family of pesticides has evolved through successive generations since their first introduction in the 1960s, but their high efficacy means they are still widely used with more limited alternatives.

The distance to target for **Glyphosate** reflects the very low EQS which was selected because of concerns for risks to drinking water. Where glyphosate is one of the most widely used pesticides globally, the high volumes applied to land help validate the concerns raised in the EQS dossier. In this case a wide range of chemical alternatives exist, suggesting that a **combination of reduced use** (either through restriction or encouraging the adoption of alternatives) **along with pathway disruption** could successfully help achieve the recommended EQS. Therefore, the cost impacts may be less severe than for pyrethroids.

Imidacloprid and triclosan) were assessed as having a medium sized distance to target. For these two substances the primary issue relates their to use as a biocide and subsequent loss to sewer. While end-of-pipe options for imidacloprid (ozonation) is reasonably cost effective it looks more challenging for triclosan (reverse osmosis). An argument could be made for the societal benefits of veterinary use of imidacloprid and EPR to recover costs associated with end-of-pipe treatment. For triclosan the use is limited to medicated soaps and disinfectants, where more onus could be given to alternatives.

The following substances were assigned to the group with a small distance to target: nicosulfuron, acetamiprid, clothianidin, thiamethoxam, and thiacloprid. T**hiacloprid** no longer has any approved commercial uses, and so the **natural attenuation pathway** is likely to be favoured. For the remaining substances use is either heavily restricted already, or low-cost options at source control are available. The one possible exception is acetamiprid which would have very high end-of-pipe treatment costs. However, a range of alternatives exist, and therefore a restriction on use or control of wastes from biocidal application of acetamiprid are likely to be relevant.

Industrial substances

Option 1 would apply to the following industrial substance: PFAS, Bisphenol A (BPA).
The distance to target for PFAS and Bisphenol A (BPA) has been assessed as large.

Source control:

Bisphenol A (BPA)

The primary use of BPA (75% of all use) is in the manufacture of polycarbonate. In turn, polycarbonate is used in the manufacture of products such as building and construction materials, coatings (automotive/domestic appliances), sports equipment, medical and dental devices, electronic equipment, and food packaging materials. The second largest use (17% of all use) is in epoxy resins, which have applications within construction, particularly in conjunction with plastic pipework (both drinking water and wastewater). BPA is also used in products such as protective coatings (automotive), marine vessels and equipment, laminates, adhesives as well as water infrastructure and food packaging materials. Numerous other uses exist as well[188,189].

[188] Fischer, Benedikt., Milunov, Milos., Floredo, Yvonne., Hofbauer, Peter., Joas, Anke. 2014. “Final report to the Federal Environment Agency (Germany): Identification of relevant emission pathways to the environment and quantification of environmental exposure for Bisphenol A.” Project No. (FKZ) 360 01 063. Report No. (UBA-FB) 001933/E.

[189] HBM4EU policy brief (internal, not published), and references therein

Restrictions have already been implemented for some applications (thermal papers and use within plastics for babies' bottles and toys) but could be extended further to help limit emissions.

In 2016, the Commission decided that thermal paper (which was often used in receipts) must not contain BPA. As a result, from 2January 2020 BPA was not allowed to be placed on the market in thermal paper in a concentration equal to or greater than 0.02 % by weight. The estimated average yearly costs between 2019 and 2030 associated with this substitution and compliance were deemed to be €43m - 151m (or an average of €97m)[190].

Additionally, improved emission controls for BPA particularly for the manufacture of polycarbonate could limit losses to wastewater systems.

Per and polyfluorinated alkyl substances
PFAS represent another group of substances for which industry costs may be significant, especially as PFAS are used across a wide variety of products (e.g. textiles, fire-fighting foams, oil and gas sector applications, automotive, paper and pulp, electronics, aviation, healthcare, cosmetics, and personal care products). Part of the argument to date has been that the unique physical properties of PFAS (water and oil repellence) make them ideally suited to specific applications where they are potent even at low concentrations. These same physical properties are part of the reason that they represent quite such a significant risk to the environment and human health (i.e., very persistent, very mobile, potential for bioaccumulation, cause adverse effects).

Currently, five Member State authorities are preparing a restriction dossier covering all PFAS for all uses, subject to further discussion and identification of what exemptions might be justified. The restriction of use is already included within the dynamic baseline. However, the restriction would only provide controls on new manufacture and use. Existing products already in-use would be unaffected. Furthermore, given their very long-lived environmental footprint, this category of substances represents a sub-set within the overall potential additions. Namely, substances likely to present significant legacy issues even if intervention is tabled early in the life-cycle (prohibition on manufacture and use). Where such legacy issues are present, it poses challenges for Member State authorities to achieve the recommended EQS, in part because the 'polluter' may no longer exist/can easily be identified. In these cases, it is likely the taxpayer would have to support the costs of measures needed to help achieve the recommended EQS.

In terms of emissions to surface water and major pathways / sources. The highest priorities likely relate to fire-fighting foams (which are used in a wide and dispersive fashion), as well as applications which can provide significant losses directly to the wastewater system. In particularly this would cover home textiles, clothing, kitchenware, and electronics which emit contaminated dusts within the indoor environment which inevitably adhere to skin and clothing.

The 2022 Annex XV restriction report for the proposed restriction of PFASs in firefighting foams estimates that the ban may cost society €6.8 billion over a 30-year period (this cost was for the restriction on the export, placing on the market and use after use/sector-specific

[190] https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e?t=1613386316829

transitional periods). This is an average of €515 per kilogram of emission avoided. However, this report highlights that this value could be €3 billion as a minimum or as high as €17 billion due to the inherent uncertainties in the calculations. The cost to the EU is estimated at €390 million per year during the 30-year period using a 4% discount rate for an emission reduction of 440 tonnes per year.

The breakdown of estimated costs of this restriction per industrial sector are provided in Table 8-13.

Table 8-13 Estimated cost of restriction on placing on the market and use after use/sector-specific transitional periods (both including or excluding restrictions on export)

Sector/type of use	Estimated cost (NPV € over 30 years)
Seveso establishments	4.9 billion (2 to 13 billion)
Other industries	27 million (9 to 60 million)
Civil aviation	70 million (6 to 160 million)
Defence	45 million (3 to 100 million)
Municipal fire services	1.2 billion (0.6 to 3 billion)
Ready-to-use applications	7 million (0 to 15 million)
Marine applications	390 million (150 to 900 million)
Training and testing	130 million (0 to 310 million)
Total	**6.8 billion (3 to 17 billion)**

Although the costs associated with source control for candidate priority substances under this option are hard to determine, indicative values from other sources can be used to illustrate the costs involved.

The present study has analysed a range of source control measures which are most likely to be used in order to meet a recommended EQS. The most likely measures from this long-list are presented, along with the available cost estimates for the measures, in Table 8-14 for both BPA and PFAS.

Table 8-14 Industrial substances for which a source control measure was identified as being useful

Substance	Measure 1	Cost (EUR)*
BPA	Controls on use of BPA for manufacture of polycarbonate. Monitoring, abatement, and destruction	No data
BPA	Controls on BPA contaminated construction wastes - particularly epoxy resins	No data
PFAS	Remediation of all fire-fighting sites in the EU.	

		0.7-3 million per site.
PFAS	Take back schemes / incentives to replace home products (textiles, kitchenware, electronics, and clothing) that may contain PFAS to end emissions more quickly.	Millions per MS

Pathway disruption

Bisphenol A (BPA)

From the analysis of measures conducted within this study, it appears that the use of physical barriers to disrupt the pathway to environment could be an important intervention. The majority of BPA is used in the production of polycarbonate (a clear, durable, scratch resistant, plastic-like material). However, after production it is estimated that 0.01kg/tonne residual BPA remains trapped within the polycarbonate[191]. Use of polycarbonate as a coating within automotive settings, along with construction, would suggest that abrasion and atmospheric deposition could be a pathway (noting that this material would also constitute micro-plastics). Deposition onto hard surfaces such as roads and amenity areas, would highlight the possibility for run-off to storm drains and potentially the environment from CSOs during heavy rain events. A possible pathway disruption could be the **targeted use of gully-pots** to capture material before it's released.

Additionally, **landfill leachate** containing BPA could be an important source for both SW and GW. It has been highlighted that there are concerns on making the requirements too strict for landfills preventing them from operating in a sustainable fashion[192]. However, there was little with respect to the Landfill Directive under the dynamic baseline that appeared to impact this. The main issue would be better capture landfill leachate and improve wastewater treatment at industrial sites in the order of 246MT of leachate, equivalent to 4.8 million p.e. This study has identified, in general terms, that the use of physical barriers to control landfill leachate to surface waters would be most applicable to BPA. The estimated total cost for this has been provided in Table 8-17.

Per and polyfluorinated alkyl substances (PFAS)

The highly mobile nature of PFAS means it has the capacity to move between different environmental compartments (including migration via the terrestrial environment to surface water and deposition from atmosphere). The key pathways in this case relate to **contaminated sites** (mostly linked to former use of fire-fighting foam) and placing on the land of wastes that contain PFAS (either as **land spreading of sewage sludge** or **articles placed to landfill**). The POPs regulation already provides a low POP content threshold (above which the waste must be destroyed) for PFOS, with proposed thresholds for PFOA and PFHxS in discussion. However, where the current study looks at 24 PFAS species it recognises that many of these substances are not currently actively managed in the waste stream. Therefore, two measures are possible, firstly **better management of landfill leachate** (discussed above under BPA), and more active intervention and **separation of wastes within the end-of-life**

[191] UBA, 2014, ''Identification of relevant pathways to the environment and quantification of environmental exposure for Bisphenol A', report 41/2014'

[192] https://ec.europa.eu/environment/integration/research/newsalert/pdf/volume_leachate_environmental_impact_landfills_reduced_legacy_effects_remain_483na3_en.pdf

cycle. This would focus primarily on municipal waste (textiles, clothing, and kitchenware) and bulky waste (such as soft furnishings). To implement such an intervention would require significant amendment of the infrastructure for municipal waste, information campaigns, new sorting centres, and likely new hazardous waste streams requiring high temperature incineration. The nature and scale of how this would work in practice is likely country and region specific but would be expected to cost millions of euros per Member State.

Table 8-15 provides an overview of the measures identified.

Table 8-15 Example costs for physical barriers for industrial substances[193]

Technology	Cost
Further separation and handling of waste textiles and clothing likely to contain PFAS	Millions of euro per MS
Constructed wetland	€43.7 per m3 (assume 1 metre depth)
Gully pots to capture particles from run-off from road	€50 per gully-pot (assume spacing of 40-50m)
Physical barriers to surface improved controls for landfill leachate	€103.7 million*

* Costs are in EU27 in Euros annually - for large infrastructure measures costs are amortised (assuming 25-year asset lifetime)

End of pipe:

Table 8.-4 Table 8-4 identifies that wastewater treatment works will be a major pathway to environment for both BPA and PFAS. Using the same methodology previously detailed under the section for pharmaceuticals, preferred advanced treatment technologies, unit costs and efficacy have been identified. This again notes that the overall associated costs for upgrade of wastewater treatments works have been covered by the JRC study to support the revision of the UWWTD. Table 8-21 provides the results of this analysis.

Table 8-16 Most cost-effective end-of-pipe measures for BPA and PFAS

Substance	Measure	Cost (as € per population equivalent, per annum)	Source of cost data	Efficacy (%)	Source of efficiency data
BPA	WWTWs - Nanofiltration	20.7	[1]	75	[2]
PFAS	WWTWs - GAC	26.2	[1]	90	[3]

* all costs are in EU27 in Euros annually - for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

[1] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/CWW_Bref_2016_published.pdf

[2] https://link.springer.com/content/pdf/10.1007%2Fs13762-016-1056-6.pdf

193 Values derived from the 2012 Impact Assessment of the review of Priority Substances and amended for inflation

[3] https://www.epa.gov/system/files/documents/2021-09/multi-industry-pfas-study_preliminary-2021-report_508_2021.09.08.pdf

For PFAS the analysis illustrates that reverse osmosis (unit price of €20 per p.e. per year) is highly effective (>90%) against longer chain PFAS. However, the efficacy of the technology struggles to effectively treat shorter chain (<C6) PFAS species and works less well against low concentrations. Therefore, in order to provide a high level of effectiveness against all PFAS species it is necessary to revert to GAC, which is a more expensive option. Note that aside from the economic cost associated with using GAC there are also significant environmental costs. This includes the thermal treatment of raw carbon sources (coal, wood, coconut shells) to create activated carbon, the transport and logistics of supplying GAC to WWTWs. The energy intensive nature of reactivating spent GAC to remove chemicals using thermal treatments or chemical scrubbing so that GAC can be re-used. Note also where PFAS binds tightly to GAC reactivation may not be possible. Spent GAC is usually either incinerated as a fuel source or consigned to landfill[194]. All of these processes are likely to resource intensive and generate greenhouse gas emissions, which are less desirable.
For BPA only limited data was available on the efficacy of technologies, with nanofiltration coming up as the most effective choice. However, there is high uncertainty around this specific substance and other technologies may also provide a valuable choice.

Natural attenuation and monitoring (incl. dredging):

This category of measures is reserved for those cases where new / continuous use has ceased, but exceedances in the ambient environment still occur due to either legacy issues, high persistence of the substance or both. For BPA, where new and continuous use is ongoing measures under this group would be an inappropriate selection and more focus should be given to source control.

For PFAS the situation is more complex. Some PFAS species have now been banned, notably PFOS and PFOA, with restrictions in place for PFHxS. In the case of PFOS in particular ambient concentrations in the surface water environment have declined since use significantly declined in 2002. Although, PFAS are referred to as 'forever chemicals', with good reason. It is unclear whether decline in concentrations is more a reflection of PFOS moving through the environment to other compartments or degradation of PFOS itself.
For those PFAS species that are banned and no longer used, natural attenuation could be a possible measure, but realistically where good chemical status has to be achieved within 15 years, and given the very persistent nature of the chemicals, this is not a desirable approach and other measures should be used first.

Summary

Based on the distance to target, both BPA and PFAS are in the large gap category. In the latter case where the entry is proposed to cover 24 PFAS as PFOA-equivalents, the wide-spread use of PFAS across many applications represents a very significant challenge. The dynamic baseline already takes into account the REACH restriction on new use of PFAS, recognising that the discussions are still ongoing and realistically exemptions will be applied.

[194] Tarpani et al, 2018, 'Life cycle costs of advanced treatment techniques for wastewater reuse and resource recovery from sewage sludge', Journal of cleaner production vol 204.

However, for those articles already in use, no control or restriction will apply. The potential legacy issues and multiple pathways to environment mean that **a package of measures tackling source control, pathway disruption, and end-of-pipe treatment will be needed**. The likely cost impacts will be significant, and likely borne by consumers, tax-payers or under EPR through to manufacturers, but it can be expected that such costs will likely be passed on to consumers. The complexity of the issue and the high persistence of PFAS means that a range of novel measures will be needed (e.g. **take back schemes / incentives for general public to disposal of in-use stocks** more quicky, further **separation of waste** within the waste cycle, significant increase within high temperature incineration capacity), this sits alongside more conventional measures such as upgrades to WWTWs, improved landfill leachate systems, and management of contaminated sites.

For BPA the range of uses is more narrow and measures to tackle the issues are more straightforward, meaning the potential impacts could be more manageable. However, issues with use of epoxy resins in construction, particularly pipework, diffuse emissions such as contamination of micro-plastics and need for end-of-pipe treatment also mean that the cost impact could be significant.

Metals

Option 1 would apply to the following metals: Silver and its compounds.
The distance to target for Silver and its compounds has been assessed as medium.

Source control:

Silver is a naturally occurring rare earth metal often found deposited as mineral ore in association with other elements. In terms of its pathways to surface water, major sources include **mining operations, smelting, coal combustion, and production of articles that contain silver, including the use of nanoform silver in medical applications**.

Given its nature and qualities transition to alternatives (e.g. steel, titanium, cobalt) are likely to be limited, and it is duly noted that other metals have also had concerns raised about environmental impact. Silver is used as an essential component for many applications, including: metals, welding & soldering products, metal surface treatment products, adhesives and sealants, biocides (e.g. disinfectants, pest control products), coating products, laboratory chemicals, lubricants and greases, metal working fluids and pharmaceuticals. Not only do multiple industries rely on silver for its unique properties but silver has a high value to the mining industry itself (it is valued at 791.23 USD per kg[195]). Silver is registered under the REACH Regulation (manufacture and / or imported to the European Economic Area) at the ≥ 10,000 to < 100,000 tonnes per annum registration bracket (i.e., between 10,000 and 100,000 tpa per registrant)[196]. Further information from ECHA suggests that in 2018 total EU manufacture and use of silver was between 100,000 – 1,000,000 tonnes /year[197] . The use of silver is steadily increasing (year-on-year increases vary between 5-13% in recent years)[198].

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[195] 04/04/2022, https://markets.businessinsider.com/commodities/silver-price
[196] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/40a35be9-f2e1-4221-b12b-4d3c3f8fcb9d
[197] Substance Evaluation Conclusion as required by the REACH substance evaluation process (Article 48 of REACH Regulation (EC) No 1907/2006) and evaluation report for Silver: EC No 231-131-3
[198] https://www.silverinstitute.org/silver-supply-demand/

The antibacterial activity of silver has led to an increased use of silver in an ever-wider range of consumer products. The different forms of silver, including silver salts (e.g. silver nitrate), silver oxides and silver materials appear as silver wires, silver nanoparticles (Ag-NP) and others, which are used in consumer and medical products. In medical care, forms of (nano)silver are used, for example in wound dressings and catheters to reduce infections. In consumer products, forms of (nano)silver are used, for example in sports and other textiles, washing powders and deodorants, where (nano)silver should reduce odours producing bacteria.

Products containing silver (in ionic form and as nanoparticles) can act as environmental contaminants in general and in relation to the development of anti-microbial resistance. Releases into the environment of silver are likely to occur from both from mining operations and industrial use: in the production of articles and manufacturing of the substance. Other releases to the environment of silver are likely to occur from: indoor use in long-life materials (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment) and outdoor use in long-life materials (e.g. metal, wooden and plastic construction and building materials) (ECHA, 2021).

According to ECHA information based on REACH dossiers, and tests performed with the smallest nanoform with the highest specific surface area, have indicated that silver nitrate (ionic silver) is more toxic than the nanoform of silver (toxicity to algae and long-term toxicity to aquatic invertebrates) and that silver nitrate is equally or more toxic than the nanoform of silver (toxicity to soil microorganisms).

The scientific evidence of silver-driven co-selection of antibiotic resistance determinants is numerous. This demonstrates that micro-organisms become resistant against silver. Since silver exhibits bactericidal activity at concentrations that are not cytotoxic to human cells, they are important for medical use especially in the context of treatments of multi-resistant bacteria. Also, silver strongly enhances the antibacterial activity of conventional antibiotics even against multi-resistant bacteria through synergistic effects[199]. Consequently, they are important as a 'last' resort for treating infections with multi-resistant bacteria[200]. The bacterium '*Acinetobacter baumannii*' (a bacterial pathogen) is listed as the "number one" critical level priority pathogen because of the significant rise of antibiotic resistance in this species[201]. Currently, silver still has proven bactericidal activity towards this bacterium even against strains that display multi-drug resistance. Therefore, it is of utmost importance to avoid /limit silver resistance in bacteria to avoid limiting its effectiveness in treatments for infectious diseases. With the rise of antibiotic resistant bacteria, there are also serious concerns of pathogens developing resistance to silver.

The widespread use of (nano)silver and has already led to the release and accumulation of silver in water and sediment, in soil and even, wastewater treatment plants (WWTPs) and is

[199] Bacterial resistance to silver nanoparticles and how to overcome it; Aleš Panáček, Libor Kvítek, Monika Smékalová, Nature nanoparticles, 2018, volume 13 p.65-71: https://www.nature.com/articles/s41565-017-0013-y

[200] Effect of Graphene Oxide and Silver Nanoparticles Hybrid Composite on P. aeruginosa Strains with Acquired Resistance Genes; Povila Lozovskis et.al., International Journal of Nanomedicine, 17 July 2020, p. 5147-5163: https://pubmed.ncbi.nlm.nih.gov/32764942/

[201] Emerging Concern for Silver Nanoparticle Resistance in Acinetobacter baumannii and Other Bacteria; Oliver McNeilly, et.al, Frontiers in Microbiology 16 April 2021, https://www.frontiersin.org/articles/10.3389/fmicb.2021.652863/full

thus impacting microbial communities in different environmental settings. The resistance mechanism is also linked to the increasing pools of many antibiotic resistance genes already detected in samples from different environmental media, which will likely find their ways to animals and humans. This is worrisome, as the increasingly indiscriminate over-use of silver in non-essential consumer products further promotes the development of silver resistance in bacteria. The combined ecological impacts of NAg call for a prudent use of silver and AgNPs and minimising their water related emissions in order minimise future significant health care related costs triggered by antimicrobial resistance for silver. Finally, physical and chemical transformations of silver can shift the diversity and abundance of microbes, including those that are important in nitrogen cycles and decomposition of organic matter and other key metabolic processes. All in all, the combined impacts underline the importance of minimising water related silver-emissions[202].

To achieve the most effective minimisation of environmental silver concentrations, Source control options are likely to focus on capturing or minimising silver before its released to the environment. Issues with mine drainage are discussed under pathway disruption. However, for other anthropogenic activities (smelting, combustion of coal, manufacturing of products that contain silver), the source control options will likely cover increased abatement and monitoring. This could include **pre-treatment or onsite wastewater treatment** prior to direct discharges or releases to sewer.

The specific nature of the abatement and control (e.g. electro-static precipitation, adsorption techniques, filtration) are likely to be site-specific, and therefore it is challenging to comment on costs, other than to note that the key stakeholders impacted would be in the metal production and manufacturing sectors following polluter pays principles.

Source control could include pre-treatment or onsite waste water treatment by reverse osmosis (RO) prior to direct discharges or releases to sewer, amounting to an estimated cost of 0.1% of the industry's annual turnover[203]. Alternatively, urban waste water treatment plants would need to invest in reverse osmosis to clean such effluents. Assuming that between 1-5% UWWTPs would have to deploy reverse osmosis, costs for EU taxpayers would be between €2,184,600 and €109,230,000.

Antimicrobial resistance is threatening the capacity to prevent and cure infectious diseases. In the European Union, it causes an estimated 35 000 deaths per year as a direct consequence of an infection due to bacteria resistant to antibiotics[204], and places an annual financial burden of €1.1 billion on healthcare systems. In 2019, the World Health Organization declared antimicrobial resistance (AMR) to be one of the top 10 global public health threats facing humanity causing an annual estimate of 1.27 million deaths globally[205]. In July 2022, the Commission, together with the Member States, identified antimicrobial

[202] The impact of silver nanoparticles on microbial communities and antibiotic resistance determinants in the environment, Kevin Yonathan et.al. Environmental Pollution 15 January 2022, p.293-

[203] An extrapolation of the RO costs based on the number of EU non-ferrous metals production facilities 84754 in 2019, assuming that around 5% - 10% of effluents need treatment, would potentially result in EU wide costs ranging from €423,500 to €8,470,000. In relation to the annual turnover of the EU non-ferrous metals industry (120 billion54) this would equal 0.1%.

[204] https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf

[205] https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)02724-0.pdf

resistance (AMR) as one of the top three priority health threats[206]. The health impact of AMR is comparable to that of influenza, tuberculosis and HIV/AIDS combined. Overall, the latest data[207] show significantly increasing trends in the number of infections and attributable deaths for almost all bacterium–antibiotic resistance combinations, especially in healthcare settings. It is estimated that around 70% of cases of infections with antibiotic-resistant bacteria were healthcare-associated infections. Also, the health impact of fungicide-resistant fungi has become more apparent over the years.

The benefits of removing silver to reduce the risk for AMR and other risks, similar to the benefits of reducing AMR from antibiotics, are large. In 2014, it was estimated that infection from antibiotic-resistant / multi-drug resistant bacteria in the United States resulted in a loss of over $20 billion in direct economic costs, and $35 billion through decline in societal productivity[208] [209], adding up to a total of $55 billion, which corrected for inflation would result in 63 billion in 2021[210]. In 2021 this would translate to costs of $0,19 billion per million inhabitants. Assuming comparability in US and EU rates of AMR and their related avoided costs / benefits this translates to €84 billion of EU wide AMR-related avoided costs (benefits)[211]. When assuming that the benefits of reducing silver related AMR would amount to between 50% to 100% of the AMR costs for antibiotics, this translates to EU-benefits of between €42 to €84 billion.

Pathway disruption

Table 8-4 identifies **mining operations and manufacturing** as the major sources for release to environment, with the pathways associated with these sources being dominated with wastewater generation. In terms of measures that could be used to disrupt the pathway of releases getting to surface water the primary issue will be diffuse emissions from mine drainage.

The physical barriers in this case would relate to the **capture and treatment of mine drainage water** before it reaches rivers, lakes, and other forms of water course. In practice the types of technology deployed to treat such waters would not be dissimilar to advanced treatment used at municipal WWTWs. The primary aim being the removal of silver as dissolved particles in the water column. Table 8-17 provides data from the BREF document on wastewater to help provide steer on the types of technology and associated cost. Cost for mine drainage (e.g. for Mercury / Nickel) are assessed at between €100,000 -€10,000,000 per plant and €0.4 per dm3 operating costs.

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[206] https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en
[207] https://www.ecdc.europa.eu/en/news-events/eaad-2022-launch
[208] Zhen, X., Lundborg, C. S., Sun, X., Hu, X., and Dong, H. (2019). Economic burden of antibiotic resistance in ESKAPE organisms: a systematic review. Antimicrob. Resist. Infect. Control 8:137. doi: 10.1186/s13756-019-0590-7: https://pubmed.ncbi.nlm.nih.gov/31417673/
[209] Golkar, Z., Bagasra, O., and Pace, D. G. (2014). Bacteriophage therapy: a potential solution for the antibiotic resistance crisis. J. Infect. Dev. Ctries. 8, 129–136. doi: 10.3855/jidc.3573: https://pubmed.ncbi.nlm.nih.gov/24518621/
[210] https://www.in2013dollars.com/us/inflation/2014?endYear=2021&amount=55
[211] No. of EU inhabitants in 2021: 447 million (https://european-union.europa.eu/principles-countries-history/key-facts-and-figures/life-eu_en)

Given that these are substantial it is expected that this would be a targeted application based on geological mapping and monitoring to define risk and the most suitable location for plants. The number of plants needed is likely to vary Member State to Member State. Where these issues are likely to relate to legacy emissions, it may prove more challenging to apply polluter pays principles, as the originator may no longer exist or is difficult to identify. Therefore, management of mine drainage waters may be funded from public funding against the taxpayer.

Additionally, as a minor pathway to environment, other pathway disruption measures may relate to **management of landfill leachate**. But given the high value precious nature of silver landfill leachate may only be a minor source.

Table 8-17 Costs of physical barrier measures for silver

Substance	Measure	Total cost (€)*	Notes
Silver and its compounds	• Physical barriers to surface improved controls for mine drainage (see notes to right) • Physical barriers to surface improved controls for landfill leachate (see notes to right)	RO investment costs €100,000 -€10,000,000 per plant. €0.4 per dm^3 operating costs[212]. Capture and treatment of leachate where relevant.	Based on light metals, Reverse Osmosis is 99% effective, nanofiltration is around 90%. Ozonation has a range of 60-94% efficacy, but performance is more variable[213,214]. Additionally, chemical precipitation or electroflocculation also like possibilities[215].

* all costs are in EU27 in Euros annually — for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

Restricted / reduced use of nano form silver in medical applications

As indicated previously silver has important antibacterial properties and has been used in a wide range of medical applications for this purpose. However, as also indicated, there is mounting concern for what role silver, particularly nano-form silver might play in spurring on anti-microbial resistance. Silver has a key role to play in helping boost the effects of antibiotics, particularly against strains of bacteria which are becoming resistant to antibiotics. A full restriction / prohibition on the use of silver for medical applications is likely too heavy handed, and there is clear evidence of the societal benefits of using silver outweighing a full restriction / prohibition.

However, given the wide use of silver for antibacterial applications, it could be possible to limit use to the most critical applications. Particularly for applications where there is a greater risk of direct release to water (e.g. anti-bacterial applications in sports clothing and textiles which will be subject to laundry washing).

[212] JRC, 2016, BREF document fir wastewater and waste gas treatment systems, EIPPCB
[213] Qdais et al, 2004, 'removal of heavy metals from wastewater by membrane processes: a comparative study', Desalination Vol 164, issue 2.
[214] Honarmandrad et al, 2020, 'efficiency of ozonation process with calcium peroxide in removing heavy metals (Pb, Cu, Zn, Ni, Cd) from aqueous solutions', SN applied sciences article 2.
[215]Vidu et al, 2020,'Removal of heavy metals from wastewaters: a challenge from current treatment methods to nanotechnology applications", Toxics vol 8 issue 4.

Work on alternatives to nano silver within textile applications are being developed. For example, Andersson et al (2014[216]) discusses the possible use of lanasol (a compound naturally formed within seaweeds of the family *Rhodophyta*) within plastic polymers, to provide microbial resistance to the polymer fibre. Das et al (2020[217]) provides further discussion on the use of lanasol with polymer fibres to produce face masks with added microbial resistance during the corona virus outbreak of 2020/21.

A further exploration of the ways that nanoform silver is used within medical applications, to derive best benefits, while limiting the risks of additional anti-microbial resistance, could help define critical uses and viable alternatives where needed.

End of pipe:

Table 8-4 identifies that wastewater treatment works are only a minor pathway to environment for silver, with mining, smelting, and manufacturing being the major sources. Despite this being the case wastewater generated from manufacturing processes or use of consumer products containing silver or silver-based compounds (e.g. use in textiles, washing powders, and deodorants (nano silver)). Use as a biocide (e.g. disinfectants and pest control products) is also likely to be a minor pathway to the wastewater system. As with the other categories of candidate substance an analysis has been completed to identify the like preferred technology, unit cost, and efficacy for advanced treatment. Table 8-18 provides the results of this analysis.

Table 8-18 Most cost-effective end-of-pipe measures for silver

Substance	Measure	Cost (as € per population equivalent, per annum)	Source of cost data	Efficacy (%)	Source of efficiency data
Silver and its compounds	WWTWs – Reverse Osmosis	20.7	[1]	99	[2]

* all costs are in EU27 in Euros annually – for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

[1] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/CWW_Bref_2016_published.pdf

[2] Value has been estimated based on the high removal efficiency of other heavy metals such as nickel

As indicated under the pathway disruption section, where metals form particulates technologies aimed about breaking compounds (e.g. ozonation) are less relevant. In this case based on cost and efficacy reverse osmosis was identified as the most effective. However, screening technologies such as sand filters and electroflocculation could also provide a valuable means of silver removal. However, again this is a minor pathway, and therefore implementation into wastewater treatment works is likely to be more limited based on identified local/regional risks and need.

[216] Anderson et al, 2014, 'Antibacterial properties of tough and strong electrospun PMMA/PEO fiber mats filled with lanasol - a naturally occuring brominated substance', 'International Journal of Molecular sciences vol 15.
[217] Das et al, 2020, 'The need for fully bio-based facemasks to counter coronavirus outbreaks: A perspective", The science of the total environment vol 22.

Natural attenuation and monitoring (incl. dredging)

In the current case natural attenuation for anthropogenic uses of silver would not be appropriate where the possibility of intervention earlier in the life-cycle is possible. For naturally occurring silver, this issue is already managed by the WFD and EQSD as natural background concentrations.

Summary

The distance to target assigns silver to the 'medium' gap target group, based primarily on the concerns for the role of nanoform silver or ionic silver in helping drive anti-microbial resistance.

The major pathway to environment based on the current analysis is therefore diffuse emissions associated with mining operations and potentially emissions from manufacture and combustion of fossil fuels that are not fully addressed.

The measures are therefore focussed on improved abatement technologies and the application of capture and treat facilities for mine drainage based on targeting of high-risk location. Cost data is likely site specific and highly variable among Member States, noting that some Member States have elevated concentrations of naturally occurring silver within surface water already. The costs of improved abatement are not insignificant but could be expected to be targeted to highest risk and therefore consummate with water protection goals.

Microplastics

Source control

Microplastics (MP) are not specifically addressed in the existing UWWTD, WFD, EQSD or GWD, although WFD Annex VIII (indicative list of the main pollutants) includes materials in suspension. Eunomia et al (2018)[218] provide some estimates on the scale of the issue, noting that brake and tyre wear is the single largest source of microplastics, accounting for 500,000 tonnes per annum in the EU. These can enter sewers through run-off. The use of the Tyre Approval Regulation to remove the worst performing tyres from the market has previously been assessed[219]. It was shown that Tyre Approval (alone) as well as Type Approval plus including tyre abrasion rates on the EU tyre label (combined) were cost-effective in reducing the entry of microplastic to the environment compared to other measures assessed. This study estimated that the testing needed for each tyre in order to implement the measure could add between €0.03 and €1.43 onto the cost of a new tyre. Furthermore, even the combined measure is believed to only reduce the entry of microplastics to the environment by 33%[220].

In 2020, the Committee for Socio-economic Analysis (SEAC) adopted its opinion on the restriction proposal to ban microplastics in a range of products, including fertilisers, cosmetics, detergents. It is estimated that this would prevent the release of 500,000 tonnes of microplastics into the environment over a 20-year period and that the total cost to

[218] Eunomia, (2018), 'Investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products', Report on behalf of the European Commission.
[219] https://bmbf-plastik.de/sites/default/files/2018-04/microplastics_final_report_v5_full.pdf
[220] https://bmbf-plastik.de/sites/default/files/2018-04/microplastics_final_report_v5_full.pdf

European society would be €10.8 to €19.1 billion. This range would be dependent on the method through which the environmental risks from the granular infill material used in artificial sports turf is addressed[221]. On a smaller scale, the banning of plastic microbeads in cosmetic products in the UK in 2017 was estimated to have a net cost to businesses of £0.4m per year[222].

Pathway disruption:

The single biggest source of secondary micro-plastics is tyre and brake wear, with run-off from road a potential issue. Other major diffuse sources would include land spreading of sewage sludge, with run-off from field a possible issue, and atmospheric deposition where micro-plastics are light weight and easily carried by the wind. In terms of physical barriers to disrupt the pathway to water, the most obvious choices are the use of gully pots or other form of particulate capture system for road-side run-off. For agricultural run-off buffer strips and constructed wetlands could perform a useful role to limit the direct egress from terrestrial environments.

Management of atmospheric deposition is more challenging, but where landfills are a potential source, suitable landfill management techniques to limit airborne debris could prove useful.

Table 8-19 provides details of unit costs for these measures, noting that application would vary Member State to Member State, depending on a range of geographic factors.

Table 8-19 Example costs for physical barriers for microplastics[223]

Technology	Cost
Buffer strips	€160 per hectare
Constructed wetland	€43.7 per m3 (assume 1 metre depth)
Gully pots to capture particles from run-off from road	€50 per gully-pot (assume spacing of 40-50m)

End of pipe:

It has previously been identified by Eunomia[224] that both improvement to wastewater treatment as well as improvements to stormwater treatment can be effective in the prevention of microplastic entry to the environment.

For a cost between €0.08-0.20 per cubic metre of wastewater treated per year, current treatment technologies are believed to enable close to 100% capture of microplastics in WWT plants. However, it was noted that much of the microplastic removed from the wastewater is partitioned to sludge which can still provide a path to the environment, suggesting direct placing on the land is problematic and alternative disposal options such as covered landfill, incineration, or separation of plastic from sludge is needed. Upgrades to treatment plants in the EU so that all can provide a tertiary level of treatment (a form that will increase

[221] https://echa.europa.eu/-/scientific-committees-eu-wide-restriction-best-way-to-reduce-microplastic-pollution
[222] https://www.legislation.gov.uk/ukia/2017/178/pdfs/ukia_20170178_en.pdf
[223] Values derived from the 2012 Impact Assessment of the review of Priority Substances and amended for inflation
[224] Eunomia, 2018, 'investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products, Report for European Commission.

microplastic capture rates), could cost between €0.76—3.14 billion per year. However, it was noted that increasing compliance with the UWWTD by 2035 could lead to these costs being reduced to between €0.6—2.4 billion with an average of €1.49 billion[225]. The costs of WWT improvement could be applied to different product groups based on their proportional contribution to the WWT process as shown in Table 8-20.

Table 8-20 Application of costs of WWT improvement applied to different product groups[226]

	WWT improvement costs (billion €)	
Emission Source	**Upper**	**Lower**
Washing of clothing/textiles	0.97	0.51
Pellets	0.48	0.05
Automotive tyres	0.38	0.37
Artificial turf	0.05	0.05
Road markings	0.04	0.04
Building paint	0.03	0.01
Total	1.49	1.49

Natural attenuation and monitoring (inc. dredging)

Not applicable to micro-plastics.

Summary

Microplastics have been identified as a significant environmental challenge with a range of undesirable impacts for species in the terrestrial and aquatic environment, as well as human health. In terms of emissions to environment secondary microplastics form the larger fraction of what is emitted which poses challenges for control and intervention. Restrictions and management of primary (intentional use) microplastics have already been proposed for micro-beads and uses which are washed directly to drains (i.e., cosmetics, personal care products, laundry aids, etc[227]). The current study has not undertaken a 'distance to target' assessment for microplastics (as an EQS has not yet been proposed), but it could be assumed that the target is between medium and large.

Major sources of secondary microplastics to environment relate to brake and tyre wear, and emissions to municipal WWTWs (particularly from laundered items such as clothing). Measures to disrupt pathways and end-of-pipe treatments could be effective, but as illustrated by the work reported by Eunomia costs of upgraded treatment could be significant. Where the treatment relates to managing particulates the assessments reported in the JRC study for revision of UWWTD (primarily focused on GAC/PAC/Ozonation) may need to consider additional treatment options for microplastics as a supplementary measure. This is because GAC/PAC/Ozonation are targeted at removing and/or destroying chemical substances by attacking their chemical properties. To remove microplastics further attention may be needed on techniques involving screening, filtration, and sludge treatment.

[225] https://bmbf-plastik.de/sites/default/files/2018-04/microplastics_final_report_v5_full.pdf
[226] https://bmbf-plastik.de/sites/default/files/2018-04/microplastics_final_report_v5_full.pdf
[227] Microplastics - ECHA (europa.eu)

Administrative cost burden — Member State monitoring obligations

The preceding sections have provided an overview of the potential measure selection, and associated costs and impacts of implementing measures for all of the candidate priority substances under Option 1. The addition of substances to the priority substance list carries with it obligations that have to be met by Member States as part of the EQSD. This includes monitoring and analysis of priority substances to determine chemical status and reporting obligations. As part of the impact assessment these costs have been included separately from the consideration around achieving good chemical status for each of the candidate substances.

The study has assumed that where existing monitoring networks are now in place for priority substances, they are relatively mature given the first implementation of the EQSD in 2008. The sampling needed to carry out analysis of additional substances should be possible with minimal additional cost and disruption to the existing activities already undertaken.

The additional chemical analysis for new priority substances however would infer additional costs, depending on the substance in question, whether analytical standards and methods already exist, and whether the substance should be analysed on its own or part of suite of similar substances (i.e., same chemical family). To help better understand the cost impacts of analysis the targeted expert consultation for the study asked respondents to indicate the cost of analysis for each candidate substance based on pricing ranges.

Table 8-23 provides the results of the targeted consultation, with the price range with the highest frequency response shown for each substance in the table. The EEA dashboard indicates approximately 120,000 water bodies in the EU. While the WFD notes that sufficient monitoring and analysis should be undertaken to provide a representative sample for determining chemical status, i.e., we do not expect monitoring to occur at each and every water body. The impact assessment for the previous revision of PS list performed in 2012, indicated that there were approximately 3,600 monitoring sites with monthly monitoring and analysis of surface water to determine annual average and maximum concentrations. Note that the 2012 assessment predates the entry of Croatia into the European Union and exit of the United Kingdom. Therefore, it could be possible that there are between 2,500 and 3,500 monitoring locations across the EU-27.The WFD stipulates that monitoring should be conducted monthly for water, and once every three years for sediment and biota. These estimates along with the data in Table 8-21 can be used to help determine the overall additional costs of analysis per candidate substance.

Table 8-21 Cost of analysis based on results of targeted consultation

Substance	Analytical cost range in €/per sample
Estrone (E1)	11-100
17-Beta estradiol E2	11-100
Ethinyl estradiol (EE2)	11-100
Estrogens as a suite	501-1,000
Azithromycin	11-100
Clarithromycin	11-100
Erythromycin	11-100
Macrolides	101-250
Diclofenac	11-100
Carbamazepine	11-100
Ibuprofen	11-100
Nicosulfuron	11-100
Acetamiprid	11-100
Clothianidin	11-100
Imidacloprid	11-100
Thiacloprid	11-100
Neonicotinoids	250-500
Bifenthrin	11-100
Deltamethrin	11-100
Esfenvalerate	11-100
Permethrin	11-100
Pyrethroids	101-250
Glyphosate	11-100
Triclosan	11-100
PFAS	101-250
Bisphenol A	11-100
Silver	11-100

The fitness check of reporting and monitoring of EU environmental policy estimated the approximate annual administrative burden for the WFD to be between €100 000 and 1 million[228]. The approximate annual administrative burden to Member States for the EQSD were estimated to be within the range of €30,000 and €100,000[229].
The impact assessment for the EQSD estimated the additional costs of monitoring to be €15-36 million per year for the whole EU. Costs of €2-4 million per year for the EU were estimated for a database and the costs to develop technical specifications for monitoring were estimated at <€0.2 million per year for the whole EU)[230].

[228] European Commission (2017) — SWD (2017) 230.
[229] https://ec.europa.eu/environment/water/fitness_check_of_the_eu_water_legislation/documents/Water%20Fitness%20Check%20-%20SWD(2019)439%20-%20web.pdf
[230] https://op.europa.eu/en/publication-detail/-/publication/21bf36f4-64e1-11ea-b735-01aa75ed71a1/language-en/format-PDF/source-254240730

Economic impacts — *Benefits*

Economic benefits largely relate to benefits to companies manufacturing alternative substances/ products containing alternative substances. Further benefits include avoided costs from pollution incidents which may occur if the additional substances are not added under the EQSD. The probability of such events depends on current concentrations of the substances in the environment as well as current and future emissions levels.

Other economic benefits may include:

- For some substances, e.g. diclofenac, the substitution with alternatives may be less of an economic challenge and more of an opportunity for the companies selling alternatives.
- Many of the substances are toxic to aquatic life, e.g. E2 and PFAS harm reproduction and therefore damage reproductive success and overall population health. Therefore, regulation through the EQSD will have positive impacts on fish farming and aquaculture.
- There may also be savings in drinking water treatment due to improvements in water quality.

Pharmaceuticals

The impact of the candidate priority substances on aquatic life has been discussed thoroughly in the environmental impacts benefit section. Many of the substances, such as E2 and PFAS, can harm reproduction, reproductive success and population health in fish populations. Therefore, regulation through the EQSD will have positive impacts on fish farming and aquaculture through the avoidance of costs associated with the use of these substances. Despite the lack of information on the extent of the damage and the exact losses it may cause for the aquatic environment, there is enough evidence that the current profits derived from fish farming and aquaculture will decease gradually. Below[231] we give an overview of the economic benefits of the fish species most impacted and well documented in studies.

- In 2019, the EU produced 192.450 tonnes of trout, mostly rainbow trout which was valued at €677 million.
- The price of seabass in EU in 2020 was €8.67 /kg. In 2019, the EU produced 86.149 tonnes with a total value of €491 million.
- In 2019, the landings of crustaceans in the EU totalled 164.980 tonnes with a total value €1,05 billion. The total value of Norway lobster, shrimps, and mussels landed in the EU was €337, €433 and €451 million respectively.
- In 2019, the EU farmed production of salmon was 203.832 tonnes.
- Overall, at the EU level, the combined production from fishery and aquaculture was a total of 6.2 million tonnes in 2019. In 2020, exports, on the other hand amounted to 2,21 million tonnes with a total value of terms at €6.96 billion.

[231] The EU fish market. https://www.eumofa.eu/documents/20178/477018/EN_The+EU+fish+market_2021.pdf/27a6d912-a758-6065-c973-c1146ac93d30?t=1636964632989

Pesticides and biocides

Given the adverse effects that pesticides and herbicides have on bees and other pollinators, it is important to note that restrictions on these substances will help avoid an economic loss brought about by the decline in pollinators. Across Europe, **crop pollination** by insects accounted for approximately €14.6 billion annually; This production value corresponds to almost 12% of the total economic value of annual crop production[232]. More recently, it was reported that around 76% of European food production is dependent on pollination by both wild and domestic bees as well as other pollinators. It has been estimated that insect pollination is responsible for approximately 10% of the total economic value of the European agricultural output for human food produce, which amounted to €14.2 billion for the EU in 2015[233]. According to the IUCN, 78% of native flora and 84% of crops are either partially or fully dependent on invertebrates for pollination, bringing the agricultural contribution of pollinators to the EU economy alone to a total of €15 billion[234,235].

Additional drinking water treatment may be required due to the risk posed by the candidate substances to human health (see the social impact section). The following costs could be avoided if restrictions are put in place to limit the concentration of the candidate substances in surface water. Table 8-8 provides a summary of the water treatment technologies and the estimated cost incurred by the population. Moreover, in France, it is estimated that, relative to the average price, drinking water prices can increase by 1 to 14% with additional treatment. Since the average price of water in France is 56c€/m3, the estimated increase in price corresponds to an increase of 5.6 to 6.4c€/m3. If we follow the neo-classic economic theory where prices equal marginal costs, this increase in prices is due to additional costs and would incur + 5.6 to 6.4c€ of benefit per cubic meter of treated water[236]. In Belgium in 2010, it was estimated that the cost of drinking water treatment was €120 to €190 million[237]. Moreover, in 2015, approximately €0.5 billion was spent annually as lower treatment costs to remove pesticides in wastewater treatment plants (WWTP) in Europe[238]. In addition, in the period between 1990-2010, the average household, in the OECD countries, was willing to pay as high as €250-270 to improve the drinking water quality[239].

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232 Leonhardt et al. (2013). Economic gain, stability of pollination and bee diversity decrease from southern to northern Europe. https://doi.org/10.1016/j.baae.2013.06.003

233 EGP Council, Antwerp, 18 - 20 May 2018 Adopted Resolution- https://europeangreens.eu/sites/europeangreens.eu/files/news/files/4.%20Adopted%20No%20bees%2C%20no%20food.pdf] [http://step-project.net/img/uplf/STEP%20brochure%20online-1.pdf

234 https://www.iucn.org/regions/europe/our-work/biodiversity-conservation/pollinators-europe

235 Potts S. et al (2015). Status and trends of European pollinators. Key findings of the STEP project. http://step-project.net/img/uplf/STEP%20brochure%20online-1.pdf

236 Simoni et al (2016). Eau potable et assainissement : à quel prix ?. https://cgedd.documentation.developpement-durable.gouv.fr/documents/Affaires-0008960/010151-01_rapport.pdf

237 Dogot et al (2010), Estimating the costs of collective treatment of wastewater: the case of Walloon Region (Belgium). Water Science & Technology 62(3): 640-648

238 UNEP (2019). Economic benefits of action and costs of inaction - Foundational paper for GCO-II. https://wedocs.unep.org/bitstream/handle/20.500.11822/32619/1/TyrerEB.pdf

239 OECD (2012). Agriculture and Water Quality: Monetary Costs and Benefits across OECD Countries. https://www.oecd.org/greengrowth/sustainable-agriculture/49841343.pdf

Industrial substances

Specifically for PFAS, according to a study by the Nordic council of ministers[240], an upgrade to water treatment plants is estimated to cost €300 per person for the capital cost and €19 per person for the maintenance cost. Other costs include monitoring PFAS water concentrations through sample testing, health assessments and biomonitoring (€50 per person), and when found, excavation and treatment of contaminated soil (€5 million per case). In another study[241], soil excavation and offsite disposal were estimated to cost between €0.5-18 million, while soil excavation and incinerations cost anywhere between €2.5-38 million. The study also estimated the treatment cost for groundwater including pumping to range between €1.2-30.3 million, while using reverse osmosis to produce drinking water would cost €2.9-39.8 million.

Environmental impacts — Costs

A potential negative environmental impact is that improvements in WWTP may be accompanied by higher energy demand and **carbon emissions**, although the level of emissions associated with increased wastewater treatment depends on the source of the electricity itself. It has been estimated that UWWT facilities alone (on average) utilised between 1% to 3% of the total electric energy output of a country[242]. Modelling by the JRC illustrates that WWTPs in the EU are responsible for GHG emissions of 41.8 million t CO2e/year. Approximately 17.9 million t CO2e/year of GHG emissions are attributed to the WW infrastructure. Some of these emissions cannot be reduced through changes to the operation of the treatment plants e.g. emissions from the sewer network will not be impacted by changes to the treatment[243]. This suggests that in terms of the benefits a holistic approach is needed to also fully consider any undesirable unintended impacts that may occur.

Another environmental impact could result from the banning or restricting of substances as part of restriction control measures. For the pharmaceuticals, it was identified that some of the most likely alternatives were other substances in the same, or similar, substance category. For example, the most likely alternative to erythromycin would be another macrolide antibiotic. If this were to occur, the effectiveness of substitution would be reduced as these alternatives have similar environmental impacts.

Environmental impacts — Benefits

Environmental benefits associated with the addition of substances to the priority list under the EQSD constitute the main benefit, as it would ensure the highest levels of control, and impetus for environmental protection. This aspect was further characterised by comparing existing monitoring data for ambient concentrations in surface water against the proposed EQS within the distance to target assessment. The results of this assessment have been covered previously in this section and the results of this are displayed in Table 8-3. Such a

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[240] Nordic Council of Ministers (2019). The cost of inaction A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. http://norden.divaportal.org/smash/record.jsf?pid=diva2%3A1295959&dswid=4908

[241] Wood (2018). The use of PFAS and fluorine-free alternatives in fire-fighting foams. ECHA. o https://echa.europa.eu/documents/10162/28801697/pfas_flourine-free_alternatives_fire_fighting_en.pdf/d5b24e2a-d027-0168-cdd8-f723c675fa98

[242] U.S. Department of Energy, (2014), The Water-Energy Nexus: Challenges and Opportunities

[243] Wood E&I GmbH, 2022, Study to support the Impact Assessment of the UWWTD

comparison allowed an estimation of the magnitude of the risk posed by specific substances, and therefore the extent of the environmental benefits from minimising the risk and avoiding potential impacts on aquatic environment. The distance to target assessment indicated that the largest gaps between environmental concentrations and the proposed EQS are for ethinyl estradiol (EE2), diclofenac, carbamazepine, bifenthrin, deltamethrin, esfenvalerate, permethrin, glyphosate, bisphenol A, and PFAS.

Some additions may be considered in line with the precautionary principle, as substances have been shown to incur negative effects on biota in vivo and are predicted, or thought, to have negative impacts on wildlife. For example, carbamazepine affects growth and development in vivo[244], and there are concerns about potential environmental impacts on aquatic life. The scale of anticipated beneficial impacts will be determined by the gap between current concentrations (based on monitoring data) against the proposed EQS , acknowledging that the proposed values represent a high level of environmental protection.

The existence of the **pharmaceutical group of substances** in the environment without further restrictions does pose a high risk in terms of biodiversity in both the aquatic and terrestrial ecosystems. In particular, the toxic qualities of diclofenac led to a decline in the vulture populations on the Indian subcontinents where the poisonous effect of the substance caused kidney failure[245]. Carbamazepine was also shown to increase the aquatic risk by 10 to 20 folds over a period of 20 years (1995- 2015)[246]. Several studies have shown how carbamazepine affects the growth of larvae and reduces the egg viability in zebrafish[247,248,249] as well as a lowering the reproductive capabilities of crustaceans[250]. Moreover, the three estrogens E2, EE2 and to a lesser extent E1, have shown a disruptive effect on reproduction in fish and neurotoxicity leading to a decrease in some fish populations[251,252].For example, studies have shown EE2 to cause fish feminization in lobster[253] and seabass[254] populations, while E1 and E2 have been shown to increase the risk of pancreatic infections in the rainbow trout and Atlantic salmon[255]. Moreover, studies have linked macrolide antibiotics to tissue

[244] Qiang et al. (2016) Environmental concentration of carbamazepine accelerates fish embryonic development and disturbs larvae behavior. Ecotoxicology 25(7); 1426-37

[245] Mudgal et al., (2013). Study on the environmental risks of medicinal products. Executive Agency for Health and Consumers. https://ec.europa.eu/health/system/files/2016-11/study_environment_0.pdf

[246] Oldenkamp et al., (2019). Aquatic risks from human pharmaceuticals—modelling temporal trends of carbamazepine and ciprofloxacin at the global scale. Environ. Res. Lett. 14 034003. https://iopscience.iop.org/article/10.1088/1748-9326/ab0071

[247] Sabtos et al., (2018). Chronic effects of carbamazepine on zebrafish: Behavioral, reproductive and biochemical endpoints. Ecotoxicology and Environmental Safety 164: 297-304. https://doi.org/10.1016/j.ecoenv.2018.08.015

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damage in rainbow trout[256]. Finally, Ibuprofen was found to cause acute toxicity in some instances to aquatic organisms[257,258,259] as well as cause reduction in testosterone levels and negative reproduction complications[260,261].

The negative impact of the proposed **pesticides and biocides** have been well documented in the literature. Despite the recent effort in keeping the pesticide concentrations in Europe below the levels causing instant death of bees among other pollinators, it is still found at concentrations that lead to similar results such as chronic exposure to high doses leading to eventual acute toxicity. Moreover, high concentrations, even though not lethal, still affect the lifespan of bees and other pollinating insects as well as changing their behaviour[262]. In particular, neonicotinoids (thiamethoxam, thiacloprid, acetamiprid, clothianidin and imidacloprid) are a group neurotoxic to a range of organisms. Pyrethroid group (bifenthrin, esfenvalerate, deltamethrin, and permethrin) also has high toxicity effect on a range of organisms. A notable study conducted in Sweden investigated the real-life effects of both neonicotinoid clothianidin and the non-systemic (i.e. not taken up by the plant and into its leaves) pyrethroid β-cyfluthrin on wild bees. The results found that application to oilseed rape seeds reduced wild bee density, solitary bee nesting, and bumblebee colony growth and reproduction under field conditions[263]. Another study investigated the implications of the increased usage of pyrethroids and neonicotinoids on the communities of both bees and aquatic invertebrates. The study systemically interpreted the changes in the use of 381 pesticides over 25 years by considering 1591 substance-specific acute toxicity threshold values for eight species groups untargeted by these substances through their application. Their results show that pyrethroids and neonicotinoids have become increasingly toxic at a higher rate than the increase in application quantities implying an exponential toxicity effect[264]. Another study was conducted in Germany over the period between 1989 and 2016 across 96 unique locations to investigate the total aerial insect biomass. The study was representative of Western European low-altitude nature protection areas embedded in a human-dominated landscape. The results estimated a seasonal decline in flying insect biomass over the 27 years of study with more than 75% decline in total flying insect biomass in protected areas.

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The study concludes that this decline is apparent irrelevant of habitat type, changes in weather, land use, and habitat characteristics. The study attributed the decline to agricultural intensification, including pesticide usage[265].

Glyphosate is another candidate in the list for restricted use that poses multiple environmental concerns as it affects non-target plants direly. Glyphosate can potentially and indirectly increase the risk of diseases spreading in plants by affecting their vigour and growth as well as altering the soil microflora causing insufficiency in the nutrients vital for disease resistance[266]. Glyphosate was also found to increase the phytotoxicity to sensitive plants through root uptake[267]. Moreover, by indirectly altering the microbial colonial composition, glyphosate can reduce the beneficial gut bacteria in animals as well as enhance the pathogenic ones leaving animals and birds more susceptible to toxic Clostridium and Salmonella species and putting bees under heightened risks of Serratia and deformed wing virus[268]. A study shed light on the gastrointestinal and neuroglial impacts of glyphosate on cattle and goats as well as the increasing mortality rate of Danish pigs linked with the herbicide[269]. In regard to triclosan, once it reaches the environment, and given its bioaccumulative property, it can be toxic to aquatic organisms. This includes rainbow trout where even at low concentrations of triclosan they showed low survival rate as well as hatching delay, and mortality in the embryos and larvae of zebrafish[270]. Some animal studies have shown that triclosan affects the hormone levels, which could result in neurotoxicity, decreased thyroid function and breast cancer[271,272]. Moreover, given its antimicrobial property, triclosan has a potential antibiotic resistance effect in the environment[273].

Bisphenol A is chemical substance belonging to the list of industrial substances. It is considered to be an endocrine disruptor in vertebrate animals[274,275] as well as a cause of adverse effects in the reproduction system[276,277]. Several studies have linked bisphenol A to the reduction of fertility as well as reproduction problems in fish, including zebra fish[278],

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medaka[279], and rainbow trouts[280]. Others have associated exposure to bisphenol A with neurogenesis[281,282] and cardiovascular effects in fish[283].

Another industrial chemical that is a strong candidate for restriction of use is the **PFAS** group. PFAS have been associated with adverse effects in aquatic animals, mammals, and humans. Upon reaching the environment, PFAS affects the aquatic environment's structure and function impacting the aquatic organisms[284,285,286,287], as well as aerial and terrestrial birds[288,289,290,291].

Due to their widespread use and high persistence, PFASs have been detected in a wide range of environmental compartments, including surface water, groundwater [292] [293] [294] [295] [296] [297] [298]

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[299] [300] [301], soil[302] [303] [304] [305], and landfill leachate[306] [307] [308] [309]. Furthermore, their harmful effects on human health and the environment are also extensively scientifically documented. For example, exposure to PFAS has been linked to numerous health issues, including kidney and testicular cancers[310] [311] , elevated cholesterol, [312] obesity [313] [314], immune suppression[315] [316] [317], and endocrine disruption[318] [319]. The presence of PFAS in the environment is attributed to direct release from manufacturing plants, disposal of consumer products containing PFAS, fire-fighting foams (Aqueous Film Forming Foams AFFF), treated municipal wastewater

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discharge, sludge, and leachate from solid waste landfills. Consequently, maximum limits (by setting an EQS) for PFAS in surface water and groundwater are essential to reduce exposure of the population and limit the harmful effects resulting from exposure.

Silver, a metal that has various uses, including its compounds, can be particularly toxic to the aquatic environment. For example, it has been shown that silver nanoparticles can pose as a toxic hazard to prokaryotes, invertebrates and fish[320]. Moreover, several studies have suggested that silver nanoparticles may impair or modify the functioning of aquatic organisms[321,322,323]. Crustaceans in particular have been investigated to examine the adverse effects and toxicity of silver on aquatic organisms[324,325].

Given the free mobility of **microplastics** and their various uses, they can reach the aquatic environment in large quantities interacting with all marine biotas including fish, birds, turtles, and mammals[326]. Ingestion of microplastics by fish and seabirds can cause toxicity effects[327]. Moreover, studies have found that microplastics ingestion affects food consumption and digestion of marine organisms such as copepods[328] . Microplastics can also cause reproduction disruption in marine filter feeders such as oysters[329]. In addition, microplastics can indirectly cause adverse effects on the marine organisms through their adsorption of chemical pollutants into their surface[330,331,332,333].

Overall, it is evident that the substances in the candidate list pose a risk to the biodiversity of the marine organisms as well as terrestrial animals. There is wide range of studies attempting to capture the public’s willingness to pay to preserve biodiversity. In a study conducted in Greece, it was estimated that the willingness to pay for marine biodiversity protection is €29 per person[334]. In another study investigating public’s willingness to pay for

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biodiversity restoration and preservation in in some unique coralligenous habitats in the North Adriatic Sea, Italy, the estimated willingness to pay was €35.42 per household[335]. A similar study in Italy for the coralligenous habitats found a willingness to pay between €10.30 and €64.02 per household, for biodiversity restoration and conservation[336]. In 2013, in Croatia, a case study of the Lastovo Archipelago marine park reported a willingness to pay of €2.03 — 4.31 per visitor for improving marine biodiversity[337]. In Norway, a study was conducted to examine people's willingness to pay for the reduction of both macro-plastic and microplastics in the marine environment around the archipelago of Svalbard[338]. The study estimated an average annual willingness to pay value of NOK 5,482 (approx. 576 euros[339]) per household. In 2007 and 2008 in Gdansk, Poland, a valuation study[340] was conducted to estimate the public's willingness to pay to preserve marine biota. In 2007, the study estimated an average willingness to pay of €16 per person to avoid 25% reduction in sea mammals, followed by €11- 13 for fish, €8 – 10 for birds, and €5 – 6 for macroalgae and invertebrates. In 2008, the study reported a €64 willingness to pay to avoid 50% reduction in fish. In 2007, a study was conducted in Greece to estimate the public's willingness to pay to avoid a loss in marine species including mammals, fish, algae, and birds[341]. The study found that the willingness to pay to avoid a loss in the number of all marine species was €40 – 605 as a onetime payment. In Spain, data was collected between 2005 and 2008 to estimate a willingness to pay for non-use values associated with biodiversity losses resulting from oil spills which was reported to be an average €31.18 per person[342]. Moreover, in the Netherlands, biodiversity of birds was valued by the local residents at a marginal willingness to pay value of €72 for 'more birds' and €51 for 'many more birds', while tourists and natural scientists valued the "Many more birds" at €96 and €51, respectively[343]. However, improvements in monitoring as a result of substances being added to the EQSD list, could also confer indirect additional benefits by **improving the scientific understanding** of substance occurrence in European waters, and thus, allowing better control of the risk against an evolving knowledge base. This is in line with the overall principals of the WFD to avoid deterioration of water quality for the aquatic environment.

In terms of source control, an argument can be made about the intrinsic value of a substance to society. The revision of the EU REACH Regulation will include greater consideration of what defines 'essential use' in terms of authorisation and restriction. An argument could be

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[335] Tonin (2019). Estimating the benefits of restoration And preservation scenarios of marine biodiversity: An application of the contingent valuation method. Environmental Science & Policy, 100:172-182. https://doi.org/10.1016/j.envsci.2019.07.004

[336] Tonin (2018). Economic value of marine biodiversity improvement in coralligenous habitats. Ecological Indicators, 85: 1121-1132. https://doi.org/10.1016/j.ecolind.2017.11.017

[337] Getzner et al (2017). Willingness-To-Pay for Improving Marine Biodiversity: A Case Study of Lastovo Archipelago Marine Park (Croatia). Water, 9(1). https://doi.org/10.3390/w9010002

[338] Abate et al (2020). Valuation of marine plastic pollution in the European Arctic: Applying an integrated choice and latent variable model to contingent valuation. Ecol Econ. 169, 106521. doi:10.1016/j.ecolecon.2019.106521

[339] Used an exchange rate of EUR 1 = NOK 9.52

[340] Zarzycki et al (2012). Towards an ecosystem approach for understanding public values for marine biodiversity loss. Marine Ecology Progress Series 467(467):15-28. DOI:10.3354/meps09967

[341] Ressurreição et al. (2011). Economic valuation of species loss in the open sea. Ecological Economics, 70(4): 729-739. https://doi.org/10.1016/j.ecolecon.2010.11.009

[342] Leon et al. (2014). Heterogeneity and emotions in the valuation of non-use damages caused by oil spills. Ecological Economics, 97. https://doi.org/10.1016/j.ecolecon.2013.10.010

[343] Nunes et al. (2009). Decomposition of warm glow for multiple stakeholders: Stated choice valuation of shellfishery policy. Land Econ. 85, 485–499.

made for substances such as PFAS that the correct intervention is to prohibit the manufacture and use of PFAS at source to protect the wider environment (see section 7.3 on dynamic baseline). Conversely, for substances within the pharmaceutical (and possibly pesticide categories) there may be an argument that the benefits to society (healthcare and food security) mean that prohibition or restriction is harder to justify. This would place greater onus on managing the environmental impacts via end-of-pipe treatment, with a wider question over who should pay for that enhanced treatment step. Note the comments on the pharmaceuticals strategy about extended producer responsibilities.

An indirect benefit of implementing more advanced WWTP technologies as tertiary treatment will be the improved removal of not only the existing priority substances but also a range of candidate substances. For example, granulated/powdered activated carbon has been shown to be an effective treatment option (albeit an expensive one) against a range of micro-pollutants. The one caveat here might be that during the evaluation of the urban wastewater treatment Directive, stakeholders did highlight that the wide range of physical-chemical properties and low concentrations of chemical pollutants can pose challenges for wastewater treatment. It is sometimes the case that tertiary treatment options need to combine a suite of different treatments to effectively combat all possible chemical substances. Therefore, it is possible that the wider adoption of advanced tertiary treatments to combat one set of priority substances is likely to have beneficial impacts for treatment of other priority or candidate priority substances, but the efficacy is likely to vary substance by substance.

Social impacts — *Costs*

Costs of different mitigation measures (source control, pathway disruption and end-of-pipe treatment measures in particular, are likely to result in costs to consumers through increased prices of products and services (including water and sewage charges). A number of Member State stakeholders raised concerns in particular about the addition of the synthetic estrogen hormone (EE2) to the priority substances list. This substance in particular has a key societal role in birth control and hormone replacement therapies. The concern raised was that given the wide spread use and possible release to environment (via wastewater), compliance against the EQS could amount as a defacto ban / heavy restriction on use, which would have clear negative societal consequences. The counter-factual to this position is that the evidence presented within the JRC dossier documents potential health effects for aquatic species, mammals and human health, particularly linked to endocrine function, negative impacts upon reproductive systems, and stress upon renal systems[344]. Further review papers by Wojnarowski (2021)[345], and Adeel et al (2017)[346] underscore potential health impacts and causal links to breast cancer. This suggests that the negative environmental and health impacts are reaching a weight of evidence where action is needed to control unintentional exposure. A balance therefore needs to be found to manage societal costs. It was noted by one stakeholder that although the 'polluter pays principle' should apply, the cost of increased treatment at wastewater treatment plants will need to apply extended producer

[344] German Environment Agency, 2021, EQS datasheet for EQS of 17 Alpha Ethinylestradiol (EE2)
[345] Wojnarowski et al, 2021, 'impact of estrogens present in environment on health and welfare of animals', published in the journal Animals vol 11
[346] Adeel et al, 2017, 'Environmental impact of estrogens on human, animal and plant life: a critical review', Environment International vol 99

responsibility, and this could mean that society collectively bears the burden of costs for the societal benefits that the identified pharmaceuticals provide.

Social impacts — *Benefits*

Positive social impacts include those on **human health, consumer confidence, and recreational benefits,** e.g. for outdoor swimming and water sports, recreational anglers, etc.

The candidate substances have adverse impacts on the **human health**. Some of the substances are considered as endocrine disruptors that may potentially cause reproductive diseases, and those include E1**Error! Bookmark not defined.**, E2**Error! Bookmark not de fined.**, EE2**Error! Bookmark not defined.**, pyrethroids, glyphosate[347], triclosan[348], Bisphenol A[349], PFAS[350,240]. Another subset of the substances (namely, glyphosate[351], PFAS240, EE2[352], triclosan348,[353]) are considered a carcinogenic and have been linked to testicular, breast, and kidney cancer. Moreover, glyphosate[354] and macrolide antibiotics can cause antimicrobial resistance (AMR). Uncertainty of attribution factors make it difficult to measure and monetize the benefits of reduced diseases due to reduced emissions of hazardous chemicals. However, below we attempt to provide an approximate estimate of the costs associated with the stated health risks (that could be reduced and/or avoided).

Annual costs related to endocrine disruptors exposure were estimated to be €163 billion (above €22 billion with a 95% probability and above €196 billion with a 25% probability)[355]. This is due to the fact that endocrine disruptors in Europe contribute substantially to neurobehavioral deficits and disease, with a high probability of >€150 billion costs annually[356] as well as childhood obesity which costs €1.54 billion annually355. Since endocrine disruptors can impair reproduction processes, it was estimated that the annual costs of assisted reproductive technologies to be €4.71 billion for the women cohort of age 20-40355. Additionally, the cost of male reproductive diseases attributed to endocrine disruptors

[347] Brugen et al. (2021). Indirect Effects of the Herbicide Glyphosate on Plant, Animal and Human Health Through its Effects on Microbial Communities. Front. Environ. Sci. https://doi.org/10.3389/fenvs.2021.763917
[348] Olaniyan et al. (2016). Triclosan in water, implications for human and environmental health. SpringerPlus 5, 1639. https://doi.org/10.1186/s40064-016-3287-x
[349] Rochester (2013). Bisphenol A and human health: A review of the literature. Reproductive Toxicology, 42. https://doi.org/10.1016/j.reprotox.2013.08.008
[350] Vested et al. (2013). Associations of in utero exposure to perfluorinated alkyl acids with human semen quality and reproductive hormones in adult men. Environmental health perspectives, 121(4), 453–458. https://doi.org/10.1289/ehp.1205118
[351] Samsel and Seneff (2015). Glyphosate, pathways to modern diseases IV: cancer and related pathologies. Journal of Biological Physics and Chemistry 15(3):121-159
DOI:10.4024/11SA15R.jbpc.15.03
[352] Omoto et al. (2015). Immunohistochemical analysis in ethinylestradiol-treated breast cancers after prior long-term estrogen-deprivation therapy. SpringerPlus, 4, 108. https://doi.org/10.1186/s40064-015-0851-8
[353] Dinwiddie et al. (2014). Recent Evidence Regarding Triclosan and Cancer Risk. Int. J. Environ. Res. Public Health, 11(2), 2209-2217. https://doi.org/10.3390/ijerph110202209
[354] Bruggen et al. (2018). Environmental and health effects of the herbicide glyphosate. Science of The Total Environment. 616-617. https://doi.org/10.1016/j.scitotenv.2017.10.309
[355] Trasande et al (2016). Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis.
https://www.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&retmode=ref&cmd=prlinks&id=27003928
[356] Bellanger et al. (2015). Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, The Journal of Clinical Endocrinology & Metabolism, 100(4): 1256–1266, https://doi.org/10.1210/jc.2014-4323

exposure in the EU was €15 billion annually in 2010[357]. Moreover, endocrine disruptors can cause an early onset of puberty which was estimated to cost around $10,605 annually in the US in 2012[358].
In regard to cancer, according to ECHA, the average society willingness to pay to avoid cancer is €3.5 to €5 million per fatal cancer case[359]. Moreover, in 2016 the Dutch institute RIVM estimated that, in the EU in 2012 cases of cancer diagnosis were 122,600 and those were caused by past exposure to carcinogenic substances at work. Of those cases, there were 79,700 death cases corresponding to around 1.2 million years of life lost due to premature death. These numbers bring about a societal cost of approximately €334 billion annually[360].

AMR is another health risk associated with the candidate substances and it's estimated that by 2050, if no action is taken, approximately 390,000 premature deaths will happen annually due to AMR. It was estimated that the corresponding DALYS to AMR cases were 870,000 in the EU in 2015[361,362]. In 2009, it was estimated that for the previous decade AMR had cost €1.5 billion per year due to direct cost of infections in the EU, Norway, and Iceland[363]. It is also estimated that AMR costs the EU €1.5 billion per year in healthcare costs and productivity losses[364]. Moreover, in the EU, approximately €1.1 billion are expected to be spent annually on health care due to AMR if the AMR rates follow the current trends[365]. Furthermore, analysis has shown that MRSA infections attributed to AMR increase the length of hospital stay by 2 to 10 days on average corresponding to €1,200–€50,000 and more in costs[366].

Specific to **PFAS**, a study by the Nordic Council of Ministers240 estimated the annual health expenditure due to kidney cancer caused by PFAS exposure to be €12.7 to €41.4 million in the EEA countries. The study also estimated around €10.7 to €35 billion of annual health costs due to hypertension brought about by background exposure (exposed via consumer

[357] Hauser et al. (2015).

[358] Chen et al. (2012). Medical resource use and costs related to central precocious puberty: a retrospective cohort study. Endocr Pract. doi: 10.4158/EP11293.OR. PMID: 22440983.

[359] European Commission, Directorate-General for Environment, Study on the cumulative health and environmental benefits of chemical legislation : final report, Publications Office, 2017, https://data.europa.eu/doi/10.2779/070159

[360] W.P. Jongeneel et al. (2016). Work-related cancer in the European Union -Size, impact and options for further prevention. RIVM Letter report 2016-0010. https://www.rivm.nl/bibliotheek/rapporten/2016-0010.pdf

[361] Cassini et al. (2018). Attributable discapacity-adjusted-life-years caused by infected with antibiotic-resistant-bacteria in the EU and the European Economic Area in 2015. The Lancet. https://doi.org/10.1016/S1473-3099(18)30605-4

[362] Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. 2014. https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

[363] European Centre for Disease Prevention and Control (ECDC)/European Medicines Agency (EMEA) (2009). The bacterial challenge: time to react. http://www.ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf.

[364] https://ec.europa.eu/health/antimicrobial-resistance/eu-action-antimicrobial-resistance_en

[365] OECD (2018), Stemming the Superbug Tide: Just a Few Dollars More. https://www.oecd.org/health/stemming-the-superbug-tide-9789264307599-en.htm

[366] Antoñanzas and Goossens, (2019) . The economics of antibiotic resistance: a claim for personalised treatments. Eur J Health Econ 20: 483–485. https://doi.org/10.1007/s10198-018-1021-z

products, background levels). Finally, it is worth noting that Bisphenol A is associated with childhood obesity which could cost the EU around €1831[367] million[368].

Several **recreation activities**, such as angling and hiking, are dependent on water quality and the corresponding improvement in water quality can generate additional benefits for recreation activities and tourism. The benefits acquired through recreation activities cannot be monetized directly, however, there is an abundant literature reporting willingness to pay values quantifying the benefits that society associate with such activities. For example, in the Guadiana Estuary of Portugal and Spain, it was estimated that the economic benefits of water quality changes over a period of 20 years would surpass the costs by €3.1 million, knowing that the highest costs reported were €9.4 million that would bring the benefits to a total of €12.5 million[369].

The total annual recreation benefits were estimated to be approximately €15 billion for the Baltic Sea and under a water quality improvement scenario, they are estimated to increase by 7 to 18% across the Baltic Sea countries[370]. Similarly, in 2014, for the Baltic coastline in Finland, a five-class water usability index (poor-passable-satisfactory-good-excellent) was developed based on 15 ecological and chemical criteria that influence recreation use and the corresponding willingness to pay values were the following: poor −€19,931 to −€32,216, passable −€4190 to −€4521, good €2729 to €4169, and excellent €5877 to €9272[371]. In Sweden, in 2009, an average willingness to pay of €9.9[372] per person was estimated to improve the quality of water for fishing, bathing, and hiking activities[373].

8.2.4 *Option 2: Review 4 groups for potential 'family' EQS additions - Hormones (estrogens and macrolide antibiotics), PPPs, Pharmaceuticals.*

Option 2 is analogous to option 1 in terms of adding candidate substances to the EQSD, however, under this option, the substances would be added under family groupings; **estrogenic hormones** (E1, E2, and EE2), **macrolide antibiotics** (azithromycin, clarithromycin, erythromycin), **neonicotinoids** (acetamiprid, clothianidin, imidacloprid, thiacloprid, thiamethoxam) and **pyrethroids** (bifenthrin, deltamethrin, esfenvalerate, permethrin). Further note that where PFAS is understood to cover between 4,000 and 7,000 substances (depending on definition) addition of these substances would require grouping approaches irrespective. For PFAS, the use of a relative potency factor (RPF[374]) approach was

[367] Based on an exchange rate of 1 EUR = 1.09 USD

[368] Grandjean & Bellanger (2017). Calculation of the disease burden associated with environmental chemical exposures: application of toxicological information in health economic estimation. Environmental health : a global access science source, 16(1), 123. https://doi.org/10.1186/s12940-017-0340-3

[369] Guimarães et al. (2012). The impact of water quality changes on the socio-economic system of the Guadiana Estuary: an assessment of management options. Ecology and Society 17(3): 38. http://dx.doi.org/10.5751/ES-05318-170338

[370] Czajkowski et al. (2015). Valuing the commons: An international study on the recreational benefits of the Baltic Sea. https://doi.org/10.1016/j.jenvman.2015.03.038

[371] Artell (2014). Lots of value? A spatial hedonic approach to water quality valuation. J. Environ. Plan. Manag, 57: 862–882.

[372] Based on an exchange rate of 1 EUR = 10.31 SEK

[373] Östberg et al. (2012). Non-market valuation of the coastal environment - Uniting political aims, ecological and economic knowledge. J. Environ. Manage. 110, 166–178. doi:10.1016/j.jenvman.2012.06.012

[374] PFOA-equivalent relative potency factors are an indication of the relative toxicity of a PFAS substance compared to PFOA.

considered for setting a group EQS but the scientific justification for that is still too uncertain to be introduced in the legislation.

The reason that option 2 was included within the consideration of the impact assessment is because there can be good practical reasons for why a grouping approach is warranted. The bullets below provide some examples of this reasoning:

- The substances within the group have the same/similar uses, including acting as alternatives for one another. Addressing these substances individually could mean that measures to address one substance, creates regrettable substitution for substances in the same family. Grouping would therefore improve the consistency of the approach.
- The substances within the group have similar toxicity and modes of action, meaning possible cumulative / additive effects. Assessing the substances as a group could help better understand the overall risk as oppose assessing the risk one by one.
- There are issues with environmental fate and pathway to environment. i.e., one substance in the group can degrade in the environment to form another substance in the same group. Therefore, identifying the sources and pressures for surface water needs a group approach to take these issues into consideration. This is an issue particularly relevant for PFAS.
- Issues with substances in the same group being managed differently across the policy landscape. Including possible issues with antagonisms or incoherence's as a result. An argument could be made that by grouping the substances it will help identify such issues more easily and proactively manage them to provide a more consistent approach.

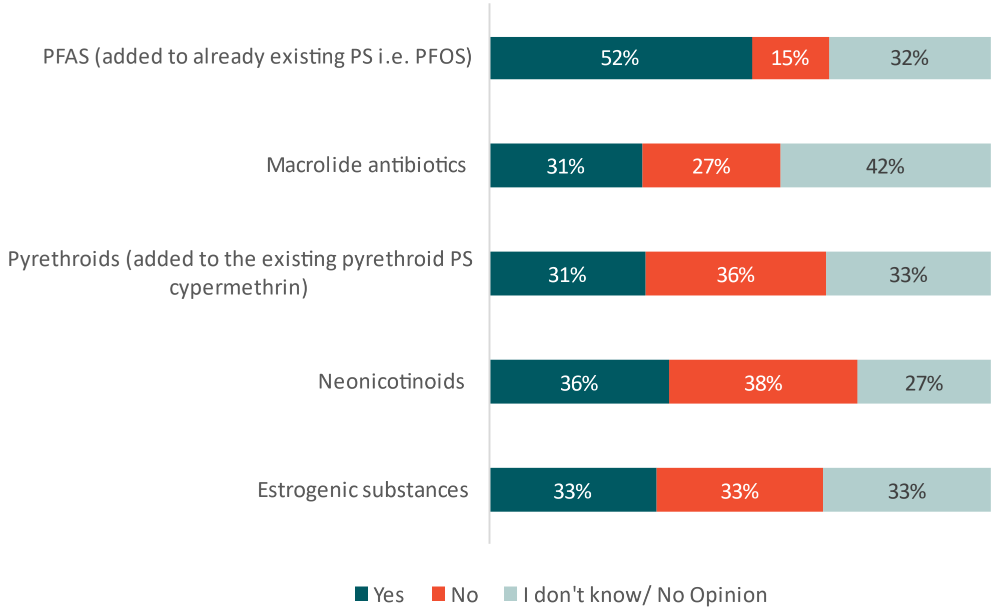
Equally there can be negative effects for applying a grouping approach inappropriately, for example:

- The substances in the group have sufficiently different sets of uses, toxicity, and mode of action, that applying a grouping approach leads to a loss of critical information or creates incoherence.
- One substance in the group is used in considerably higher quantities than the other members, meaning that a grouping approach creates a diluting effect and masks the fact that one substance in particular creates the overall problems.
- One substance is considerably more potent than the other members meaning that a group approach could underestimates / minimise potency effects. i.e., important not to treat all group members equally. This may be relevant for the estrogenics where EE2 is more potent than E1 and E2.
- Substances within the group will still need to be monitored and analysed individually to understand the contribution of each individual member. Therefore, unlikely to be a cost saving in terms of monitoring and analysis. Which means there needs to be an implicit overall benefit from other aspects otherwise grouping may add little value.

These points will be key to understanding the costs and benefits of applying grouping approaches for the four potential 'family' EQS additions against the candidate priority substances. As part of this analysis, the targeted consultation specifically posed the question of whether grouping was appropriate or not in the expert questionnaire. Figure 8-1 provides the results of this consultation with some further commentary based on the response to the open question on grouping immediately after the figure.

Figure 81 Response from the targeted consultation

[Q2] An alternative approach to adding all of the candidate substances individually is to add them to the Directive as groups of substances, as has already been done for the polyaromatic hydrocarbons. Please indicate whether you think the substances should be added as groups.



- *Estrogenic substances*. The responses for this family of chemicals were mixed. Some respondents favoured a grouping approach on the basis of analytical approaches and similar modes of action, meaning that burden could be managed. Another respondent highlighted that this group could be a good candidate for effect-based methods as part of the analysis. Respondents who were against grouping, highlighted that the relative abundance of different substances is likely to vary markedly, and furthermore that the family includes both naturally occurring and synthetic chemicals which would make grouping scientifically unsound.
- *Macrolide antibiotics*. There were mixed responses to a proposed grouping for macrolide antibiotics. Some respondents highlighted that the modes of action would be similar, and a group listing could be beneficial for a more generic approach to managing anti-microbial resistance. Respondents who opposed a grouping strategy highlighted that the substances would still need to be monitored and analysed separately, and that the relative potency of the different substances also varied meaning different levels of risk.
- *Neonicotinoids*. Similar comments were also received for the neonicotinoids highlighting that only one out of the five substances have an active approval. Granularity of data was seen as important to understand trends between different neonicotinoids. Arguments were also made against grouping based on potency of toxic effects and variation in the level of risk.
- *Pyrethroids*. The general concerns raised by the respondents against a grouping for pyrethroids, was that some members are allowed banned/no longer used, while others are in active use. A grouping approach would lose the granularity over specific substance risks. The respondents also highlighted that the potency of individual pyrethroids can vary

widely, meaning they are better suited as separate entries. Those in favour of a grouping approach highlighted that the modes of action are likely similar, and a mixture-based approach could be very useful.

- *PFAS*. It was recognised that thousands of substances are classed as PFAS, so a grouping approach based on the most relevant/potent substances was a reasonable approach. One respondent commented that equivalence based on the potency against PFOA was a good compromise to managing a wide range of complex substances. The counterpoint to these comments from other respondents was that the physical-chemical properties of individual PFAS can vary widely and standards for analysis only currently exist for 10 substances. Other respondents highlighted concerns around the coherence between the EQSD, DWD and GWD for which PFAS substances are included.

Economic impacts — *Costs*

See option 1. However, because this option includes all substances using groups of substances where appropriate in the priority substances list and sets corresponding EQS (using markers or the sum of substance concentrations in the case of groups). There could be a slight increase in administrative burden on behalf of the European Commission. However, this cost would likely be small.

Further comments can be made as follows:

- *Estrogenics*: anthropogenic uses of the three estrogenics broadly align, as do the pathways to environment. However, where E1 and E2 are also generated naturally, and the potency of the different potential group members vary considerably. Equally in terms of end-of-pipe treatment, while ozonation was identified as effective against E1 and E2, it falls below 75% efficacy for EE2, suggesting a mismatch and potential incoherence issues if grouped. In terms of distance to target, EE2 is also in a higher group (large) than E1 and E2.

- *Macrolide antibiotics*: the main issues identified for this potential grouping is differences in potency between members and fact that Azithromycin sits in a high distance to target group than its other potential members.

- *Neonicotinoids*: Multiple issues have been identified, differences in regulatory status of the potential members, differences in toxicity, different pathways to environment, different end of pipe treatments needed. Grouping in this case could create multiple incoherence's resulting in economic costs and loss of granularity in data.

- *Pyrethroids*: Similar issues as above, different regulatory status for different members. Some used as pesticides, some used as biocides, meaning pathway to environment varies and importance of pathway also varies. Grouping could create loss of granular data and incoherence resulting in economic costs.

Economic impacts — *Benefits*

Economic benefits are assessed to be largely the same as for option 1. Note as indicated each substance would still need to be monitored and analysed individually, meaning no cost savings for monitoring or analysis. However, there are some potential economic benefits which have been identified:

- *Estrogenics*: in terms of source control the same alternatives are identified for E1 and E2, while there may also be some overlap for EE2. A grouping approach and recognition of the relationships between the different estrogenic substances, could mean a coherent and considered approach is developed for source control that avoids regrettable substitution. This would mean managing the issue could be handled more effectively.
- *Macrolide antibiotics*: Option 1 recognises the importance of end-of-pipe treatments as a measure for pharmaceuticals. In this case the same technology is applicable to all three substances and therefore a grouping could help consolidate the measures providing cost savings. Equally, the potential alternatives for all three substances are the same, with individual members likely substituted for other members. A harmonised approach is strongly needed to help proactively manage the use, emission, and work to intervene against anti-microbial resistance. This suggests possible cost savings by using a group approach.
- *Neonicotinoids:* no additional benefits identified.
- *Pyrethroids:* Very few alternatives identified, including cypermethrin (which is already a priority substance). If source control utilises restrictions / bans need to avoid regrettable substitution. A group approach could help limit this impact, but equally could lead to loss of granular data per substance.

Environmental impacts — *Costs*

The environmental costs are assessed to be broadly the same as option 1, with the following caveats:

- *Estrogenics:* The potency of EE2 is considerably stronger than E1 and E2. Additionally, E1 and E2 are naturally produced, while EE2 is synthetic. While there are strong arguments that the use and mode of action is broadly the same, suggesting a group approach could be positive. In reality, grouping could have a diluting effect in terms of the importance of EE2. This would have negative environmental impacts.
- *Macrolide antibiotics:* The main argument against grouping macrolide antibiotics is the variation in potency which is evidence by the differences in the distance to target. A grouping approach could lead to a loss of granular data which would lead to environmental impacts if the correct weight of attention was not placed on key members of the potential grouping.
- *Neonicotinoids:* The primary issue identified for grouping neonicotinoids is the fact that the different substances within the group are at different regulatory status. This includes one live approval and non-approvals for the remainder. Where emergency authorisations have been contentious, a grouping here could lead to a loss of granular data which could be used to correlate ambient concentrations against use and pathway to environment. The loss of that granularity would likely hamper selection of measures and response to achieving good chemical status to the detriment of the environment.
- *Pyrethroids*: There are similar issues for the pyrethroids (as with neonicotinoids). The use profile and regulatory status of the different substances varies significantly. This

also impacts the pathway to environment. Grouping could lead to incoherent approaches that reduce the effectiveness of measures. A further point is that the analysis has identified cypermethrin as a key alternative (which is already a priority substance). In this case greater granularity of monitoring data would be important, and a grouping could damage availability of such data.

Environmental impacts - *Benefits*

Assumed to be the same as for option 1, with the following caveats:

- *Estrogenics:* no additional benefits identified.
- *Macrolide antibiotics:* Improved consistency and coherence of approach for macrolide antibiotics and links to wider anti-microbial resistance approaches, could have synergistic benefits for the environment.
- *Neonicotinoids:* Managing the neonicotinoids as a group could have synergistic benefits to greater coherence with other policy work on protecting pollinators. The main caveat here, being that data would need to reflect the impacts of approved / not approved group members. i.e., the impacts of acetamiprid would still need to be disaggregated from neonicotinoids as a group.
- *Pyrethroids*: no additional benefits identified.

Social impacts - *Costs*

Social costs are assessed to be the same as option 1, with the following caveats:

- *Estrogenics:* Where the potency of different substances in the potential group vary, and where EE2 is synthetic, a grouping approach could mask the impact of individual members. This could mean in terms of measure selection, particularly for alternatives, that availability of medicines is impacted negatively for human use. Granularity of data will be important in decision making, and this has impacts for selection and availability of medicines.
- *Macrolide antibiotics*: The main argument against grouping is a loss of granular data, and how that might impact measure selection. Particularly source control and restrictions on use. This could have impacts for availability of antibiotics and their alternatives. However, in reality the study notes that alternatives are very limited, often swapping one of the candidate substances for another. It is likely in the case of antibiotics that end-of-pipe measures will be more prominent. In that respects the societal costs of using a grouping approach here could be limited.
- *Neonicotinoids:* no additional costs identified.
- *Pyrethroids*: no additional costs identified.

Social impacts - *Benefits*

Assessed to be the same as for option 1, with the following caveats:

- *Estrogenics:* societal benefits from adding estrogenics as a group vs individually may be more limited, but one possible issue is source control options and alternatives. Where E1 and E2 have the same alternatives, a group approach could help more effective management and selection of alternatives, which would have societal benefits. Note however, EE2 has a slightly different profile, so would need to be treated differently.

- *Macrolide antibiotics:* A group approach could provide an improved approach and management of issues leading to antimicrobial resistance, which would have clear societal benefits. The justification in this case is that the alternative substance for one macrolide antibiotic is likely to be another macrolide antibiotic from the same group. Treating them individually and applying measures based on distance to target would likely lead to an increased uptake of the next macrolide antibiotic, replacing one problem with another, while not suitably supporting societal needs.
- *Neonicotinoids:* Greater coherence and consistency across the policy landscape for protection of pollinators could be seen as a societal benefit. Note that only one of the five neonicotinoid substances has an approval in place. Greater comparison and coherence regarding environmental concentrations treating them as a group would highlight whether acetamiprid needs further restriction.
- *Pyrethroids*: no additional benefits identified.

Summary

Option 2 aimed to assess whether grouping approaches could be useful in terms of adding candidate substances to the priority substance list. In this respect five different potential groups were identified, with a grouping strategy already in place for PFAS (on the basis that this family spans 4,000 – 7,000 member substances). The remaining four potential groups were then assessed as part of the impact assessment. The contextual points made in section 8.4.2 help define the potential positives and negatives for why a grouping approach might be taken. To further illustrate the points raised as a set of metrics for the four potential groups Table 8-22 provides a high-level overview. This illustrates that the macrolide antibiotics have the greatest potential for addition as a group, with the main limiting factor being the different potency between group members, which would impact the EQS.
The two plant protection product groupings (for neonicotinoids and pyrethroids) look more problematic, with more negative correlations than positive. This is likely to mean the cost impacts outweigh the benefits of using a grouping approach in this case.

Table 8-22 Summary of comparable metrics to help determine potential for grouping

Substance	Potency	Mode of action	Uses	Pathway to environment	Alternatives	End-of-pipe treatments	Societal benefits
Estrogenic hormones	X	✓	✓	✓	✓	X	✓
Macrolide antibiotics	X	✓	✓	✓	✓	✓	✓
Neonicotinoids	X	✓	X	X	X	X	✓
Pyrethroids	X	✓	X	X	✓	X	X

8.2.5 *Option 3: Assess EQS for targeted set of high priority substances identified by the Commission and JRC*

Option 3 involves amending the EQS for existing priority substances following a thorough examination of the new scientific data that has emerged since the original addition of the substance to the priority substance list. On the basis of this new data, it has been possible to reassess the potential risks and assign EQS accordingly. These amendments can take one of three forms:

- A reduction in the threshold value where the existing threshold is not cautious enough.
- An increase in the threshold value where the existing threshold is found to be overly cautious.
- New elements added to the EQS that were previously missing. For example, the current EQS for mercury in water include only a Maximum Allowable Concentration (MAC). The revision of the mercury EQS will now include for the first time a proposed Annual Average EQS to complement the MAC threshold.

The substances that have been prioritised for review and potential amendment of the EQS largely come from the set that were included within the original 2008 EQS list of 33 substances, with a smaller set also included from the update in 2013 that added a further 12 substances:

- Substances for review that were added to the EQS in 2008: PBDEs (entry 5), chlorpyrifos (9), diuron (13), fluoranthene (15), hexachlorobenzene (16), hexachlorobutadiene (17), mercury (21), nickel (23), Nonyl-phenol (24), PAHs (28), and tributyltin (30).
- Substances for review that were added to the EQS in 2013: dicofol (entry 34), PFOS (now proposed to be merged into PFAS) (35), dioxins and furans (37), cypermethrin (41), and heptachlor and heptachlor oxide (44).

Where all of the proposed substances for EQS amendment have been part of the priority substance list for at least 9 or more years, it can be assumed that a suitable body of monitoring data has been developed to better understand chemical status. Furthermore, where exceedances of status exist it is anticipated that Member States will act accordingly and develop programs of measures to address the exceedances identified. This pre-existing data and activities already defined form part of the overall dynamic baseline. The impact assessment, therefore, is focused on any impacts created by changes to the existing status. For example, if the existing EQS is reduced significantly triggering a new wave of exceedances, it can be reasoned that the existing program of measures may be insufficient, and additional effort or packages of measures may be needed to address the issues, with the resulting economic, social, and environmental impacts. The counter-factual in this example is that a reduction in threshold (based on new scientific evidence) and resulting new measures, would improve environmental protections and help minimise or eradicate impacts previously left unchecked.

Section 8.1 provides details of the distance to target assessment and size of the gap, based on the existing state (baseline) and proposed new EQS. This very broadly identifies two outcomes, in the first case the amendment of the EQS results in **no change to the distance to target grouping** (large/medium/small), and secondly the changes do result in a change (promotion or demotion between groupings). Where there is a change in distance to target it is possible to more strongly make the case that there will be a change in the impacts (positive and/or negative) spanning economy, environment, and society. For the cases where there is no change group, it is anticipated that the existing measures and approach are already sufficient and the only impact would be improved protection for the surface water environment on the basis of the most relevant and up to date data being used. However, it is also possible that even if there is no change in distance to target group, because of a range of subtle factors, it may have impacts for measure selection which need to be considered. Therefore, the analysis has considered these elements as part of the review.

One further comment is that because the identified substances have been part of the EQS priority substance list for a considerable time, environmental concerns are well established, and this can mean that commercial manufacture and use ceased quite some time ago. In these cases, source control is unlikely to be relevant for measure selection on the basis that there is no ongoing manufacture or use.

To help provide a further contextualisation of the situation for the substances covered by option 3, Table 8-23 provides details of the major and minor pathways to environment that have been identified and their current legislative status (banned / still in use).

Table 8-23 Overview of pathways to environment

Substance	Legislative status	Major Pathways	Minor Pathways
Pesticides and biocides			
Chlorpyrifos	Not approved for use since 2019, and now identified as a candidate POP under the Stockholm Convention. No ongoing commercial use.	Legacy sites of manufacture. Other legacy sites of contamination	Management of obsolete stocks
Cypermethrin	Used in the protection of wood against wood-destroying insects, applied as an insecticide in agriculture and applied topically in veterinary applications[375]. Approved as both a pesticide and biocide.	Manufacturing sites Run-off from fields (agricultural application)	Wastewater treatment works.
Dicofol	Note approved for use since 2008. No ongoing commercial use.	Legacy contaminated sites.	
Diuron	Not approved for use in the EU as a biocide or PPP. However, can be used within industrial chemicals manufacture. Suggest move to industrial chemicals. Pesticide use has ceased. Still used within industrial chemicals.	Industrial manufacturing processes.	Legacy sources.
Heptachlor/Heptachlor oxide	Banned in the EU since 1984. Added as a POP to the Stockholm Convention in 2004.	Legacy contaminated sites.	

[375] Cypermethrin EQS dossier, 2022

Substance	Legislative status	Major Pathways	Minor Pathways
	No ongoing commercial use.		
Hexachlorobenzene	Banned in the EU since the early 1980s. Added to the Stockholm Convention in 2004. No ongoing commercial use.	Atmospheric deposition linked combustion of fossil fuels. Landfill leachate. Legacy contaminated sites.	Land spreading of sewage sludge. Leaching of formerly treated timber.
Tributyltin	Banned, but previously used as an antifouling paints on ships and boats No ongoing commercial use.	Wastewater treatment works (linked for historic sources). Legacy contaminated sites.	Landfill leachate
Industrial chemicals			
Dioxins and furans	No formal commercial uses. Produced as a by-product of incomplete combustion where there is a source of chlorine and organics. Unintentional formation	Atmospheric deposition from incomplete combustion sources. Metal smelting manufacture.	Landfill leachate.
Fluoranthene	Use as a binding agent in industrial processes, in consumer products such as clay pigeons, and active carbon, and in professional uses such as road construction[376]. Ongoing commercial use	Industrial petroleum manufacturing processes. Wastewater treatment works.	Atmospheric deposition.
Hexachlorobutadiene	Unintentional by-product of the chemicals industry e.g. the manufacture of chlorinated solvents, magnesium production and incineration. Unintentional formation	Unintentional by-product from industry production.	Legacy contaminated sites.
Nonyl phenol	Since 2003 the production and majority of uses of nonylphenols have been restricted. Unintentional formation	wastewater treatment works (based on imported textiles) Landfill leachate.	Land spreading.
PAHs	Unintentional by-products from incomplete combustion of organic materials. Oil residues containing PAHs are added to rubber and plastics as a softener or extender. Ongoing commercial use and unintentional formation	Atmospheric deposition from combustion. Manufacturing involving use of oil/petroleum-based products.	Run-off from road

[376] https://circabc.europa.eu/sd/d/4336e1e5-ba0c-4545-abee-7743d2085bc3/Fluoranthene%20EQS%20dossier%202011.pdf

Substance	Legislative status	Major Pathways	Minor Pathways
PBDEs	Use of lower order homologues was banned internationally in 2004 and use of DecaBDE should have ceased by 2021. No ongoing commercial use.	Wastewater treatment (based on indoor contaminated dusts). Deposition from e-waste handling sites.	Atmospheric deposition. Contaminated legacy sites
Metals			
Mercury	Quantity from coal combustion declining as other energy sources utilised. Estimated 40-80%[377] of total mercury deposition in EU originates from outside. Ongoing commercial use / natural substance /unintentionally formed.	Atmospheric deposition from combustion of fossil fuels. Manufacturing processes using mercury. Artisanal mining activities.	Wastewater treatment works (range of sources) Use of fungicides, antiseptics, and disinfectants in outdoor settings. Natural sources.
Nickel	Naturally occurring element with a range of uses. Ongoing commercial use / natural substance	Atmospheric deposition from combustion of fossil fuels. Mining operations. Wastewater treatment (range of sources) Naturally occurring substance	Land spreading of sewage sludge. Landfill leachate.

Economic impacts — *Costs*

Further measures would be required for some substances in order for more stringent EQSs to be met. The sectors bearing the costs of the measures associated with amendment of EQS will depend on the substance amended. The scale of the costs depends on the type of measures MSs and sectors will choose to implement as well as the scale of action, based on the degree of existing and potential EQS exceedance.

For most of these substances, use is either heavily regulated (e.g. nonylphenol and PBDEs) or banned (e.g. chlorpyrifos, hexachlorobenzene, hexachlorobutadiene, heptachlor, tributyltin (TBT) and some PBDEs). Therefore, the main pressing topics could relate more to legacy issues, which could be in some cases more challenging to address (in part because the originator of the source may no longer exist, and in part due to the long-lived nature of substances in the environment). The level of the EQS will determine how substantial the measures may need to be, with the costs to achieve good chemical status likely to fall on the taxpayer via the Member State authority (in the case of legacy pollution). Regarding TBT, it should be noted that Member States asked the Commission to assess if an EQS for TBT in sediments could be derived to facilitate the monitoring of this substance, because the EQS in water is so low that it is difficult to determine accurately whether it is being exceeded. The proposed EQS for TBT in sediment takes account of the tendency of TBT to accumulate in sediments and is based on scientific studies on the toxicity of TBT to sediment-dwelling

[377] HBM4EU policy brief (internal, not published), and references therein

(benthic) organisms. It is not possible to precisely determine how the sediment EQS equates to a concentration in water, because there is some uncertainty about the equilibrium partitioning coefficient, but the sediment EQS probably provides a similar level of protection to that provided by the current water EQS. Thus, implementation of the sediment EQS should in principle not result in additional costs for measures, although in Member States that have until now failed to detect exceedances because of the difficulty of analysing TBT in water, exceedances in sediment might become detectable and require measures to be taken.

Measures to reduce emissions are also well-established for most PS substances, e.g. industrial emissions for dioxins are very strictly controlled under related legislation such as the Industrial Emissions Directive and current emissions levels are decreasing or 'plateauing'. Further reductions could be very costly and challenging for increasingly reduced benefit. There may also be economic costs to deal with diffuse sources (e.g. household burning and waste combustion), which are accounting for a larger share of overall dioxins emissions. However, these sources are difficult to control so the feasibility of measures would be uncertain. They may involve similar measures as for PAHs, for example raising public awareness and changing domestic fuel use. For some substances (those produced unintentionally and/or naturally such as PAHs), emissions cannot be completely eliminated and additional measures might not be feasible. For PBDEs, their widespread presence means that further emissions reductions are very costly and challenging.

Similar to other options, different measures within the four emission reduction measure categories (source control, physical barriers, end-of-pipe treatment and natural attenuation and monitoring) could be deployed to enable existing priority substances to meet their new EQS (if these thresholds are stricter).

Pesticides and biocides

Option 3 would apply to the following pesticides/biocides: chlorpyrifos, cypermethrin, dicofol, diuron, heptachlor/Heptachlor oxide, hexachlorobenzene, and tributyltin.
The distance to target for these pesticides and biocides has been assessed as:

- Large – none
- Medium -chlorpyrifos, cypermethrin, tributyltin, diuron
- Small – dicofol, heptachlor/Heptachlor oxide, hexachlorobenzene

Source control:

Based on the substances covered by option 3 under the category of pesticides and biocides, only one substance still has live approvals as both a pesticide and biocide, namely cypermethrin. It is further noted that the approvals for diuron and chlorpyrifos only expired recently (2020 and 2019 respectively), with the last of the remaining stockpiles likely now used up. This means that measures associated with source control will relate to one substance only. The proposed EQS amendment for cypermethrin would reduce the EQS for annual average concentration from 0.00008 µg/L to 0.000054 µg/L. While the distance to target grouping has remained the same, it is possible that the lower threshold would see an increase in exceedances, warranting additional measures.
Where control at source is a key point of intervention, it is possible to see restrictions on use as a viable solution. As with option 1, an analysis of possible alternative pesticides has been

completed and reported in -Table 8-24. This includes a small number of substances, including acetamiprid (listed as a candidate for inclusion within the priority substance list – see option 1).
Alternatively, there are also non-chemical alternatives, with Willoughby et al[378] provides details of integrated pest management within the forestry sector that could successfully replace the need for cypermethrin use.

Table 8-24 Chemical alternatives to cypermethrin

Original substance	Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)	Alternative	Cost (EUR) per hectare (using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022)
Cypermethrin	0.07	Acetamiprid	3.43
Cypermethrin	0.07	Malathion	4.0
Cypermethrin	0.07	Pirimiphos-methyl	0.06

Pathway disruption

Cypermethrin is a current pyrethroid pesticide that is approved as an insecticide within Regulation EC 1107/2009 and is approved as a biocide/wood preservative and insecticide under the BPD[379]. A couple of measures were identified relating to the disruption of cypermethrin's pathway from its use as a pesticide to the environment. Substances for which a physical barrier measure was identified as being useful:

Table 8-25 Chemical alternatives to cypermethrin

Substance	Measure	Total cost (€)*
Cypermethrin	• Physical barriers — additional controls and treatment for farmed animal use • Physical barriers to surface water buffer strips	• 27,600,000[380] • No data

* all costs are in EU27 in Euros annually — for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

In Sweden, it was estimated that 1.3kg of diuron per year is emitted to air from dry paint on inner walls (Sweden only)[381]. It was also estimated that based on the assumption of 5% of paint being emitted to wastewater, 60kg of diuron is emitted to wastewater per year[382]

[378] Willoughby et al, 2020, 'are there viable chemical and non-chemical alternatives to the use of conventional insecticides for the protection of young trees from damage by large pine weevil hylobius abietis L in UK forestry', Forestry vol 93, issue 5.
[379] Cypermethrin Dossier
[380] Cost calculation is based on the average cost of dip pens and containment areas to allow drying €1,120 as a one off cost multiplied by the number of sheep farms in Eurostat (24,600) rounded to three significant figures.
[381] https://www.chemitecs.se/download/18.15a855cb14c38029e64374/1427888970455/Chemitecs%20P5-D1b%20SFA%20diuron%20final.pdf
[382] https://www.chemitecs.se/download/18.15a855cb14c38029e64374/1427888970455/Chemitecs%20P5-D1b%20SFA%20diuron%20final.pdf

(Sweden only). Annual deposition on inland surface water and on land in Sweden is estimated to be 0-2 kg respectively 0-30 kg[383].

As a result, the use of remediation measures, such as the replacement of diuron-contaminated wooden infrastructure, was identified as being a likely measure which could be used to address this pathway to the environment. However, no cost could be attributed to this measure.

Table 8-26 Substances for which a source control measure was identified as being appropriate

Substance	Measure
Diuron	• Remediation – removal and replacement of wood-based infrastructure contaminated with Diuron.

End of pipe:

The most likely end-of-pipe measures which could be used to reduce the size of the gap between the environmental concentrations and the proposed EQSs for cypermethrin shown in -Table 8-27. As with option 1, total costs of wastewater upgrade for advanced treatments would defer to the study completed by the JRC to support revision of the UWWT directive (see -Table 8-8). However, an analysis has been completed using the same methodology set out under option 1 to identify the most likely treatment options.

Table 8-27 Most likely end-of-pipe measures to reduce the size of the gap, by substance

Substance	Measure	Cost (as € per population equivalent, per annum)	Efficacy (%)
Cypermethrin	WWTWs – GAC	1.17 to 26.2	99%

* all costs are in EU27 in Euros annually – for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

Wastewater treatment is effective for Mercury, Nickel, PAH and Cypermethrin so the cost range of €1.17- €26.2 per population equivalent, per annum (technology dependent) will generate benefits for various substance categories simultaneously which makes it difficult to attribute to a single substance.

Note that in the case of cypermethrin the treatment options were more limited, with the best cost/efficacy combination being GAC. This along with the related technology, PAC, are the most expensive options. Given the potential reduction in EQS for cypermethrin, its possible that source control through greater restriction of biocidal use may be preferable to upgrade using GAC.

Additionally, for diuron which was been used as a timber treatment and only recently had its approval end (in 2020), there are further end-of-pipe possible measures. The proposed EQS is expected to be more stringent (AA concentration moving from 0.2 to 0.002µg/L, and MAC from 1.8 to 0.268µg/L). The distance to target has been promoted from small to medium,

[383] https://www.chemitecs.se/download/18.15a855cb14c38029e64374/1427888970455/Chemitecs%20P5-D1b%20SFA%20diuron%20final.pdf

and therefore could lead to an increase in exceedances, at least in the short-medium term (5-10 years) where legacy issues present.

Where diuron has previously been used as a pesticide and biocide to treat building/construction surfaces, it can enter surface water during rain events as a result of leaching from building materials as well as being transported from water coming from agricultural areas[384]. Diuron has been detected in Polish rivers and a drainage ditch draining water from arable fields[385]. The highest concentration of diuron in the Wilsla River was thought to be due to the use of impregnating agents used in the maintenance of ship hulls as the biocide was only determined to be present in the summer months and not the winter months[386].

Natural attenuation and monitoring (incl. dredging):

Where the majority of substances included under the pesticide category are no longer in commercial use, its likely that natural attenuation could be a preferrable strategy. It should be noted that the proposed EQS for heptachlor (and heptachlor oxide), and hexachlorobenzene are less stringent than the existing thresholds suggesting **no new abatement measures would be needed** and monitoring may be sufficient.

In some instances, the use of dredging may be appropriate for the removal of substances bound to the sediment in waterbodies. In the Andalusia region of Spain, the average cost of dredging 1 m^3 at each port in the region was calculated[387]. The highest costs for one port came to EUR 78.45/m^3 due to the special treatments the dredged material required prior to being sent to its final destination. The second highest cost for another port came out at EUR 18.21/m^3 and the lowest cost at a port came out at EUR 3.51/m^3. However, it should be noted that these were based in a marine/coastal environment. The mean cost of dredging in the Atlantic ports came to EUR 6.28/m^3 and the mean cost came to EUR 8.28/m^3 in Mediterranean ports[388].

In the UK, the Canal & River Trust spent £8.2 million on dredging in the 2019/2020 financial year and £7.2 million in 2018/19 in the financial year. They estimated that 1 km of dredging costs approximately £75k–£200k/project[389].

Summary

Based on the substances covered by the pesticides and biocides for amended EQS and analysis completed here, it is possible to foresee that additional measures may be needed for cypermethrin, chlorpyrifos and diuron as a result of the proposed EQS changes. For the other substances (dicofol, heptachlor, hexachlorobenzene and tributyltin) the impacts are likely to be less pronounced, either because the threshold is less stringent, or because even with more stringent thresholds the number of exceedances is likely to be within the range that existing measures will be sufficient.

Two of the three substances (diuron and chlorpyrifos) are already no longer approved for use (albeit only recently), while cypermethrin is used as both a pesticide and biocide. Given that

[384] https://link.springer.com/content/pdf/10.1007/s11356-020-11581-7.pdf
[385] https://link.springer.com/content/pdf/10.1007/s11356-020-11581-7.pdf
[386] https://link.springer.com/content/pdf/10.1007/s11356-020-11581-7.pdf
[387] https://www.mdpi.com/2077-1312/8/3/186/pdf
[388] https://www.mdpi.com/2077-1312/8/3/186/pdf
[389] https://canalrivertrust.org.uk/media/original/42694-boater-report-2020.pdf?v=8f4602

the end-of-pipe option would involve GAC a restriction of use in biocides (particularly where there is a risk for release to sewer) may be the preferrable measure by MSs. Additionally, pathway disruption and management of legacy aspects of the remaining emissions may be employed by MSs. However, environmental costs of dredging would need to be considered and it may not to be a desirable course of action, given its wider issues and potential impacts.

As mentioned previously under the Drinking Water Directive (EU 2020/2184) a group standard is applied for pesticides total, with a maximum allowable concentration in drinking water of 0.5 µg/l. While the standard does not currently apply to surface water, it is recognised that drinking water can be abstracted from both surface and ground water sources. This means the ambient concentration of priority substances in surface water can have an impact for drinking water abstraction and total concentration of all pesticides. Van der Hoek[390] comment on a survey of Eureau members in 2010 for different types of abstraction and commonly used treatment. For surface water abstraction (without artificial recharge), the most common treatments involve coagulation, sedimentation, and filtration. Further advanced treatment (which is used less often) included use of oxidation processes, membrane filtration and desalination where needed. While this paper is older (2010) it suggests the pre-existing conventional treatment would have some limited benefit in reducing the concentration of pesticides, particularly those bound to suspended sediment (such as the POP-based pesticides). However, to achieve compliance with the 0.5 µg/l standard for total pesticides, if the existing pesticides on the priority substance list plus candidate substances (see Option 1 and 2), additional methods may be needed. This likely includes the pathway disruption options already detailed to reduce surface water concentrations, and potentially advanced filtration processes using GAC (see costs outlined in Table 8-27)

Industrial

Option 3 would apply to the following industrial chemicals: Diuron (where relevant), Dioxins, Fluoranthene, PAHs, Hexachlorobutadiene, Nonyl phenol, PBDEs. For PFOS see the entry under PFAS for option 1.

Unlike the substances covered under pesticides, the majority of the substances listed under industrial chemicals are either still commercially in use or are formed unintentionally from ongoing activities. The exception being PBDEs which are now banned. Based on the proposed EQS, some are less stringent than the existing threshold (fluoranthene, PBDEs, and dioxins), while others are more stringent (PAHs, and hexachlorobutadiene). One substance — nonyl phenol — has a more complex picture; the proposed AA concentration is more stringent but the MAC is less stringent.

-Table 8-28 (below) provides an indication of the current rates of exceedances based on monitoring in the EU 27. The distance to target analysis identifies two substances which would potentially change group based on the new EQS. Fluoranthene has been demoted from ‘medium’ to ‘small’, and PAHs have been promoted to ‘medium’.

[390] Van der Hoek et al, 2010, ‘Drinking water treatment Technologies in Europe: State of the art – vulnerabilities – research needs’, published by Delft University, the Netherlands

Table 8-28 Number of failures to achieve good chemical status due to option 4 substances[391]

Substances	Total number of waterbodies	Number in which failure to achieve good	Percentage within EU27 (%)
Fluoranthene	97,000	1321	1.4
Hexachlorobutadiene	97,000	26	0.03
4-nonylphenol	97,000	162	0.2
Benzo(a)pyrene	97,000	1620	1.7
EEA Total benzo(b)fluoranthene + benzo(k)fluoranthene	97,000	458	0.5
Anthracene	97,000	102	0.1
Naphthalene	97,000	24	0.02
EEA Total benzo(g,h,i)perylene + indeno(123-cd)pyrene	97,000	3105	3.2
EEA Brominated diphenyl ethers	97,000	23315	24.0
Dioxins	No data	No data	No data

The distance to target for industrial chemicals has been assessed as:

- Large — PBDEs
- Medium - Dioxins and Furans, Diuron, PAHs
- Small — Fluoranthene, Hexachlorobutadiene, Nonyl phenol.

Source control:

For the industrial chemicals there are potentially four substances which have ongoing intentional commercial use:

- Diuron (100 - <1,000t per annum) Used as an intermediate in manufacture of rubber products.
- Decabrominated diphenyl ether (100 - <1,000t per annum), used within legacy components for the automotive and aviation sector. (all other PBDE family members are banned).
- PAHs - found as a mixture within crude oil and petroleum-based products, including fuels, road surfacing materials, and lubricants.
- Fluoranthene found within PAH mixtures, range of uses including dyes, pharmaceuticals, and insulating oils.

Note, that 4-nonyl-phenol branched also has a live REACH registration (EU quantities >10,000 - <100,000 tonnes per annum). However, the entry details that use is as an intermediate in polymerisation reactions that occur outside of the EU. Nonyl-phenol is expected to be consumed during polymerisation, but possible for unreacted monomer to still be present in very low concentrations.

[391] https://www.eea.europa.eu/themes/water/european-waters/water-quality-and-water-assessment/water-assessments/chemical-status-of-surface-water-bodies

PBDEs and PAHs are both recognised as POPs under the Stockholm Convention and UNECE POPs Protocol respectively. For PAHs and fluoranthene in particular, their presence is linked to the production of crude oil and petrochemical industries. In the case of fluoranthene the proposed EQS amendment is less stringent; therefore, additional source control measures beyond those already included in programs of measures are unlikely. In terms of PAHs, where they are recognised as a POP under the UNECE Convention on Long Range Transboundary Air Pollution[392] controls and measures have already been significantly implemented. But it is possible that additional measures under the EQSD to protect water specifically could be needed, including restrictions on the domestic combustion of coal, and on-site treatment of wastewaters from petroleum industries could be used to further limit releases of PAHs. Additionally, in 2019, ECHA's committees adopted their opinion on the restriction proposal which would ensure that granules or mulches (in particular from end-of-life tyres) are not placed on the market for use or used as infill material in synthetic turf pitches or similar applications if they contain more than 20 mg/kg in total of the eight indicator-PAHs. It has been estimated that this restriction would cost the EU society approximately €5m per year. This cost estimate factors for increased production costs (improved tyre selection), revenue losses from selling incompliant infill on alternative markets, increased testing costs and enforcement costs. The overall societal costs were estimated at approximately €30-€55m over a 10-year period. The midrange scenario was assumed to equate to €45m[393].

For **nonylphenols and nonylphenol ethoxylates** significant steps have already been taken within the EU to restrict and control their use (see ECHA 2016-2020 study[394]). The costs of restricting nonylphenol (NP) and its ethoxylates (NPE) in textiles was estimated to cost the EU €3.2m per annum for a reduction of 15 tonnes of NP/NPE released to surface water. These are aspects already included within the dynamic baseline. The remaining issues for nonylphenol relate to the import of textiles that have been treated with nonyl phenol outside of the EU, and legacy contaminated sites. Where clothing supply chains, in particular, are complex and lengthy, it makes the issue of identification and management challenging. But it could be foreseen that additional control measures may place requirements for testing of specific types of garment and greater enforcement on imported goods to help further limit emissions to sewer.

Pathway disruption

Based on the substances identified within this category, the main issue for pathway disruption relates primarily to **run-off from road**. For substances such as PAHs, fluoranthene, and dioxins and furans atmospheric deposition will be a major pathway to the surface water environment. Atmospheric transport over long distances is complex and therefore the rates of deposition will vary hugely. However, direct release onto hard surfaces such as roads (from road transport) as well as deposition from atmosphere onto hard surfaces, provides a conduit where quantities can concentrate and then be washed directly to drains, which can

[392] The Convention and its achievements | UNECE
[393] https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e?t=1613386316829
[394] https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e?t=1613386316829

also include surface water, particularly for CSO systems in storm events[395,396,397]. Therefore, similar to the measures for pathway disruption of industrial chemicals under option 1, -Table 8-29, indicates that capture and management systems are likely to prove beneficial in managing the flow of material from hard surfaces, particularly roads. As a secondary point the use of constructed wetlands could also be a valuable approach for managing atmospheric deposition in specific settings, where run-off is an issue.

For PAHs, e.g. the REACH restriction proposal[398] which would ensure that granules or mulches (in particular from end-of-life tyres) are not placed on the market for use or used as infill material in synthetic turf pitches or similar applications if they contain more than 20 mg/kg in total of the eight indicator-PAHs would cost €45m over a 10-year period, which are excluded as they are attributed to that proposal while driving down PAH emissions to water.

Table 8-29 Overview of example costs for physical barriers

Technology	Cost
Constructed wetland	€43.7 per m^3 (assume 1 metre depth)
Gully pots to capture particles from run-off from road	€50 per gully-pot (assume spacing of 40-50m)

* Costs are in EU27 in Euros annually — for large infrastructure measures costs are amortised (assuming 25-year asset lifetime)

Run-off disruption from roads would cost €75 million to install gully pots. Data suggests that gully pots cost €50 per item to install and to be effective should be placed 50 metres apart. Based on the total length of all EU27 motorways (75,000 km), around 1,500,000 gully pots should be installed. Also, water from the road surface from motorways is typically channelled into surface water untreated. Minor roads/city roads on the other hand are often connected to a Combined Sewer Overflow (CSO) system and go to WWTWs. Therefore, minor roads were excluded from the calculations.

End of pipe

As with the other preceding sections, the costs of upgrading wastewater treatment works for losses to sewer are covered by the JRC study supporting the revision of the UWWT Directive. -Table 8-30 provides the results of the analysis from the current study. In this particular case a key point of reference is that many of the substances within -Table 8-34 are hydrophobic, with a number of the substances now recognised as POPs. This means that in many cases the larger fraction of the substance entering the wastewater process is partitioned into sewage sludge during treatment. For PBDEs in particular, Olofsson, 2012[399], highlights as much as 95% of the PBDEs will end up in the sludge phase, with standard technologies able to further reduce the remaining concentrations within the effluent phase.

395 Murakami et al, 2004, 'modelling of run-off behaviour of particle-bound polycyclic aromatic hydrocarbons (PAHs) from roads and roofs', Water resources vol 38
396 Gasperi et al, 2011, 'priority pollutants in urban stormwater: Part 2 case of combined sewers', Water Research vol 46
397 Stephansen et al, 2020, 'relationship between polycyclic aromatic hydrocarbons in sediments and invertebrates of natural and artificial stormwater retention ponds', Water vol 12.
398 https://echa.europa.eu/-/echa-s-scientific-committees-support-restricting-pahs-in-granules-and-mulches
399 Ulrika Olofsson, 2012, 'removal processes in sewage treatment plants – sludge quality and treatment efficiency of structurally diverse organic compounds', Umea University.

For PBDEs in particularly, where new use is now banned, and a major pathway to environment is contaminated indoor dust which is then washed to drain through bathing or laundry, wastewater is a key source. This means the bigger issue for the hydrophobic substances is how the sludge is managed and potential emissions to surface water from run-off linked to land spreading of sewage sludge.

Table 8-30 Most common end-of-pipe measures by substance

Substance	Measure	Cost (as € per population equivalent, per annum)	Efficacy (%)
Dioxins and furans	Ozonation	10	84
Fluoranthene	GAC	26	>90%
PAHs	GAC	26	>90%
PBDEs	Standard treatments already effective for water – advanced technology not required		
Hexachlorobutadiene	Ozonation	10	75
Nonyl phenol	Ozonation	10	96

* all costs are in EU27 in Euros annually – for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)

Natural attenuation and monitoring (incl. dredging):

This final category of measures is best suited to those substances with a high persistence and legacy issues, where it is not possible address issues at source. For the PBDEs in particular, this has been problematic for Member States under the EQSD, particularly due to the highly hydrophobic nature of PBDEs and their very long residence time in sediment, where materials can concentrate. Dredging could be a viable option to manage this issue, but as indicated in the previous sub-section can be very costly (1 km of dredging costs approximately €90k-€240k/project) and create issues of its own in terms of turbidity, ecosystem damage, reintroduction of chemicals to the water column, and costly management of dredged material.

For the substances under review, fluoranthene, PBDEs, and dioxins are all proposed to have less stringent EQS, which would suggest natural attenuation may be a viable strategy in some MSs. For PAHs, hexachlorobutadiene, and nonyl phenol the amended EQS is proposed to be more stringent. In this case, natural attenuation may be a less viable or practical solution.

Summary

The substances included under industrial chemicals for option 3, are largely dominated by substances that are primarily generated unintentionally by other processes. This includes several POPs substances. Based on the proposed EQS amendments and dynamic baseline, it is possible to argument that the less stringent EQS for PBDEs (which are been a source of many exceedances - distance to target is large and remains large) may mean the measures focus on natural attenuation and control of sewage sludge as part of land spreading. Due to the very highly hydrophobic nature of PBDEs and partitioning into sludge.

The two substances likely to elicit the need for additional measures above and beyond what is already listed in POMs are **nonyl-phenols** and **PAHs**. For the former, the issue primarily relates to import of clothing and textiles treated outside of Europe. Stronger enforcement and testing may be needed as a source control measure, while end-of-pipe treatment is likely the most effective choice for direct control on releases, particularly where ozonation is effective.

For PAHs the issue is more complex with atmospheric deposition a major pathway, other pathways include releases via run-off from road and manufacturing. Source control measures would likely focus on combustion activities to better limit atmospheric PAH emissions. Equally pathway disruption may be important to further limit releases where possible. These options are likely to carry significant costs and societal impacts but would be aligned with the EU's wider climate change targets and transition away from fossil fuels.

For nonyl phenol a combination of better source control for imported clothing and end-of-pipe treatment is likely to be the most effective measures. For hexachlorobutadiene the emissions are already very low with limited exceedances and site-specific measures more appropriate. For PAHs, better targeted source control and pathway disruption are likely to be the most effective pairing.

Metals

Option 3 would apply to the following metals: mercury, nickel.

The distance to target for these metals has been assessed as:

- Large – mercury
- Medium — nickel

Source control:

In terms of the two metals identified within this category, it is key to note that **mercury** in particular is the substance that causes the greatest number of chemical status failures in the EU for all priority substances. Despite this fact the integrated assessment of the second river basin management plans (2019)[400] failed to identify any direct measures within any EU program of measures for any EU Member State. Part of the issue here is that the pathways to environment are complex, and largely driven by atmospheric deposition from the combustion of fossil fuels. This includes long range transport and potentially atmospheric loads from outside of the EU. The issue is further complicated by the fact that mercury is a naturally occurring substance (which is also the case for nickel), and loadings to surface water can further be driven in part by mine drainage and run-off from fields and road as particulate. The existing EQS for mercury covers MAC (0.07 µg /L) and biota (20 µg/kg wet weight). The proposed EQS would further add an AA concentration threshold (0.047 µg/L) and reduce the biota threshold from 20 to 5.44 µg/kg wet weight. The distance to target for mercury is already identified as 'large' and will remain so under the proposed EQS. But it can be reasoned that the rates of exceedance are likely to rise and potentially by significant margins. This notes that 25 out of 27 EU Member States already have at last 1 water body failure for mercury.

For **nickel** the picture is equally complex. The EEA dashboards for reported monitoring data highlight that 1,840 water bodies (out of a possible 97,000) were in poor chemical status across 21 of the 27 EU Member States. The data suggests in many cases more localised issues with the rate of failure affecting a smaller number of water bodies per MS, but with a high

[400] Integrated assessment of the 2nd river basin management plans - Publications Office of the EU (europa.eu)

proportion of MS having an issue. The overview of pathways to environment (see-Table 8-27) indicates a number of pathways to environment including atmospheric deposition (linked to combustion of fossil fuels), mining operations, smelting, metal finishing activities including cannery operations, wastewater treatment works, and natural sources of nickel. This would make selection of measures challenging and greater importance on identifying sources (based on the inventory of sources) at regional and national level.

For both metals, combustion of fossil fuels and metal manufacturing activities are identified as key sources, and therefore it can be assumed that measures associated with better atmospheric abatement and treatment of wastewater, including on-site treatment prior to release to sewers are likely to be key.
It was already identified as part of the dynamic baseline that strengthen of targets under the IED may already be part of the planning for metals (particularly nickel in operations such as ceramics and porcelain enamelling), but where plant performance varies across the EU there may also be scope to further improve. -Table 8-31 provides indicative costs for a range of atmospheric abatement technologies that could further limit emissions of mercury and nickel affecting atmospheric deposition rates.

Table 8-31 Overview of atmospheric abatement technologies (based on BREF document)

	Annual Costs (US$ 2008/MWh)		
Emission control technology	Investment cost	Operating cost	Total cost
Dry ESP	0.5	0.9	1.4
Fabric filter	0.5	1.5	1.9
Dry ESP - retrofitted from medium to high control efficiency	0.9	0.5	1.4
Fabric filter + wet or dry scrubber + sorbent injection	2.7	3	5.7
Dry ESP + wet or dry scrubber + sorbent injection	2.7	2.4	5.1

Pathway disruption

Based on the pathways to environment, there are three primary issues that could be managed as pathway disruption. Firstly, mine drainage is potentially an issue and this could be handled through wastewater treatment processes as capture and treat before the substances reach rivers, lakes, and other forms of water course. Similar to option 1 (see the

discussion around silver), reverse osmosis looks to be the most effective option, although the use of chemical agents to drive precipitation reactions can also be effective for nickel.
The secondary major issue relates to direct egress from run-off, this is where particulate forms of mercury and nickel deposition from atmospheric loads to fields and hard surfaces, such as roads and paved areas. In these cases, as discuss for other substances capture of the substance before it reaches rivers would be key, through techniques such as gully pots for roads, and constructed wetlands for rural settings. Table 8-32 provides an overview of these measures.

Table 8-32 Overview of example costs for physical barriers

Technology	Cost
Capture and treat for mine drainage. Reverse Osmosis is 98% effective at nickel removal, and 80-85% effective against mercury. Chemical precipitation techniques (using sulfides) also look effective against both[401].	RO investment costs €100,000 -€10,000,000 per plant. €0.4 per dm^3 operating costs[402]. Additionally, chemical precipitation or electroflocculation also like possibilities[403].
Constructed wetland	€43.7 per m3 (assume 1 meter depth)
Gully pots to capture particles from run-off from road	€50 per gully-pot (assume spacing of 40-50m)

* Costs are in EU27 in Euros annually — for large infrastructure measures costs are amortised (assuming 25-year asset lifetime)

End of pipe

Releases via WWTWs may be a possible source to the surface water environment for both mercury and nickel, ATSDR (2005)[404] comments that domestic wastewater treatment facilities are a major source of nickel. Based on data from Sweden, the ATSDR report comments that 29% of influent concentrations coming of nickel come from domestic properties and retail business, with a further 31% coming from water treatment chemicals. A further 5% comes from run-off from road into wastewater systems.
Although, conventional treatment of wastewater already significantly reduces the toxicity exposure from inorganic constituents (including heavy metals) on freshwater and seawater, recent available data on heavy metal speciation and removal shows that, during primary settling, sorption technologies may cost effectively enhance the removal of Cu and Ni, while coagulation may be efficient for Cd, Cr, Cu, Pb, Zn and Hg removal (but not as efficient for Ni removal)[405] [406]. Also, scientific results show that Apatite can be suitable material to remove cadmium, copper, nickel, cobalt and mercury from water[407].

[401] Estay et al, 2021, 'metal sulfide precipitation: recent breakthroughs and future outlooks', Minerals vol 11
[402] JRC, 2016, BREF document fir waste water and waste gas treatment systems, EIPPCB
[403]Vidu et al, 2020,'Removal of heavy metals from wastewaters: a challenge from current treatment methods to nanotechnology applications", Toxics vol 8 issue 4.
[404] ATSDR, 2005, US Department of health and human services – toxicological profiles – nickel', US Report.
[405] Heavy metal removal from wastewater using various adsorbents: a review: https://iwaponline.com/jwrd/article/7/4/387/28171/Heavy-metal-removal-from-wastewater-using-various
[406] https://www.researchgate.net/publication/350998245_Removal_of_Heavy_Metals_during_Primary_Treatment_of_Municipal_Wastewater_and_Possibilities_of_Enhanced_Removal_A_Review
[407] Removal of cadmium, copper, nickel, cobalt and mercury from water by Apatite: https://pubmed.ncbi.nlm.nih.gov/21871722/

As with the other substances under review the wastewater costs will be deferred to the JRC study supporting revision of the UWWT Directive. The current study has applied the same methodology (previously detailed) identify technology selection based on cost and efficacy. This is presented in Table 8-33 (below). The current analysis has focussed on the most common advanced wastewater technologies identified, which in this case suggests that reverse osmosis and use of membrane filters is the most cost-effective way of removing metals.

However, it was also identified that use of chemical agents to help drive precipitation reactions can be valuable tool to help remove metals in the liquid fraction of wastewater. Katochvil et al, 2015[408] provides commercial case studies for the implementation of precipitation techniques at wastewater works, involving the use of additional settling tanks and chemical agents to help precipitate and remove metal fractions.
Additionally, partitioning of metals into sewage sludge fractions and land spreading can be a source of materials to land and a risk via run-off. The sewage sludge directive already provides limit values for mercury and nickel, but a possible measure could be to reduce these limits in line with water protection needs.

Table 8-33 Most common end-of-pipe measures by substance*

Substance	Measure	Cost (as € per population equivalent, per annum)	Efficacy (%)
Mercury	Reverse osmosis	20	80-85%
Nickel	Reverse osmosis	20	>98%
Mercury and Nickel	Sulfide precipitation processes**	1.17	>90%

* all costs are in EU27 in Euros annually — for large infrastructure measures costs are amortised (assuming 25 year asset lifetime)
**CAPEX costs for metal sulfide processes amortised over 20 years.

Natural attenuation and monitoring (incl. dredging)

This final category of measures relates primarily cases where measures under other categories are not possible. This is primarily the case because all commercial manufacture and use has already ceased. The ambient concentrations in this case relate to legacy issues and very persistent chemicals. Anthropogenic uses of metals should be addressed by measures within the other categories. Naturally occurring concentrations of substances are already covered by the WFD and EQSD as natural background concentrations.

As indicated the integrated assessment of RBMPs did not identify any direct measures for mercury. This could be because it was hoped that measures in related policy areas to manage atmospheric emissions would over time benefit surface water concentrations, which could be a form of strategy akin to monitoring and allowing natural attenuation. The extent of exceedances for mercury and the proposed EQS amendments which are likely to result in

[408] Kratochvil, 2015, ‘Commercial case studies of life cycle cost reduction of ARD treatment with sulfide precipitation’, 10th ICARD IMWA conference.

greater numbers of exceedances would suggest that more directly intervention will be needed if good chemical status is to be achieved.

Summary

The rate of exceedances for mercury in particular are problematic for the goals of the EQSD and good chemical status. While nickel has a far lower rate of exceedances (1,840 water bodies out of 97,000), it still affects 21 of the 27 EU Member States, again with the rate of exceedances expected to increase under the new proposed EQS amendments.

This would suggest additional measures will be needed to help achieve good chemical status. The main issue being the complexity of the emissions to environment, long-lived ambient concentrations, and further issues due to the fact that both metals are naturally occurring. It is likely greater source controls for fossil fuel combustion and manufacturing could help but would need to be implemented as part of a wide-ranging package of measures also including pathway disruption and end-of-pipe.

While source control measures would likely see economic impacts for power generation and manufacturing, the wider set of options will likely require deferring the economic costs to the taxpayer. This is due in part to the fact that identification of polluter under polluter pays will be challenging and fact that nearly a third of influent concentrations at wastewater plant come from the general public.

The scale of the challenge to meet good chemical status is really very challenging (as indicated by the distance to target) and therefore the scale of costs associated with achieving good chemical status will also be very significant.

Administrative cost burden — Member State monitoring obligations

The current option covers the amendment of thresholds for pre-existing priority substances. As such the establishment of monitoring networks can be assumed to be part of the dynamic baseline. Additionally, costs associated with the analytical component of monitoring could be largely assumed to be part of the dynamic baseline as the amended EQS would not affect pre-existing monitoring requirements. The possible impact of additional costs would fall where the EQS is significantly lowered beyond the existing limits of detection used by laboratories in the dynamic baseline. Such a lowering of the threshold may require more advanced analysis techniques incurring additional costs, or new analytical methodologies capable of reaching lower concentration thresholds.

The substances with the most significant reduction in EQS are chlorpyrifos, cypermethrin and dioxins and furans. For these substances the water concentrations for chlorpyrifos and cypermethrin are two orders of magnitude lower. For dioxins and furan concentrations in biota the proposed threshold falls from 6.5 ng/kg wet weight to 0.035 ng/kg wet weight.

Therefore, potentially there could be cost impacts for analytical capabilities for these substances in particular.

Economic impacts — *Benefits*

The 15 substances identified for review of EQS broadly fall within a small number of categories, including POPs, pesticides, metals, and one industrial chemical. Consequently, much of the information on economic impacts is considered to be the same as for option 1. While new use may have been banned for the high majority of the list, their long-lived environmental presence, potential for bioaccumulation and adverse effects for human health and aquatic species poses significant challenges for the environment. As stated, the development of an EQS is aimed at denoting where risks appear, allowing Member State competent authorities to take appropriate action to mitigate and manage the risks presented.

Where the science continues to evolve our understanding of the behaviour and impact of substances also evolves. Revision of the EQS based on sound scientific evidence developed since the original adoption of the EQS helps improve the identification and management of the risks posed by the priority substances.

For substances such as fluoranthene where it is provisionally assumed that the EQS may be relaxed, it would allow the Member States to reprioritise and use existing budgets to more effectively to tackle the issues presented. For substances which may have their EQS lowered in light of new evidence, given their inherent nature (i.e, POPs, Pesticides, Metals etc) the revised understanding of the issues and priorities should help Member States to plan more effectively.

Environmental impacts — *Costs*

The proposed amendments to the EQS have been completed following a thorough analysis of the available scientific data and feedback from a range of stakeholders. It is therefore assumed that the proposed thresholds represent a true assessment of the risk and need to protect surface waters. Where EQS have been lowered significantly (e.g. chlorpyrifos, cypermethrin etc). It is possible to foresee that additional measures will be needed to help achieve good chemical status. Implementation of these measures can be potentially resource intensive (e.g. GAC treatments for WWTWs, dredging, etc) and this will have impacts in terms of carbon releases and greenhouse gas emissions. For substances that heavily partition into sludge such as PBDEs it can also present issues if the measures ban land spreading in favour of alternatives such as incineration / thermal destruction.

Environmental impacts — *Benefits*

Based on current knowledge and using the latest science, the current EQS for the substances covered under this option are deemed to be set at an inappropriate level. The implementation of option 3 has the potential to cause one of two levels of impact by lowering the EQS for these substances. For several of these substances, the present EQS could be viewed as overly cautious and for these, there is scope for the EQS to be relaxed without causing any loss of traction. As a result, for these substances it is assumed that there would be no environmental costs associated with changing to a lower EQS. For others, the current EQS may not be stringent enough. Therefore, by setting a more stringent EQS, greater environmental costs would be avoided. It is assumed that some of the substances with the greatest environmental impact will be those in which there are the largest differences between the current EQS and the proposed EQS. Some of these, along with their associated environmental impacts, are illustrated below.

Cypermethrin is authorised as an insecticide active ingredient in wood preservatives to protect wood and construction timber against wood destroying insects. It is also used as an insecticide and acaricide for the protection of crops and is further used in outdoor surface sprays. Cypermethrin shows both acute and chronic toxicity in the aquatic environment to a variety of organisms. It has been shown to be acutely toxic to fish (*Cnesterodon decemmaculatus* / 96 h / LC50: 0.43 µg/l), increasing the mortality of both adults and larvae alike. It is also acutely toxic to freshwater insects (Aedes aegypti / 24 h / immobility / purity a.i. >85% (nominal) / EC50: 0.03 µg/l), invertebrates, and algae and aquatic plants (*Pseudokirchneriella subcapitata* / 96 h / EC50: > 33 µg/l (> water solubility)). For the same groups it has also been shown to be chronically toxic. Indeed, cypermethrin has been shown to impact fish (*Oryzias latipes* / 96 h / embryo abnormality (nominal) / NOEC: 6.3 µg/l), insects (*Chironomus* (larvae) / 28 d post-hatch / NOEC: 0.024 µg/l) and affects the reproduction of invertebrates (*Daphnia magna* / 21/23 d / NOEC: 0.031 µg/l)[409].

Chlorpyrifos is not approved for use in plant protection products or as a biocide, and it is now banned in the EU. Previous emergency authorisations in 2019 have been used to enable use on corn, sunflower and rapeseed against moths and larvae. It is a persistent organic pollutant with PBT qualities[410]. In terms of acute toxicity in the aquatic environment, chlorpyrifos has been shown to impact the mortality of amphibia (*Pseudacris regilla* (amphibia) / 96 h / LC50: 121.87 µg/l), the mortality of fish (*Oncorhynchus mykiss* / 96 h / LC50: 25 µg/l), the mortality and mobility of invertebrates and the growth of algae and aquatic plants (*Chlorella* sp./ 96 h / EC50: 1290 µg/l). In terms of chronic impacts, chlorpyriphos has been shown to increase the mortality of freshwater fish (*Pimephales promelas* / 34 wks / NOEC: 0.568 µg/l), after the reproduction, growth and survival of invertibrates (*Hyalella azteca* / 10 d / growth (weight) / NOEC: 0.012 µg/l), and the ability for aquatic plants and algae to photosynthesise (*Nitzschia closterium* / 70 min photosynthesis IC10: 38 µg/l)[411].

Dioxins and furans have no commercial use but are generated as unintentional pollutants from a range of sources. In particular this includes the manufacture of metals, incineration of waste, open fires, accidental fires, and as a contaminant in some chloro-organic chemicals. There is less data on the ecotoxicity of dioxins and furans compared to other substances mentioned here. However, their acute effects on aquatic invertebrates has been shown (Crustacean, unknown species / unknown duration / most probably mixtures of PCB 118 and non-DL-PCBs / $EC_{50\text{-crustaceans}}$ = 0.002 mg/l) as well as on freshwater fish (*Oncorhynchus mykiss* / 56 days / 2,3,7,8-T4CDD / EC50 = 4.6 x 10-8 mg/l). Chronic effects have also been shown in fish (*Oncorhynchus mykiss* / 28d / 2,3,7,8-T4CDD / NOEC = 1.1 x 10-9 mg/l), invertebrates (*Daphnia magna* / 32d / 2,3,7,8-T4CDD / NOEC = 3.1 x 10-9 mg/l) and algae and aquatic plants (*Oedogonium cardiacum* / 33d / 2,3,7,8-T4CDD / NOEC = 3.1 x 10-9 mg/l)[412].

Furthermore, the European waters assessment 2018 highlighted that mercury was the main substance responsible for chemical status failures in water bodies across the EU (responsible for failure of 45,973 water bodies (approximately 43% of all EU waterbodies))[413], and

[409] Cypermethrin 2022 Dossier
[410] https://echa.europa.eu/substance-information/-/substanceinfo/100.018.969
[411] Chlorpyrifos 2022 Dossier
[412] Dioxins 2022 Dossier
[413] https://www.eea.europa.eu/publications/state-of-water

therefore, a relaxing in the EQS for mercury would significantly increase the number of water bodies achieving good chemical status across the EU. The European waters assessment of status and pressures for 2018 (published by the EEA), goes on to comment that 46% of all water bodies failed to achieve good chemical status, with this value dropping to 3% if mercury was excluded from the equation. The key point to highlight here is that the EQS are developed through careful consideration of the available data to help denote where a chemical risk may be present. The nature of how the risk manifests in terms of environmental/biological/ecological impact will vary substance by substance. A re-analysis of the EQS based on new data that has emerged since its original adoption, may illustrate that the threshold is set at a less appropriate level warranting amendment.

Where mercury is responsible for so many of the chemical status failures it represents a practical and political challenge for Member States. This is due in part to deposition of mercury from atmospheric emissions which are challenging to manage in aquatic settings, and the environmental fate and behaviour of mercury once in the environment. The assessment for EQS is still ongoing so it is difficult to comment further. However, assuming based on strong scientific evidence that the threshold could be relaxed, it would mean no negative impacts to the aquatic environment in terms of risks and impacts, but a possible positive benefit in that it would allow Member State authorities to refocus and reprioritise other substances posing a risk, that have to date been given lower priority than mercury.

Social impacts — Costs

Assessed to be similar to option 1. Costs of different mitigation measures (source control, pathway disruption and end-of-pipe treatment measures in particular, are likely to result in costs to consumers through increased prices of products and services (including water and sewage charges). However, as the EQS of substances is being amended rather than new substances being added under this option, and for most substances no additional abatement measures would be required, the costs would be less that those under option 1 (and 2).

Social impacts - *Benefits*

Chlorpyrifos and PBDE as endocrine disruptors were associated with attention deficit hyperactivity disorder (ADHD) and with other cognitive deficiencies. The productivity loss caused by these disorders is estimated to be €124 billion annually in EU. Additionally, prenatal exposure to chlorpyrifos across the EU would cost an additional €21.4 billion in social costs. The neurotoxicity of chlorpyrifos is estimated to be 70 to 100% according to the epidemiological and toxicological evidence, which corresponds to a social cost of €46.8 billion and €195 billion annually in the EU[414]. It was also estimated that the cognitive deficits caused by chlorpyrifos, PBDE, and methylmercury would cost the EU €177 billion, €11.5 billion, and €9.89 billion, respectively. Moreover, testicular cancer and Cryptorchidism associated with PBDE would cost the EU approximately €100 million and €158 million[415,416].

[414] Bellanger et al. (2015). Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, The Journal of Clinical Endocrinology & Metabolism, 100(4):1256–1266, https://doi.org/10.1210/jc.2014-4323

[415] Grandjean & Bellanger (2017). Calculation of the disease burden associated with environmental chemical exposures: application of toxicological information in health economic estimation. Environmental health : a global access science source, 16(1), 123. https://doi.org/10.1186/s12940-017-0340-3

[416] All estimates from this source have been converted to euros based on an exchange rate of 1 EUR = 1.09 USD

One key benefit of reviewing EQS in light of new scientific evidence, is the possibility to improve coherence between the EQSD and other related chemical policy, particularly if thresholds are implemented in related legislation. Greater continuity between the EQSD and its most closely related legislation has the societal benefit that management of chemical risks are addressed in a more complete and holistic fashion.

8.2.6 *Option 4 Review possible deselection of substances shortlisted by the COM following JRC deselection criteria approach.*

The Environmental Quality Standards Directive defines a list of substances (under Annex I) which represent an EU-wide risk to surface water and environmental quality standards (under Annex II) to help quantify that risk. To date the EQSD does not include a mechanism to remove substances from Annex I once they no longer represent an EU-wide risk. The Joint Research Centre is collaborating with the Commission to develop and apply a set of criteria to help identify which priority substances may no longer represent an EU-wide risk.

Option five would see the candidate priority substances for deselection removed from the EQSD. As a caveat it is worth commenting further that the EQSD is intended to cover those substances that represent an EU-wide risk, and that deselection from that list does not preclude their inclusion into river basin specific pollutants, where a national level risk is still identified.

Based on the criteria developed by the Joint Research Centre, the **priority substances identified for potential deselection** include already banned substances (alachlor, chlorfenvinphos, and simazine), and two approved substances/groups of substance (trichlorobenzenes and carbon tetrachloride). These were selected based on monitoring data and criteria that; i) the substance poses a very low risk confirmed by RQ<1 ii) the substance should be measured in the majority of EU countries and exceedances of the EQS should occur in less than four of these.[417] Since carbon tetrachloride has been judged by the JRC (in accordance with these criteria) to be a candidate for deselection, this substance is better suited to be included under this option.

Table 8-34 Overview of pathways to the environment

Substance	Major Pathways	Minor Pathways	Comments
Alachlor	Legacy	N/A	Banned in the EU
Chlorfenvinphos	Legacy	N/A	Banned in the EU
Simazine	Legacy	N/A	Banned in the EU
Trichlorobenzenes	Industrial processes	N/A	Use as chemical intermediates
Carbon tetrachloride	Industrial processes Wastewater treatment works	Surface water and air emissions following bleach use	Intermediate in the manufacture of other chemicals (primarily rubber and polymers). Release from household bleach-containing product use.

[417] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a953a59a-b899-4b8e-9815-0fee9006239f/details

Economic impacts — *Costs*

Deselection of the priority substances identified will likely result in cost savings, not additional costs in most cases. Water quality monitoring can be performed with smart digital sensors in which highly integrated multi-parameter measurements are performed while using on-chip systems that control and measure electrochemical sensors and biosensors all at once. Such integrated multi-parameter sensor devices can simultaneously measure multiple parameters and transmitter the measured data. If such devices are used, adding or removing parameters to be measured can likely be done without cost effects, at least within certain ranges. It is possible that removal of these substances may have an indirect impact for selection of monitoring locations and the need to move monitoring locations, which would incur new costs. However, given that the identified substances may already be of lower overall priority, the potential impact from such relocation is likely minimal.

Economic impacts — *Benefits*

The deselection of substances is likely to bring cost savings from no longer needing to complete analyses of the substances in question. Table 8-35 provides an aggregated set of costs for the EU-27, which has been derived through a combination of data on monitoring from the JRC study on deselection, and the costs of analysis from the targeted consultation. It is assumed that cost savings for monitoring would be neutral as samples are taken to cover a wide batch of substances at the same time. Therefore, monitoring would still be needed as usual. Locations of monitoring stations could potentially be affected (as discussed in costs above). The benefits here are that costs saved from analysis could be redeployed for other substances to help manage overall finite resources. One possible caveat here is that the costs of analysis for new substances may be higher than cost savings from analysis of deselected substances. It is important to stress that it is not a 'one for one' relationship. i.e., costs saved from not analysing alachlor may not be equal to costs of analysing water for PFAS.

Table 8-35 Potential cost savings from no longer needing to complete analysis of deselected substances[418]

Substance	Number of monitoring sites	Derived sampling frequency per site per year	Low range €/sample	High range €/sample	EU27 Euros per annum Low estimate	EU27 Euros per annum High estimate
Alachlor	3376	4.8	11	100	176,776	1,607,050
Chlorfenvinphos	3053	4.9	101	250	1,520,606	3,763,875
Simazine	3545	4.7	11	100	184,377	1,676,150
Carbon tetrachloride	3580	4.3	101	250	1,540,200	3,812,375
Trichlorobenzenes	1648	2.0	101	250	333,780	826,188
				Total	**€3,755,737**	**€11,685,638**

[418] Deselection of existing Priority Substances v5, 15 March 2022, provides data on total number of sites and samples taken over 2015-2018 for the deselection candidates.

Environmental impacts — *Costs*

The selection criteria developed by the JRC specifically includes requirements for monitoring across a wide set of Member States with very few exceedances. It is possible to envisage that with deselection in the cases where exceedances have been detected that the substance could transition from the priority substance list to river basin specific pollutant list without a loss of continuity. One potential risk for environmental impacts is that monitoring over several years builds up a valuable dataset with trend data. A cessation in monitoring would break that time-series data and mean that any future increase in emissions (and by proxy ambient concentrations) would go undetected. That being the case the criteria also largely target substances which are banned with no new ongoing use, suggesting increasing trends would be unlikely. In case of persisting concerns at River Basin District level, a substance can be retained as an RBSP.

There are several direct, potential environmental costs associated with the deselection of alachlor, chlorfenvinphos, simazine, trichlorobenzenes and carbon tetrachloride. These costs are the result of the potential negative impacts these substances could have on ecosystems in the event that particular threshold environmental/toxicological concentrations are reached.

Alachlor: Alachlor is a pesticide that is very toxic to aquatic life and is suspected to be carcinogenic[419]. Alachlor has a recorded acute 96-hour LC50 of 1.8 mg/l in the fish species *Oncorhynchus mykiss*. It has also been shown to have an acute 48-hour EC50 of 10 mg/l in aquatic invertebrates such as *Daphnia magna***.** Chronic effects have also been shown in both fish and aquatic invertebrates. Furthermore, the growth and biomass of aquatic plants and algae are also negatively impacted by the presence of alachlor. Aquatic plants such as *Lemna minor* have an acute 7-day EC50 for biomass of 0.01 mg/l whereas algae such as *Chlorella pyrenoidosa* have a chronic 96 hour NOEC for growth of 0.02 mg/l[420].

Chlorfenvinphos: Chlorfenvinphos is very toxic to aquatic life from both an acute and chronic perspective. Chlorfenvinphos has a recorded acute 96 hour LC50 of 1.1 mg/l in the fish family *Salmonidae*. The toxicity of chlorfenvinphos to aquatic invertebrates is represented by a measured acute 48 hour EC50 of 0.00025 mg/l and a chronic 21 day NOEC of 0.0001 mg/l in *Daphnia magna*. The growth of algae have also been shown to be negatively impacted by the presence of chlorfenvinphos which can be shown by an acute 72 hour EC50 of 1.36mg/l in *Scenedemus subspicatus*[421].

Simazine: Simazine is very toxic to aquatic life and has a long-lasting effect[422]. Simazine has been shown to have both an acute and chronic effect no the mortality of fish species. An acute 96 hour LC50 of 90 mg/l has been shown in *Lepomis macrochirus* and a chronic 21 day NOEC of 0.7 mg/l in other fish species (the source of the latter was not identified). Simazine impacts aqutic invertebrate such as *Daphnia magna* which is shown by an acute 48 hour EC50 of 1.1 mg/l. An acute 96 hour LC50 of >1.0 mg/l has been demonstrated in the sediment dwelling organism *Chironomus tentans*. The impact of simazine on the growth and biomass of aquatic plants and algae has also been shown. For example, an acute 72 hour EC50 of 0.04

[419] https://echa.europa.eu/substance-information/-/substanceinfo/100.036.448
[420] http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm
[421] http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm
[422] https://echa.europa.eu/substance-information/-/substanceinfo/100.004.124

mg/l has been shown which reflects the impact of simazine on the growth of algal species *Scenedemus subspicatus*[423].

Carbon tetrachloride: Carbon tetrachloride is toxic to aquatic life and is damaging to the ozone layer[424]. Acute exposure to carbon tetrachloride increases the mortality of fish such as Pimephales promelas with an acute 96 hour LC50 of >43 mg/l. The negative effects on aquatic invertebrates are illustrated by the acute 48 hour EC50 of >29 mg/l in *Daphnia magna*. Algae have also been shown to be negatively impacted by the presence of carbon tetrachloride. The growth of Chlamydomonas reinhardtii has an acute 72 hour EC50 of >0.217 mg/l[425].

Trichlorobenzenes: The trichlorobenzenes are a group of substances which are known to cause both acute and chronic toxic effects, in particular within the aquatic environment[426]. One example of a trichlorobenzene would be 1,2,4-trichlorobenzene. 1,2,4-trichlorobenzene has been shown to have chronic toxic effects on fish. *Danio rerio* appears to be particularly sensitive to the substance with a 21 day NOEC of 0.04 mg/L for the endpoint behaviour in a prolonged toxicity test. Other species such as *Poecilia reticulata* has a 14 day NOEC of 0.11 mg/L and *Salmo gairdneri* has a 85 day NOEC of 0.13 mg/L. 1,2,4-trichlorobenzene also chronically impacts invertebrates. For example, the 16 day NOEC for the endpoint of reproduction was shown to be 0.06 mg/L and for the endpoint of mortality was 0.19 mg/L. Algae and aquatic plants have also previously been shown to be affected, and acute effects of the substance are also present[427].

If the environmental concentrations of these substances reach the described threshold levels following deselection, there is the potential to incur negative environmental impacts. However, the number of waterbodies in which these substances are the cause of ‘failing to achieve good chemical status’ is low. This can be seen as a percentage of the total number of waterbodies in the EU27 in Table 8-36. Although, these substances are unlikely to have a largescale environmental impact following their deselection, the deselection is more questionable given the degree of risk they pose and their relevance for the MSFD.

Table 8-36 Number of failures to achieve good chemical status due to option 4 substances[428]

Substance	Total number of waterbodies	Number in which failure to achieve good status
Alachlor	97,000	5
Simazine	97,000	4
Chlorfenvinphos	97,000	6
Trichlorobenzenes	97,000	3
Carbon tetrachloride	97,000	1

[423] http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm
[424] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.239
[425] http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1350.htm
[426] https://echa.europa.eu/substance-information/-/substanceinfo/100.031.272
[427] https://echa.europa.eu/documents/10162/f6875856-854c-43f4-a393-7ab293056024
[428] https://www.eea.europa.eu/themes/water/european-waters/water-quality-and-water-assessment/water-assessments/chemical-status-of-surface-water-bodies

Furthermore, these substances meet the criteria for deselection of i. the substance poses a very low risk confirmed by RQ<1, and ii. The substance should be measured in the majority of EU countries and exceedances of the EQS should occur in less than four of these.[429] As a result, the risks and the potential for environmental impacts are low.

Environmental impacts — *Benefits*

The wider benefit here is retaining the priority substance list at a manageable list of substances so that finite resources can be deployed to best effect. Removal of substances that no longer represent an EU-wide risk would allow Member State Competent Authorities the chance to refocus and prioritise on some of the emerging chemical risks. This is particularly important in light of the new candidate priority substances covered by options 1 and 2.

Social impacts - *Costs*

The social costs of deselection of the priority substances would be the potential negative impacts on human health associated with their presence in the environment and their consumption in drinking water.

Alachlor: Alachlor is a pesticide that is harmful if swallowed, suspected to be carcinogenic, and can cause an allergic skin reaction[430]. Haematotoxicity has been observed as a subchronic toxic effect and tumours have been observed in animal studies. This effect cannot be ruled out in humans[431]. Toxicity has been previously seen in the liver, bone, kidney and nasal olfactory mucosa of mice fed the following doses of alachlor over 18-months: 16.6, 65.4 and 262 mg/kg bw/day (males), and 23.7, 90.3 and 399 mg/kg bw/day (females). Another study on rats observed a NOAEL of 14 mg/kg bw/day, above which concentration tumours in the nasal epithelium, stomach and thyroid were seen alongside changes to the liver and ocular lesions[432].

Chlorfenvinphos: Chlorfenvinphos is fatal if swallowed and toxic in contact with skin[433]. An acute oral LD50 of 12 mg/kg has been demonstrated in rats, a dermal LD50 of 31 mg/kg body weight has been shown in rabbit and an inhalation LC50 of 0.05 mg/l has been shown in rats[434].

Simazine: Simazine is suspected to be carcinogenic[435]. In rats, the acute oral LD50 has been shown to be >5000 mg/kg, the dermal LD50 has been show not be 2000 mg/kg body weight and the inhalation LC50 has been show not be 5.5 mg/l[436].

Carbon tetrachloride: Carbon tetrachloride is determined to be toxic if swallowed, toxic/fatal in contact with skin and toxic if inhaled. It can cause damage to organs through

[429] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a953a59a-b899-4b8e-9815-0fee9006239f/details
[430] https://echa.europa.eu/substance-information/-/substanceinfo/100.036.448
[431] http://www.pic.int/Portals/5/DGDs/DGD_Alachlor_EN.pdf
[432] http://www.pic.int/Portals/5/DGDs/DGD_Alachlor_EN.pdf
[433] https://echa.europa.eu/substance-information/-/substanceinfo/100.006.758
[434] http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm
[435] https://echa.europa.eu/substance-information/-/substanceinfo/100.004.124
[436] http://sitem.herts.ac.uk/aeru/ppdb/en/index.htm

chronic exposure, it is suspected of causing cancer and is suspected of damaging fertility or the unborn child[437].Following inhalation and ingestion in animals, the most sensitive organ to damage by carbon tetrachloride is the liver. Following a 4-hour exposure of rats to 530 ppm or above of carbon tetrachloride, changes in serum enzyme levels indicated liver damage. Signs of CNS depression have been observed in animals at concentrations of 7000 to 10500 ppm. Some studies in humans have reported CNS effects as low as 10 ppm. Following the ingestion of 20 mg/kg bw carbon tetrachloride by rats, a study has also shown evidence of liver toxicity among other changes. Occupational studies have suggested associations with non-Hodgkin lymphoma in humans. However, this evidence is weak, and it is animal studies from which the association with carbon tetrafluoride and cancer is derived[438].

Trichlorobenzenes: The chronic exposure of workers to trichlorobenzenes has previously been shown to lead to liver problems as well as blood conditions such as anaemia[439]. A previous study placed rats on diets containing different concentrations of trichlorobenzenes (3 different isomers) to assess the effects of acute exposure. All isomers at a dietary concentration of 1000 mg/kg caused an increase in liver and kidney weights as well as histological changes in in the thyroid and liver in male rats. Other studies have shown similar physiological changes upon exposure to trichlorobenzenes[440]. A dermal study on the chronic toxicity of trichlorobenzenes in mice illustrated that the administration of 1,2,4-TCB twice a week could induce clinical toxicity, decrease survival and increase the keratinization of the epidermis. The causes of mortality in these mice were most frequently infection, amyloidosis and tumours[441].

Should the environmental concentrations of these substances reach the appropriate threshold levels following deselection, there is the potential to incur each of these human health impacts. However, the same arguments that were laid out for the environmental costs apply here; these substances meet the criteria for deselection, and the number of waterbodies in which these substances are the cause of ‘failing to achieve good chemical status’ is low.

Social impacts — *Benefits*

The EQSD is intended to provide a direct response to the chemical risks posed for surface water against a range of chemicals stemming from anthropogenic activities. As society and industry changes the risks will also change with a great deal of research going into identifying and quantifying chemicals of emerging concern. Where resources are finite, it is appropriate to manage the EQSD against the emerging risks while recognising when work has been completed to eliminate the old ones. Deselection of substances that no longer represent an EU-wide risk is a healthy approach to managing resources while providing the greatest levels of protection. This benefits society both in terms of avoided health impacts, but preserving surface water as an important ecosystem service for the planet.

[437] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.239
[438] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/337683/Carbon_Tetrachloride_Toxicological_Overview_phe_v1.pdf
[439] https://www.ospar.org/documents?v=6954
[440] https://www.who.int/water_sanitation_health/dwq/chemicals/trichlorobenzenes.pdf
[441] https://www.who.int/water_sanitation_health/dwq/chemicals/trichlorobenzenes.pdf

Summary

It has been shown by the JRC research that the 5 substances (alachlor, chlorfenvinphos, simazine, trichlorobenzenes and carbon tetrachloride) meet the criteria for deselection (i.e. the substance poses a very low risk confirmed by RQ<1, ii. The substance should be measured in the majority of EU countries and exceedances of the EQS should occur in less than four of these). Of these 5 substances, 3 have already been banned within the EU (alachlor, chlorfenvinphos, and simazine) and the remaining two substances are used primarily in industrial applications.

The reduced regulatory requirements that would be imposed on these substances following deselection would likely lead to few economic costs. Social and environmental costs following deselection are anticipated to be minimal due to the low number of MS showing exceedances.

However, deselection of Trichlorobenzenes is more questionable than for the other substances given the degree of risk they pose and their relevant for the (Marine Strategy Framework Directive (MSFD).

Following deselection, these substances would instead be kept with their EQS in an Annex to the EQSD as substances which Member States should consider identifying as RBSPs if they are still of national or local concern, and thus including them in their River Basin Management Plans.

8.2.7 *Option 5: Review the status of 'eight other pollutants' added to the EQSD from the former dangerous substances directive (76/464/EEC) (which are not currently priority substances).*

Prior to the adoption of the EQSD chemical risks for surface water were managed through the Directive on Dangerous Substances (DSD) (67/548/EEC). The Directive applied a similar approach of using thresholds to denote chemical risk for water bodies. When the EQSD was adopted and the first list of priority substances developed, an assessment was completed of the substances identified under the DSD as well as new potential candidates. At the conclusion of this process, eight of the substances from the DSD were identified as not being suitable for inclusion on the priority substance list. However, where an EQS had already been developed, the threshold was retained in Annex II of the Directive for the following substances:

- Cyclodiene pesticides (aldrin, dieldrin, endrin, isodrin)
- Tetrachloroethylene
- Trichloroethylene
- Carbon tetrachloride, and
- DDT.

These substances have remained within Annex II since the adoption of the EQSD but do not carry a legal requirement in terms of achieving good chemical status. Note they do carry requirements for monitoring where an EQS exists. Given the time that has elapsed since the adoption of the EQSD in 2008 (and the fact that many of the eight substances have long been banned in the EU) it is likely to be appropriate to reassess their status and determine whether they should be added to Annex I as PS (**sub-option 1**), removed from Annex II (given the EQS are now likely close to 20 years old) (**sub-option 2**) or retained as they are (**sub-option 3**).

As part of their work on deselection criteria, the JRC have already assessed all eight substances against the criteria finalised in March 2022. As part of this assessment, carbon tetrachloride was found to meet the criteria for deselection and is included in the assessment under option 4 of this study. The remaining seven substances were identified as failing the deselection criteria and therefore were not considered as candidates for deselection.-Table 8-37 provides a high-level extract taken from the JRC report detailing the assessment carried out and why the conclusions lead to the recommendation made. In the case of the four Cyclodiene pesticides and DDT the primary driver is that fact that they are recognised as POPs under the UNEP Stockholm Convention. Where POPs have very long-lived environmental half-lives and have the potential to bioaccumulate up food chains, the deselection was concluded as inappropriate. For the three chloro-organic solvents, while it was concluded that these substances are not POPs, for tetrachloroethylene and trichloroethylene concerns were raised that exceedances are still detected (albeit in a small number of water bodies), and concentrations may have increased in recent years. Carbon tetrachloride was noted not to have the same rate of exceedance or issues and was therefore a better suited candidate for deselection.

Therefore, this section provides data on carbon tetrachloride for contextual elements only, with further discussion on deselection under option 4.

It can be seen in Table 8-37 that five of the substances have been banned in the EU for many years (aldrin, dieldrin, endrin, isodrin and DDT) and that their main pathways to the environment are from legacy sources. For the remaining substances (tetrachloroethylene, trichloroethylene, and carbon tetrachloride), the main pathways to the environment are from their use in industrial processes. These differences in the pathways to the environment will influence the type of measures that can be implemented e.g. measures for legacy sources are largely restricted to either direct intervention in the environment (e.g. land remediation, dredging, and capture and treat, etc) or natural attenuation and monitoring.

Table 8-37 Overview of deselection assessment for eight other substances

Substance	monitoring	Summary of conclusions	Recommendation
Cyclodiene pesticides: Aldrin, Dieldrin, Endrin, Isodrin	2106 samples (1.8% quantified) from 381 sites in 4 MS in Sc3 (2015-2019) (only 3 non-quantified samples in MS #19 were taken with LOQ=0.05 µg/L and have to be eliminated from Sc2 dataset). One MS (#19) holds about 60.6% from all samples. All other non-quantified	Aldrin and Dieldrin are suspected to be Carcinogenic and recognised as POP. Endrin is recognised as POP. Isodrin is very toxic to aquatic life with long lasting effects. RQ(P95)=0.5 ((0.2 if MS#19 is excluded). No exceeding MS at P95 level regarding AA-EQS. There is a low variable temporal trend of annual P95. However, it was observed a slight increase of P95 in 2019 because the most data-rich MS has reported 2 elevated concentrations at one site, but the P95 in all years remain below AA-EQS. The annual mean concentrations at all sites are below AA -EQS, thus there is a compliance with AA -EQS. The MAC – EQS is	Not candidate for deselection

Substance	monitoring	Summary of conclusions	Recommendation
	samples were analysed using sufficiently sensitive methods with respect to the current AA-EQS.	not available for this substance. Two MS showed max concentration exceeding AA -EQS, however P99 ≤ AA – EQS in all MS. Although no failure of the compliance check, the group of cyclodiene pesticides is considered as an inappropriate candidate for deselection because these substances are included in the Stockholm convention for POPs. In addition, they have a median relevance for MSFD monitoring.	
DDT	For total DDT: 3993 samples (3% quantified) from 536 sites in 5 MS (2015 – 2019; not monitored in all years). Only 2 non -quantified samples in MS #19 are taken with LOQ=0.1 µg/L and have to be eliminated from Sc2 dataset. Two MS (#19 and #26) hold about 79.2% from all samples.	The isomer 111 -trichloro -22 bis (p – chlorophenyl) ethane is recognised as POP and is suspected to be carcinogenic. DDTs are suspected to be endocrine disruptors. RQ(P95)=0.2 (0.08 if MS #19 and #26 are excluded). No exceeding MS at P95 level regarding AA -EQS. There is a low variable temporal trend of annual P95 values and P95 in all years remain below AA -EQS. The annual mean concentrations at monitoring sites are below AA -EQS, except for 2 sites in 2019, thus there is a compliance with AA -EQS. MAC -EQS is not available for this substance. One MS showed max concentration exceeding AA -EQS, however P99 ≤ AA - EQS in all MS. Although no failure of the compliance check, the group of cyclodiene pesticides is considered as an inappropriate candidate for deselection because these substances are included in the Stockholm convention for POPs. In addition, they have a high relevance for MSFD monitoring.	Not candidate for deselection
Tetrachloroethylene	65081 samples (5.6% quantified) from 3565 sites in 16 MS (2015-2019). One MS (#12) holds about 71.8% from all samples. All reporting MS provided non-quantified samples analysed using sufficiently sensitive methods with respect to the current AA-EQS	It is not PBT but is suspected to be Carcinogenic. RQ(P95)=0.05 (0.25 if MS#12 is excluded). No exceeding MS at P95 level regarding AA-EQS. There is a low variable temporal trend of annual P95 which remain below the AA-EQS and also no failure of compliance in regards to the AA-EQS. In the period 2007-2018, a diminishing trend of riverine emissions was observed but there is an unexpected increase in 2019 caused by one MS. It showed a low/medium level of failures in regard to good chemical status in 2nd RBMP. This substance is relevant to the recast DWD 2020. The analysis showed that annual mean concentrations at monitoring sites and annual P99 of concentrations reported by MS extensively exceeded the freshwater	Not candidate for deselection

Substance	monitoring	Summary of conclusions	Recommendation
		AA-EQS in all reporting years. The number of sites where annual mean concentrations exceed the AA-EQS is 6-52 per year and the number of MS exceeding the AA-EQS at P99 level is 1-5 per year. It has a median (lower range) relevance for MSFD monitoring.	
Trichloroethylene	64744 samples (4.4% quantified) from 3551 sites in 16 MS (2015-2019). One MS (#12) holds about 72.7% from all samples. All reporting MS provided non-quantified samples analysed using sufficiently sensitive methods with respect to the current AA-EQS.	It is approved for a restricted use in EU. It is not PBT but according to ECHA it is officially recognised in the EU as Carcinogenic and is suspected to be Mutagenic. RQ(P95)=0.05 (0.1 if MS#12 is excluded). No exceeding MS at P95 level regarding AA-EQS. There is a low variable temporal trend of annual P95 which remain below the AA-EQS and also no failure of compliance in regards to the AA-EQS. In the period 2007-2019, a diminishing trend of riverine emissions was observed. It showed a low/medium level of failures in regard to good chemical status in 2nd RBMP. This substance is relevant to the recast DWD 2020. The analysis showed a variety of annual mean concentrations at monitoring sites exceeded the freshwater AA-EQS for each year excluding 2008 (range 1-7 per year) and exceeding P99 of MS exist in almost all reporting years (range 1-2 per year). Moreover, this substance should be evaluated in groundwater together with Tetrachloroethylene which showed several exceedances in all reporting MS. It has a median (lower range) relevance for MSFD monitoring.	Not candidate for deselection
Carbon tetrachloride	60998 samples (0.6% quantified) from 3580 sites in 15 MS (2015 – 2018). One MS (#12) is overrepresented in the dataset for recent MEC since holds about 69.4% from all samples. All reporting MS provided non-quantified samples analysed using sufficiently sensitive methods with respect to the current AA-EQS.	It is not uPBT but is suspected to be Carcinogenic (ECHA). RQ(P95)=0.042 (0.083 if MS#12 is excluded). No exceeding MS at P95 level regarding AA-EQS. There is a low variable temporal trend of P95 and values are below AA-EQS. All monitoring sites showed annual mean concentrations that are below the AA-EQS. All reporting countries showed maximum concentrations which not exceeding the AA-EQS value (MAC-EQS is not available for this substance). In the period 2007-2019, a diminishing trend of riverine emissions was observed. It showed a low level of failures in regard to good chemical status in 2nd RBMP. This substance is not relevant for RECAST DWD 2020, anyway no threat was found for ground water. It has a median (lower range) relevance for MSFD monitoring.	Suitable candidate for deselection

Table 8-38 Overview of pathways to environment

Substance	Major Pathways	Minor Pathways	Comments
Aldrin	Legacy	N/A	Banned in the EU for more than 40 years.
Dieldrin	Legacy	N/A	Banned in the EU for more than 40 years.
Endrin	Legacy	N/A	Banned in the EU.
Isodrin	Legacy	N/A	Co-produced with aldrin which is banned in the EU.
Tetrachloroethylene	Industrial processes. Unintentional release (dry cleaning).	Energy generation (coal). Legacy.	Releases primarily due to industrial applications (solvent) and unintentional releases during dry cleaning.
Trichloroethylene	Industrial processes. Legacy.	Natural sources.	Releases primarily due to industrial applications and legacy issues from previous contamination of metal with Trike.
Carbon tetrachloride	Industrial processes. Wastewater treatment works.	Surface water and air emissions following bleach use.	Intermediate in the manufacture of other chemicals (primarily rubber and polymers). Release from household bleach-containing product use.
DDT	Legacy	N/A	Banned in the EU for more than 40 years.

Economic impacts — *Costs*

The eight other pollutants are not formerly included within the legal requirements of the EQSD (i.e., to achieve good chemical status), however, many Member State Competent Authorities do undertake monitoring and analysis. Under **sub-option 1**, depending on the outcome of the reassessment (for the Cyclodiene pesticides, DDT, tetrachloroethylene and trichloroethylene), costs could manifest in a number of ways. For those Member States that do not currently complete monitoring this would become mandatory and incur costs. Additionally, where EQS are exceeded the Member State Authority would have an obligation to include measures aiming to ensure achievement of the EQS within their program of measures.

Importantly, the EQS quoted within the Directive stem directly from the DSD and have not been reviewed in over 15 years (likely closer to 20 years), with the threshold values themselves likely based on older scientific understanding (possibly considerably older). Where exceedances have been detected for the three industrial chemicals (albeit in a very limited number of water bodies), it could mean that if the scientific evidence suggests a lower threshold would be more appropriate, the number of exceedances could rise noticeably. This underscores that use of all three substances are still active, albeit with strict regulatory controls, particularly where use relates to applications as solvents and degreasers.

In the event that this option leads to an increase in exceedances from a change in EQS, an increase in the application of emission reduction measures would be required. However, the number of waterbodies in which these substances cause a ‘failing to achieve good chemical status’ is low. This can be seen as a percentage of the total number of waterbodies in the EU27 in Table 8-39. Due to the low levels of failures caused by these substances, it is unlikely that a potentially tighter EQS would lead to high costs.

Table 8-39 Number of failures to achieve good chemical status due to option 5 substances[442]

Substance	Total number of waterbodies	Number in which failure to achieve good status
Cyclodiene pesticides (aldrin, dieldrin, endrin, and isodrin)	97,000	20
Tetrachloroethylene	97,000	6
Trichloroethylene	97,000	3
Carbon tetrachloride, and	97,000	1
DDT	97,000	34

Nevertheless, similar to other options, different measures within the four emission reduction measure/treatment categories (source control, pathway disruption, end-of-pipe treatment and monitoring/natural attenuation) could be deployed to enable these substances to meet good chemical status should they be added to the Annex I list of priority substances.

For aldrin, dieldrin, endrin, isodrin and DDT commercial uses no longer exist as these substances have been banned in the EU for decades and were added to the Stockholm Convention on POPs in 2004 (note that isodrin is an isomer of aldrin). As a result, for these substances the most likely treatment option would be for natural attenuation and monitoring of the situation. As has been described previously, the costs of this approach have the potential to be low but will obviously depend on the level of active monitoring deployed. The costs associated with the latter have been described under option 1.

Tetrachloroethylene, trichloroethylene, and carbon tetrachloride are still in use in a number of industrial applications. Carbon tetrachloride is used as an intermediate in the manufacture of other chemicals (primarily rubber and polymers), tetrachloroethylene is used as a solvent in several industrial processes and trichloroethylene is used as a solvent and intermediate in the production of CFC alternatives. The most likely treatment types which could be deployed for these substances would be source control, and end-of-pipe treatment as well as monitoring/natural attenuation. End-of-pipe treatment is assumed to include treatment in both an industrial wastewater treatment plant as well as in a municipal wastewater treatment plant. The unit costs of different advanced wastewater treatment processes for different loads of wastewater treated have been collated by the JRC (Table 8-40).

[442] https://www.eea.europa.eu/themes/water/european-waters/water-quality-and-water-assessment/water-assessments/chemical-status-of-surface-water-bodies

Conversely, if the eight other substances were removed from the EQSD entirely for **sub-option 2**, it could mean that monitoring would cease where no risks were identified (particularly for the five pesticides), allowing redistribution of resources.

Table 8-40 Costs associated with advanced wastewater treatment as obtained from the JRC (unpublished)

type of treatment	*Total cost/CAPEX/OPEX*	*Country*	*Units*	for 2000 PE	for 10000 PE	for 20000 PE	for 50000 PE	for 100000 PE	for 500000 PE
O3 + sand filtration	Total	Switzerland	Euro per PE per year		25.38	22.5	13.724	12.596	
PAC in CAS + sand filtration	Total	Switzerland	Euro per PE per year		27.26	24.722	17.108	16.074	
PAC + sand filtration	Total	Switzerland	Euro per PE per year		30.08	26.884	17.296	15.792	
GAC	Total	Switzerland	Euro per PE per year		31.96	29.093	20.492	17.39	
O3	CAPEX	Sweden	Euro per m3			0.035	0.025	0.025	
O3	OPEX	Sweden	Euro per m3			0.015	0.015	0.015	
Sand filtration	CAPEX	Sweden	Euro per m3			0.06	0.035	0.025	
Sand filtration	OPEX	Sweden	Euro per m3			0.001	0.001	0.001	
GAC	CAPEX	Sweden	Euro per m3			0.06	0.045	0.035	
GAC	OPEX	Sweden	Euro per m3			0.055	0.055	0.055	
O3	Total	Sweden	Euro per m3	0.0725	0.04	0.029		0.0195	0.0145
BAF(GAC)	Total	Sweden	Euro per m3	0.11	0.085	0.065		0.0475	0.035
O3+BAF(GAC)	Total	Sweden	Euro per m3	0.15	0.11	0.075		0.05	0.04
PAC-UF	Total	Sweden	Euro per m3	0.53	0.21	0.16		0.13	0.12
UF-BAF(GAC)	Total	Sweden	Euro per m3	0.51	0.21	0.155		0.11	0.09
PAC sedimentation	CAPEX	Sweden	Euro per m3					0.015	
PAC + sludge management	CAPEX	Sweden	Euro per m3					0.015	
PAC + sludge management	OPEX	Sweden	Euro per m3					0.05	

Note: Data was derived from Baggenstos, 2019 and from a Swedish investigation (from a consultancy) that is not published

The costs associated with source control of these substances is expected to be low as five out of the eight substances are already banned in the EU and the remaining 3 substances are already under tight regulatory control. For example, carbon tetrachloride is used in dispersive applications such as aerosols and refrigerant gases was therefore phased out in the mid-1990s. Further tight controls have been applied to reduce emissions to air from industrial applications since this date (which may be part of the reason the rate of exceedance is particularly low). Indeed, trichloroethylene was added to the REACH authorisation list in 2013 with a sunset date of 2016, after which use is not allowed unless an Authorisation is in place. Furthermore, the production of CFC alternatives led to a large drop in the production of trichloroethylene in the years up until 2011 which would mirror the PRTR emission date[443]. This phase out of the use of these substances could let one argue that the use of source control measures would be unnecessary as a phase out is already in place.

As stated under previous sections, the costs associated with natural attenuation, most applicable to the legacy five substances, would come at a minimal cost since the MS would only be required to allow natural attenuation to take place and to continue with monitoring to ensure the situation remains stable or improves.

Economic impacts — *Benefits*

Under **sub-option 2**, if the eight other pollutants were deemed to be no longer an EU-wide risk and removed from the Directive entirely this would remove the need for monitoring and analysis, representing a cost saving for Member State authorities and the opportunity to reprioritise.

Environmental impacts — *Costs*

Under **sub-option 2**, one of the potential issues that could arise from removing the eight other substances from Annex II entirely is the loss of monitoring data. This becomes a problem in particular if the use of the eight substances increased in the future causing additional environmental damage and risk to human health. In this respect five of the eight have been banned for many years and are recognised internationally as POPs. This would suggest little risk of re-emergence. For the remaining three substances, health and environmental concerns are well founded, with strict regulatory controls already in place. This would suggest that continued use and risk of increasing emissions will already be kept in check by other policy areas. Again, the risk of re-emergence would be limited if the substances were removed from the PS list and managed as RBSPs where necessary.

Environmental impacts — *Benefits*

The **pesticides** aldrin, dieldrin, endrin and isodrin[444] have been banned for 40 years in the European Union. Ambient concentrations are likely to be very low, although where aldrin, dieldrin and endrin are all persistent organic pollutants (POPs) under the Stockholm Convention, they are also likely to be long-lived and persistent.

The pesticide DDT was restricted within the European Union in 1979 and prohibited entirely since 1983. While use globally has continued (primarily to fight malaria), presence in the EU

[443] Information collected internally from multiple sources

[444] Note that isodrin is a chemical relative of aldrin and they are found together. No commercial use was recorded.

would likely be either from import of contaminated fruit and vegetables or residual legacy concentrations. The pesticide residue regulation already sets maximum limits for DDT which are very rarely exceeded.

While the five pesticides have long since been banned in the European Union, the remaining three substances are **industrial chemicals**, with some remaining use as solvents and chemical intermediates, albeit with strict regulation and control. Based on REACH registrations tetrachloroethylene is used in the EU at >100,000 to 1 million tonnes per annum, trichloroethylene at >10,000 to <100,000 tonnes per annum and carbon tetrachloride at >1,000 to <10,000 tonnes per annum. Based on the existing EQS, exceedances for trichloroethylene are found in 2 MS (4 water bodies), for tetrachloroethylene, 6 water bodies across 3 MS, and carbon tetrachloride – only 1 water body (little impact).

Given that the EQS listed within Annex II predates the 2008 EQSD, the scientific understanding is likely to have advanced significantly. This could mean that the EQS underestimates the risk, and a wider consideration is needed. Depending on the action (added as a PS, deselect, leave as is), there would be corresponding impacts for the natural environment and human health via the environment.

For **sub-option 1**, the amendment of EQS for these substances has the potential to confer environmental benefits. However, given the low number of failures of waterbodies caused by these substances and the low number of exceedances already, the thresholds imposed on these substances would likely have to be much lower than the current requirements. However, as aldrin, dieldrin, endrin, isodrin and DDT have been banned in the EU for a long time and given the limited approaches that are available for these options beyond natural attenuation, it is unlikely there would be any environmental benefits for these substances. For the remaining 3 substances, a low threshold for these substances could provide additional benefits in the form of environmental costs avoided.

Tetrachloroethylene is a suspected carcinogen and is used in industrial processes such as dry cleaning, industrial textile treatment, metal surface cleaning, catalyst regeneration, and applications within oil refinery businesses. It has been shown to be acutely toxic to fish, invertebrates and algae. In terms of acute toxicity, the increased mortality in freshwater fish has been shown to occur at the lowest concentration in *Oncorhynchus mykiss* for which the LC50 was 5 mg/l in validated data. In invertebrates the lowest EC50 from validated data is 8.5 mg/l (in *Daphnia magna*) and in algae the lowest EC50 from validated data is 3.64 mg/l (*Chlamydomonas reinhardtii*). Chronic toxicity has been shown in fish, Daphnia and algae. A 10-day NOEC of 1.99 mg/l and a 28-day NOEC of 2.34 mg/l are reported for the larvae and fry of Jordanella floridae, a type of fish[445].

Carbon tetrachloride is a suspected carcinogen and is used in a range of industrial processes, in particular as an intermediate in the manufacture of other chemicals. This substance shows toxicity to fish, aquatic invertebrates as well as algae and cyanobacteria. One of the lowest available acute toxicities in fish is an LC50 (96 h) of 24.3 mg/L for *Brachydanio rerio*

[445] https://echa.europa.eu/registration-dossier/-/registered-dossier/14303/6/2/1

Hamilton-Buchanan (Teleostei, Cyprinidae). Long term toxicity has been shown by a NOEC of 2.5 mg/L for zebrafish. The available short term toxicity data for invertebrates is less reliable but an EC50(48h) in the range 10 – 100 mg/L for daphnids has been suggested. With respect to long term toxicity, a NOEC of 3.1 mg/L for the invertebrates *daphnia magna*has been established[446].

Trichloroethylene is carcinogenic and suspected as mutagenic and is used as a chemical intermediate and is widely used as an intermediate in the production of CFC alternatives. The acute toxicity of trichloroethylene has been establish for fish, invertebrates and algae and long term toxicity data for fish. In terms of acute toxicity for fish, an 96-h LC of 28.3 mg/l was determined in freshwater fish (*Jordanella floridae*) and for freshwater invertebrates a 48h IC50 for *Daphnia magna* of 20.8 mg/l was determined. With respect to the long term toxicity of the substance, a 10-day NOEC of 5.76 mg/l and a 28-day MATC of 14.85 mg/l have previously been reported for the larvae and fry of *Jordanella florida*.

The avoidance of this toxicity through a lower, updated EQS could be therefore viewed as an environmental benefit.

For **sub-option 2**, the removal of substances from Annex II would confer no additional environmental benefits.

For **sub-option 3**, environmental benefits are anticipated to be no different to the current arrangement. Given the low number of waterbodies in bad chemical status caused by these substances and the low number of exceedances, the environmental benefits attributable to these substances is low (relative to the current scenario).

Social impacts – *Costs*

Assessed to be negligible.

Social impacts – *Benefits*

The eight substances were originally added to the DSD over concerns for environmental and human health impacts. The five pesticides are now long since banned in the European Union (despite being POPs). The three industrial chemicals are still actively used, albeit with strict regulatory controls. Better understanding about environmental releases and ambient concentrations could have societal benefits in the way that environmental (and humans via the environment) risks are identified and managed. This would also further support the wider chemical acquis in managing the risks at source by providing a valuable environmental evidence base.

For the three industrial substances for which uses are still ongoing, the formation of an EQS for these substances could lead to improvements to human health. This would particularly benefit particular workers in industry (such as dry cleaners for tetrachloroethylene) who may experience a greater exposure to these substances.

[446] https://echa.europa.eu/registration-dossier/-/registered-dossier/14940/6/2/1

Tetrachloroethylene has been identified as a potential PBT. For this substance, 20 ppm (138 mg/m3) has been identified as the NOAEL (DNEL, OEL) for human repeated dose toxicity via the inhalation route (expressed as an 8 hours TWA value (SCOEL))[447]. It has uses in dry cleaning, industrial textile treatment, metal surface cleaning, catalyst regeneration, and applications within oil refinery businesses. For workers in these environments, the proposed DNEL for worker long-term systemic exposure via the dermal route is 39.4 mg/kg bw/day[448].

Carbon tetrachloride, which is used as an intermediate in the manufacture of other chemicals (primarily rubber and polymers), is also toxic to humans. The liver is most sensitive via the repeated-dose toxicity by oral and inhalation routes. For oral administration, the lowest relevant NOAEL is 1 mg/kg bw/day from a 12-week study and for inhalation, the lowest NOAEC is 5 ppm from a 2-year study. Carbon tetrachloride is not considered to be directly genotoxic but can act as a carcinogen (and has been shown to induce cancer in rodents)[449].

Trichloroethylene is used as a chemical intermediate and is widely used as an intermediate in the production of CFC alternatives. It is widely recognised in the EU as being mutagenic and carcinogenic although only 16.67% of REACH registrations indicate that this is the case[450].

It is for these three substances that the greatest range of measures are available as they are still in active used. Given the range of measures available, it could be assumed that the health impacts associated with these three substances would be easiest to avoid should such measures be required. Given that the primary measure for the remaining five disused substances is natural attenuation and monitoring, the health benefits of this option for these substances may be less apparent.

Summary

It has already been shown in -Table 8-30 that the percentage of total waterbodies in which there is a failure to achieve good chemical status caused by each substance is low (<0.1% for each substance). Therefore, significant additional measures in order to meet compliance are unlikely. Indeed, for the cyclodiene pesticides (aldrin, dieldrin, endrin and isodrin) and DDT, these substances have been banned in the EU for many years and the remaining sources/pathways to the environment come from legacy sources. The primary, if not only practical way to handle these legacy sources is to allow for natural attenuation and to monitor the situation. For the remaining substances (tetrachloroethylene, trichloroethylene and carbon tetrachloride) their uses are still ongoing in a number of industrial applications. Carbon tetrachloride has already been identified as a candidate for deselection. In the case of tetrachloroethylene and trichloroethylene, in the event that the provision of an EQS for these substances leads to the need for further treatment, the primary treatment approaches would be the use of source control, end-of-pipe measures and, to a lesser extent, allowing for natural attenuation. End-of-pipe processes can be either in the form of industrial or municipal wastewater treatment and the unit costs of these were highlighted in -Table 8-31 as obtained by the JRC.

447 https://echa.europa.eu/documents/10162/827c5a7a-181f-2308-bf14-4fe414401d3b
448 https://echa.europa.eu/documents/10162/827c5a7a-181f-2308-bf14-4fe414401d3b
449 https://echa.europa.eu/documents/10162/8bdf4479-4a7c-261b-f195-ad8b4bd6170e
450 https://echa.europa.eu/brief-profile/-/briefprofile/100.001.062

8.3 Groundwater options

A key aspect of understanding the potential impact of the options set out in Section 8 is defining the "gap" between the baseline situation and meeting the proposed GWQS or likely requirements of Annex II set TVs. Subsequently this assessment is used as the basis for determining the types and potential level of uptake of measures needed to get to good chemical status, and how their implementation would impact stakeholders. Here, the likely environmental, economic and social impacts are provided including environmental and social benefits of the options and cost estimates. The impacts of the options are described through the costs and benefits of the economic, environmental and social impacts including the additional administrative burden on responsible authorities for GWD implementation.

8.3.1 *"Distance to target" assessment*

In order to understand the gap, the number of GWBs at risk of failing to meet good chemical status, number of MS reporting a failure and the level of exceedance as a result of the inclusion of PFAS, pharmaceuticals and nrMS in Annex I or Annex II needed to be defined.

Methodology for groundwater distance to target

Groundwater status is assessed on the basis of evidence of widespread pollution, deterioration (i.e. environmental significant trends); or harm to receptors including protected areas and ecosystems. Unlike for surface water, there is no specific requirement for MS to monitor for LFR substances unless they pose a risk to groundwater. Therefore, in the absence of evidence of the impact of PFAS, pharmaceuticals and nrMs on groundwater receptors or trends in concentrations, only the baseline scale of pollution was assessed in Section 4. It was assumed that TVs would be set using drinking water standards under Annex II and that the GCA test would be the primary test used. Emissions, pathways, detection in groundwater and benchmarking against the GWB status due to substances with similar patterns of emissions, environmental fate and persistence which are already listed in the GWD Annexes were all considered.

The main differences between the baseline situation and the policy options set out in Section 7 for the proposed additions to the GWD are the level of GWQS (where added to Annex I) and the substance ranges (groups or individuals) to which these standards apply. Therefore, the magnitude (the level of exceedance over the target) and scale (additional number of GWBs failing) of the distance to target, will change depending on the option selected. Where options are to add pollutants to Annex II then the situation is likely to be closer to the baseline, although MS are obliged to consider these substances when setting TVs.

To further characterise the distance to target for each option, the baseline impact is re-assessed using expert judgement and the indication of likely level of exceedance over GWQS or reported TVs already used by MS for Annex II (or a DWS). The GW WL data[451] is used qualitatively to extrapolate a likely level of failure based on proportion of MS reporting an exceedance and the increase in GWBs failing based on the increase in monitoring points with an exceedance. The GW WL dataset is much more constrained compared to surface water watchlist data and the outcomes of the distance to target assessment subject to a high level of uncertainty due to the following:

- GW WL data from the UK and Switzerland is not used for consistency.
- Less than half of all EU 27 provided data for the relevant substances: 14 for nrMs, with 12 for pharmaceuticals and 10 for PFAS. These were typically MS in north-western Europe, with a small number of Mediterranean and eastern European MS. A small number of MS sometimes provided a large proportion of the data for specific substances.
- Data is provided as the number of monitoring sites reporting a detection within a concentration range, and in most cases the reported concentration ranges do not allow differentiation between the likely impact of some GWQS (i.e. they sit in the same concentration range).
- The date ranges of concentrations provided are not for the same period (can be from 2007 to 2021)
- Some monitoring locations could relate to local investigations into polluted sites and therefore are unlikely to be representative of wide-spread pollution. As the numbers of monitoring points are not related to the WFD related groundwater monitoring networks the data therefore cannot be used to accurately calculate the proportion of failures. It also cannot be used to estimate the likely numbers of GWB failures.
- Due to the third party nature of some of the data, it is used in an anonymised fashion.

It is noted that for the 15,930 GWBs reported by the EU27 in 2016[452], a large number of water bodies will have no monitoring (too remote or economically unfeasible) with status being assessed through grouping of characteristics including pressures and risk. Therefore, GWB status at the European level is already subject to a level of extrapolation of evidence using expert judgement.

Here the level of exceedance above GWQS is estimated by calculating the proportion of monitoring locations and MS reporting concentrations above these targets. The caveats listed above sets out the reasons why this approach is highly uncertain and direction of uncertainty (i.e. under or over estimation) is unclear. For options related to Annex II it has been assumed that TVs would be related to a DWS (if available) without the use of a safety margin. For each group of options, the distance to target is determined subjectively, following the surface water categories and using the criteria in Table 8-41.

[451] The GW WL dataset, provided voluntarily by MS, identifies, by participating country and individual pollutant: the LOQ, date range of data provided, analytical method, and the number of monitoring points for with concentrations within set ranges.
452 452

Table 8-41 Approach to evaluation of likely GWB status for LFR substance groups

Size of gap	Criteria for scale of distance to target
Small	Scale: Predicted GWB failure in ≤33% of MS reporting data (based on baseline impact and difference between GWQS and use of DWS)
	Magnitude: Extrapolation of GW WL results – 0-33% of monitoring points in the GW WL exceed the GWQS (or DWS if option is for an Annex II listing)
Medium	Scale: Predicted exceedances 33% to 66% of MS of MS reporting data (based on baseline impact and difference between GWQS and current day use of DWS)
	Magnitude: Extrapolation of GW WL results – where 33-66% of monitoring points in the GW WL would exceed the GWQS (or DWS if option is for an Annex II listing)
Large	Scale: Predicted exceedances in over 66% of MS of MS reporting data (based on baseline impact and difference between GWQS and current day use of DWS)
	Magnitude: Extrapolation of GW WL results – where 66% to 100% monitoring points in the GW WL would exceed the GWQS (or DWS if option is for an Annex II listing)

PFAS Distance to target

In the GW WL dataset ten of the EU27 have reported data for different periods between 2007 and 2020 for 30 PFAS substances (seven MS did not include PFAS in WFD related groundwater monitoring[453]).

The LOQ values in the dataset reported ranges from 0.5 ng/l to 0.1 µg/l. The frequency of concentrations detected by PFAS substance, by MS are reported for the following ranges: LOQ to 0.05 µg/l, 0.05 to 0.1 µg/l, 0.1 to 1.0 µg/l, 1.0 to 3.0 µg/l, 3.0 to 10.0 µg/l and >10.0 µg/l.

The following estimate of impacts of options is based on the GW WL datasets:

- Option 1a requires a GWQS of 0.1 µg/l for the ten detected PFAS in groundwater and this would lead to seven MS reporting an exceedance for one or more PFAS at between 1 and 75% of monitoring points.
- Option 1b requires a GWQS of 0.5 µg/l for the sum of all PFAS but due to the groupings of reported concentrations the same number of exceedances are indicated as Option 1a. For Option 1a and 1b therefore, seven of ten MS (i.e. 70% of this subset) would report exceedances at up to 75% of monitoring locations.
- Option 1c to add these substances to Annex II and this would most closely replicate the baseline situation, although MS would be obligated to consider setting TVs for PFAS. For PFAS the current day estimated impact is for the failure of around 0.9 to 2.5% of GWBs with around 35% of MS (around 9) reporting a failure. The magnitude of exceedance, based on the use of DWS (as for Option 1a and 1b) is likely to be large.
- Option 1d is most stringent, specifying the use of RPF equivalent to 4.4 ng/l PFOA, with GWQS for 24 proposed EQSD PFAS from 0.00044 µg/l (PFDA) to 4.4 µg/l (PFHpA) and assuming 4.4 ng/l GWQS where there is no RPF. In this case nine of the ten MS would have an exceedance of the GWQS at up to 68% of monitoring points. The use PFOA equivalents provides a range of GWQS for at least the 24 EQSD PFAS which means the impact extrapolated from the GW WL dataset is similar overall to Option 1a and 1b.

[453] WFD CIS 2020. Voluntary Groundwater Watch List Group. Study on Per- and Perfluoroalkyl substances (PFAS) - Monitoring Data Collection and Initial Analysis. pp 19.

In summary Option 1a, 1b and 1d are likely to lead to a large-scale distance to target and large magnitude of exceedance of the targets set. Option 1c will have a medium scale distance to target with a large exceedance.
These conclusions are strongly caveated on the basis of the skewed GW WL data and the fact that there are many more PFAS not reported. This means that the impact of Option 1b which looks at all PFAS and the gap to get to good status is likely to be underestimated / uncertain. The percentages of scale of impact and magnitude of exceedance given above are assessed using criteria in Table 8-42.

Table 8-42 Distance to target based on GWQS for PFAS in groundwater at EU27 level

Distance to target	Option group
Large scale, large magnitude (70% of reporting MS with exceedances at 75% of monitoring points) - overall Large	Option 1a PFAS (list of 10 at 0.1 µg/)
Large scale, large magnitude (70% of reporting MS with exceedances at 75% of monitoring points) - overall Large	Option 1b PFAS (sum of all at 0.5 µg/l)
Medium scale, large magnitude (35% of MS with 2.5% GWBs failing based on proxy substance) - overall Large	Option 1c PFAS (Annex II) — assume TVs set using DWS
Large scale, large magnitude (90% of reporting MS with exceedances at 68% of monitoring points) - overall Large	Option 1d PFAS (list of 24 with PFOA equivalent 4.4 ng/l. All other PFAS use PFOA equivalents if available, or the PFOA value)

Pharmaceuticals distance to target

The GW WL data for pharmaceuticals was provided by seventeen EU27 MS for different periods between 2011 to 2020. The concentration ranges reported are: <LOQ, LOQ to 0.05 µg/l, 0.05-0.075 µg/l, 0.075-0.1 µg/l, 0.1-1.0 µg/l, 1.0-3.0 µg/l, 3.0-10 µg/l and >10 µg/l.

Option 2a which adds carbamazepine (0.5 µg/l) and sulfamethoxazole (0.1 µg/l) to Annex I would lead to exceedances for carbamazepine at 0-8% of sites reported by 3 out of 8 MS, and an exceedance of the proposed GWQS for sulfamethoxazole at 0.43% of sites for 1 of 8 MS. Therefore, this would lead to a small distance to target. It is noted that the original assessment include data from the UK and Switzerland which is excluded here.

Option 2b requires a group GWQS of 0.5 µg/l for the group of all pharmaceuticals. The GW WL data shows an exceedance of this proposed GWQS at up to 50% of monitoring points in 8 MS of the 17 (47%). The impact expands to a much wider group of MS and monitoring points putting this option into the medium distance to target group.

Option 2c, would add all pharmaceuticals to Annex II with specific consideration of Primidone. For pharmaceuticals the baseline impact is small and therefore comparable, with an estimated 1% of GWBs at poor status or at risk, and 10% of MS reporting a failure. Assuming a TV of 0.1 µg/l for Primidone would lead to an exceedance at between 7 and 24 monitoring points in two MS. This option would sit in the small distance to target category. The impact from pharmaceuticals on groundwater in the baseline situation and based on GW WL data, is likely to be limited, with greatest impact from Option 2b.

Table 8-43 Distance to target based on GWQS for pharmaceuticals in groundwater at EU27 level

Distance to target	Option group
Small scale, small magnitude (carbamazepine - 8% sites with exceedance reported by 37% of MS, sulfamethoxazole 0.43% of sites with exceedance reported by 12.5% of MS) - overall Small	Option 2a Pharmaceuticals (carbamazepine and sulfamethoxazole)
Medium scale, medium magnitude (47% of reporting MS, with 50% of monitoring points with exceedances) - overall Medium	Option 2b Pharmaceuticals (group)
Small scale, small magnitude (1 of 6 MS reporting detection of Primidone report an exceedance of suggested drinking water standard at 1% of monitoring points) - overall Small	Option 2c Pharmaceuticals (group — Annex II) considering Primidone

nrMs distance to target

The GW WL data for nrMs was provided by fifteen MS and covered different periods between 2010 to 2019. The concentration ranges reported are: <LOQ, LOQ to 0.05 µg/l, 0.05-0.075 µg/l, 0.075-0.1 µg/l, 0.1-1.0 µg/l, 1.0-3.0 µg/l, 3.0-10 µg/l and >10 µg/l, with LOQ values between 0.0002 and 0.1 µg /l.

Option 3a sets a GWQS of 1 µg /l for 16 individual nrMs detected in groundwater whilst Option 3d sets a more stringent target of 0.1 µg /l for the same group. Based on a 1 µg /l GWQS the GW WL data suggests that between 0 and 29% monitoring points across 12 MS would report an exceedance. Using the more stringent target would lead to up to 59% of monitoring points with an exceedance across 14 MS.

Option 3b sets a GQWS of 10 µg /l for all nrMs whilst Option 3e sets a much more stringent target of 0.1 µg /l for all nrMs. At a GWQS of 10 µg /l, up to 6% of monitoring points would report an exceedance located in 13 MS, whilst the lower GWQS (Option 3e) would lead to an exceedance at up to 59% of monitoring points in 14 MS.
Option 3c requires addition of all nrMs to Annex II, and therefore follows the baseline situation, although MS would be obligated to consider setting TVs. The estimated impact on baseline status for nrMs is likely to be between 0.5 and 2% of GWBs with up to 40% of MS reporting a failure.

Between the options for nrMs the proportion of MS which would report an exceedance is likely to stay high (i.e. over 66%) and the extent of monitoring points with an exceedance increases from small to medium magnitude of impact as the GWQS becomes more stringent.

Table 8-44 Distance to target based on GWQS for nrMs in groundwater at EU27 level

Distance to target	Option group
Large scale, small magnitude (80% of MS with exceedance at 29% of monitoring points) - overall Medium	Option 3a nrMs (list of 16 at 1 µg/l))
Large scale, small magnitude (87% of MS with exceedance at 6% of monitoring points) - overall Medium	Option 3b nrMs (group of all at 10 µg/l)

Medium scale, small magnitude (40% of MS with exceedance at 2% of GWBs failing) – overall Medium	Option 3c nrMs (Annex II)
Large scale, medium magnitude (93% of MS with exceedance at 59% of monitoring points) – overall Large	Option 3d nrMs (list of 16 at 0.1 µg/l)
Large scale, medium magnitude (93% of MS with exceedance at 59% of monitoring points) – overall Large	Option 3e nrMs (group of all at 0.1 µg/l)

8.3.2 *Identification of possible measures and impacted stakeholders*

The distance to get to good status in the baseline situation and the identification of measures already in place which will help achieve good status has been established under the dynamic baseline. Here the different impacts of the individual policy options on the distance to get to good status are compared in terms of further measures required to close the gap. The diffuse or point source emissions and pathways to groundwater of PFAS, pharmaceuticals and nrMs have been identified along with the legislation controlling emissions and how the dynamic baseline would evolve with no policy options (Section 7). The distance to target analysis above sets out the estimated size of the problem by policy option and this helps to identify the types of measures which could be implemented to achieved good chemical status. For example, a large scale largely diffuse problem could call for more stringent wide measures. The stakeholders and actors which might be impacted by costs incurred due to the policy option implementation also need to be identified as part of the impact assessment.

Identification of measures to close the gap

The method used to identify measures follows that set out in the Better Regulation Toolbox #16[454], which involves the setting of the baseline situation including measures / legislation already in place, compiling a wide range of measures which are then screened and the final list of measures is investigated further for identification of associated impacts (costs, benefits).

The following steps have been used in this process:

Step 1 Measures identification

A wide-ranging review of all possible measures including technical and policy options which could help to close the distance to target was made, for each of PFAS, pharmaceuticals and nrMs. Measures are classified on the basis of the point at which they act:

- **Source control** i.e. reduction or removal of the source term of the pollutant (including banning production / use, restrictions on use including in specific geographies, reduction in entry to waste-stream). The strategies and legislation described as part of the dynamic baseline typically focus on source control measures.
- **Pathway disruption** in its purest sense puts a barrier between the emitted pollutant the receptor. In the case of groundwater, the receptor is too wide / big to sensibly be able to disrupt all pathways. The barrier / diversion from groundwater would be to line the base of the soil zone which clearly is not feasible.
- **End of pipe treatment**: for groundwater this group of measures sits within the pathway interruption group but specifically covers technological / chemical treatment of wastewater discharges / biosolids / manures etc.

[454] br_toolbox_-_nov_2021_-_chapter_2.pdf (europa.eu)

- **Receptor based measures:**
    - **Natural Attenuation**: In groundwater remediation this is specific technique that is used for pollutants that are likely to reduce in concentrations through biodegradation or dilution from aquifer recharge within a relatively short timeframe. This option is not relevant for the LFR pollutants which are persistent. Here this is used to describe the continued monitoring of groundwater to ensure that concentrations continue to follow the expected trajectory once the source term is removed and the aquifer recovers. In practical terms this is the "measure" currently being used for metabolites of banned pesticides such as atrazine.
    - **Groundwater and soil remediation**: typically hugely energy intensive, expensive and takes a long time, but where aquifers are significantly polluted by persistent highly toxic substances, this is the only measure which will clean up the problem within a reasonable timescale.

In addition, the type of pollution i.e. point or diffuse will commonly dictate the type of measure used. Wide-spread diffuse pollution is more likely to be addressed through stringent source controls (bans and restrictions) to try and capture all pathways of pollution. Point source pollution, often where the polluter is clearly identified, are more likely to be dealt with through pathway disruption / end of pipe treatment or receptor-based measures.

End of Pipe – Quaternary treatment
It is recognised that end-of-pipe measures are a key element of the overall package of possible interventions for achieving good chemical status (with extended producer responsibility and polluter pays principles duly recognised). However, it also needs to be recognised that the UWWTD has recently undergone a fitness check and options appraisal to maintain a high level of protection for water. This recognised that EU wastewater treatment works use primary and secondary treatment technologies as a minimum, and increasingly have adopted tertiary treatment technologies to manage nutrient loading for treated effluent. The further expansion to advanced technologies (quaternary treatment) for micro-pollutants is an area still under development. The JRC have undertaken an extensive cost benefit study to complete analysis of quaternary treatment technologies, with ozonation, granulated activated carbon (GAC), and powdered activated carbon (PAC) identified as the most cost effective, either on their own or in combination. Following this study recommendations have been included within the proposals for amendment of the UWWTD. This follows a phased approach to implementation, including: • 2025: Update of risk registers for key micro-pollutants in treated effluents. • 2030: Upgrade to quaternary technologies for wastewater treatment plants serving population equivalents of 100,000 or greater.

End of Pipe – Quaternary treatment
• 2040: Upgrade to quaternary technologies for wastewater treatment plants serving population equivalents of between 10,000 and 100,000, where risk of pollution is identified due to low dilution issues (broadly assumed to affect 70% of works). Where these implemented changes will not start to take effect until 2030, the inclusion of the amendments and need for upgrade of wastewater treatment works has not been included in the dynamic baseline. However, double counting within the wider impact assessment for the substances identified should be avoided. As pointed out previously, for groundwater any entry of hazardous substances such as PFAS should already be prevented i.e. through removal from discharges to ground. Although this is unlikely to take place at the current time, it should be part of the baseline measures already in place. For groundwater where end of pipe treatment has been identified in the long list of potential measures, these have not been taken forward to the screened short-list as the costs of upgrading wastewater treatment works will fall under the requirements of the revised UWWTD so form part of the baseline.

Step 2 Screening of measures

The unconstrained long list of measures was reviewed and screened using expert judgement and feedback from stakeholder engagement workshops. Measures were evaluated on the basis of the key criteria specified by the Better Regulation Guidance, namely: effectiveness (including practicability), efficiency (economic feasibility) and coherence (legal feasibility and coherence with other legislation). Relevance and EU added value are addressed in earlier sections of this report. In addition, consideration was given to whether the measures were acceptable to a range of stakeholders including the public. During this stage it was considered whether the measure was likely to be implemented as a result of existing legislation or planned legislation or other interventions and therefore is part of the baseline and so not considered further.

Step 3 Identification of impacted sectors

Based on the preceding steps, using the screened list of measures, the key sectors likely to be impacted by the costs of implementing the measures from step 2 were identified.

The long list is set out by group in Appendix J of this report and shows the decisions made in selecting measures for the constrained list set out for PFAS, Pharmaceuticals and nrMs. Measures are grouped by the point of interception as set out in Step 1 with a “other” category which includes high level measures to invest in research into innovative techniques and collection of data on emissions which will help to develop action plans and programmes of measures.

For some measures, the screening and evaluation process was overridden due to the necessity of the measure. For example, the remediation of groundwater for PFAS, which is evaluated as a low scoring measure due to its cost and timescale for an impact is still likely to be used to deal with legacy pollution. Finally, the measures for each option are discussed in further detail in the following sections.

Table 8-45 Overview of measure categories and applicability to each of the groundwater substance groups

	Pharmaceuticals	nrMs of		Industry chemicals
		Pesticides	Biocides	
Intervention at source	✓	✓	✓	✓
Pathway disruption	✓	✓	✓	✓
End-of-pipe	✓			✓
Other	✓	✓	✓	✓
Receptor based measures (Natural attenuation, groundwater and soils remediation)	✓	✓	✓	✓

Stakeholders impacted by the implementation of the measures

The approach to identification of the sectors / actors which would be affected by the implementation of the various options was carried out in parallel with the surface water analysis as there are direct overlaps with the same substances or substance groups being considered. Table 8-46 lists the stakeholders likely to be impacted by short listed measures for each of the substance groups being considered.

Table 8-46 Key stakeholders impacted by groundwater measures

PFAS	Pharmaceuticals	rnMs (Pesticides)
Manufacturing - clothing, textiles, printing, chemicals (multiple sectors)	Wastewater companies (EPR) and drinking water companies	Agriculture – Farmers / landowners
Wastewater companies (EPR) and drinking water companies	Pharmaceutical manufacturers	Veterinary applications - biocides,
Waste disposal (Landfill)	Veterinary applications (domestic pets)	Pesticide manufacturers
Member State Authorities - guidance and permitting	Agriculture - farmed animals and horses	National Agencies - guidance and enforcement
Healthcare Sector	Healthcare Sector	Healthcare Sector
Society – costs to consumers/ taxpayers	Society – costs to consumers/ taxpayers	Society – costs to consumers/ taxpayers
	Waste disposal (Landfill)	Drinking water companies

8.3.3 *Option 1 Impact of options to add of PFAS to the GWD*

The option to add PFAS to the GWD Annexes has four different iterations:

- Option 1a PFAS (Group of 10) included in Annex I and assigned a GWQS of 0.10 µg/l (based on the drinking water standard for 20 identified PFAS - the 10 PFAS would be a subset of the 20)

- Option 1b All PFAS added as group to Annex I with a GWQS for "PFAS total" of 0.5 µg/l (again following the drinking water standard for PFAS total);
- Option 1c All PFAS added as a group to Annex II for MS to consider for the development of a TV for specific substances posing a risk to GWBs.
- Option 1d PFAS (Group of 24 proposed as additions to the surface water Priority Substance list) included in Annex I and assigned a GWQS of 4.4 ng/l PFOA equivalent; For PFAS substances not included on the PS list, the PFOA relevant potency factor (RPF) should be used to calculate the GWQS. If no RPF exists, then the RPF of PFOA should be assumed and a GWQS of 4.4 ng/l applied.

Here the economic, environmental and social impact of these options is compared building on the dynamic baseline, distance to target, constrained measures list and sectors / actors impacted developed prior to this point.

Economic Impacts: PFAS Options

The direct economic impacts of the addition of PFAS to the GWD Annexes will result from:

- The cost of additional monitoring for PFAS across MS, which will comprise: analytical costs, data processing and reporting costs[455].
- Updates to risk and status assessment for GWBs (update of conceptual models, data analysis and reporting).
- The programme of measures required to maintain or restore good chemical status with respect to PFAS.

These are discussed and estimated costs and benefits list with a comparison between Options 1a to 1d.

Impacts on the Administrative Burden of adding PFAS to the GWD

Additional administrative burden for MS will increase for all Options 1a to 1d to add PFAS to the GWD Annex I or II as follows:

- The size of the MS WFD related groundwater monitoring programmes will increase;
- Investment in analytical techniques for low levels of PFAS or "sum of PFAS";
- If Option 1c is selected (addition to Annex II) then MS will need to consider setting a TV for PFAS substances;
- Additional chemicals will require further risk and status assessment against GWQS or TVs;
- GWBs which fail to meet good chemical status will require a programme of measures to be implemented to achieve good status and reverse adverse trends; and
- Future proofing national legislation.

The extent of the increase in administrative burden will depend on the option and on the level to which individual MS are already investigating the risks posed by PFAS to groundwater.

[455] The Polluter Pays Principle could help polluters to become incentivised to avoid environmental damage and be held responsible for the pollution they cause and their remediations costs. This could for example be done by introducing an Extended Producer Responsibility but this was not part of this IA support study and would require additional work similar to that done in the context of the Impact Assessment support study for the revision of the Urban Wastewater Treatment Directive.

The recent recast of the DWD is likely to reduce the administrative burden for MS with respect to PFAS as set out below[456].

Expansion of monitoring analysis

Only Option 1a limits the number of PFAS to be investigated to 10, of which all are on also listed on the DWD. The remaining options require that all PFAS are added to the GWD Annexes and assessed with a group total GWQS (Option 1b) or as individual substances (Option 1c and 1d). Therefore, the increase in size of monitoring requirements will be smallest for Option1a and possibly Option 1c if MS risk assessments suggest that only a small number of PFAS are putting GWBs at risk. It is noted that some MS already monitor for a wide number of PFAS substances. For example, Sweden and Germany already monitor for most of the LFR PFAS substances and have been doing so for a number of years (driven by groundwater pollution events), whilst in 2020 seven out of 18 MS providing feedback to the GW WL process were not monitoring for PFAS at that point. More MS have agreed to add at least the group of 10 PFAS on the LFR to their monitoring networks by 2027 (note that this would mean that significant trends in PFAS concentrations would not be assessed until at least 2033).

Investment in analytical techniques

There is currently, no agreed method for analysis of "all PFAS" and a range of analytical options are available, some of which are expensive. It is likely, in practice, that PFAS analysis will be standardised around a methodology such as that being developed for the DWD for 20 PFAS substances. Option 1b is consistent with the group approach to PFAS that has been adopted by the EU Chemicals Strategy. A similar analytical approach exists for polynuclear aromatic hydrocarbons (PAHs), where a standard suite of 16 PAHs is often used and for pesticides, where several standard suites are typically used. It is, however, possible that advances in analytical techniques will permit analysis for a wider range of PFAS compounds at reasonable cost. The timescale for this advance in techniques is likely to be 5 years which has implications for how effectively this option could be applied until analytical techniques are developed. Option 1d, requires some very low concentrations (sub nanogram scale) to be analysed for in groundwater for some PFAS substances. The same proposed quality standards are set out by the JCR for 24 EQSD PFAS for surface water, which are based on human health impacts and the total weekly intake criteria published by EFSA. Therefore, analytical techniques should already be available for these substances at the concentrations indicated and the expense is likely to reduce as analytical techniques develop and improve with time.

Setting of Threshold Values (TVs)

Under Options 1a, 1b and 1d, an EU wide GWQS is proposed, meaning that the MS do not need to develop a TV for PFAS. However, the DWD does already provide DWS for 22 PFAS substances and these could be used directly under Option 1c. This option could also lead to differences in the proportion of GWBs assigned poor status between MS and hence the need

[456] Under the DWD recast 22 PFAS have been assigned DWS which are the same as the GWQS proposed here and there will be a requirement for testing of all public drinking water for PFAS from 2024 onwards. The DWD sets standards for PFAS compounds as PFAS (total) and / or PFAS (sum) and the EC will provide an analytical method by 2024.

for measures. For cross-border GWBs there are potential inconsistencies in both the substances with TVs and in the TV concentration that will need to be resolved between MS. The separate development of TVs in each MS is potentially onerous, as it requires each MS to consider the risks posed by PFAS, understand their occurrence in their GWBs and then develop an appropriate TV. It also potentially creates varied TVs and lists of substances across the EU which reduces harmonisation in conflict with the recommendations in the GWD amendment (2014). As noted in the review of the occurrence of PFAS in groundwater[457], four countries reported TVs or other types of limiting or guiding values for several PFAS ranging between 0.1 and 3 µg/l.
Option 1d requires the continued development of PFOA RPFs for PFAS which are not published at the current day. Given the wide list of over 4000 PFAS keeping such a list of RPFs up to date and publicly available will require some effort.

Additional risk and status assessment

Further work to develop risk assessments and carry out GWB status assessment is likely to be small in comparison with additional laboratory analysis of samples for PFAS. The process for risk and status assessments should be developed already. The wide number of sources and pathways through which PFAS may reach groundwater are numerous, and the inputs from each pressures / activity is not always well known.
The PFAS drinking water standards will affect the General Chemical Assessment test and Drinking Water Protected Area test and failure of these tests will result in poor GWB status. Due to the overlap between the DWD PFAS and the proposed group of 10 on the LFR the additional burden on MS from Option 1a may be lower than the addition of all PFAS to Annex I or II (Options 1b and 1d) as more information may shared on risks and observed concentrations by the water sector. In addition, water companies / providers will also need to monitor raw water quality for 22 PFAS substances as part of DWD compliance, and update their drinking water safety plans, and this data should be available as part of the baseline scenario. Therefore, under all options for the addition of PFAS, the information collected by the water sector will be invaluable in reducing the administrative burden.
Option 1c requires that MS consider the risk posed by PFAS to GWBs, but if the characterisation process is insufficiently thorough and does not identify a risk from PFAS (due to lack of knowledge of possible sources which are numerous or pathways) then the appropriate surveillance monitoring may not be put in place to confirm the risk. This risk is likely to be minimised through the knowledge sharing work of the GW WL process and the data collected through compliance with the drinking water safety plan (catchment risk assessment) elements of the DWD.

Future proofing legislation

The main administrative benefits of including all PFAS (Options 1b and 1d), as opposed to the group of 10, are that it “future proofs” the listing by including PFAS compounds that have yet to be identified as groundwater pollutants and allows use of a wider range of analytical techniques. It therefore avoids the risk that substances in the group of 10 in Option 1a or the 20 DWD PFAS will be substituted for alternative but similar substances.

[457] Voluntary Groundwater Watch List Process Study on Per- and Polyfluoroalkyl substances (PFAS) – Monitoring Data Collection and Initial Analysis – Draft V.2.3 / 23. February 2020

The use of all PFAS also means that data collection is not focussed just on the substances already identified in groundwater by existing monitoring as it allows for detection, monitoring and use in status assessments of a wider range of PFAS, which may emerge as contaminants.
Addition to Annex I and development of a GWQS of PFAS under Options 1a, 1b and 1d allows collection of data and assessment that will support consistent action across the EU to seek to ban or restrict the use of PFAS further (as set out in the Chemicals Strategy), if required. In comparison, an Annex II listing will provide more limited and less consistent data and assessment across European groundwater.

Costs of the Administrative Burden for PFAS

As noted previously the administrative burden and the costs of monitoring may lower for some MS as some have already been monitoring for PFAS for several years. The requirements of the DWD recast means will result in be more data being available as part of the dynamic baseline for the group of 10 PFAS. To estimate the additional costs it is assumed that:

- only MS that already monitor for PFAS will continue to do so;
- MS will choose the cheapest option.

The cost per sample of the group of ten PFAS (Option 1a) has been estimated at €360 (based on commercial laboratory quotes). The additional cost of extra sampling administration could be around €200 per sample (coordination, data management, analytical technique development etc.). There are 13,746 GWBs in the EU27, and it is likely that on average each will have at least 2 monitoring points (based on some having zero monitoring and others over 50 locations). On this basis the additional cost of operational and surveillance monitoring (assuming one sample per year per monitoring point) would be between €15-16 million across Europe.
Option 1b which requires a total PFAS analysis and Option 1d which specifies 24 PFAS, some of which (but not all) have much lower GWQS than Option 1a. It is likely that under Option 1b MS will include the PFAS from the DWD as well as further PFAS, and their approach to Option 1d could follow a similar route i.e. the DWD PFAS and EQSD PFAS plus any "emerging" PFAS which are of concern. Although the costs associated with additional monitoring for Option 1b and 1d are likely to be higher than Option 1a, the total number of PFAS actually analysed for under these options could be closer to 20-30 rather than >6000. Therefore, the costs associated with additional monitoring under Option 1b or 1d could be up to three times that for Option 1a i.e. circa €45-48 million.
Option 1c is unlikely to lead to a cost of additional analysis that is higher than for Options 1a, 1b or 1d although all MS may choose to include the DWD list of 20 PFAS using the DWS as this becomes an established methodology. There is a risk that in the longer term the limited monitoring under this option will lead to increased costs for implementation of measures at a later stage after more groundwater pollution has occurred leading to increased treatment or remediation costs. Costs to human health could also potentially increase if a lower level of protection is provided due to chronic health effects.

The additional administrative costs for coordination / additional risk assessments and status assessments are likely to be incorporated into the baseline costs for these tasks as new risks change between RBMP cycles requiring further assessment.

Summary PFAS Administrative Burden

Options 1a and 1c will have least impact, given the DWD requirements and additional data collated. This is especially the case for the MS which already monitoring for PFAS and have carried out risk assessments for groundwater the additional administrative burden, is likely to be absorbed into the baseline increase in costs that would occur anyway. However, these options are likely to be least protective of groundwater. The main additional expense for most MS will be the costs of laboratory analysis, and in particular Option 1b and 1d where a "sum of" methodology or very low concentrations need to be analysed are likely to require more effort.

Costs of measures to achieve good status under the PFAS policy options

Where a GWB is at poor status due to PFAS then further economic impacts may arise as a result of the measures required to achieve good status. There are a series of measures including legislation and EU level strategies which will lead to the reduction in emissions of specific PFAS, including in the LFR and the proposed EQSD PFAS listing, over the next 5-6 years (Section 6). As noted earlier it is foreseen that updates to the UWWTD will mean that measures to treat for PFAS in wastewater discharges are included in the dynamic baseline.

The focus of measures to deal with PFAS could be on point sources which could be dealt with through receptor remediation or end of pipe / pathway disruption measures. The larger distance to target will be caused by more diffuse sources where source control measures are required. Aside from Option 1c (addition to Annex II) all of the options for PFAS were identified as leading to a large distance to target in terms of the spatial scale (i.e. numerous MS will report failures) and for more stringent targets a greater level of exceedance. Therefore, it is likely that all measures identified for PFAS could be used by MS under Options 1a, 1b and 1d.

Despite the restrictions listed above, there remains an un-quantified volume of PFAS in the environment, in domestic products (clothing, textiles, personal care products, food packaging, building materials) which will leach and join various waste streams (landfill leachate, effluent, biosolids, recycled paper industry waste etc.) and be emitted to the water environment, or via aerial deposition of stack emissions to eventually reach groundwater.

Where waste stream by-products such as biosolids are spread to agricultural land there is a risk to groundwater. The PFAS content of sewage sludge is reported as on average 195 ug/kg, increasing to 1000 ug/kg where industrial wastewater is included[458]. The spreading of waste materials such as paper crumb from the paper recycling industry to agricultural land (including PFAS containing printing inks) will also provide a leachable source of PFAS to groundwater. The source term of **landfill leachate** is less well characterised (1-90 kg/yr reported across three MS[459]) but can be assigned by waste acceptance criteria as municipal non-hazardous and hazardous waste are likely to contain PFAS at different concentrations,

[458] USEPA, 2020. Wastewater Treatment and Land Application of Biosolids/Wastes. Presentation available at: https://www.epa.gov/sites/default/files/2020-10/documents/r1-pfas_webinar_day_2_session_6_mills_final.pdf
[459] Nordic Council of Ministers (2019). The cost of inaction A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. http://norden.divaportal.org/smash/record.jsf?pid=diva2%3A1295959&dswid=4908

and inert waste should not contain PFAS. For most modern engineered landfills where water ingress is restricted, the main source of PFAS will be leachate production. This is then treated on site or sent to wastewater treatment works.

Apart from manufacturing sites, there are also the legacy PFAS sources in soils at airfields and other firefighting practise areas, unintended emissions from industrial sites linked to metal plating and historical unlined landfills with of domestic and building material waste which contain PFAS.
These are likely to be more concentrated point sources for groundwater.

Based on these sources and pathways the measures identified as likely to be used to address PFAS pollution by MS could therefore be similar for all options (aside from Option 1c) and include:

- Source control:
    - Banning of specific PFAS substances and costs to industry for substitution for less harmful substances requiring product reformulation, with potentially higher material costs;
    - Raising awareness (guidance) or restriction through the use of water protection zones of the leaching of PFAS from biosolids / materials spread to land;
- Pathway disruption / end of pipe controls through preventing emissions to groundwater:
    - Treatment requiring additional wastewater treatment and potentially higher waste disposal costs (as noted previously this has been assumed to be part of the baseline measures);
    - Capture and treatment of sewage sludge / biosolids and anaerobic digestate;
- Receptor remediation: Remediation of existing / historical sources (additional cost to MS where original polluter is not identifiable or no longer exists).

It is likely that Option 1c would mainly lead to the reactive use of groundwater or soil remediation measures in response to identified PFAS contamination which impacts on human health through drinking water or food ingestion (e.g. Ronnerby, Sweden, and Baden-Wuerttemberg, German[234]). These remediation techniques are energy intensive and slow compared to the movement of contaminated groundwater away from the pump and treat locations[460].

Under Options 1a, 1b and 1d where the scale of the distance to target indicates that action to control diffuse pollution is needed the measures should deal with the source term or disrupt the pathway.
The most effective source control measure to reduce the future source term of PFAS in the environment will be to use less harmful substitutes which could require product reformulation, and potentially higher material costs. Action is most likely at the national or

[460] Banzhaf, Stefan et al. "A review of contamination of surface-, ground-, and drinking water in Sweden by perfluoroalkyl and polyfluoroalkyl substances (PFASs)." Ambio vol. 46,3 (2017): 335-346. doi:10.1007/s13280-016-0848-8

EU level. It is noted that for the regulated PFAS (PFOS, PFOA, PFHxS, PFHxA and the C9-C14 carboxylic acids) a stringent measure that restrict emissions are already in place and it is likely that for the remaining group of 10 substances, which overlap with the DWD substances and the EQSD proposed, further controls could be instigated at the EU level with the obvious cost to industry. In dealing with the existing environmental source term better information / awareness raising for the public around separation of waste streams in the end of life cycle could also be used as measures.

Pathway disruption measures include the capture of contaminated biosolids (assumed 10% of annual production) could be carried out, although this involves high temperature incineration to destroy PFAS (>1400°C) or removal to landfill which would just move the PFAS around. Installation of treatment for PFAS at landfill sites with onsite treatment could be carried out. These measures are energy intensive and costly (Table 8-47) and do not meet with the Zero Pollution aims of the EU Green Deal. The costs of biosolid capture are within the same range as the cost of restriction of use of PFAS and so realistically this measure would only be suitable in extreme circumstances. Guidance for the agricultural sector on the best practise use of waste and wastewater by-products in agriculture and understanding the implications of contamination by PFAS and other micropollutants could be a useful and potentially effective measure.

The costs of the measures which may be implemented by MS are estimated in Table 8-47. Given the huge energy costs of destruction of biosolids and paper sludge, incompatibility with climate change targets and Zero Pollution ambition, and the loss of a hugely important organic soil conditioner for agriculture these measures are unlikely to be extensively used. Instead for Options 1a, 1b and 1d it is more likely actions to restrict use of PFAS and better management of waste streams, as well as groundwater or soil remediation will be used. Five MS are already preparing restrictions for PFAS use and this is part of the dynamic baseline. Option 1c will be the least cost option in terms of costs of programmes of measures, but this is unlikely to afford the same level of protection of groundwater across Europe for what has been identified as a large scale and large magnitude distance to target.

Table 8-47 Costs of selected measures to address PFAS in groundwater

Measure	Type of measure	Unit	Unit cost	Comment on calculation
Soil remediation	Receptor remediation	EU level	€5 to €760 million at EU level (one off cost)	Remediation of point sources based on assumption that 10 MS have an issue at airfields / fire training stations with 1 to 2 sites per MS. At EU level this is 10-20 sites identified for remediation over the next review period. Soil remediation costs per site are given for low (2700 m^3) and high (28125 m^3) volumes of contaminated soils: • Soil incineration - €0.5-18 million per site (€5 to 360 million for 10-20 sites) • Landfill – €2.5-38 million per site (€25-760 million for 10-20 sites) Groundwater pump and treat costs per site is €2.9-30.3 million over a 30 year period of construction, operation and
Groundwater remediation	Receptor remediation	EU level	€1.7-€35 million / yr at EU level	

Measure	Type of measure	Unit	Unit cost	Comment on calculation
				maintenance[461] Annual equivalent costs (4% discount rate, 30 years) are €0.17 million-€1.75 million per site respectively.
Capture of biosolids for treatment.	Source control – WWT	EU level	€201 million per year to send to landfill €503-755 million/yr for high temperature incineration	High temperature sludge incineration: Total sludge generated in EU: 441 million (population) x 0.0782 kg per person/day (dry weight) = 34,398 tonne/day or 12.6 million tonnes /yr. Assume 10% requires incineration - 1.26 million tonnes /yr at a cost of €400-600/tonne = €500-755 million/yr. Cost to send to landfill of the 1.26 million tonnes /yr (2013 highest landfill gate fee and tax of €160 per tonne[462]) - €201 million per year. Note EU requirement to reduce landfill to 10% by 2035 and the high energy costs of incineration so this measure is not coherent)
Capture of industrial waste e.g. paper mills	Source control – WWT	EU level	Landfill - €76.72 million / yr High temperature incineration - €191.8 to €287.7 million / yr.	The 894 paper mills in the EU recycled 47,950,000 tonnes of paper in 2020[463].10% ends up as recycling paper sludge waste with potential for spreading to land i.e. 4,795,000 tonnes /yr available. Assume that a further 10% of this sludge waste is contaminated with PFAS i.e. 479,500 tonnes per year requires treatment. Cost to send the same volume to landfill (using the highest gate fees in 2013 of €160/t) is €76.72 million / yr. High temperature incineration (as for biosolids) - €191.8 to €287.7 million/yr. Not costed - the loss to the farming sector of cheap soil improver.
Landfill leachate treatment	Source control	Per site	Between €530 and €358 million	Capex and Opex for two pass reverse osmosis system with pre-treatment and evaporation ponds dealing with 17.5 m3/yr leachate [464]
Guidance on proper use of PFAS containing products which could be spread to land	Source control (Behavioural)	One set of European level guidance or per MS	€50,000	
Take back schemes / incentives to replace domestic products that	Source control (Behavioural)	per MS	Millions	See section 8.2.3 for derivation

[461] Source: "The use of PFAS and fluorine free alternatives in firefighting foams. EC/ECHA 2020
[462] https://www.eea.europa.eu/data-and-maps/figures/typical-charge-gate-fee-and - 2013 figures.
[463] https://www.cepi.org/key-statistics-2020/
[464] Kanchanapiyaa, P and Tantisattayakulb, T. 2022. Analysis of the additional cost of addressing per- and polyfluoraoalkyl substance contamination from landfill leachate by reverse osmosis membranes in Thailand. *Journal of Water Process Engineering*. Vol 45, 102520.

Measure	Type of measure	Unit	Unit cost	Comment on calculation
may contain PFAS				
Restriction of use of PFAS in one sector (fire fighting foams)	Source control	EU level	€390 million /yr over 30 years (per use)	Cost of restriction on PFAS in fire-fighting foams, based on estimated cost on placing on the market and after use / sector specific transitional periods (see Section 8.2.3 for derivation) Cost is for use of PFAS. Other key sectors are personal care products, food packaging, chrome metal plating, building materials, electronics - assuming replacement in 10 further uses - €3,900 million / yr over 30 years.

Environmental impacts: PFAS options

Costs

The main environmental costs of adding PFAS to the GWD would be the implementation of measures which are energy intensive, use a high of chemical treatment and require a significant intervention. In particular the high temperature incineration of biosolids or industrial waste to destroy PFAS rather than spreading to land or land filling will be especially costly and have negative impact on the environment. Groundwater and soil remediation, and landfill leachate treatment (normally via wastewater treatment works) are also energy intensive and require treatment media such as granular activated carbon on or reverse osmosis resins.

Benefits

The specific environmental benefits of all options to add PFAS to the GWD include:

- Lower risk of (irreversible) damage to natural resources such as groundwater and connected surface waters and ecosystems (i.e. reduced impact on sensitive water bodies such as wetlands and rivers, and fish);
- Benefit (avoided costs) associated with availability of clean raw groundwater for abstraction (for irrigation, livestock watering taken directly from a GWB).
- Lower production and maintenance costs through availability of cleaner raw water, reducing pre-treatment needs / avoided costs of drinking water (pre)treatment as a result of improved quality of groundwaters used for drinking water abstraction. It is noted that for the group of 10 which are also on the DWD list of PFAS, these benefits may already be part of the baseline, albeit at the abstraction catchment rather than GWB / river basin scale.
- Benefits from reduced energy costs and related process costs for wastewater treatment to tackle PFAS.
- Benefits from increased quality of process water from groundwater for agriculture and industry (e.g. vegetable washing or use in industrial processes).

Options 1a, 1b and 1d which set a GWQS will not only have a Europe wide impact of the benefits listed above but will also lead to:

- An assessment criterion against with environmental risk can be evaluated leading to clear outcomes and decision-making.

- A standard which will be used when assessing environmental risk assessments for chemicals for approval / authorisation potentially leading to them not being approved / authorised thus preventing future pollution.
- Only Options 1a and 1b would give clear and consistent messaging about PFAS by providing the same values as the DWD.

Further beneficial environmental impacts may result from increased resource efficiency through reuse and recovery of materials that are free of PFAS (e.g. use of treated sludge and wastewater).

Options 1b and 1d will have wider impacts due to the inclusion of all PFAS rather than a targeted analysis. This approach potentially further reduces the risk of irreversible damage to groundwater systems by including newer substitutes for substances that have already been withdrawn from use and is, therefore, in line with the precautionary principle. These options also provide clear evaluation criteria for risk assessments to inform the approval of new products, including substances for which there are no current regulatory standards.

Social impacts: PFAS options

Costs

The main costs to society of adding PFAS to the GWD is likely to be through payment for additional treatment / technological measures which are expensive and where the polluter pays principle cannot be enforced i.e. in the case of legacy pollution where the original polluter no longer exists, then society will pay through government clean up operations. In addition, the treatment of wastewater and landfill leachate is likely to eventually come back to the public through funding of landfill operations by local authorities or wastewater bills.

Benefits

The social impacts of the addition of PFAS to the GWD under Option 1a may include:

- Increased public knowledge and understanding of the risks that PFAS pose which may help to address citizen concerns about “forever chemicals” in water.
- Benefits from reduced risk of illnesses and premature deaths related to chronic ingestion through drinking water and irrigated crops. Avoided health costs of chronic low level exposure (e.g. estimated the annual health expenditure due to kidney cancer caused by PFAS exposure to be €12.7 to €41.4 million in the EEA countries (207.8 million population); hypertension in the EEA countries estimated at €10.7 to 35 billion per year based on monetised cost of 3,066 to 10,035 lives lost – equivalent to €20-70 billion across EU27; supressed immune function in children leading to more sick days / intensity of illness).
- Improved well-being (e.g. through improved ecosystem services from and access to healthy ecosystems)
- Benefits from increased potential employment opportunities
- Tourism as a result of a cleaner environment, healthy ecosystems (forests, bathing waters, nature reserves), recreational anglers (higher population of healthy fish and lower risk of bioaccumulation if catch is consumed).

- Impact on level of activity of affected firms/sectors where high quality of the raw water is essential e.g. mineral water sector or shellfish sector (where estuaries discharge high baseflow of groundwater).

These benefits only apply to the social impact of reductions in the listed group of 10 PFAS in Option 1a. However, there are over 6000 PFAS substances and therefore the social impacts may be lower in comparison to Option 1b or 1d, although the group of 10 are those most commonly found in groundwater. Option 1b and 1d provide a much greater increase in evidence base and public reassurance that all possible PFAS pollutants are being monitored. A wider range of protection compared to Option 1a is provided in terms of improvements to health and wellbeing (reduction in chronic ingestion / bioaccumulation in agricultural crops irrigated with groundwater, and healthier rivers and wetlands), and protection of industries dependant on a high-quality groundwater environment (e.g. bottled water and shellfish). Option 1d has the additional benefit of GWQS which are based on the latest understanding of human health and tolerable weekly intakes, and so is considered to be more protective of human health.

Finally, the social impacts of Option 1c are restricted to the areas over which they are applied. Indeed, the opportunity to increase knowledge and understanding of the risks that PFAS pose is missed with data collected for problem areas unlikely to address citizen concerns about “forever chemicals” in water. The benefits of reduced risk of water-related illnesses and premature deaths from improved quality of groundwater and drinking water is restricted to specific areas. Improved well-being (e.g. through improved ecosystem services from and healthy ecosystems and increased potential employment opportunities benefits (e.g. tourism) as a result of a cleaner environment, healthy ecosystems (forests, bathing waters, nature reserves) may already be achieved through wider measures to address other pollutants as part of the baseline. However, benefits from impacts on the activity of affected firms/sectors reliant on high quality groundwater is restricted to the specific GWBs identified as being at risk.

8.3.4 *Option 2 Impact of options to add Pharmaceuticals to the GWD*

Here the following options for pharmaceuticals are compared with respect to their environmental, economic (costs and benefits), and social impacts:

- Option 2a Named pharmaceuticals (Carbamazepine and Sulfamethoxazole) added to Annex I and assigned GWQS of 0.5 and 0.1µg/l respectively (protective of human health).
- Option 2b All pharmaceuticals added as a group to Annex I and assigned a GWQS of 0.5 µg/l
- Option 2c All pharmaceuticals added as a group to Annex II for MS to consider for the development of TV for substances that pose a risk to their GWBs. The specific pharmaceuticals on the LFR are included in the minimum list for consideration, with a guideline to include primidone.

In stakeholder feedback on the options for adding pharmaceuticals to the GWD annexes, the majority of correspondents favoured Option 2a. The EurEau representatives of the European Drinking Water Company organisations were keen to ensure that source control measures including green pharmacy and drug return schemes should be included. There are several schemes at national level which are successfully implemented and funded through the prescription costs (e.g Sweden) or operated by private companies (France).

Economic Impacts: Pharmaceuticals Options

Impacts of the Administrative Burden of adding pharmaceuticals to the GWD

Expansion of monitoring network

The additional administrative burden to MS of adding the two pharmaceuticals under Option 2a to Annex I will be to the increase groundwater monitoring programmes and the addition of further chemicals to risk and status assessment against the GWQS. Where a GWB fails to meet good chemical status due to these two substances then programmes of measures may be required to achieve good status and reverse adverse trends. Where MS already monitor and assess GWB status with respect to these two substances then this increase will not occur. A number of MS have agreed to add the LFR and GW WL substances to their monitoring, and therefore the dynamic baseline may mean that the overall administrative burden is not as large as if no MS were considering pharmaceuticals. Overall, the impact of Option 2a on administrative burden is likely to be negligible. However, the option is not future proofed, and there are several pharmaceuticals which have been identified in groundwater, which may reach the criteria of the LFR (as primidone has) in the next few years. In this case, Option 2b reduces the administrative burden of adding new substances to legislation.

Investment in analytical techniques

In comparison, it is clear that Option 2b greatly increases the range of pharmaceuticals and could significantly increase analytical costs, and widen the scope for measures to address impacts. However, the additional information on the distribution and concentration of pharmaceuticals in groundwater will support the implementation of the Pharmaceuticals Strategy in terms of developing environmental risk assessments for all polluting substances. This option also provides greater future proofing as it will not require further amendment should new pharmaceutical products be released. However, the GW WL process did not find evidence for widespread occurrence of other pharmaceuticals in groundwater although this dataset for pharmaceuticals is to be updated. Therefore, there is a risk that the additional monitoring analysis and risk assessments for GWBs may not lead to additional benefit. For the implementation of the Pharmaceuticals Strategy, which aims to develop environmental risk assessments for substances, the data collected through monitoring and risk assessments could help to develop the evidence base used in such risk assessments thus reducing uncertainty and potentially administrative burden.

Setting of Threshold Values (TVs)

For Option 2c the size of the impact on administrative burden to MS will be smaller and depend on:

- Whether a MS already has a TV for primidone;
- Whether a MS develops a TV for other individual pharmaceuticals or pharmaceuticals as a group;
- The value of TV selected, which could be different (higher or lower) than the proposed GWQS under Option 2b;
- The extent to which TVs are developed as they may not include all GWBs within a MS and pharmaceutical analysis may not be required not at risk which will reduce the cost of monitoring.

However, the potential for MS to take different approaches means that there is greater uncertainty regarding the impacts of Option 2c when compared to Options 2a and 2b. There are currently no drinking water standards for pharmaceuticals, and MS may use national guidance or European level / WHO guidance on criteria to use. This is likely to lead to variability in TVs set, which moves away from harmonisation of these standards. This option gives MS the flexibility to target just those pharmaceuticals that are used in their country and that pose a risk to groundwater through risk assessment. The risk assessment process will also lead to a better understanding of pharmaceutical use and pathways to the groundwater environment.

Additional risk and status assessment

Further work to develop risk assessments and carry out GWB status assessment is likely to be small for Option 2a and 2c compared to 2b (all pharmaceuticals). The process for risk and status assessments should be well developed already and the pathways for pharmaceuticals to reach groundwater are likely to be restricted to human and animal waste streams. Under Option 2b the level of effort to consider all pharmaceuticals increases, and the distance to target for this option (small to medium) suggests that this could be an overinvestment for what could be a lower risk group of pollutants.

Future proofing legislation

The main administrative benefits of including all pharmaceuticals (Options 2b), as opposed to just the two selected substances is that it “future proofs” the listing by including substances which may come to be an issued in future and pushes for the expansion / investment in new analytical techniques. It therefore avoids the risk that substances under Option 2a will be substituted for alternative but similar substances which pose a risk to groundwater. Adding all pharmaceuticals to Annex I reduces the risk pollution from substitutes for substances that have already been withdrawn from use and is, therefore, in line with the precautionary principle.

Costs of administrative burden

The direct economic impacts include the cost of additional monitoring for the two specific pharmaceuticals across MS, which will require comprise: analytical costs, data processing and reporting costs. In addition, these two pharmaceuticals will need to be considered when

undertaking GWB status assessment. Although the costs, compared to Option 2b (addition of all pharmaceuticals to Annex I) is likely to be much lower due to the lower cost of analysis (circa €80 per sample based on commercial laboratory quotes which equates to around €2 million per year assuming no extra administrative costs), the majority of sources and pathways for entry of human medicines to groundwater would still need to be considered under this Option.
Under Option 2b the wide range of chemical properties of pharmaceutical substances means that the group level analysis may be costly and not combinable within a single suite. Using the group pesticide analysis already required by the GWD as an example, the costs of analysis can be in the order of €200. Therefore, the direct costs for Option 2b will be higher than 2a (around €5.5 million plus addition administrative costs ~ €11 million). For Option 2c the analytical costs will vary between MS depending on the TVs adopted and the monitoring strategy used.

Costs of measures

The main pathways for pharmaceuticals to reach groundwater are likely to be through wastewater discharge (to surface water and to ground), biosolids spreading to land and landfill. Veterinary medicines will have a wider impact through the spreading of animal manures and digestate to land. The size of the distance to target for Option 2a and 2c is small, and probably relates to point sources or specific aquifer conditions. For all options the possible measures which are likely to be selected to address poor groundwater status could include:

- substitution with other pharmaceuticals or product reformulation, and potentially higher material costs;
- control of the source term through the use of "green pharmacy" measures including national returns schemes for medicines, smart prescribing and better labelling of the environmental impact of medicines on packaging[465].
- prevention of emissions to groundwater through treatment requiring additional wastewater and sewage sludge treatment and potentially higher waste disposal costs;
- remediation of existing / historical sources (although such sources are not common).
- Reduction in microbial resistance in environment could help to reduce costs of developing new anti-bacterial pharmaceuticals which deal with resistant bacteria.

The measure of product substitution is assumed to be viable for animals i.e. for anti-biotics there is a wide range of available alternatives at similar cost. For carbamazepine, however, trials of treatment for headshaking in horses found that carbamazepine (in combination with cyproheptadine) was most effective in 80% of cases[466]. Similarly, in humans, there are numerous other factors which should be considered including barriers related to the prescription of alternatives where the efficacy of the alternatives are not as good as the original or side effects are unacceptable to some patients. Under Option 2a there are substitutes for carbamazepine as shown below (extract from Table 8-23). Any estimates of

[465] Pharmaceutical Group of European Union, 2022. Best Practice Paper on Green and Sustainable Pharmacy in Europe. Pp 27.
[466] Newton SA, Knottenbelt DC, Eldridge PR. Headshaking in horses: possible aetiopathogenesis suggested by the results of diagnostic tests and several treatment regimes used in 20 cases. Equine Vet J. 2000 May;32(3):208-16. doi: 10.2746/042516400776563617. PMID: 10836475.

the total cost of product substitution for carbamazepine in horses or humans will therefore be quite uncertain and has not been costed. For sulfamethoxazole there are numerous alternatives which would not lead to increased cost.

Cost per prescription of carbamazepine (EUR)*	Alternative substance	Cost per prescription of alternative (EUR)*
7.45	Phenytoin	23.40
	Phenobarbital	28.74
	Oxcarbazepine	33.92
	Gabapentin	6.33
	Pregabalin	4.36
	Lacosamide	102.18
	Vigabatrin	66.65

* Costs are 2021 values and converted from GBP using an average of 1 GBP = 1.15 EUR over period from 2 January 2020 to 31 December 2021[467].

Under Option 2b the use of product substitution for "all pharmaceuticals" is likely to be technically unfeasible and unacceptable to society. Instead measures around green pharmacy including smart prescribing to reduce the level of wasted active substance and returns schemes are more likely to be acceptable to society. A significant impact is expected for Sulfamethoxazole from the baseline measure of restrictions on prophylactic used of anti-biotics in livestock.

Under Option 2c to add Primidone to Annex II, measures are likely to be implemented at the MS level, and could be site specific but are likely to be within the range of measures.

Estimated costs of measures which could be used by MS to control pharmaceuticals reaching groundwater are shown in Table 8-48. As previously noted, the Pharmaceuticals Strategy aims to reduce the environmental impact of pharmaceuticals in the environment, however, where there is a conflict with human or animal health then the environmental impacts may not be dealt with.

Table 8-48 Costs of selected measures to address pharmaceuticals in groundwater

Measure	Type of measure	Sulfamethoxazol	Carbamazpine	Primidone	unit	unit cost	Comment
Ban use in agricultural animals	Source control (animals)	Y	N	Y	0	0	Sulfamethoxazole – Assume no cost difference for many alternatives available but risk of swapping pollutant is possible.

[467] https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-gbp.en.html

Measure	Type of measure	Sulfamethoxazol	Carbamazpine	Primidone	unit	unit cost	Comment
Provide guidance on proper disposal	Source control (prescribing)	Y	Y	Y	One set of European level guidance or per MS	€50,000 circa	
Improved returns program for unused drugs	Source control (prescribing)	Y	Y	Y	MS level	Less than €1-10 million	Represents better investment / expansion of a returns scheme to more substances (based on France Cyclamide scheme – population circa 60 million)
Establish national returns programs (if non existent)	Source control (prescribing)	Y	Y	Y	MS level	€1-10 million	Costs based on France Cyclamide scheme - (actual costs will depend on population of MS – FR population circa 60 million)
Innovation in green pharmacy - allow medicine experts to promote prudent use and correct disposal of pharma -	Source control (prescribing)	Y	Y	Y	MS level	€1-10 million	Costs based on France Cyclamide scheme - (actual costs will depend on population of MS – FR population circa 60 million)
Tailoring drug dosage/ providing a range of package sizes	Source control (prescribing)	Y	Y	Y	MS level	0	Likely to be cost neutral / administrative costs / start up but will use less of the active ingredient
Improved sludge management at wastewater treatment works	End of Pipe / pathway disruption	Y	Y	Y	EU level	€201 million per year to send to landfill €503-755 million//yr for high temperature incineration	High temperature sludge incineration. Total sludge generated in EU: 441 million (population) x 0.0782 kg per person/day (dry weight) = 34,398 tonnes/day or 12.6 million tonnes/yr. Assume 10% is highly contaminated and requires incineration – 1.26 million tonnes / year at a cost of €400-600/tonne= €503-755 million/yr. Cost to send to landfill of the 12.6 million tonnes /yr (2013 highest landfill gate fee and tax of €160 per tonne[468]) - €201 million per year. Note EU requirement to reduce landfill to 10% by 2035 and the high energy costs of

[468] https://www.eea.europa.eu/data-and-maps/figures/typical-charge-gate-fee-and - 2013 figures.

Measure	Type of measure	Sulfamethoxazol	Carbamazpine	Primidone	unit	unit cost	Comment
							incineration so this measure is not coherent.

Environmental impacts: Pharmaceuticals options

Costs

The main environmental costs of adding pharmaceuticals to the GWD would be implementation of measures to deal with wastewater / biosolids which can be energy and chemical use intensive. The incineration / landfilling of biosolids is suggested here as a measure as there is no viable treatment to remove pharmaceuticals from these media.

Benefits

The environmental benefits of Option 2b are wider ranging that those for Option 2a which only adds two substances to Annex I. In adding carbamazepine and sulfamethoxazole to Annex I this would:

- Reduce the risk of (irreversible) damage to natural resources such as groundwater and connected surface waters (i.e. reduced impact on sensitive water bodies such as wetlands and rivers).
- Have impacts on climate change / chemical use through reduced energy / chemical resources to treat drinking water and reduce CO_2 emissions.
- Increase resource efficiency through reuse and recovery of materials (e.g. use of sludge, treated wastewater).
- The addition of Sulfamethoxazole (an anti-microbial) could also support the reduction of anti-microbial resistance, especially in soils although this will be limited to reducing the impact from this one substance.
- Avoid damage to shellfish / fishing industry due to chronic exposure to carbamazepine and impacts on stock health[469][470].
- Reduced human health risks due to chronic ingestion through shellfish from bioaccumulated carbamazepine in baseflow rich river / estuaries.

The lower risk of (irreversible) damage to natural resources such as groundwater and connected surface waters is a key environmental impact, which is likely to be greater from Option 2b due to the wider range of pharmaceuticals addressed. The identification of pollution and the reversal of trends through implementation of the GWD could lead to variable impacts on climate change and sustainability through changes in energy use (e.g. due to changes to wastewater and drinking water chemical treatment processes) leading to

[469] Oropesa et al., (2016). Assessment of the effects of the carbamazepine on the endogenous endocrine system of Daphnia magna Environ. Sci. Pollut. Res. 23: 17311–21
[470] EPA, 2015. Pharmaceuticals in the Aquatic Environment: A Short Summary of Current Knowledge and the Potential Impacts on Aquatic Biota and Humans. EPA Research Report 142. Pp 42.

changes in CO_2 emissions. Further impacts may result from increased resource efficiency through reuse and recovery of materials (e.g. use of sludge, treated wastewater). A greater environmental impact could be the risk of anti-microbial pharmaceuticals (human and veterinary medicines) in GWBs requiring application of measures to reduce their presence. This would support the Eus aim to reduce anti-microbial resistance in soils and the environment.

Option 2c will have similar environmental impacts to Options 2a and 2b at a much reduced scale. The extent of these same impacts will depend on how many MS adopt pharmaceutical based TVs and for which compounds or group. The outcome may also depend on the method of analysis used and the number of GWB that are monitored. The possibility of reducing the low level presence of anti-microbial substances in groundwater to support the lowering of resistance bacteria is also considerably reduced.

Social impacts: Pharmaceuticals options

Costs

There is scope under the options to add pharmaceuticals to the GWD for conflict between the environmental benefits when set against the consequences for human /animal health of limiting use of some pharmaceuticals. Measures to control the use of pharmaceuticals may impact on the health and well-being of those using them, particularly if no suitable alternatives can be identified. This scope increases more widely under Option 2b.

Benefits

The social impacts of options to add pharmaceuticals to the GWD may include:

- In the case of anti-microbials and the known impact of their emission on increasing AMR there are huge benefits to society of reducing this phenomena in terms of protecting the range of anti-biotics which can be used to treat infections. The health risks associated with AMR could lead to an estimated 390,000 premature deaths by 2050. It is estimated that AMR costs the EU €1.5 billion per year in healthcare costs and productivity losses[471]. MRSA infections attributed to AMR increase the length of hospital stay by 2 to 10 days on average corresponding to €1,200–€50,000 and more in costs[472].
- Increased knowledge and understanding of the risks that these specific pharmaceuticals pose to the water environment.
- Benefits from reduced risk of illnesses and premature deaths from chronic ingestion through improved quality of groundwater and drinking water (although the fact that these substances are administered safely to humans means that this impact is low).
- Improved well-being e.g. through improved ecosystem services from and healthy ecosystems.
- Benefits from increased potential employment opportunities benefits (e.g. tourism) as a result of a cleaner environment, healthy ecosystems (forests, bathing waters, nature reserves) and the indirect impact as a result of impact on level of activity of

[471] https://ec.europa.eu/health/antimicrobial-resistance/eu-action-antimicrobial-resistance_en

[472] Antoñanzas and Goossens, (2019) . The economics of antibiotic resistance: a claim for personalised treatments. Eur J Health Econ 20: 483–485. https://doi.org/10.1007/s10198-018-1021-z

affected firms/sectors which require high quality groundwater, in particular bottled water. The level of bioaccumulation of these two pharmaceuticals is unknown but may have an impact on shellfish and fisheries where groundwater inputs to rivers and coastal estuaries is significant.

Under Option 2b the addition of all pharmaceuticals to Annex I will greatly increase the evidence and understanding of the impact of these substances in groundwater. By placing anti-microbial pharmaceuticals on Annex I, the aim of the Pharmaceuticals Strategy to reduce the level of anti-microbial resistance in the environment and therefore extend the timespan of the effectiveness of current anti-microbials is supported.
Under Option 2c the social impacts are similar to those identified for Options 2a and 2b, but similar to option 2b, the increased knowledge and understanding of the risks that pharmaceuticals pose will be limited to national / localised evidence rather than a Europe wide picture. Measures to control the use of pharmaceuticals may be difficult to implement at the local or national level, and the conflict with human / animal health may mean that the environment is not favoured. This option also reduces the scope to reduce anti-microbial resistance in the environment. The other social impacts previously identified under Options 2a and 2b will also be reduced in extent i.e. the benefits from reduced risk of water-related illnesses and premature deaths from improved quality of groundwater and drinking water; Improved well-being through healthy ecosystems, and tourism employment opportunities. Finally, there may be localised benefits to the level of activity of firms/sectors requiring high quality groundwater (bottled water / shellfish).

8.3.5 *Option 3 impact of options for addition of nrMs to the GWD*

Here the impact of the options which add nrMs to the GWD are discussed in relation to their environment and societal costs and benefits, and the additional administrative burden on MS. The options are:

- Option 3a nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 1 µg/l. This based on reported TVs used by MS of 0.1 µg/l – 1 µg/l (with an exceptional case of 4.5 µg/l for one particular nrM) and a uniform value of 1 µg/l is proposed by analogy with the existing uniform value for individual “pesticides” in Annex I of the GWD.
- Option 3b All nrMs added to Annex I as a group and assigned a group GWQS of 10 µg/l (analogous with the existing group value for “pesticides”)
- Option 3c All nrMs added to Annex II for MS to consider for the development of a TV for substances that pose a risk to their GWBs
- Option 3d nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 0.1 µg/l (protective of human health and groundwater biota)
- Option 3e All nrMs added to Annex I as individual substances with a GWQS of 0.1 µg/l (protective of human health and groundwater biota)

In stakeholder feedback, the options for nrM additions to the GWD have driven some discussion with various opposing viewpoints given yet with no firm conclusion or agreement. Feedback on the options to add all nrMs and on the proposed GWQS was mixed at the stakeholder workshops. There was some discussion around the use of precautionary principle where the pesticide industry representatives (Croplife Europe) noted that there was scientific information available on the group of 16 individual nrMs toxicity to human health. The opinion of Croplife Europe was that the use of precautionary principle instigated by the SCHEER opinion to put forward a higher level of protection for sensitive groundwater biota was not science / evidence led. In targeted stakeholder feedback Croplife Europe indicated that a GWQS for the 16 nrms of 9 µg/l could be calculated using a Threshold of Toxicological Concern approach[473]. However, the EFSA methodology does state that this approach should not be used for substances for which EU food/feed legislation requires the submission of toxicity data or when sufficient data are available for a risk assessment). It was noted that at least 20 pesticides could lose their authorisation if a limit of 0.1 µg /l was placed on all nrMs. The position from the EEB and Health Care without Harm Europe (HCWH) was that Europe wide legislation was needed to ensure that the levels of nrMs reduced in groundwater and that more sensitive biota in groundwater ecosystems were protected. Impacts on microbiological denitrification in anoxic conditions, such as those of confined aquifers, from metolachlor ESA and OXA metabolites of s-metolachlor above 10 µg /l have been identified[474]. The impact of cocktail effects on biota i.e. of mixtures of nrMs and other substances in groundwater remains unclear, although the impacts are likely to come from a smaller number of individual substances. This suggests that a precautionary approach is needed to protecting the ecosystems services provided by groundwater biota i.e. the well-known microbiological processes which lead to degradation of pollution and aquifer recovery. The drinking water industry (EurEau) and MS agreed that there is widespread detection of nrMs in groundwater and that this situation needs to be addressed, but were not committed on the level of protection i.e. the GWQS. It is worth noting that the GWD requires that inputs of non-hazardous substances are limited in their entry into groundwater, and assuming that nrMs fall within this group, further regulation of the entry of nrMs to groundwater is needed to deliver on this requirement.

Economic Impacts: nrMs Options

Impacts of the Administrative Burden

The additional administrative burden of all of the option to add nrMs to the GWD Annexes includes increasing MS groundwater monitoring programmes and the addition of further chemicals to risk and status assessment against the GWQS. Given that nrMs are breakdown products of pesticides, for which extensive risk assessment for GWBs already exist, the administrative burden due to the addition of chemicals to risk and status assessments is likely to be minimal in this case. The main additional administrative burden will be the cost of sample analysis for the nrMs. Therefore, between the different options the costs will increase based on the complexity of the method used (i.e. total nrMs as opposed to individual). The range of concentrations to which substances must be detected i.e. below the GWQS are likely to be achievable using the same analytical processes, and therefore it is assumed that there is no significant cost differential between the options due to different GWQS.

[473] Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment | EFSA (europa.eu)
[474] Michel C, Baran N, André L, Charron M, Joulian C., 2021. Side Effects of Pesticides and Metabolites in Groundwater: Impact on Denitrification. Frontiers in Microbiology, Vol 12. Available at www.frontiersin.org/article/10.3389/fmicb.2021.662727

Investment in analytical techniques

There is currently, no agreed method for analysis of “all nrMs” and a range of analytical options are available. It is likely that, in practice, that nrM analysis will be standardized around a methodology such as that used for pesticides, where a number of standard suites are typically used. It is, however, possible that advances in analytical techniques will permit analysis for a wider range of nrMs. As noted previously some MS already monitor for a range of nrMs and therefore additional burden to these countries is likely to be lower.

For Options 3a and 3d which focus on the 16 individual nrMs with different levels of GWQS the additional cost of monitoring is likely to be minimal compared to the baseline situation, with analytical techniques already developed for pesticides and metabolites. A small increase in costs is likely for Options 3b and 3e which require that “all nrMs” are included in analysis, and this would be equivalent to the “total pesticide” calculation.

A number of MS already monitor for nrMs and treat all pesticide metabolites in the same way (e.g. Denmark and Luxembourg). These MS have collected a significant body of data and more have agreed to add at least the group of 16 to their monitoring networks by 2027. Therefore, there may not be an additional burden on some MS, and additional monitoring may already be planned by some countries.

Setting of Threshold Values (TVs)

The addition of nrMs to Annex II under Option 3c will require action by MS to carry out a risk assessment and developed TVs for nrMs for GWBs identified as being at risk. Here the additional burden is in the setting of the TV for nrMs. Several MS have already set TVs for individual nrMs, ranging between 0.1 and 4.5 µg/l, with most values were below 1 µg/l, and more recently the French Health Agency have set a TV of 0.9 µg/l for nrMs which goes beyond the SANCO guidance. The lower value corresponds with the GWQS for individual pesticides. The extent of the additional burden of setting TVs will depend on how many MS identify a risk to groundwater and at what scale. Under the remaining options, the assignment of a EU wide GWQS means that individual MS do not need to develop a TV for nrMs. The recast DWD requires that MS consider setting guideline values for nrMs but does not provide a method which should be followed.

Additional risk and status assessment

Where a GWB fails to meet good chemical status then programmes of measures may be required to achieve good status and reverse adverse trends, adding to the administrative burden. However, the parent compounds of the majority of the nrMs within the Option 3a and 3d group of 16 have already been banned, and therefore the most stringent measure has already been applied for these. For the remaining substances there are several baseline strategies already in place which should reduce the additional administrative burden. The EU Farm to Fork Strategic aims to reduce hazardous pesticide use by 50% by 2030 which is likely to lead to reductions in permitted parent compound use, and will be delivered in part through the Sustainable Use Directive for Pesticides and existing national action plans for pesticide use reduction. These two existing measures mean that the administrative burden on MS with respect to designing and actioning POMs should be reduced.

By including all nrMs in Annex I under Options3b and 3e, the administrative burden may be reduced further as the legislation is “future proofed” by including nrMs compounds that have yet to be identified as groundwater pollutants and allows use of a wider range of analytical techniques. Compared to Option 1a the risk posed by unidentified nrMs forming if the parent compounds of the nrMs in the group of 16 in Option 1a are be substituted for alternative but similar substances, is reduced. The addition of all nrMs also means that data collection is not focussed just on the substances already identified in groundwater in existing monitoring as it allows for detection, monitoring and use in status assessments of a wider range of nrMs, which may emerge in future as contaminants.

Summary

In summary the additional costs of adding nrMs to monitoring networks is likely to be the main burden on MS, as the risk and status assessment elements, and programmes of measures for nrMs are likely to be covered by existing framework for assessing risk to groundwater from pesticides and their relevant metabolites and the action plans in place to deal with these. Between Options 1a, 1b, 1d and 1e, the cost differences are linked to the number of substances analysed for, i.e. the addition of all nrMs will cost more that focusing on the group of 16 nrMs. Obviously, the administrative burden of Option 1c will be smaller at the European level compared to the other options, However, at the MS level the possible need to set TVs at the GWB / river basin / national level could lead to a higher level of effort being required.

Costs of measures

Here the costs of the programme of additional measures required achieve good status are set out. Only five parent pesticides of the listed 16 nrMs in the LFR are still authorised (glyphosate, metazachlor, flufenacet, dimethachlor, and fluopicolide) and therefore the most stringent measures is already part of the baseline for the remaining nrMs. There are significant dynamic baseline measures which are already in place which will already be having an impact on reducing concentrations of parent products emitted to the environment, and hence will have an impact in future on the concentrations of nrMs in groundwater. These include the existing national action plans developed under the Sustainable Use of Pesticides Directive[475] which include: training of users, advisors and distributors of pesticides, inspection of pesticide application equipment, the prohibition of aerial spraying, limitation of pesticide use in sensitive areas, and information and awareness raising about pesticide risks. The current EC Farm to Fork Strategy includes legally binding targets (for the EU and for MS) to reduce the use and risk of synthetic chemical pesticides.
The policy options set out in the proposed impact assessment and review of the Sustainable Use of Pesticides Directive include:

- Creating a clearer link between the objectives of the SUD and other legislation linked to their implementation such as the CAP and **WFD**;
- Improved enforceability of the SUD, for example through better operationalisation of integrated pest management principles, a greater emphasis on implementation of national action plans and possible annual reports on progress achieved by Member

[475] Sustainable use of pesticides (europa.eu)

States, improved guidance and possible trainings from the Commission, or the possibility of changing the legal instrument to a Regulation to ensure direct applicability in all Member States;
- more effective supervision of SUD implementation by Member States, for example through detailed rules on official controls performed by national competent authorities as per the new official controls Regulation, and heightened enforcement oversight by the Commission for example through expert audits;
- **promotion of use of new technologies and alternative techniques to reduce the use and risk of chemical pesticides** and better achieve the objectives of the SUD;
- **reduce the use and risk of chemical pesticides through additional measures**;
- mandatory collection and sharing of more detailed statistics on pesticides use (going beyond the planned proposal on farming statistics) and implementation of various aspects of the SUD (such as training of operators and testing of pesticide application equipment) will also be considered to facilitate the possible development of new monitoring indicators on the use of more hazardous active substances and overall dependency on pesticide use to better assess the extent to which the objectives of the SUD are being achieved.

Where these proposed changes to the SUD are implemented over the next years, they will help to reduce the emissions of pesticides and therefore the volume of nrMs in groundwater. In the context of the current baseline for nrMs and their parent pesticides, the long list of measures (Appendix B) includes mainly baseline measures. Measures focusing on source controls include the reduction in parent product use or their restriction in sensitive areas, and these are already available through baseline legislation.

The distance to target analysis identified that the impact of listing nrMs is likely to be widespread (following pesticide failures) but that the level of exceedance could be small to medium. Therefore, the effort required to get to good status will depend on the GWQS implemented. Given the significant effort already in place to deal with parent pesticide use by the agricultural sector, the list of additional measures considered here go mainly focus on the amenity / legacy pollution including:

- substitution for less harmful substances requiring product reformulation, and potentially higher material costs and reduced crop yield as a result of using potentially less effective pesticides;
- remediation of existing / historical sources e.g. where legacy pollution, in particular for un-authorised substances may include historical (unlined) landfill (e.g. agricultural waste or amenity waste such as treated grass clippings);
- Use of other weed control methods for amenity use;

There is a potentially higher risk of more GWBs failing to achieve good status due to a more stringent target (Option 3d) or the inclusion of a wider range of nrM compounds (Option 3e). Estimated costs of using substitution products are shown in Table 8-49 noting that alternatives do exists for the five permitted parent pesticides, with similar or large cost ranges.

Table 8-49 Costs of selected measures to address nrMs in groundwater

Measure	Type of measure	unit	unit cost	Comment
Ban / restrict agricultural uses of parent pesticide (use substitute)	Source control	Cost difference of use of substitute per hectare	Flufenacet can be 3 times cheaper Fluopicolide - 30 to 100 times more costly Glyphosate similar or up to 40 times more expensive Metazachlor - one eight to half the cost	Costs of permitted parent substitute pesticides - dimethachlor substitute is metazachlor so not appropriate
Historical landfill remediation to deal with pesticide contamination	End of pipe / pathway disruption	EU level	Average of €690,000 up to €77 million per site	Irish EPA expenditure on landfill remediation in 2019 at 122 sites €158.4 million ranging from €77 million to €690,000 per site.

Environmental impacts: nrMs options

Costs

The possible environmental costs of these measures include:

- Using substitutes that have an impact on other environmental compartments;
- Climate change impacts through increased/ reduced energy use (e.g. due to changes to wastewater and drinking water treatment processes).
- Un-intentional impacts for example glyphosate is used to destroy cover crops, which are used to mitigate nutrients in run-off / leaching from agricultural fields over winter.

Benefits

Environmental impacts include:

- The lower risk of (irreversible) damage to natural resources such as groundwater and connected surface waters (i.e. reduced impact on sensitive water bodies such as wetlands and rivers).
- Reversal of impacts on groundwater biota and on the important ecosystems services provided by microbiology i.e. on natural attenuation and aquifer recovery from pollution;
- Under Option 3c the extent of these impacts will depend on the TV adopted and for which compounds or groups, the outcome may also depend on the method of analysis used and the number of GWB that are monitored.

Social impacts: nrMs options

Costs

The main costs of the addition of nrMs to the GWD with a GWQS will be to the pesticide and farming sectors. The crop protection industry may be impacted by the additional data collected for groundwater which may lead to the revocation of authorisation of permitted pesticides during the ten year review period for authorised products. The increased dataset could also have an impact on the ability to gain authorisation for new products with similar metabolites.

If measures to control nrMs in groundwater include source control such as restrictions on use then this could have a huge impact on the farming sector and crop yields. Crop Life Europe have estimated that 20 authorised substances could lose their certification if nrMs are added to the GWD with a low GWQS of 0.1 µg/l, although there are 600 remaining authorised pesticides. A level of minimisation of impacts could be had if statutory measure such as water protection zones were used to restrict pesticide use. Long term agreements with farmers would be needed along with enforcement and monitoring to ensure that conditions are adhered to and these agreements may be too restrictive for farmers without compensation for lost income.

Benefits

- Benefit (avoided costs) associated with availability of clean raw groundwater for abstraction (for irrigation, livestock watering taken directly from a GWB)
- Lower production and maintenance costs through availability of cleaner raw water, reducing pre-treatment needs / Avoided costs of drinking water (pre)treatment as a result of improved quality of groundwaters used for drinking water abstraction
- Benefits from increased quality process water from groundwater for agriculture and industry
- Benefits from reduced risk of water-related illnesses and premature deaths from improved quality of groundwater and drinking water.
- Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment.
- Improved well-being e.g. through improved ecosystem services from and healthy ecosystems.
- Benefits from increased potential employment opportunities benefits (e.g. tourism) as a result of a cleaner environment, healthy ecosystems (forests, bathing waters, nature reserves), or on the level of activity (turnover) of firms/sectors requiring a high quality of groundwater such as bottled water or aquaculture).
- Benefits to recreational users of rivers with high baseflow and inputs of pesticides and nrMs e.g. anglers in terms of health of fish population.

The social impacts are similar between the options for nrMs but Option 3b and 3d will be wider ranging due to the inclusion of all nrMs. There may be more wide ranging impacts e.g. a reduction or change in crops, which can be successfully grown, leading to changes in farming approaches.

For Option 3c there is potential for greater variance between MS in the extent of impacts resulting from differences in TVs and monitoring strategies.

8.4 Monitoring, reporting and administrative streamlining options (Complementary options)

Clear synergies exist between the policy options delineated in this section and the Zero Pollution Outlook, and the Commission proposal for a Regulation of the Industrial Emissions Portal (IEPR, former E-PRTR), the EU Strategy for Data, the INSPIRE Directive, the Open Data Directive[476] and the Directive on Public Access to Environmental Information. In particular, options focused on improving availability of data but also its accessibility will significantly support tracking the progress and achievements of obligations and commitments under other key legislations such as the Sustainable Use of Pesticides Regulation, the Biodiversity Strategy to 2030 and the Common Agricultural Policy (CAP), to name but a few.

Options within policy option 1 presented below take the form of guidance documents. Options 1-3 presented below take the form of guidance documents. For the economic impacts of these options, the primary cost will be the development of the guidance document itself. In order to estimate the costs of developing a guidance document, it is important to note that these are largely dependent on the scope of the guidance, its breadth and the process followed. Guidance documents that involve a technical input (e.g. Best Available Technique Reference Documents under the Industrial Emissions Directive), will take significantly longer to develop than technical guidance drafted within a comitology process (e.g. the Water Framework Directive Common Implementation Strategy guidance). The primary difference between these two cost-estimates stems from the effort required in establishing the guidance document. One-off estimates of cost for the development of guidance documents are presented in the table below, followed by a brief explanation of each category.

Table 8-50 Categories for estimating cost of guidance documents

Type of guidance	Range of cost per guidance (in EUR)
Simple	Up to 290,000
Elaborate	290,000 – 500,000
Extensive	5 – 10 million

Simple guidance documents are those where existing information can be used as a base, and the subject has been frequently discussed by stakeholders (e.g. monitoring and reporting best-practices and standardisation). Thus, the costs to establish further guidance will be lowest. The study by Tucker et al., 2013[477] estimated that the cost of developing guidance documentation with existing knowledge (in this example, guidance on the management of farmland in Natura 2000 areas) was approximately €290,000[478]. This estimate included both targeted stakeholder workshops with key government officials and the production of official guidance documents. The majority of guidance documents in this study would be linked to

[476] Directive (EU) 2019/1024 of 20 June 2019 on open data and the re-use of public sector information https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561563110433&uri=CELEX:32019L1024
[477] Tucker et al., 2013, Estimation of the financing needs to implement Target 2 of the EU Biodiversity Strategy. Available at: https://ec.europa.eu/environment/nature/biodiversity/comm2006/pdf/2020/Fin%20Target%202.pdf
[478] Adjusted to 2022 prices to account for inflation is approximately €290,000

already established stakeholder engagement activities (such as CIS working groups) and build upon knowledge and guidance which has previously been developed.

Elaborate guidance documents are defined here are those that rely on existing information, but the scope covers a larger range of topics. The main driver here is the extent and length of the document due to a number of topics that are linked and/or cross-cutting being developed within one document, as well as the technical context behind those. Cost estimates here are drawn from previous project experience in the development of such documentation.

Extensive guidance documents are based on new topics, which have less consensus and existing information available, and will require more effort to establish a well-rounded guidance document. An example is the Best Available Technique Reference Documents (BREFS) which are publications resulting from the exchange of information between stakeholders, industry and environmental non-governmental organisations and cover a range of operating conditions and emission rates of industrial processes. MSs are required to take these into account when determining their best available techniques under the Industrial Emissions Directive (IED). The OECD estimated that administrative cost associated with the development of the BREFs was €5-10 million per BREF[479]. The cost reflects the time needed for various stakeholders to be involved in the development of guidance documents on a more focused level and the time that best-practice sourcing and document development can take.

Thereafter, the **cost of implementing** the guidance at a MS level would depend on 1) the current level of implementation that exists and therefore the implementation gap and 2) the extent of uptake. It is not possible as part of this assessment to make such cost estimates at an EU level, due to the absence of baseline data and an inability to predict how many MS would voluntarily implement guidance documents, and to what extent. However, the effectiveness of guidance documents can be increased when these are formulated and developed in consideration of the relationship between different pieces of legislation (e.g. SSD, DWD, EQSD and IED), which can ultimately reduce the administrative and cost burdens.

There are of course also benefits from these measures. Guidance documents can reduce the costs for MSs, as instructions and best-practices are readily available for MSs to begin implementing. Such documents can also trigger innovation, and the exchange of knowledge and best practices, which can all reduce costs. In addition, they can stimulate funding for new resources as new approaches are widely recognised and shared, and thus result more quickly in the intended environmental and other benefits of the underlying legislation. It should be noted that for all options based on guidance documents, the overall impact will depend among other things on how far the guidance is implemented and on how far it accelerates the achievement of the objectives in the relevant legislation in each MS, which is difficult to estimate. As such, the analysis of guidance-document impacts below is purely qualitative.

[479] European Commission, SWD (2020) 182 final

8.4.1 *Policy option 1: Improving monitoring approaches*

Option 1a: Develop guidelines on applying innovative methods in monitoring procedures, including continuous/automated monitoring techniques.

Option 1 seeks to produce guidelines on harmonised approaches to innovatively measuring pollutants. The guidance document would seek to assist stakeholders involved in water quality monitoring through providing information on how innovative procedures could assist in creating efficiency gains (explained in the 'economic impact' section below) and enhance knowledge on water quality.

Conventional water monitoring systems are mainly based on laboratory instruments or sophisticated and expensive handheld probes for on-site analysis, both requiring trained personnel and being time-consuming. This, coupled with the time/resources required to conduct lab analyses, means that conventional monitoring practices are gradually becoming obsolete and inadequate in supporting modern water quality monitoring and reporting frameworks. Consequently, manual monitoring methods will increasingly be phased out and replaced by state-of-the art technology in the coming years.

The guidance document would focus on presenting key information on the potential costs and benefits of implementing 'mature' technologies,[480] operational guidance, and key learnings from previous experiences. This would include technologies such as fluid sensors, remote (satellite) technologies, and continuous/automated monitoring techniques. Illustrative examples would be integrated throughout the document, such as the project 'Internet of Water'[481], which is tackling water challenges through innovation. Information on fluid sensors would be relevant to include in the context of water quality issues, as such technology can simultaneously measure several water quality parameters such as pH, ions such as chloride and sodium, conductivity, temperature, dissolved oxygen, etc., whereby collected data can be combined with other data sources and processed on a cloud platform. Such a digital water management system allows water managers to: a) monitor the quality of their water reserves in real time; b) predict the evolutions of the water reserves; c) act proactively to better align water reserves with demands.

Environmental impacts

The environmental impacts of this option are largely dependent on the uptake of measures prescribed in the document. If the guidance document would lead to significant uptake of innovative monitoring approaches, positive environmental impacts could be expected through directing measures to improve the condition of water bodies. The increased accuracy in real-time pollutant identification could ultimately increase knowledge of the causes of water status failures, allowing greater effectiveness and efficiency of directed measures.

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[480] Technology Readiness Levels (TRLs) are generally used to assess the maturity of a new technology towards full economic operation. Many innovations and new technologies evolve from a 'prototype demonstration' phase (TRL 6-7) via a 'pre-commercial' stage (TRL 8) to an 'industrial roll-out' stage (TRL 9) in which components and devices can be mass produced. Many new technological innovations relevant for the water sector have TRLs of 8 or 9 and are expected to be implemented on a larger scale within years. The guidance document would focus on technologies within the final stages of TRL.

[481] https://www.internetofwater.be/en/

Economic impacts

The option is considered an ‘elaborate’ guidance to develop (i.e. €290,000-500,000), requiring consultations with relevant stakeholders to develop key information (particularly costs, benefits, and key learnings from implementation of innovative approaches considered within the guidance) and integrate learnings from harmonised measurement method implementation. Beyond this, economic costs cannot be calculated as this would largely depend upon the uptake of guidance provided, and no (baseline) data on the current implementation of innovative monitoring and measurement methods exists. It can be foreseen that the following costs would be incurred:

- Costs to managing authorities to procure innovative monitoring technologies, train staff, develop data flow management procedures and infrastructure to align with new data flows;
- Costs to industrial actors to recalibrate with emission legislation, given the likely increase in accuracy of monitoring procedures requiring further actions to limit emissions;
- Costs potentially to wastewater treatment plants to upgrade facilities to comply with emission legislation, given the likely increase in accuracy of monitoring procedures requiring further actions to limit emissions.

Regarding the last two points above, additional capital expenditure (CAPEX) and operating expenditure (OPEX) would depend upon the changes to water quality status following (projected) improved accuracy of monitoring, and the costs required (if applicable) to upgrade facilities.

However, it is expected that the aforementioned costs would be covered by the following economic benefits in the medium-long term if innovative monitoring procedures are implemented:

- Fewer human resources required by managing authorities for manual monitoring data inputs;
- Greater effectiveness and efficiency at developing and targeting programmes of measures (PoMs) to address water quality issue due to significantly increased knowledge.

Social impacts

The production of the guidance document under option 1 is unlikely to result in significant impacts on employment in the EU. Companies involved in the production and distribution on innovative monitoring technologies may increase revenues through sales of equipment to managing authorities. Managing authorities will likely need to upskill staff to effectively use new technologies, whilst employment will likely be required to implement supporting infrastructure (such as IT systems). Economic actors (predominantly heavy industry and wastewater treatment) may require additional staff to retrofit facilities.

Option 1b- Follow-up to improve existing guidelines in view of setting application 'trigger values' in practice to improve monitoring of groups/mixtures of pollutants by using effect-based methods (EBMs), and trigger values

Option 1b involves the development of guidelines on the types of effect-based methods[482] (and corresponding trigger values for mixture pollutants) available, the application of tools such as effect-directed analysis to identify causes of pollutants, and guidance on the links between exposure and effects. Effect-based methods guidance would cover non-monitored substances such as estrogenic substances, in addition to providing information on in vitro and in vivo bioassays to assess chemical mixture effects on the environment and biota. These methods would allow the identification of the causes of impacted water quality and would help develop programs of measures to improve them.

Policy option 1b would consolidate information on effect-based methods (EBMs) and effect-directed analysis (EDA). Information on the range of EBM techniques available, the effects these techniques monitor in relation to groups of chemicals toxicological endpoints of concern, establishment of trigger values, and use of effect-directed analysis would be presented. Ultimately, this could assist in detecting the effects of compound mixtures on ecosystems (and human health)[483], detecting contamination hot spots, identifying risk drivers and prioritising measures to tackle these. Simultaneously, the document would assist in presenting effect-based trigger values for EBMs- which would define an acceptable level of effect for chemical mixtures. This would likely impact the analysis of condition of surface water bodies (depending upon the agreed trigger values for pollutants) and the identification of RBSPs throughout EU river basin districts.

The guidance document would set further standardization of EBM-test systems. Importantly, the guidance should lead to an agreement and establishment of a coherent series of bioassays in order to cover modes of actions of all chemical groups being considered and lead to standardisation of the EBM-test systems to facilitate practices. EBMs can be applied for both diagnostics and monitoring purposes to assess the likelihood of impacts of chemical pollution, and can be applied in the field as well as under laboratory conditions.

Tools that can be applied include biosensors (converting biological receptors response into quantifiable signals), biomarkers (quantifying biological sub-cellular stress response to pollutants), bioassays (both in-vitro and in-vivo assessments of pollutants impacts on organisms health and fitness) and Biological Early Warning System (BEWS, whole organism bioassays and cell-based biosensors that can be applied to obtain real-time data on water quality and pollution toxicity levels)[484].

While EBM can detect the hazards induced by pollutants and provide information regarding toxicity levels for organisms, it cannot provide insights to identify pollutants and the link to exposure of the effects. As such, EBM is most effective in combination with effect-directed analyses (EDA), which harnesses biological effects as a basis to direct chemical analyses to

[482] EBMs are methods which use the response of whole organisms (in vivo) or cellular bioassays (in vitro) to detect and quantify the effects of groups of chemicals on toxicological endpoints of concern

[483] As demonstrated in the NORMAN and SOLUTIONS studies- which demonstrated that EBM can quantify steroidal estrogen concentrations which traditional chemical analytical methods could not quantify.

[484] Hunting et al (2017). Assessment of monitoring tools and strategies safeguarding aquatic ecosystems within the European water framework directive. Institute of Environmental Sciences (CML), Leiden.

the compounds that contribute the most. EDA therefore allows the unravelling of the substances that are the primary cause of toxicity and therefore identify those substances with primary impact on the water quality. The guidance document therefore encompasses EBM and related trigger-values, as well as the combined utilization with EDA and relevant assessment methodologies.

Environmental impacts

Due to the mounting evidence that chemical mixtures can produce toxicity levels which surpass individual chemical toxicity, developing guidelines on monitoring mixture toxicity will be essential to facilitate routine mixture monitoring.

Case studies conducted for the first CIS technical report[485], on EBM application across MSs showed the impacts on the environment, and overall health of water bodies, is often more severe than estimated[486]. The application of EBMs therefore has the potential to give further insights into the health of water bodies than possible when focusing only on specific substances and allow pollutant mixtures posing significant risks to be addressed under the WFD[487].

The currently monitored 45 PS and over 300 RBSPs represent only a fraction of the overall chemical risk, and entirely ignore the impact of mixtures. While the focus on these encourages the reduced use of them, the replacement of these substances by alternatives that pose similar hazards remains unaddressed. EBM application enables not only the detection of effects of mixtures of compounds in water resources, but furthermore minimizes the risk of overlooking hazardous substances and transformation products, as well as detecting hot spots of contamination. As such, the implementation of EBM plays a significant role in improving water quality and addressing chemical status of water sources beyond the limited range of PS and RBSPs.

Addressing the impacts of alternative substances and mixtures is of necessary priority if good chemical status is to be achieved. In addition, use of EBM for identifying the need of abatement measures as well as assessing their efficiency will increase environmental protection. Combine application with EDA would further assist in the detection of critical substances of concern that are driving toxicity levels, and therefore assist in implementing targeted measures that could more quickly reduce the load release and alleviate the pollution stress on the environment more efficiently. EBM could also assist in detecting new chemical pollutants that may be considered for RBSP selection, thus further driving the improvements in water quality and environmental protection

However, as the option is aimed at increasing knowledge and providing information for voluntary action, rather than directly implementing actions, the environmental impacts are estimated as being limited. If the guidance were to lead to enhanced monitoring of mixture

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485 EC (2014). Technical report on aquatic effect-based monitoring tools, Annex. Technical Report 2014-077. Luxembourg: Office for Official Publications of the European Communities, https://circabc.europa.eu/sd/a/161d57fc-5557-4e9f-95fc-85883c32508d/Effect-based%20tools%20CMEP%20report%20annex%2028%20April%202014.pdf

486 Wernersson et al. (2015). The European Technical Report on aquatic effect-based monitoring tools under the Water Framework Directive. Environmental Science Europe, 27

487 Brack et al (2019). Effect-based methods are key. The European collaborative projects SOLUTIONS recommends integrating effect based methods for diagnosis and monitoring of water quality, Environmental Science Europe, 31.

pollutants and development/deployment of cost-efficient methods to address specific modes of action, it can be assumed that pollutant occurrence could be significantly reduced.

Economic impacts

The guidance document should lead to more consistent use of EBM, an agreed application of trigger values and the use of EDA. The uptake of EBM and EDA would improve the accuracy of identifying pollutant sources, thus improving the cost-effectiveness of developing measures to tackle pollutants, whilst simultaneously increasing the costs to control the source of pollutants borne by, for example, industry.

The identification of toxic mixtures and particularly contributing substances could lead to the identification of primary sources responsible for the release of the pollutant. On the one hand, this would allow authorities to take swift action, implementing measures in a cost-efficient manner. On the other hand, the identification of substances causing mixture effects can lead to targeting specific sectors more persistently than others, leading to the question of with whom the responsibility lies in preventing pollution and, importantly, who will carry costs for preventative measures to be put into place. This is particularly important when considering the trigger values. It is worth noting that these possible impacts of EBM and trigger will positively contribute to the development of the polluter pays principle in the WFD as well as wider EU environmental policies[488]. During the OPC and workshops, stakeholders expressed a high interest in guidance documents for EBM, and noted that these would be highly useful as harmonisation approaches for some substances and establishing of trigger values have thus far failed.

In terms of cost-effectiveness, EBM present an opportunity for more cost-effective monitoring programmes and in combination with EDA can assist in detecting substances of specific ecological relevance. Particularly costs of bioassays are generally substantially lower than chemical analyses of regulated compounds, and a comprehensive analyses and comparison on these have been previously conducted[489].

However, due to the voluntary nature of guidance documents it is not possible to estimate the full economic impact as the expected scale of implementation is unknown. The option is considered an simple guidance and would cost up to **€290,000** to develop. The implementation of guidance is likely to trigger the development of new cost-effective methods that will address MoA not yet covered.

Social impacts

The impacts of guidance documents on social factors cannot be quantified, as they remain voluntary actions and will depend on the extent of implementation. .

[488] European Court of Auditors (2021). The polluter pays principle: inconsistent application across EU environmental policies and actions. Available at: https://www.eca.europa.eu/Lists/ECADocuments/SR21_12/SR_polluter_pays_principle_EN.pdf

[489] EC (2014) Technical report on aquatic effect-based monitoring tools, Annex. Technical Report 2014-077. Luxembourg: Office for Official Publications of the European Communities, https://circabc.europa.eu/sd/a/161d57fc-5557-4e9f-95fc-85883c32508d/Effect-based%20tools%20CMEP%20report%20annex%2028%20April%202014.pdf

Option 1c: Develop a harmonised measurement and monitoring methodology and guidance for microplastics, as a basis for mandatory MS reporting on microplastics and a future listing under EQSD/GWD

Regarding microplastics, no commonly agreed standard for measuring their presence in EU freshwaters exists. Such a standard is however a prerequisite for monitoring and taking targeted policy action such as setting an actual EQS. Mandatory monitoring according to a harmonised methodology will provide a wealth of monitoring data on types and quantities of microplastics occurring in surface water, groundwater and coast waters. Firstly, this is paramount for improving the current limited understanding of the environmental fate and behaviour of microplastics. Secondly this supports follow-up studies and allows developing and validating future simulation models (no microplastics simulation model was found in the EC Modelling Inventory (MIDAS)). Consequently, the development of a harmonised measurement and monitoring methodology and guidance for microplastics is a basis for mandatory MS reporting on microplastics and a future listing under EQSD/GWD.

Option 1c therefore has a step-wise approach, in that it first aims at providing guidance for developing harmonised measurement methods in relation to microplastics. This would provide methodological guidance on how to measure microplastic pollution in EU water bodies. Once a standardized method has been defined and feedback has been gathered from stakeholders on the implementation of this approach by the Commission, it would then be refined, and potentially result in a provision in relevant legislation- obliging MSs to monitor and report on microplastics using the defined approach. Upon receiving the first datasets from MSs, the Commission would oblige itself to set an EQS based on the monitoring results within a certain period.

Environmental impacts

Between 200,00 to 500,00 tonnes of microplastics from textiles enter the global marine environment; an estimated 8% of European microplastics are released to the oceans[490]. The focus of microplastics is on particle pieces less than 5mm in length/diameter. The micro-sized synthetic polymers can easily enter spoil, water, air, food webs and living organisms, accumulating and causing hazardous impacts in the long-term. Due to their small size microplastics have been found in all spheres of life. Most recently, researches discovered microplastics in the deep sea – a testament for how easily these microparticles can travel and distribute in our environmental and contaminate natural resources and habitats[491]. Their small size also means microplastics are easily ingested by animals and humans alike. Manufacturers add compounds such as plasticizers, stabilisers, and pigments to plastics, which when ingested can cause chemical toxic loads inside organisms[492].

Organisms in all ecosystems and of all sizes have shown to ingest microplastics. For animals in particular, the ingestion of microplastics can block the gastrointestinal tracts of wildlife (including birds, fish and other species consumed by humans) causing not only physical

[490] EEA (2017). Microplastics from textiles: towards a circular economy from textiles in Europe. Available at: https://www.eea.europa.eu/publications/microplastics-from-textiles-towards-a

[491] Barrett et al (2020). Microplastic Pollution in Deep-Sea sediments form the Great Australian Bight. Frontiers in Marine Science.

[492] Lim (2021). Microplastics are everywhere – but are they harmful?. Nature News Feature. Available at: https://www.nature.com/articles/d41586-021-01143-3

internal damages such as laceration or irritation, but furthermore give wildlife a false feeling of satiety and leading to nutritional starvation and mortality[493].

Once released, microplastics are difficult to breakdown by nature and by organisms. Hence, the particles preside and circular in the environment for a long time. This not only presents a risk of accumulation but furthermore, microplastic can continue to further degrade to nanoparticle size. Nanoparticles have been the same dimensions as biological molecules that assist in cells function in all organisms (e.g. proteins) and as such, pose an even more significant risk to biological systems and healthy functioning of living organisms[494].

The option has the potential to therefore have significantly positive impacts by addressing microplastics pollution. However, the guidance document in itself will likely be ineffective if it is not quickly followed up with actions and obligations such as the implementation of strict and scientifically relevant EQS for microplastics. As such, it remains difficult to assess the full extent of environmental impacts that the option could have.

Economic impacts

It is important to consider both at-source and end-of-pipe measures when addressing microplastics, as on the one hand there is a need for innovation of materials, manufacturing processes and substitution to more sustainable materials (e.g. biobased plastics) and, on the other, a need to clean up and prevent microplastics from entering ecosystems to combat pollution. As such, addressing microplastic pollution is strongly linked to the application of polluter pays principles and related EPR schemes. The recent impact assessment on the Urban Waste Water Treatment Directive (UWWTD) showed that there is a pressing need to also address microplastic pollution and wastewater treatment plants, introducing further tertiary treatment methods to ensure that microplastics are more effectively removed from water before it is released. However, this directly increases the microplastic content inside the produced sludge, which consequently beg questions on the costs of sludge prior to it being re-used in nutrient recovery and land-use. The complexity of addressing microplastics therefore shows a series of measures are needed, which are likely to result in significant short-term costs for producers and other economic operators. However, in the long term, the costs borne can be expected to fall as products are incentivised to be more durable, biobased and produced with circularity/recycling in mind.

As a relatively unchartered territory, initial costs may be higher than for traditional chemical substances or groups of substances. It is however a vital prerequisite for monitoring by Member States and future development of policies to reduce emissions to surface water, groundwater and coastal waters. Based on expert judgement from the JRC related to developing a harmonised measurement and monitoring method for microplastics in drinking water, and information from EU funded projects supporting the EU Plastic Strategy[495], the

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[493] Wildlife Health Cooperative – Wildlife ingestion of microplastics. Available at: http://www.cwhc-rcsf.ca/docs/fact_sheets/Wildlife%20ingestion%20of%20microplastics.pdf
[494] Nanoparticles. DG Health and Consumer Protection. Available at: https://ec.europa.eu/health/scientific_committees/opinions_layman/en/nanotechnologies/l-2/6-health-effects-nanoparticles.htm
[495] Horizon 2020 EUROqCHARM project works towards validated harmonised methods for monitoring & assessing macro-, micro- and nanoplastics in environment: https://www.euroqcharm.eu/en

development of a harmonised measurement and monitoring methodology for microplastics and the accompanying guidance is estimated to cost between €290,000 to €500,000[496].

Social impacts

As mentioned above, accumulation of microplastics in humans through ingestions can have chemically toxic impacts due to the manufacturing process and coating of plastic material. Moreover, research has shown that huma exposure to microplastics can occur also through inhalation and dermal contact, due to the presence in food, water and consumer products. In addition studies have demonstrated that the accumulation of microplastic can lead to metabolic disturbances, neurotoxicity and increases in cancer risks in human[497]s. Hence, addressing microplastics is of highest urgency, and reducing their presence in the environment will reduce health risks. Important to note, that only a mandatory EQSD on microplastics would have a significant impact; a guidance document without further actions would limit any social (or environmental) benefits described here. As such, the guidance document proposed here sets a pre-requisite for further actions to be taken.

Positive impacts, at a market level, include not only improvements on durable products for consumers, but also may boost the demand for sustainable products along the value chain.

Option 1d- Develop guidelines on sampling frequency for priority substances (PS) and river basin specific pollutants (RBSPs)

This option involves the development of a guidance document for MSs on best-practice sampling approaches for PS and how to integrate such approaches into water-quality assessments and monitoring strategies to support WFD objectives. The guidance would address key points, such as: (1) possible changes to the different types of monitoring under the WFD and EQSD for PS in surface waters (WFD Annex V point 1.3 and EQSD Article 3(6)), (2) the recommended monitoring frequencies (Annex V point 1.3.4) and their suitability for assessing average concentrations, seasonal peaks and long-term trends, and (3) the environmental matrices in which PS should be monitored.

The concentrations of certain pollutants vary considerably in water bodies throughout the year (e.g. pesticides used in higher concentrations during growing seasons). In addition, water quality status can be impacted seasonally due to population size/structure (holiday period- and age-related, the occurrence of seasonal diseases (which may increase the presence of pharmaceuticals in wastewater) and the seasonal growth/senescence cycle of habitats. Furthermore, increased rainfall and temperatures can cause changes in the composition of pollutant loads[498]. Multiple sampling of priority substances throughout the year can therefore give a better overview of the pollutant load, distribution, and the overall impact on a temporal scale.

[496] Estimate based on development of microplastics methodology for Drinking Water Directive and the qualification of guidance documents from Annex 10 Table A10.5.
[497] Rahman et al., (2021). Potential human health risk due to environmental exposure to nano- and microplastics and knowledge gaps: A scoping review. Science of The Total Environment, 757 (25).
[498] Liu et al. (2016). Characterization and explaining spatial-temporal variation of water quality in a highly disturbed river by multi-statistical techniques. Springerplus, 5.

Compounding the issue of data accuracy due to seasonal variations is the high variability in the number of sampling stations and sampling frequency per station between MSs. A comprehensive study on water quality across the EU showed that an increase in sampling frequency reflected an increase in detection of almost all chemical classes[499]. The study further found that unacceptable aquatic risks were detected throughout all of Europe where sporadic averages exceeded set limits and had a negative environmental impact. The substantial variability for many substances has demonstrated that the sampling of surface waters on one or two occasions annually is not sufficient to classify the chemical status[500]. The results show the importance of introducing more frequent sampling, especially in consideration of seasonality, in order to capture a more complete picture of the water bodies conditions and positively impact/influence risk management strategies.

Hence, the introduction of a guidance document would assist MSs in optimizing their sampling frequency to capture a more complete picture of the water bodies' conditions and accurately inform their risk management strategies. The document would also include guidance on how to assess PS and RBSPs jointly (presenting here clear linkages to option 2)- to assist efforts to link chemical occurrence to ecological effects. This would ultimately garner a greater understanding of the causal links between chemical and ecological status, and to indicate the effects of pressures and causes of observed ecological effects.[501] Furthermore, this option presents clear linkages to option 8, through providing an overview of matrices to be used monitor and assess PS and RBSPs, to assist in overcoming the considerable variation between chosen matrices by MSs currently.[502]

Environmental impacts

The environmental impacts of this option are largely dependent on the uptake of measures prescribed in the document. If the guidance document would lead to more holistic monitoring frequencies for both PS and RBSPs, then managing authorities could prioritise sampling in periods when pollutants are more likely to occur in the environment. This would likely impact the detection of pesticides during crop growing seasons, and pharmaceuticals during low flow conditions.[503] Ultimately, the increased detection of such substances within water bodies would impact water quality status throughout the EU, particularly in MSs where the use of pesticides and pharmaceuticals is prevalent. Similarly, the Maximum Acceptable Concentration (MAC) EQS is meant to protect ecosystem from short term concentration peaks, it is only beneficial if there is frequent monitoring that allows for peak detection, especially during periods where increases in emissions can be expected. Hence, providing improved guidance on sampling frequency can have significant positive environmental impacts, as more effective measures can be put in place that adequately reflect local needs.

[499] Wolfram et al. (2021) Water quality and ecological risks in European surface water bodies – monitoring improves while water quality decreased. Environmental International, 51.
[500] Toernemann and Johannson (2008). Temporal variation of WFD priority substances. Swedish Environmental Protection Agency Technical Research Report, SWECO.
[501] EEA (2018) Chemicals in European Waters- Knowledge Developments. Available at: https://www.actu-environnement.com/media/pdf/news-32729-produits-chimiques.pdf
[502] Trinomics et al., (2019) Fitness Check Evaluation of the Water Framework Directive and the Floods Directive
[503] Toernemann and Johannson (2008). Temporal variation of WFD priority substances. Swedish Environmental Protection Agency Technical Research Report, SWECO

Economic impacts

The option is considered an elaborate guidance document (i.e. between €290,000 - €500,000) to develop. Decisions regarding whether an increased sampling frequency is necessary or adequate should be considered in the cost-effectiveness analysis (CEA) conducted by MSs. The guidance document would provide information on how to best identify and prioritise certain water bodies that are more likely to benefit more frequent sampling, thus increasing the likelihood that investment into monitoring leads to positive impacts. As an initial estimate, considering only the impacts of increased pesticide monitoring, EU-wide additional annual costs are calculated at approximately €937million.[504] However, costs are likely to vary significantly, depending upon the type of substance monitored and the associated recommended monitoring frequency decided upon. Beyond this, economic costs cannot be calculated as this would largely depend upon the uptake of guidance provided.

Where the guidance document is acted upon by MS, it can be foreseen that the following resulting costs would be incurred:

- Costs to crop farmers to limit pesticide use or find alternative practices to mitigate the application of pesticides;
- Costs to livestock farmers to install fencing to keep animals away from water courses to reduce veterinary pharmaceutical emissions to water;
- Costs on producers, formulators, farmers and/or consumers of substituting substances;
- Costs on pharmaceutical producers, heavy industry and wastewater treatment plants to retrofit/ produce substituting substances if other PSs exceed limits due to increased monitoring accuracy (due to increased frequency of monitoring).

Benefits will depend on the water body and the function that it delivers, the number of users of that water body and the stakeholders affected. Since CEAs are influenced by the scale of the problem, and the scale of the measures implemented, the guidance document would benefit from providing MSs information on best practice, cost effective monitoring of priority substances to create efficiency gains through knowledge transfer.

Social impacts

The production of the guidance document under option 3 is unlikely to result in significant impacts on employment in the EU. Managing authorities could be required to hire additional staff to accompany increased monitoring frequencies (and/or accrue funding for laboratory testing). Economic actors (predominantly heavy industry, wastewater treatment facilities, pharmaceutical manufacturer and pesticide users) may require additional staff to retrofit facilities or produce substitute products.

A better understanding of seasonal fluctuations in the quality of drinking and irrigation water sources, and in the quality of waters used for irrigation and recreation, could help protect citizens from risks, particularly in areas with large (accidental) pollutant discharges from

[504] Costs estimate include: assumed doubling of current maximum monitoring 12 times per year (to 24 times annually per substance); applied to the current monitoring of 21 pesticides included in the PS list; applied to 7,000 surface and groundwater monitoring sites which currently report pesticide (taken from EEA, 2020, Pesticides in European rivers, lakes and groundwaters –Data assessment- deducting); costs of analysis and sampling assumed at €305 per substance (taken from EC (2011) SEC 1547 final ; converted to 2022 values)

industry (e.g. high loads from industrial accidents), in urban areas at risk of storm water overflows, and in agricultural areas where plant protection products are used.

Option 1e — Provide a repository for sharing best-practices from MSs regarding available monitoring techniques, and foster cooperation to implement these

Option 1e foresees the development of an online repository of standards and best-practice approaches to improving MS monitoring techniques. This would build upon and complement option 1, providing a living, online location to allow consistent updates on monitoring techniques and providing a forum for actors (predominantly managing authorities) to facilitate knowledge transfer.

The OPC revealed that stakeholders did not feel that sharing of best-practices and cooperation for monitoring techniques were being implemented at regional, national or local level. During the workshops stakeholders expressed strong support for the implementation of the repository, in hopes that information shared would include sensitivity of sampling methods, seasonal effects, sampling methods and sharing of information to improve robustness of data. Overall, the suggested option was welcomed by stakeholders.

Environmental impacts

Making knowledge, standards and best-practices openly and easily accessible enables the transfer of information between MS. Through this knowledge transfer, it could be expected that the quality of MSs monitoring techniques would be enhanced. In addition, open access to information on monitoring techniques applied in other MS is likely to increase the coherence and comparability of monitored data across the EU. This would assist in the standardisation of monitoring approaches, which further enables the development of option 5.

Sharing of best-practices from frontrunners is likely to stimulate innovation and support transformation by encouraging innovative monitoring technologies, which are likely to have positive impact on the water quality and resource management. The scale of the environmental impacts would depend on the technological progress that can be facilitated. The option may also enable the benchmarking of monitoring practices and techniques across of different MS. Overall the option only presents light direct environmental benefits.

Economic impacts

The online repository and sharing system comes with no legal obligation and would likely lean on many existing infrastructures. As such, the costs for implementation would mostly be related to IT and associated maintenance cost. Small costs would be borne by the Commission to develop, host and maintain the online repository (calculated at approximately €100,000 per annum[505] for staff and likely some additional costs of developing and IT hosting). However, these costs could be further reduced if the repository would be hosted alongside existing open-platforms.

The benefits of the option is that it would likely lead to efficiency gains for MSs who improve their current monitoring techniques. Although costs (for MS competent authorities) could be

[505] Average cost of 1 FTE EC staff for the development and maintenance of IT systems

expected from the initial upgrading of monitoring and reporting approaches, the sharing/cooperative approach amongst MSs can be expected to limit these initial costs.

Social impacts

The option has limited social impacts. The option is unlikely to have significant impacts on employment in the EU. There may be an opportunity for requiring additional staff to set up the repository, but the administrative activities and sharing of monitoring methods will likely be conducted by existing positions. The option does however provide benefits to improving transparency on monitoring and empowering MS to compare and improve their own methods. Where the knowledge sharing can lead to innovation, there is a possibility for additional research and innovation, which may provide opportunities for additional staff and funding for institutions.

8.4.2 *Policy option 2:* Developing and improving existing obligatory monitoring practices

Option 2a: Include an obligation in the EQSD to use EBMs to monitor estrogens

Recent analyses on the concentration of estrogen ethinylestradiol in the EU showed that the majority of MS detected maximum concentrations far above the acceptable ecotoxicological level of 0.01 ng/L[506]. Option 2a thus foresees the mandatory use of EBMs to monitor estrogens to gain a greater understanding on the occurrence and threats (to ecological systems and human health) posed by estrogen exceedances.[507] Establishing a provision in the EQSD for monitoring estrogen using EBMs would rely on the recently published technical proposal for EBM application under the WFD[508], which focused on mixture effects from substances sharing the same mode of actions (MoA)(such as estrogenicity). The proposal identifies EBMs and EBM batteries that have been determined suitable and sensitive for the detection of estrogenicity.

Consultations with stakeholders (targeted consultation workshop) found that there was general support for the provision on estrogen monitoring using EBMs.

Environmental impacts

A provision to monitoring estrogen and applying an effect-based trigger value (EBT) could have significant impacts on reducing the estrogen toxicity levels in aquatic ecosystems. Elevated levels of estrogen can interfere with organisms reproductive systems, and severely impact early stage development of individuals as the substances disrupt natural endogenous hormone synthesis[509]. In addition, they can disrupt gonadal function, decrease sperm counts and consequently reduce fertility, and lead to sex changes from males to females[510]. The

[506] aus der Beek et al., (2016). Pharmaceuticals in the environment-Global occurrences and perspectives. Environmental Toxicology and Chemistry, 35(4), 823–835.
[507] Common Implementation Strategy for WFD and Floods Directive (2021) Technical Proposal for Effect-Based Monitoring and Assessment under the Water Framework Directive- EBM Drafting Group.
[508] EC (2021). Technical proposal for effect-based monitoring and assessment under the Water Framework Directive. Report to the Common Implementation Strategy (CIS) Working Group Chemicals. https://www.normandata.eu/sites/default/files/files/Highlights/211013_EBM%20report_FINAL_WG_Chem_Oct_2021%20%281%29.pdf
[509] Czarny et al (2017). The impact of estrogens on aquatic organisms and methods for their determination, Critical Reviews in Environmental Science and Technology, 47:11, 909-963.
[510] ibid

feminization of fish due to estrogenic pollution of water bodies has been well researched[511] and has in cases led to the population collapse due to lack of reproduction[512]. While the half-life of estrogens is generally low, and therefore they degrade fast, they can bind to sediment particles and affect physiochemical parameters. As such, the obligation to monitor and maintain estrogen levels would provide valuable information for the further protection of the aquatic environment. Considering that toxicity pressure from estrogen is not likely to reduce in the near future, the option presents a necessary first step towards setting an EBT value.

Economic impacts

The economic impact of monitoring estrogen can be estimated only in part, but acts as an example for assessing economic impacts of substances causing mixture effects. Estrogen bioassays sampling and analyses were estimated to a total of approx. €1,000 per sample[513], however using commercial laboratories costs are greatly reduced to between €60-200 per sample.[514] Given the current 1550 water monitoring stations distributed across 24 EU countries, and assuming an average of 4 samples per year[515] from such stations, the total cost is estimated at €372,000 – €1,240,000 annually across the EU.

Monitoring of estrogen levels and detection of possible trigger value exceedances would undoubtedly lead to more measures being taken to address risks and improve water quality. Estrogens reach water bodies most commonly via municipal wastewater and runoffs from fields where natural fertilizers are used. The observed increase in the concentrations of synthetic estrogens in water bodies is attributed to the growing use of contraceptives and hormonal drugs in humans as well as in animals where hormones are administered for therapeutic purposes and to improve breeding performance[516]. As such, sectors that would be primarily impacted would be waste water treatment and agriculture.

It would be expected that additional measures would need to be implemented. In urban waste water treatment plants there is likely to be an additional cost associated to additional monitoring for estrogen, as well as more stringent treatment to address pollutants. The monitoring of estrogen may therefore have far-reaching economic impacts. However, pressure to address estrogen in the environment will also likely lead to research and innovation. In addition, monitoring would align with ambitions of the Zero Pollution Action Plan and the findings of recent impact assessment of the UWWTD, which in the long term would allow for coherence across policy legislation and therefore associated cost-savings.

Social impacts

The option is unlikely to have significant impacts on employment in the EU, it may have impacts on consumers and consumer behaviour if a provision to monitor estrogen results in consequent measures taken by public authorities and industries.

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[511] aus der Beek et al., (2016). Pharmaceuticals in the environment-Global occurrences and perspectives. Environmental Toxicology and Chemistry, 35(4), 823–835.
[512] Kidd et al 2007 from pharma report
[513] Factsheet Monitoring Austria, obtained from the Impact Assessment on the Urban Waste Water Treatment Directive
[514] Personal communication with the Joint Research Centre
[515] GEMStat Database: https://www.waterandchange.org/en/european-water-quality-monitoring-data-in-gemstat-database-undergoes-major-update/
[516] Czarny et al (2017). The impact of estrogens on aquatic organisms and methods for their determination, Critical Reviews in Environmental Science and Technology, 47:11, 909-963

The possible increase in costs of contraceptives for women may have an impact on access to modern contraceptives and their reimbursement, and by association affecting access to family planning. Currently more than half of EU countries perform poorly under the Contraceptive Policy Atlas[517], indicating that contraceptives access and reimbursement schemes remain poorly in many countries. Increases in product costs could further increase the challenge to women's access to contraceptive supplies. Hence, it is important that the development of the option in regard to monitoring of estrogen is done in a manner that addresses the concerning toxicity levels, without negatively impacting the female population.

If appropriate measures are taken to prevent effects on female consumers, overall, the social impacts of monitoring estrogen are positive, as it provides information the water quality of recreational and drinking water sites. Furthermore, the data collected will set precedent for the development of EBT values for estrogen, which can lead to an overall increase in human health protection.

Option 2b: Consider establishing an obligatory groundwater watchlist mechanism analogous to that for surface waters and drinking water, and provide guidance as necessary on the monitoring of the listed substances

The voluntary nature of the GWWL can limit the evidence gathering of pollutants present in groundwater bodies, ultimately limiting the development of the Groundwater Regulation and the establishment of threshold values. Pollutants such as emerging organic contaminants are one example of insufficient and incomparable monitoring efforts. To increase the value of monitoring data, a higher degree of comparability and harmonisation is needed. This could be achieved through a compulsory data collection effort- assisting in building a more robust knowledge base.

The obligatory GWWL would in principle be expected to cover all groundwater bodies in the EU-27, estimated at 13,746, covering a maximum of 30 substances, unless it can be clearly and unambiguously demonstrated that a pollutant will likely be completely absent in a particular groundwater body. The WL would require monitoring of at least once per year, per groundwater body, and is expected to be reviewed every 4 years (in line with recommendations from the Fitness Check of the WFD- which noted that the speed of current revisions is too slow). The WL would be complemented by a guidance document providing an overview of commonly accepted methods of chemical analysis of new/emerging pollutants to achieve comparability of monitoring approaches between MS.

Environmental impacts

The option would primarily ensure that there is a coherent method of assessment across MSs, ultimately increasing the comparability of data regarding GWWL substances. This can be expected to improve the overall status of groundwater bodies throughout the EU, as the greater comparability of results could enable better decision-making processes to be made, particularly regarding substances which are confirmed as posing a risk.

[517] https://www.epfweb.org/node/89

Economic impacts

Costs borne by management authorities are estimated through multiplying sampling and analytical costs[518] by an assumed one sampling station per groundwater body. This assumption acknowledges that some of the 13,746 groundwater bodies will be grouped (which takes place, inter alia, for the purpose of monitoring), yet this will be somewhat compensated by the fact that water bodies often have multiple monitoring sites.[519] This results in estimated annual costs between €104-125 million (for 25 and 30 substances respectively). However, MSs are likely to likely to use / reflect upon existing monitoring techniques currently implemented under the voluntary watch list- therefore cost savings can be expected. Costs are likely to be disproportionate for MSs where current monitoring coverage is low, or MSs with a disproportionately high number of groundwater bodies, however, cost efficiencies can be gained through sharing of best practice analytical methods (the guidance document as part of this option, outlined below) and measures to address chemical status failures. In relation to MS reporting costs, it is projected that these would range between €30-100,000 per MS, per year.[520] Additional costs could be encountered due to increased laboratory demand.

Minor costs, borne by the Commission, can be expected for comitology and administration. In addition, the development of a guidance document providing an overview of approaches to chemical analysis for new/emerging pollutants is expected to cost up to €290,000 (i.e. a 'simple' guidance document).
Costs to economic actors will be largely dependent on the (type/number of) substances selected as part of the WL, and the prescribed monitoring frequency requirements. The IA of the IED (acknowledging that this only covers a % of the total number of economic actors which emit pollutants into the environment) presents estimates based on the development of a similar watch-list process for 48 pollutants. The study estimated that such a mechanism would result in one-off costs of €13.2million and recurrent costs of €4.4million for facilities impacted across the EU-27.[521]

In relation to benefits, stakeholders noted during consultations that a mandatory WL approach for all MS should help gather representative data which allows robust analysis of EU-wide risks (see workshop 2 report). This could lead to more effective and efficient application of measures to improve groundwater status, particularly through sharing of best practice approaches.

Social impacts

Overall, this option is expected to result in insignificant social impacts. Impacts on employment are expected to be minimal- with MS complementing current voluntary WL monitoring approaches potentially requiring further staff (to implement monitoring, enhance

518 Derived from EC (2011) SEC 1547 final- Impact Assessment amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy; adjusted to account for inflation to a unit cost estimate of €304
519 EC (2021) SWD 253 final, European Overview - River Basin Management Plans
520 Assuming that reporting by MS of detailed information that should already be available- taken from: ICF et al., (2017) Support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation, pg 100
521 EC (forthcoming) Impact Assessment Report Accompanying the document: Proposal on the revision of the Industrial Emissions Directive (IED) and the Regulation on European Pollutant Release and Transfer Register

data infrastructure), yet this is largely dependent on the current state of groundwater monitoring approaches per MS.

The projected environmental impacts are likely to result in positive societal health impacts- particularly through if measures to mitigate pollutants impact drinking water sources. Collating further data on groundwater substances can also improve public access to information- possibly enabling greater participation throughout environmental decision-making processes.

Option 2c: Improve the monitoring and review cycle of the surface water watch list so that there is more time to process the data before revising the list

The option focuses improving the monitoring and review cycle of the surface water watch list, to make the development and uptake of new priority substances more efficient and effective. The current surface water watch list monitoring does not require competent authorities to monitor more than once per year, which is insufficient for substances whose concentrations fluctuate significantly and show strong seasonal trends[522]. The option foresees the following legislative changes to be implemented:

- Extend the watch lists revision cycle from 2 to 3 years;
- Establish a minimum of bi-annual monitoring of substances for a total period of 2 years (possibly more for substances with strong seasonal fluctuations);
- Ensure the review of results of gathered data and decide on the uptake of new substances into Priority Substances at the end of the 3rd year;
- Throughout the monitoring cycle, the data would be periodically and thus more continuously reported, ideally by way of data harvesting. Hence, the development of this option is intrinsically linked to option 1e.

Consultations found stakeholders were broadly in agreement with increasing monitoring frequency under the WL (stakeholders were asked via a targeted survey to rate on a scale of 1-not at all useful, to 5- very useful, the effectiveness of various potential measures in improving risk response and management of the surface water watch list. Respondents identified an increase in the monitoring frequency of substances in the surface water watch list as the most effective measure- receiving the highest average score of 3.2).

Environmental impacts

The environmental impacts of the option are dependent on actions relating to prioritisation of watch list-monitored pollutants to the designation of Priority Substances. It can be expected that improved monitoring (through increased monitoring frequencies to align with seasonal changes), and the subsequent alterations to reporting would lead to a richer, more accurate data set on emerging pollutants. Similarly, through increasing the frequency of the reporting cycle, it is likely that actions and measures undertaken to tackle pollutants of

[522] Article 8b (3) of the EQSD (2013/39/EU) states: "In selecting the representative monitoring stations, the monitoring frequency and timing for each substance, MSs shall take into account the use patterns and possible occurrence of the substance. The frequency of monitoring shall be no less than once per year". As noted in EEA (2018) Chemicals in European Waters- Knowledge Developments- pesticide presence in surface waters largely corresponds to the growing season when a pesticide typically enters the water. As such, infrequent monitoring can often miss the presence of this substance in waters.

concern can be enacted more reactively- ultimately limiting the damage inflicted on the environment.

Economic impacts

Increased monitoring and reporting frequencies are expected to lead to an increased administrative burden on managing authorities, whilst also increasing costs related to gathering, analysing and sharing of necessary data. Currently, it is estimated that there are approximately 845 WL monitoring sites[523]. Assuming an increase of monitoring frequency to twice per year as stated above, this would lead total costs of approximately €9.7million[524] for the EU-27 for the current list of WL substances. However, any additional costs (compared to current WL monitoring costs) would be compensated by the decreased frequency in updating the list as well as through granting an extended period of time to assess the data from the first two years before updating a list. Furthermore, collecting enough data for a risk assessment in the suggested timeframe will also allow substances that do not pose a significant risk to be efficiently removed, thus reducing unnecessary costs and focusing on substances of importance. Ultimately, it is reasonable to assume negligible/no additional costs to managing authorities.

Further costs will be borne by the Commission (and Parliament) for any comitology processes (stemming from promotion of WL substances to PS), yet this will be dependent on the results of increased monitoring frequencies on WL substances put forth for inclusion in the PS list. The Commission will also be required to enter consultations with MSs to agree upon defined monitoring frequencies and review cycle periods, which will involve insignificant costs.

Impacts on other stakeholders would be dependent on the prioritisation of pollutants from the watch list to the Priority Substance list. Costs can be somewhat offset by the use of innovative monitoring approaches, as noted under Option 1a.

Social impacts

Regarding broader societal impacts, it is estimated that enhanced monitoring of watchlist pollutants would increase the likelihood of substances prioritisation, and subsequent implementation of measures to minimise their impacts. No labour impacts are expected on managing authorities, as current monitoring/reporting procedures will be continued. Allowing greater time to process data before updating the WL is likely to lead to greater accuracy in identifying substances which may pose significant risk, ultimately resulting in the implementation of measures to address such substances to the benefit of water quality status and related human health.

8.4.3 *Policy option 3: Harmonising and simplifying reporting mechanisms*

[523] Taken from: JRC (2018) Review of the 1st Watch List under the Water Framework Directive and recommendations for the 2nd Watch List. Note- this includes the UK, but a number of MSs are missing data, therefore this is considered the best estimated of the number of monitoring sites in the EU-27.
[524] Using substance sampling and analytical costs from: EC (2011) SEC Impact Assessment amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy , adjusted to 2022 EUR values.

Option 3a: Establish an automated delivery mechanism for the EQSD and the WFD

MS authorities make significant efforts to monitor numerous quality elements for ecological and chemical status of water bodies under the WFD. However, there is a lack of organization and accessibility of the available data, as MSs maintain their own data sources. Therefore, data points cannot be easily compared, and are not aligned in terms of spatial coverage and temporal trends. To improve the consistency and comparability for data acquired across MSs, data needs to be harmonized and of a uniform quality. The alignment of data monitoring and reporting standards would allow for effective introduction of data-harvesting mechanisms. This is particularly relevant in reference to monitoring networks that should be established for spatial coverage and considering the growing technological innovation in water monitoring and to facilitate the progress towards digitalisation. Existing datasets that are already available in MSs in relation to environmental spatial and descriptive data are already covered by the Inspire Directive, the Open Data Directive[525] and by the Access to Environmental Information Directive which require the disclosure of existing data. The aim of the option is to strengthen these already existing reporting obligations so as to ensure more frequent accessibility of monitoring and status data and show intermediate progress, moving away from active reporting every 6 years. The option sets forth that significant efforts be made to streamline reporting, which in the long-term will be compensated by reduced administrative burdens for reporting efforts. Digital reporting has become standard practice in daily life in many policy areas, and should therefore also be routinely possible under the WFD. An ‘automated data delivery mechanism’ will minimise any potential administrative burden and long-term allow for better data comparability, use and analysis.

The option takes inspiration from the recently successfully implemented Information Platform for Chemical Monitoring (IPCHEM)[526]. The European Commission designed, developed and promoted IPCHEM with the aim to offer a unique access point for discovering and accessing chemical monitoring datasets created and/or managed by European Commission bodies, research centres, MSs, international and national organisations, while respecting national and European requirements about intellectual property rights[527]. One of the main challenges in this context was the notion on how to handle and describe the data quality, since the definition of what data quality itself means, and what is good and bad, differs significantly between data producers. IPCHEM made clear that prior to data-harvesting a common understanding regarding data quality has to be established in order to actively access heterogenous data across MSs.

Hence, the option proposed for the assessment here takes a two-step approach:

[525] The directive on open data and the re-use of public sector information (a.k.a. Open Data Directive) foresees, via a future implementing act, of a list of high-value datasets to be provided free of charge. These datasets, focused on six thematic categories described in the Annex to the Directive, have a high commercial potential and can speed up the emergence of value-added EU-wide information products. The thematic categories ‘1. Geospatial’ and ‘2. Earth observation and environment’ are the categories for which the biggest synergies are to be expected.

[526] IPCHEM (2021) IPCHEM - the Information Platform for Chemical Monitoring https://ipchem.jrc.ec.europa.eu/

[527] Comero et al. (2020). A conceptual data quality framework for IPCHEM – The European Commission Information Platform for chemical monitoring. TrAC trends in analytical chemistry, 127.

1. Develop data quality standards and conceptual frameworks to be implemented by MSs

In order to enable the development of a data quality framework for the progress in data-harvesting, it is necessary to disclose existing monitoring data and the exceedances of pollutants across MSs. A common starting point would be WFD Annex V, where MSs are asked to monitor PS in SW once every month and GW once every year, but are not required to report detailed data to the Commission. In line with the recommended monitoring frequencies of Annex-V it is therefore to be expected that MSs have much more detailed information in their national databases, compared to what is reported. Since these data points are required by the WFD, implementing data harvesting would ease administrative burden by reducing reporting load. Development of data quality standards will in all cases heavily rely on MSs cooperation to disclose relevant data to the Commission and relevant institutions to assess the needs for harmonization. The databases would be made available electronically. Important to note is that under the INSPIRE Directive, effectively in force since 2015, MSs are requested to disclose existing environmental spatial and descriptive data, and thus, there should be no significant additional costs incurred in this process.

2. Use existing infrastructure to grant remote access to data sources for the establishment of a common information platform

Once data quality assurance and control mechanisms are in place the automated data flow can be tested and established on existing infrastructure tools, including for example REPORTNET 3.0. The use of an established control and validation system, along with the automated access, could significantly save administrative resources for MSs in the long term.

The option is closely linked to Policy Option 8. In this process of establishing data-harvesting mechanisms, at the same time, the assessment of the River Basin Specific Pollutants (RBSPs) should be moved from ecological status to chemical status. This would increase the logic of the chemical status assessment. Harmonisation of EQS for national river basin-specific pollutants (RBSPs), would increase the internal consistency of the legislation. By converting RBSPs from quality elements supporting the assessment of ecological status into individual data point contributions part of the chemical status assessment, the comparability between Member States could be increased. Making RBSPs part of the chemical status assessment would not change the final outcome of the overall status assessment, but merely ensure that similar approaches are taken to all chemical pollutants and would facilitate an increased understanding of the reasons for failure and thus of the potential measures to be enforced.

Environmental impacts

Evidence-based environmental management requires that data is sufficient, accessible and useful. Therefore, the most accurate and recent data on water conditions and parameters is essential in assisting decision makers in quickly responding to emerging concerns and invest the appropriate resources to mitigate risks and improve environmental protection. Improved decision-making on water bodies can be expected to produce improved environmental impacts over time.

The development of a comprehensive knowledge base will also enable assessment on the pollution levels, toxicity and risks to environmental health. In addition, the monitoring data can help provide baseline information for key data points known to be of importance but where further information is currently unavailable including: spatial trends of substances, temporal trends of substances, presence and concentration of substances especially those of emerging concern, and assessment of trans-boundary relations and interactions. In addition, the data allows for assessing the effectiveness of current regulatory frameworks in place, and evaluating the effectiveness of measures taken to achieve good status of water bodies. As such, the option could have significant positive environmental impacts through the accessibility of knowledge and empowering more protective actions to be taken.

Economic impacts

In consideration of the fact that most data being requested for harvesting should already be monitored and reported by MS internally, through the WFD, the INSPIRE Directive and the Open Data Directive, the costs for implementing the option are expected to be largely administrative and IT-related. Estimates for monitoring and reporting under the INSPIRE implementation have been reported in the range of €33,000 to €67,000. The cost estimated for step 1 and 2 below are additional costs that would be incurred, but represent conservative estimates.

In the first phase of the option, the main costs will stem from two components: the development of the data standard quality framework and the cost for reporters to align their current system with the new harvesting-friendly framework. There are already a few examples where data harvesting is used for EU reporting obligations, such as for air quality data and the European Marine Observation and Data Network, and the Structure Implementation and Information Frameworks (SIIFs) and the INSPIRE Directive already aims to tackle issues on harmonisation. Along with a number of WFD related guidance documents as presented in the baseline, there is sufficient existing knowledge and understanding to develop a data standard quality framework for data-harvesting. We estimate the cost of developing a standard quality framework to be up to €290,000 – similar to a simple guidance document.

The second step relies on using existing infrastructure to assist in aggregating the data into a centralized repository. Annual IT costs for the EEA are estimated at €100,000[528]. For setting up the data flow, testing its functionality and supporting maintenance, the EEA estimated a one-off cost of €50,000 followed by maintenance and reporter support (i.e. an existing help-desk) at an annual cost of €10,000[529].

Once a framework and a dissemination platform are in place, MS will need to ensure that their data reporting is aligned with the quality standards in order for data-harvesting to be successful. This will require reporting authorities to assess their current formats, and adapt their reporting to the new framework. For data aggregation under the HBM4EU project, it was estimated that partners making their data available had to invest 2-5 days to adjust data

[528] Average cost of 1 FTE EC staff for the development and maintenance of IT systems
[529] Personal communication with EEA, 17.03.2022

reporting[530]. However, exact costs cannot be estimated as the amount of time invested would depend on the amount of parameters that will be collected under this option.

It needs to be kept in mind that the cost for MS reporting authorities can only be determined once the quality standard framework has been developed and MS can assess their total time investment needed for adapting their data reporting. Thereafter, there are also likely to be costs for the maintenance of the new IT system. For example, the German Federal Environmental Agency estimated an annual investment of €100,000 for the maintenance of the reporting system of the E-PRTR and IED.

Concern about the possible costs that would fall on MS was also expressed during consultation by MS authorities, for the possible additional reporting burden that would come from both the initial data harmonization to the quality standard framework, as well as long-term maintenance costs of the harvesting data base.

Key benefits of data harvesting over current processes are that it can provide access to large volumes of information, including raw data, which could enable more powerful / in-depth analyses and greater potential for multipurpose use of the data; and enable more frequent, in particular real-time, reporting[531]. The facilitation of the information access will reduce the overall administrative burden, as well as the amount of outsourcing in support[532]. Most significant, however, will be the cost savings incurred by MS: administrative burden related to fulfil reporting requirements would be significantly reduced as steps in relation to processing, quality checking and transmission of data would be handled through the standard quality framework in place and the data-harvesting. Reporting obligations in MS authorities related to a number of legislations in place have been reported to range between €100,000 to €1 million[533]. With the WFD making a significant contribution to costs in monitoring and reporting obligation, the data-harvesting mechanism is likely to significantly alleviate administrative burdens experienced by MS.

Provisioning and use of adequate information are central in to effectively making investment decisions into water infrastructure, confirming environmental regulatory compliance, encouraging innovation and making rapid and effective decisions in cases of contamination and health risks. It furthermore assists MS in achieving good status for water bodies within the targets of the WFD. The benefits of good ecological status achievement for all European water bodies are estimated to be €2.8 billion a year. As such, the option has the economic benefit that it can assist in better planning of monitoring and mitigation actions, improving resource efficiency for MS and could help meeting many of the future reporting objectives.

The option also improves the timeliness of information provision. Informed decision making for MS, and sharing of data and analytical methods is likely to produce significant cost savings

[530] Personal communication with VITO Data management for HBM4EU data, 30.03.2022.
[531] European Commission (2017). Support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation – Final Report. Luxembourg Publications Office of the European Union.
[532] European Commission (2017). Support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation – Final Report. Luxembourg Publications Office of the European Union.
[533] European Commission (2017). Support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation – Final Report. Luxembourg Publications Office of the European Union.

to MS. However, for many reporting obligations not updated on continuous basis the feasibility of harvesting is limited. Furthermore, cooperation of MS to meet reporting obligation deadlines is critical to ensure that automated data harvesting can be conducted. Previous assessments have shown that over-emphasis on adopting data harvesting approaches presents a risk of creating a supply- instead of demand driven structure of reporting[534] (i.e. simply all data is collected and set up for harvesting without considering the need to harvest or the appropriateness of the specific data points to further analyses). As previously stated, harvesting will also have an initial cost and a maintenance cost of data quality and IT systems. Benefits of reduced administrative burden and cost-savings can only be incurred by MS if data-harvesting is applied in consideration of the legislative obligations (including across legislative instruments), the data type and the ultimate purpose and use of the harvested data. Overall, stakeholders expressed strong support to standardise and harmonize data quality, and for the transition to data harvesting both in the OPC and during the workshops.

Social impacts

The option improves public access to information, participation and access to justice, which indirectly empowers stakeholders to influence environmental performance ambitions and pressures to implement measures. However, the option is unlikely to have significant impacts on employment in the EU.

Fast and reliable access to data has various benefits on a social level, strongly linked to the environmental benefits of risk management and effective decision making in case of health risk. The responsiveness to pollution risks can be significantly improved if data are consistently harvested and reported in near-real time to centralized data sources accessible to local and national authorities. As such, the option could have significant positive impacts on risk management for protection of human health.

The standardisation of data collection and reporting will have the primary benefit of facilitating information sharing and comparability of data to provide more holistic overviews. Data harvesting will also enable public access to information in a user-friendly manner, and will be useful for the public's awareness as well as research and assessment studies conducted in private and public sectors. Access to information can also assist public authorities at local scales take measures and protective actions where necessary, should reporting values indicate risks of human health. In addition, standardization and aggregation of data will allow for benchmarking within MS water bodies as well as across MS.

Achieving standardised data is not only important for smart information systems, but also to facilitate data sharing practices between governments, policy fields, actors and industries. Standardisation of data will also allow for better benchmarking between MSs, giving the ability to detect poor performers and enforcements on these to improve the conditions of water bodies.

[534] European Commission (2017). Support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation – Final Report. Luxembourg Publications Office of the European Union.

Option 3b: Introduce a reference list (repository of standards) of environmental quality standards (EQS) for RBSPs as an annex to the EQSD, and incorporate RBSPs into the assessment of chemical status for surface waters

Besides the Priority Substances included in Annex X of the WFD, MSs need to identify pollutants of regional and local importance from the types listed under Annex VIII of the WFD. EQS are then set for these river basin specific pollutants (RBSP) by each MS. As mentioned in the baseline, the Fitness Check noted that the RBSP variability is wider than could be explained by any location-specific conditions.

This option aims to provide a repository of standards for all EQS applied to RBSPs (including delisted PS) once they have been agreed at EU level. This option also includes the suggestion to make RBSPs part of the chemical status assessment and not of the ecological status. Currently MSs have identified between 2-100 substances as RBSPs, because MSs have the discretion to identify and establish EQS for pollutants of national concern as part of ecological status- resulting in significant variation in EQS between MSs. The repository would assist MS (in collaboration with the JRC) in deriving EQS, in turn allowing EU standards to be developed and included in the repository following adoption by comitology. MS would be obliged (through a provision in the EQSD) to use those EQS to decide whether to designate substances as RBSPs, and to assess status. This would align with the proposal under the Chemicals Strategy, under which a repository of standards will be developed. This repository should also include the delisted substances and their EQS since several of them will remain relevant as River Basin Specific Pollutants (RBSPs). Transferring EQS for delisted substances to a common repository of standards would ensure that knowledge remains accessible to MSs and stakeholders to facilitate quality assurance and measures for RBSPs at the level of individual River Basin Districts (RBDs).

Environmental impacts

The option is focused on harmonising EQS for RBSPs. Therefore, the environmental impact of the option is ultimately dependent on the EQS being set. However, the harmonisation of the EQS across MS will allow for greater coherence in risk assessment and management. Previous research has shown that there was a significant positive relationship between the proportion of monitored water bodies failing to achieve good status within the RBD and the number of RBSPs identified and regulated through EQSs in the different MS[535].

Considering that the range of the number of RBSPs and their EQS's assigned across MS are highly variable, harmonising the substances considered as RBSPs could have a significant impact on the environmental protection of water bodies. For example, bentazone, a pesticide component, is considered an RBSP with relevant EQS in 14 MS. Yet the EQS significantly differ (from 0.1 µg/L in Luxemburg to 80 µg/L in Portugal). A harmonisation approach would not only require the monitoring of bentazone in an additional 13 MSs, but would also require an agreed value for the EQS (as well as a uniform approach for derivation) - dependent on how many MS allow the use or are affected by transboundary pollution. As

[535] WRc (2012) Comparative Study of Pressures and Measures in the Major River Basin Management Plans' - Task 2c (Comparison of Specific Pollutants and EQS): Final Report. Available at: https://ec.europa.eu/environment/archives/water/implrep2007/pdf/P_M%20Task%202c.pdf

such, the option could have significant environmental benefits, particularly in water bodies with RBSP that are transboundary. The option is therefore considered important to improving risk management.

Using the RBSP database compiled in 2012, we estimated the total impact on the scale that the RBPS alignment might have[536]. A total of 307 RBSPs had been identified in rivers and lakes at the time, for which a variable number of MS had set EQS. For the 307 substances across 27 MS there were only a total of 614 and 636 EQSrecorded in lakes and rivers respectively. Assuming that all MS would require reporting on this list of RBSPs in case they are present/pose a significant concentration concern in national water bodies, the total number of reported values would lie at around 8289. This signifies that only 7% and 8% of the total scale of RBSP reporting is currently being done in the EU. Over 90% of data on RBSP's across the EU is therefore missing. Harmonizing the identification of RBSPs across the EU would affect all MS, but would significantly improve environmental assessments and protection. Considering that the current RBSPs in place are currently detected in 4 782 water bodies out of 146,510 water bodies (out of which 2172 are in poor or bad ecological condition), obligating an EU wide reporting on RBSPs would likely reveal that significantly more water bodies are at risk.

RBSPs in chemical status would likely result in a change to the measures implemented by MSs to achieve good status under the legal framework of the WFD. The set EQS would need to be met for the water body to reach good status and thus require (more) efforts to implement mitigation and control measures if the substance was not previously designated as a RBSP or the EQS is stricter. More stringent measures to address RBSPs would have a positive impact on the health of ecosystems and likely improve the environmental protection that aquatic ecosystems receive. The move from ecological to chemical assessment for the RBSPs might reveal some water bodies as being in good ecological status. In others, where other factors are responsible for the poor ecological status, the move of RBSPs from ecological to chemical status would allow for a clearer overview of which ecological status parameters remain poor and help focus measures on the non-RBSP physico-chemical elements and biological quality elements that require further attention.

Setting an agreed EQS to RBSPs under chemical assessments would likely cause a significant number of additional water bodies to fail good chemical status. Considering that on average only few MS currently set RBSP EQS's, yet over 50,000 rivers and lake water bodies are currently failing to achieve good chemical status (as per 2018 data), RBSP EQS's could have a significant impact. The total scale of additional water bodies that would fail good status would only be possible to assess once baseline data on RBSP concentrations were available and EQS were determined. However, it can be said with confidence that aligning the RBSPs and setting EU wide EQS will have an impact on the types and extent of measures that MS will need to implement, and as such a strong positive impact on the environment.

Another reason for the potential environmental benefits is that chemical and ecological status are subject to different treatment in the context of the provisions outlined in Article

[536] https://ec.europa.eu/environment/archives/water/implrep2007/background.htm

4(7) of the WFD, although the comparison between the first assessment made after moving the RBSPs should be made based on the previous arrangement, i.e. a decrease in chemical status resulting only from the move of RBSPs so that status assessment should not be considered deteriorating.

Economic impacts

The economic impact of creating a repository of RBSPs would be rather minimal, as the component is mostly administrative and mainly relies on existing information and infrastructure. The most significant economic impacts are likely to stem from the harmonization process for the establishment of EU-wide EQS, and the impact of incorporating RBSPs into the chemical assessment. To harmonise the EQS there would likely be costs for the Commission as well as MS.

A study on the EQS standards and their variability showed that while technical guidance on methods for deriving EQSs exist since 2011, only few EQS were based on the publication of the EU guidance documents[537]. The study found that many EQS were set prior to guidance document implementations. Where values were established after, there were still significant differences in the derivation procedures, which complicates the comparison across MS. As such, we argue that RBSP EQS that would be implemented EU-wide would require additional methodology development for coherent and comparative EQS to be collected. These can be considered similar in costs to an elaborate guidance document, between €290,000 - €500,000 and would complement existing guidance. Additional hosting and maintenance costs are estimated to be minimal (i.e. 0.5 FTE costs as noted for the repository in option 1e- €50,000, plus €10-20,000 for IT consultancy/hardware required).

For MS representatives and the Commission to hold meetings, discuss and negotiate EQS to be set for specific RBSPs will require additional administrative costs. The estimated commitment reported in previous impact assessment on establishing specifications for substances under the surface water watch-list was 3 meetings per year, including 40 participants with additional 10 working days per substance[538]. We therefore assume that this would require a medium administrative service from Commission[539] and low administrative service from MS staff[540] as well as costs for support from external specialized consultants and experts[541]. Based on these assumptions we estimate that the annual cost of setting one EU-wide EQS for RBSPs would be around €373,112.

537 Aarhus University (2016) European Environmental Quality Standards (EQS) Variability Study. Danish Centre for Environment and Energy, 198.

538 EC (2012) COM, 876 final, Impact assessment on amending Directives 2000/60/EC and 2008/105/EC as regarding priority substances in the field of water policy.

539 Medium administrative services are estimated at 50% of 2 employees over 12 months using average FTE cost for Commission staff, which equates to EUR 114,132 as per 2020 Annual update of the remuneration and pensions of the officials and other servants of the European Union and the correction coefficient applied thereto: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC1211(01)&from=EN

540 Low administrative services are estimated at 10% of 2 employees over 12 months, using average FTE cost for MS staff, which equates to EUR 8980 as per Eurostat Labour cost, wages and salaries, direct remuneration (LC_NCOST_R2)

541 We assume a fixed amount for external specialized assistance activity, based on the consortium consulting experience, of EUR 250,000

The regulatory burden and associated costs that come from comitology remain unclear, as there seems to be no transparent reporting information regarding the administrative burden and costs associated to the procedure[542]. As such, the extent to which comitology will impact overall costs cannot be confidently calculated, but the additional costs that would occur during review cycles should be kept in consideration.

For MS, an average cost of monitoring for PS based on sampling, analysis and monitoring was determined at €1.7 million in 2012[543], equalling €1.9 million in 2022[544]. However, these are costs estimated for substances routinely monitored and analysed by MS. There is a need to consider development and adaptation costs for the substances that would be newly implemented as RBSPs, as they may not be analysed on a routine basis in most MS. If the types of substances are similar, the analytical techniques are frequently the same, so the costs may not differ substantially. As such, it can be assumed that setting an EQS will cost MS *at least* an additional €1.9 million per RBSP. The exact monitoring costs will depend on frequencies of sampling and whether similar analytical techniques are already implemented in the MS for other similar substances. MS with little to no RBSP monitoring will likely have the largest cost-burden to bear.

Taking the example of one specific compound, we return to bentazone, where 14 MS currently implement an EQS. A recent assessment[545] showed that only 2 of the 14 countries has used the Technical Guidance Document developed no. 27 for deriving the EQS (EC, 2011). Other countries used different methodologies to develop their values. This also highlights the need for there to be the repository of standards to be accompanied by clear methodologies of derivation practices. If an EU-wide EQS was set, an additional 13 MS would require sampling, analyses and monitoring, which would total an additional cost of €22.1 million. If the EQS set was below that used by the existing MS, it would conflict with national legislation and require the enforcing of stricter measures, hence incurring additional cost also to those MS that already have EQS.

During the workshop stakeholders expressed concern for the application of contrasting RBSP values, and highlighted that the context specific setting of water bodies would nationally influence the RBSP that was acceptable. Hence the major concern related to the etsbalishment and setting of EU-wide EQS. The OPC revealed that setting a reference list for RBSP as well as recommended EQSs received mixed support by stakeholders, with those strongly for and strongly against evenly split. However, there was consensus that harmonisation of RBSPs and the approaches taken to establish them would be important and necessary

[542] Clingendael (2014). Comitology ad regulatory burdens – a blind spot? Policy brief. Available at:https://www.clingendael.org/sites/default/files/pdfs/Comitology%20and%20Regulatory%20Burdens%20-%20Mijs&Schout.pdf
[543] EC (2012) COM 876 Final- Impact assessment on amending Directives 2000/60/EC and 2008/105/EC as regarding priority substances in the field of water policy.
[544] Eurozone inflation calculator https://www.inflationtool.com/euro/2012-to-present-value?amount=1700000&year2=2022&frequency=yearly
[545] Aarhus University (2016) European Environmental Quality Standards (EQS) Variability Study. Danish Centre for Environment and Energy, 198.

Costs to MS regarding measures that would need to be implemented to address the impact of RBSP EQS can vary significantly and will depend on the local conditions as well as the baseline of the existing RBSP and, ultimately, on the EQS that is decided upon. It is thus not possible to accurately assess the cost to MS authorities as well as bussinesses due to the uncertainties in the extent of exceedance of the EQS in different MS given the limited monitoring coverage and often differing analytical sensitivity, but also from the absence of information on production and source of specific pollutants.

By harmonising the EQS for national river basin-specific pollutants (RBSPs), where necessary, and including the RBSPs in the assessment of chemical rather than ecological status, the comparability between Member States can be increased. This will expectedly have only limited impacts as making RBSPs part of the chemical status assessment would not change the final outcome of the assessment of the status of the water body as a whole, since that comprises both chemical and ecological status. Such a measure would however ensure that similar approaches are taken to all chemical pollutants (whose effects on human health as well as ecosystems should be considered in all cases) and would facilitate a better understanding of the reasons for failure and thus of the measures to be enforced. Note that in the first assessment made after the move of the RBSPs, needs to be done based on previous assessment methods, in order to not let the move of RBSPs decrease the chemical status of the water body. Thus, the first assessment after the move, will be the most complex, and therefore administratively costly, due to the additional analytical considerations.

If chemical assessment status' result in failures (due to changing from ecological assessments), programmes of measures are likely to require waste water treatment plant upgrades, restrictions on pesticide use, switch to alternative chemicals/ controls or abatement of current manufacturing, and further waste processing stages. This would impose additional costs to businesses and industry to ensure that they control the output and therefore the overall threshold level of the designated RBSPs. Nonetheless, the measures that will need to be taken in response also have a key benefit, in that they are likely to drive innovation, both in the processing and cleaning of water effluents as well as in businesses and industries that release pollutants.

The change for RBSPs from ecological to chemical assessment is likely to cause additional administrative burden to be placed on MSs to collate and report data, whilst further obligations will be required to improve the coherence of data through bilateral discussions, formation of sub-groups for specific substances, and formulating legislative approaches at national level. Furthermore, depending on the status of EQS established (particularly significantly lower thresholds) would require improved analytical procedures, which would create cost burdens for MS including those that already have set EQS.

However, some of the cost will be mitigated by the repository- whereby harmonisation of approaches to monitoring will be undertaken. Further cost efficiencies can be expected through the process of incorporating RBSPs into chemical assessments (and identifying EU-wide EQS)-improving the transparency and coherence of RBSP monitoring throughout the EU, ultimately leading to sharing of best-practices and standardisation. This could lead to resources saved by MS. In addition, the move of RBSPs to chemical status assessment would simplify monitoring and reporting procedures for MS.

In conclusion, the implementation of the reference list itself and change of RBSPs to chemical status are likely to have minor costs. However, the consequent setting of agreed EQSs and the measures that will need to be taken to maintain water bodies below thresholds and achieve good chemical status will have significant economic impacts on MS authorities as well as businesses and industry. The total scale of the economic impact can only be assessed on a case-by-case basis of the determine RBSP EQS and the monitoring standards determined. All in all, a change will be beneficial for facilitating a better understanding of the reasons for failure and thus a better understanding of the potential measures that might need to be taken and enforced to achieve a good status overall.

Social impacts

The option is likely to have a mixed effect on employment he EU, of which the net impacts cannot be calculated at this stage. They will depend largely on the RBSPs selected and EQS set, the sectors that are most affected and the measures needed to address the substances.

Similar to environmental impacts, the option could have significant impacts on social well-being and protection. Key social benefits of uniformly monitoring RBSPs and setting standard EQSs will lead to improved status of water bodies for recreation, culture and health (especially regarding bathing and drinking water). The option would also directly assist in data aggregation for the Drinking Water Directive and the Bathing Water Directive, and ensure secure use of water resources for local communities.

8.4.4 *Policy option 4: Legislative and administrative aspects*

Option 4a: Use annex in the EQSD instead of Annex X to the WFD to define the list of Priority Substances, and consider a provision to update it by comitology or delegated acts

Annex X of the WFD was the original annex setting out the PS list, which was later replaced by the Annex II of the EQSD and most recently revised into Annex I of the EQSD. Annex I sets out the specific EQS for Priority Substances in surface waters listed under Annex X of the WFD. In order to enable a more flexible process and swift reaction to emerging risks, the Priority Substances list needs to be more regularly revised and updated, in order to reflect new scientific insights more quickly.

Currently, the revision of the Priority Substances occurs every 4 years (WFD Article 16(4)). However, amendments to Annex X and the EQSD require the revision of the regulation, which further requires the adoption by the European Parliament and Council (WFD Article 16(11)) thus taking significant time and effort. This option aims to introduce a provision into the WFD that would allow an annex in the EQSD, instead of Annex X of the WFD, to define the Priority Substances. An additional provision would set forth that by means of comitology or by means of delegated acts[546], the EQSD would therefore update Annex X of the WFD (and Annex I EQSD, i.e. references to Annex X WFD would be understood as references to Annex I EQSD). This option would avoid the requirement to alter provisions and the legal text in the WFD when updating the PS list, and (separately) allow the Priority Substance list to be amended through comitology more easily and more frequently. Hence, the option would allow PS to better reflect newest knowledge and scientific developments.

Environmental impacts

Positive environmental impacts stemming from option 7 can be expected, largely linked to the increased reactivity of the Priority Substance list to recent data outputs. This would be particularly pertinent for contaminants of emerging concern (CECs), but also helpful in relation to other pollutants, because the list could be updated more quickly, ensuring quicker actions to reduce pollutant presence in water bodies. To act on emerging substances more easily could have significant benefits to the environment, as the reaction time to include hazardous substances could be improved and allow for measures to be quickly taken. The option would link well with option 2 on EBM and EDA implementation, as the information obtained from such methods would help inform the inclusion of substances into the PS.

Economic impacts

The cost of the option being enacted would largely be administrative. However, costs relating to the addition of new PS substances will likely be incurred by MS and economic actors, but the scale of costs will need to be assessed on a case-by-case basis.

Revisions through delegated acts of comitology would reduce the administrative burden associated to the revision of Priority Substances. While changes to the annexes require involvement from the European Parliament and Council, delegated acts would reduce the overall involvement. Delegated acts allow amending, supplementing, or deleting non-essential elements of basic legislative acts and allow EU legislators to delegate power to the Commission to adopt non-legislative acts of general application. While these changes are nevertheless subject to communication to the Parliament and the Council, which retain a right to revoke or express objection, there is significantly less involvement of both. The procedure would also not incur transposition costs for MS for changing the list. However, the exact cost of comitology remain unclear[547]. Nonetheless, the delegated act would significantly reduce the costs related to the revision of PS, and furthermore not incur any transposition costs for MSs for changes to the list. The revision of the Priority Substances could therefore go from every 4 years, to every 2-3 years in reflection of findings in the surface water watch-list and other scientific insights.

In relation to economic actors (particularly businesses, heavy industry), there are expected costs due to the requirement to innovate faster to align with the increased speed in which

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[546] further to Lisbon Treaty the comitology procedures have been reconfigured resulting in the 'delegated' acts procedure for amending nonessential elements or supplementing existing legislation in addition to 'classic' comitology for implementing acts

[547] Clingendael (2014) Comitology ad regulatory burdens – a blind spot? Policy brief. Available at:https://www.clingendael.org/sites/default/files/pdfs/Comitology%20and%20Regulatory%20Burdens%20-%20Mijs&Schout.pdf

the PS list is updated. It the event that new substances are added to the list, such actors will need to implement actions to find alternative substances/reduce emissions/retrofit installations.

The recent impact assessment on the Urban Waste Water Treatment Directive considered the implementation of measures for the extension of more stringent treatment to treatment plants to deal with micropollutants, which would consequently lead to a need for plants to upgrade and retro-fit treatment equipment in order to meet the more stringent requirements. The study found that the costs for upgrading plants to take additional measures against pollutants ranged from €360 million for low ambitions up to €2 billion for very high ambitions for all plants in the EU 27[548]. More frequent addition of substances to the PS list may therefore impact actions that treatment plants need to take to address pollutants and therefore drive-up costs. However, the impact assessment also noted that the implementation of additional measures to remove pollutants would lead to more innovation in technology and encourage the development of more suitable monitoring and analytical methods, thus contributing to knowledge on emerging pollutants.

This would for example boost a continuous improvement of existing analytical methods and help improve the analytical limits of existing methods used in MS laboratories.
This can potentially be further increased by a continuation of existing practices, encouraged by the European Commission, to facilitate the sharing of experiences and best practices between Member States on the use of adequately sensitive methods.

Results from the inclusion of the hormones on the surface water watch list have for example demonstrated that Member States laboratories are capable of monitoring them.

The impacts of this (due to the results of faster listing and integration of new PS and respective EQSs) could mean that actions and measures to reduce the emissions and impacts of substances must be taken sooner, increasing short-term costs for MSs. However, the push for quick response for taking measures may also incentivize businesses to innovate sooner as well as other (sectoral) legislation to be adapted to reflect taking measures.

Social impacts

Enhancing the response rate of Priority substances would increase the rate of responses to risks and subsequent implementation of measures to minimise their impacts. As such, this is likely to derive societal benefits through the improved status of water bodies (recreational, cultural and health impacts). Further benefits can be expected to employment through the need to retrofit facilities/ innovate technologies to compensate for the greater speed in which pollutants are added to the PS list.

[548] Wood et al (forthcoming) Impact Assessment on the Urban Waste Water Treatment Directive.

Option 4b: Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of PS/PHS. *(Pesticides: Aldrin, Dieldrin, Endrin, Isodrin, DDT (all to PHS); Industrial chemicals: Tetrachloroethylene, Trichloroethylene (to PHS), Carbon tetrachloride)*

The creation of the EQSD replaced the previous legislation (the DSD) covering risks to surface water from chemical pollutants. The DSD used a similar approach to the EQSD to identify chemicals of EU-wide concern and designated concentration limits. At the time the EQSD was created all existing substances on the DSD as well as emerging concerns were reviewed to create the first priority substance list of 33 substances. A further eight substances which already had EQSD thresholds under the DSD were retained but as footnote 7 to the Annex in EQSD highlights these substances are not formally recognised as priority substances and have no legal impacts for chemical status.

This creates confusion with WFD Article 16.7. Their existing EQS monitoring feeds into surface water chemical status assessment. The results of the assessment show that seven out of eight substances either a) are covered by Regulation (EU) 2019/1021 on persistent organic pollutants (the POPs Regulation) obliging MS to put into place and maintain inventories for such substances; b) show EQS exceedances in freshwater (no declining emission trends); or c) are covered by the DWD.

Therefore, these substances should be recognised as PS to avoid incoherencies with other EU legislation. Specifically, this concerns the cyclodiene pesticides (Aldrin, Dieldrin, Endrin and Isodrin), DDT, Tetrachloroethylene and Trichloroethylene. Marking them as PS will create greater policy coherence, help track their presence in water and inform subsequent risk assessments.

Furthermore, it is not clear why some of these substances have not been designated as PHS67 under Annex II of the EQSD. Aldrin, Dieldrin, Endrin, Isodrin, DDT are POPs and Trichloroethylene is SVHC, hence fulfilling the criteria for PHS status. The result of that is that most of them (all except of carbon tetrachloride) are Persistent Organic Pollutants (POPs) or should be marked as priority hazardous substances for other legislative or toxicological reasons. Consequently, with the exception of carbon tetrachloride which is proposed for deselection (see SW option 4), all substances should be formally recognised as PS under EQSD Annex I and some also as PHS under Annex II. Assigning PS/PHS status is merely an administrative change without further negative impacts, but formalisation is preferred to continue their monitoring.

Environmental impacts

Seven of the eight substances are already identified as either being POPs or SVHCs. This means for the POP substances (e.g. Aldrin, Dieldrin, Endrin, Isodrin and DDT) there are already pre-existing obligations under the POPs Regulation to limit their use and emission into the environment. Where EQS have already been defined, designating these substances as PS/PHS would strengthen the environmental response to their management and further protect the environment.

Economic impacts

Where the seven POP/SVHC substances already have EQS moving them to become PS/PHS should be straightforward and merely administrative, with no additional costs entailed. This is true at least for the formal process of recognising them as PS/PHS within the annexes to the EQSD. For those substances listed within the annex that carry an EQS there is an expectation upon MS that monitoring will be undertaken to determine chemical status and where necessary intervention (programs of measures) applied. For the eight other substances, it is less clear how much monitoring is actually undertaken, and where they have no direct impact on chemical status the current approach at MS level. It is possible that adding them as full PS/PHS could increase the costs of monitoring for MS, but given that the seven identified as POPs/SVHC are already covered by other legislation, adding them to become PS/PHS could also strengthen continuity and provide synergistic economic benefits (e.g. monitoring under EQSD could support obligations under the POPs Regulation).

Social impacts

Where the seven identified substances are either POPs or SVHCs, their potential impacts on the environment and human health are clear. Strengthening the response to these substances and improving continuity across environmental legislation would have clear societal benefits in terms of avoided environmental damage and human health impacts.

Option 4c: Change the status of some existing PS to that of PHS where it fulfils the criteria of the POP Regulation and/or Article 57 of REACH Regulation. *(Industrial chemicals:* 1,2-Dichloroethane, Fluoranthene, Octylphenol, Pentachlorophenol; *Metals:* Lead)

Since the last EQSD revision in 2013, five existing priority substances have been identified as PHS:

- 1,2-Dichloroethane is classed as SVHC under Article 57 of REACH Regulation.
- Fluoranthene PBT vPvB and is classed as SVHC under Article 57 of REACH Regulation.
- Lead is classed as SVHC under Article 57 of REACH Regulation.
- Octylphenol ethoxylates (OPEs) are toxic to aquatic organisms even at low concentrations and show endocrine disrupting properties. They break down easily to octylphenols which are more harmful, not readily biodegradable and meet the criteria for persistence or high persistence in the environment. Consequently, OPEs are considered as SVHC requiring authorisation for specific use in the EU according to Annex XIV of the REACH Regulation.
- Pentachlorophenol (PCP) is covered by the POPs Regulation.

Additionally, note the comments under the previous sub-option for eight other substances listed within the annex of the EQSD. As indicated seven of the eight substances are either recognised as POPs or SVHC substances. Under the criteria set out in Annex II to the EQSD, these substances should also be treated as PHS.

Based on the analysis completed here it is suggested that PCP should be moved to become a PHS on the basis that it is a POP under the Stockholm Convention (Annex C – which included obligations for water emission inventories). Fluoranthene should be grouped with the other

PAH substances and treated as a POP, based on the listing for PAHs under the Convention on Long-Range Transboundary Air Pollution. Lead should be moved to a PHS listing on the basis that other metals (cadmium and arsenic) are already PHS. 1,2 dichloroethane already has sufficient EU community level concern to become a PHS, and the two octylphenol substances are recognised under REACh as SVHCs. Again, following the criteria under Annex II would suggest a PHS listing is more appropriate.

Environmental impacts

As indicated in the previous text (above) all of the identified substances meet the criteria to be considered PHS, either by being recognised POPs, SVHCs, or having wide EU community level concern. Moving these substances to PHS would strengthen the response to how they are managed and fully eliminated from the environment which could be expected to have strong environmental benefits.

Economic impacts

All of the identified substances are either already PS or have EQS assigned. Moving them to become PHS is a purely administrative task which should not include significant additional costs. Monitoring is also undertaken already for the majority of the substances with no additional burden expected. One possible set of economic impacts could be the need for improved measures, but this would be consummate with the economic benefits derived from wider protection of the environment.

Social impacts

Where the substances identified are all long-term environmental pollutants with concern for environmental damage and human health impacts. Stronger action and control on the ambient concentrations have benefits both in terms of avoided impacts, but also enriching the aquatic environment as a resource for environmental services.

9 How do the options compare and what are the preferred options?

9.1 Surface water options

9.1.1 *Option 1: Review all substances (shortlisted by the COM) as individual additions*

Option 1 provides the impact assessment for the **addition of candidate substances to the priority substance list** individually, with the caveat that PFAS will be assessed as a group (due to the very large number of substances involved). The assessment has been based on the EQS dossiers and monitoring data to derive a distance to target, apply a dynamic baseline, and assess what measures might be needed to achieve good chemical status. The distance to target can be relatively large (67-100% expected exceedance), medium (33-66% expected exceedance) or small (0%-32% expected exceedance). Additionally, as part of the impact assessment consideration has been given to the economic, environmental, and societal benefits of adding the identified candidates to the priority list of substances.

-Table 9-1 provides the comparison table and assessment of the overall conclusions and preferred options. Very broadly the outcomes can be grouped into one of three categories, those candidate substances where the benefits of adding them to the priority substance list clearly outweigh the costs. Cases where the costs outweigh the benefits, and a middle category where the costs and benefits could be argued to be broadly even, or where the range is narrower, suggesting that overall, the addition of the substance to the priority substance list considers the costs and benefits are balanced. In these cases where the cost benefit is considered balanced it means that a clear set of benefits have been identified, and that the costs of addition are consummate with the benefits. This would suggest that addition to the priority substance list is still worthwhile but that there is a closer balance between the costs and benefits.

Based on this analysis the majority of substances fall into the first category where benefits outweigh costs, which helps validate the prioritisation of substances in the first instance. The neutral category is made up of a smaller set of substances (ibuprofen, nicosulfuron, clothianidin, bisphenol A, and microplastics). As an example, the costs of helping achieve good chemical status for bisphenol A are really very challenging, given that source control alone is unlikely to be sufficient and that management of diffuse sources as pathway disruption and end-of-pipe treatment will also be needed. However, again, considering the widespread use of BPA and other bisphenols and the fact that bisphenol A has been identified to have endocrine disrupting effects[549] for both humans (particularly on childhood development), and aquatic species, and where the monitoring data suggests the problem is widespread with a high level of exceedances geographically (distance to target is large), there are very strong benefits to addressing the issues. In this case it could be argued that

[549] EDS have significant health effects that already occur even at very low concentrations.

managing bisphenol A is ‘high cost, high benefit’, and therefore it belongs in the neutral category.

For silver the benefits and costs assessed are balanced (high cost /high benefit). In this case the distance to target was identified as ‘medium’, while the specific form of silver plays a key role in its bioavailability and impacts. Where there are multiple sources and pathways to environment including mine drainage, manufacturing, use of products, run-off, end-of-pipe treatment, it means that a very targeted plan of action will be needed on a Member State by Member State basis. This makes judging the actual costs challenging in itself, but it can be reasoned that where the issue will need to tackle both point source and diffuse emissions the package of measures will need to be comprehensive, and therefore likely balance the benefits identified.

Option 1 has assessed the candidate substances as individual additions. Further discussion on the possible application of grouping strategies is further covered in option 2.

Table 9-1 Option 1 options comparison and preferred option

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
Estrone E1	Medium	Chronic ecosystem level impacts from exposure to hormones and EDC effects can be avoided.	Some potential for source control and end-of-pipe treatment. Costs look broadly comparable with risk.	Potential avoided environmental impacts and human health via exposure through environment. Ecosystem benefits, included health of aquaculture and fishing.	Societal benefits from greater health protections, food security, and ecosystem services.	The benefits of addition to the PS list outweigh the costs.
17- Beta estradiol (E2)	Medium	Chronic ecosystem level impacts from exposure to hormones and EDC effects can be avoided.	Some potential for source control and end-of-pipe treatment. Costs look broadly comparable with risk.	Potential avoided environmental impacts and human health via exposure through environment. Ecosystem benefits, included health of aquaculture and fishing.	Societal benefits from greater health protections, food security, and ecosystem services.	The benefits of addition to the PS list outweigh the costs.
Ethyl estradiol (EE2)	Large	Environmental impacts for aquatic species likely stronger than the other two estrogenics, with clear benefits for avoided impacts. The EQSD dossier indicates risk of potential biodiversity impacts from concentrations above the EQS.	Cost of management would be challenging requiring a basket of measures likely at higher costs. Impacts on pharmaceutical industries if use is restricted / banned, and limited options for chemical alternatives.	Potential avoided environmental impacts and human health via exposure through environment. Ecosystem benefits, included health of aquaculture and fishing.	Societal benefits from avoided health impacts relating to EDC and carcinogen effects. Possible societal impacts from loss of use (contraceptive pill, HRT, hormone treatments if restricted/banned).	The summed benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
Azithromycin	Medium	Primary concerns relate to build up of antibiotics within the environment leading to anti-microbial resistance (AMR). Potential toxicological effects at elevated doses, likely to be site specific / hot-spots dependent on releases.	Very limited selection of alternatives, loss of macrolide antibiotics through restriction would lead to increased healthcare costs. Largely end of pipe measures only. But Ozonation is effective and costs already captured by Forthcoming revised UWWT Directive.	Avoided costs to healthcare from protections against the development of AMR within health settings.	Protection against AMR has clear societal benefits.	The benefits of addition to the PS list outweigh the costs.
Clarithromycin	Small					The benefits of addition to the PS list outweigh the costs.
Erythromycin	Small					The benefits of addition to the PS list outweigh the costs.
Diclofenac	Large	Highlighted as one of the highest concern pharmaceuticals for environmental impacts. Potential toxic effects on avian populations via surface water species.	Source control options look viable (range of alternatives); while end-of-pipe measures look consummate to risks. Note possible economic costs on pharmaceutical industry if restricted/banned but expect production to switch to alternatives.	Economic benefits for aquaculture from improved food quality. Improved ecosystem services from protection of the aquatic environment.	Societal impacts from loss of use /restricted use if controls implemented. Additional costs for society on willingness to pay and advanced WWTWs.	The benefits of addition to the PS list outweigh the costs.
Carbamazepine	Large	Population effects for aquatic species through impacts on fertility and reproduction (particularly crustaceans).	Source control options look viable (range of alternatives although care needed as patient-to-patient viability is unclear); while end-of-pipe measures look consummate to risks. Note possible economic costs on pharmaceutical industry if restricted/banned but expect	Economic benefits for aquaculture from improved food quality. Improved ecosystem services from protection of the aquatic environment.	Societal impacts from loss of use /restricted use if controls implemented. Additional costs for society on willingness to pay and advanced WWTWs.	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
			production to switch to alternatives.			
Ibuprofen	Medium	High volume use, with potential toxic effects for some aquatic species. This includes fertility effects (hormone levels) in fish.	Potential impacts from restriction/increased control of use. Including economic costs for manufacturers and retailers as alternatives are more expensive. WWTWs options more challenging and likely costly.	Economic benefits for aquaculture from improved food quality. Improved ecosystem services from protection of the aquatic environment.	Societal cost from loss/restriction of ibuprofen and increased costs for other types of medicine. Including prescription only medications.	Benefits and costs assessed are balanced. (Medium cost / Medium benefit)
Nicosulfuron	Small	Nicosulfuron has aquatic toxicity (particularly to flora) and concerns over carcinogenicity as a secondary poisoning issue. Environmental concentrations in decline over the last five years.	Primarily intervention relates to source control and pathway disruption. Chemical alternatives are available and in use (primarily glyphosate). Pathway disruption costs consummate with risks.	Economic benefits for aquaculture from improved food quality. Improved ecosystem services from protection of the aquatic environment.	Societal benefit from protection of exposure and secondary poisoning action as a potential carcinogen.	Benefits and costs assessed are balanced. (Small cost / small benefit)
Acetamiprid	Small	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider environmental concerns for terrestrial pollinators.	Wide-range of alternatives and options for source control, including biocidal use. Pathway disruption costs look reasonable based on the scale of exceedance. End-of-pipe would require GAC, which is costly. Impacts for manufacturers, farmers,	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts from exposure to Neonicotinoids.	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
			wastewater companies, and general public.			
Clothianidin	Small	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider environmental concerns for terrestrial pollinators.	Use as pesticide has ceased. Use as biocide ongoing. Pathway disruption costs may be significant. End-of-pipe technologies based on Ozonation. Costs could be considerable to manage run-off from biocidal use in field.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts from exposure to Neonicotinoids.	Benefits and costs assessed are balanced. (Small cost / small benefit)
Imidacloprid	Medium	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider environmental concerns for terrestrial pollinators.	No use as a pesticide, but ongoing use as a biocide including veterinary use for animals and domestic pets. Limited chemical alternatives, more significant cost and effort for source control or end-of-pipe.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts from exposure to Neonicotinoids. Societal impacts for domestic pets if use is restricted.	The benefits of addition to the PS list outweigh the costs.
Thiacloprid	Small	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider environmental concerns for terrestrial pollinators. Use as a pesticide and biocide now ceased. Could expect environmental concentrations to decline.	Environmental concentrations look stable despite use ceasing. Some use issues with emergency authorisations. Multiple chemical alternatives and options to manage as source control in a cost-effective fashion.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts from exposure to Neonicotinoids.	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
Thiamethoxam	Small	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider environmental concerns for terrestrial pollinators.	No pesticide approval but use as a biocide. Limited options for source control. pathway disruption not relevant. End-of-pipe would require GAC advanced treatment, likely to be costly.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts from exposure to Neonicotinoids.	The benefits of addition to the PS list outweigh the costs.
Bifenthrin	Large	Highly toxic to the aquatic environment even at low concentrations. Possible risk of population level impacts.	Limited chemical alternatives, meaning restriction / ban would likely mean loss of crop yield, or implementation of integrated crop management. Measures linked to source control and pathway disruption, with the latter set of measures carrying significant cost given distance to target.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts where these substances are identified as EDC. Avoided impacts on pollinators. Possible food security issues if loss of use without chemical/non-chemical alternatives in place.	The benefits of addition to the PS list outweigh the costs.
Deltamethrin	Large	Highly toxic to the aquatic environment even at low concentrations. Possible risk of population level impacts.	Use as both pesticide and biocide. Limited chemical alternatives, meaning restriction / ban would likely mean loss of crop yield, or implementation of integrated crop management. Will need a package of measures source control, pathway disruption and end-of-pipe. Costs likely to be significant.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts where these substances are identified as EDC. Avoided impacts on pollinators. Possible food security issues if loss of use without	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
					chemical/non-chemical alternatives in place.	
Esfenvalerate	Large	Highly toxic to the aquatic environment even at low concentrations. Possible risk of population level impacts.	Limited chemical alternatives, meaning restriction / ban would likely mean loss of crop yield, or implementation of integrated crop management. Measures linked to source control and pathway disruption, with the latter set of measures carrying significant cost given distance to target.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts where these substances are identified as EDC. Avoided impacts on pollinators. Possible food security issues if loss of use without chemical/non-chemical alternatives in place.	The benefits of addition to the PS list outweigh the costs.
Permethrin	Large	Highly toxic to the aquatic environment even at low concentrations. Possible risk of population level impacts.	Use as both pesticide and biocide. Limited chemical alternatives, meaning restriction / ban would likely mean loss of crop yield, or implementation of integrated crop management. Will need a package of measures source control, pathway disruption and end-of-pipe. The end-of-pipe options likely to be limited and costly (PAC advanced treatment) Overall costs likely to be significant.	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality. Avoided economic impacts for agriculture (pollinators).	Avoided human health impacts where these substances are identified as EDC. Avoided impacts on pollinators. Possible food security issues if loss of use without chemical/non-chemical alternatives in place.	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
Glyphosate	Large	Potential harm to aquatic environments given the very high usage rates and risks for loss to water, including non-target aquatic flora. Exceedance rate based on potential EQS was high.	Range of alternatives available, although likely more costly. Source control and pathway disruption measures likely needed will be costly.	Avoided health impacts related to very wide use and drinking water. Avoided costs of water treatment for use as both drinking water and agriculture use.	Protection of drinking water would be a key societal benefit given usage rates of glyphosate. Avoided health impacts will be key.	Th279ummed279its of addition to the PS list outweigh the costs.
Triclosan	Medium	Toxic for aquatic organisms (particularly larvae and fish eggs). Effects identified on a range of aquatic species including amphibians. Some evidence of anti-microbial resistance issues.	Intervention is either as source control or end-of-pipe. Use as a biocidal agent in soaps. Some alternatives and options for direct source control. End-of-pipe advanced treatment likely costly.	Avoided costs of drinking water treatment. Economic benefits for aquaculture from improved food quality	Avoided health impacts for human health via exposure.	The benefits of addition to the PS list outweigh the costs.
PFAS	Large	Widespread and very long-lasting environmental effects. PFAS dubbed ‘forever chemicals’ with good reason.	Complex issue likely needing an integrated basket of measures at all stages of life-cycle. Costs are likely to be very significant.	Primarily avoided health costs from chronic exposure to pathway. Avoided environmental impacts with benefits for aquaculture, and farming.	Health concerns are well founded with human biomonitoring data highlighting societal impacts that need to be minimised.	The benefits of addition to the PS list outweigh the costs.
Bisphenol A	Large	Population level effects as an endocrine disrupting chemical for aquatic organisms (effects not limited to BPA only but also for other bisphenols).	Multiple uses and pathways to environment. Major issue is manufacture and use of epoxy resins and losses from polycarbonate and PVC articles. Package of measures needed as	Avoided costs of drinking water treatment. Avoided environmental impacts for aquaculture.	Avoided health impacts from exposure. Benefits from protection of aquatic	Benefits and costs assessed are balanced. (High cost / high benefit)

Substance	Distance to target	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
			source control, pathway disruption and end-of-pipe. Diffuse sources problematic and costs of achieving compliance likely very significant.	Innovation for development of alternative chemicals and technologies.	environment as ecosystem services.	
Microplastics	Not assessed	Chronic ecosystem level effects from physical and pathological impacts of micro-plastics for aquatic species and accumulation at higher trophic tiers.	Primary source is for secondary microplastics are brake and tyre wear, emissions to sewer from laundry activities, land spreading for sludges. Management via pathway disruption and end-of-pipe likely to be costly.	Avoided costs of drinking water treatment. Avoided environmental impacts for aquaculture. Innovation for development of alternative chemicals and technologies.	Benefits from protection of aquatic environment as ecosystem services.	Benefits and costs assessed as neutral. (High cost / high benefit)
Silver	Medium	Chronic aquatic toxicity effects, primarily for crustaceans. Nanoform of silver is the primary issue. Ionic form of silver is most probably the primary issue.	Multiple pathways and sources to environment with a package of measures spanning source control, pathway disruption, end-of-pipe (and potentially restricted use for some applications) needed to help achieve compliance. Given the 'medium' distance to target would expect prioritisation of sources nationally.	Avoided environmental impacts for human health (water can be the reservoir of bacteria resistant to the silver due to the presence of silver as pressure) and aquaculture. Innovation for development of alternative chemicals and technologies.	Benefits from avoided health impacts e.g. resulting from exposure to bacteria that are co-resistant to the antibiotics and silver together (since they share the same mechanism of the resistance). No societal impacts identified.	Benefits and costs assessed are balanced. (High cost / high benefit)

Along with the candidate priority substances for addition to the priority substance list, microplastics have also been included as an additional item for review. In this case the potential environmental impacts over the longer term (decades) were identified to be significant in terms of negative effects for aquatic species and ecosystem biodiversity. They also pose threats for impacts to terrestrial species (including birds) and human health. To address the issue fully, however, is likely to take significant effort to address the issues with material flows (particularly for secondary plastics associated with brake and tyre wear, laundered items (such as clothing), and the way that sewage sludge is managed). On that basis it could be argued that overall the costs and benefits are balanced, with a high benefit and high cost.

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances	Policy option	Environmental impacts	Economic	Social	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Estrogenic hormones 17-alpha-ethinyl-estradiol (EE2), 17-beta-estradiol (E2), estrone (E1)	Policy Option 1 (individual addition)	+++	+/-	-	++	+++	+	Estrogenic impacts on environment are of EU-wide concern. Pharmaceutical strategy covers this in part but no other regulatory drivers. Listing in the EQSD would be an effective and efficient means to address the issue and place onus on source control.	Yes
Macrolide antibiotics Azithromycin, Clarithromycin, Erythromycin	Policy Option 1 (individual addition)	++	-	--	+++	+++	++	The pharmaceutical strategy highlights strong concerns over anti-microbial resistance (AMR). The strategy largely address use and control at source. Environmental monitoring is a weaker element. Addition to the EQSD would address this issue and therefore has positive elements for effectiveness, efficiency, and coherence. Alternatives exist but can assume negative impacts for society from more limited access and use.	Yes

Substances		Policy option	Environmental impacts	Economic	Social	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Other pharmaceutical	Carba-mazepine	Policy Option 1 (individual addition)	+++	+/-	+/-	+++	+++	+	Distance to target is large, with the EQS dossier highlighting EU-wide concerns. This suggests a large positive impact from listing. Alternatives do exist (although many are more expensive), suggesting control of releases through limitations on use should be cost neutral. Environmental monitoring likely key to help manage and control the issues. Suggests strong positives for effectiveness and efficiency.	Yes
	Diclofenac	Policy Option 1 (individual addition)	+++	+	+/-	+++	+++	+	Targeted consultation suggests that this substance is the highest environmental concern of all candidate pharmaceuticals. Strong environmental benefits of listing. Alternatives exist and treatment options look reasonable. Similar to carbamazepine environmental monitoring needed to help track and control the issue. Strong benefits for effectiveness and efficiency of listing under the EQSD.	Yes
	Ibuprofen	Policy Option 1 (individual addition)	+	+/-	-	+++	+++	+	Distance to target is set at medium, with the environmental benefits of listing suggesting a small positive benefit. Other alternatives are available on the market suggesting costs could be neutral. The bigger concern is that use is increasing suggesting environmental concentrations may also increase. A listing could be an effective and efficient means of tracking and controlling release and environmental concentrations.	Yes
Neonicotinoid pesticides		Policy Option 1 (individual addition)	++	-	+/-	++	+++	++++	Primary concern for neonicotinoids relates to pollinators. However, impacts on aquatic species, particularly crustaceans is a concern. Wider protection of the aquatic environment would be beneficial.	Yes

Substances		Policy option	Environmental impacts	Economic	Social	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam									Actions have already been taken under other legislation, meaning strong positives for coherence, particularly the farm to fork strategy. Where other activities are already underway and primary concern is pollinators, expect the effectiveness to have medium benefits.	
Pyrethroid pesticides Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin		Policy Option 1 (individual addition)	++++	--	-	+++	+++	+++	Distance to target was large with the EQS dossier predicting widespread failures due to the highly toxic nature of the substances for aquatic environment. Expect very large positive benefits for environment. Limited options for alternatives and high costs for WWTW expected suggesting medium negative economic costs. Some of the substances are already no longer approved for plant protection products, while there would be positive coherence outcomes with the farm to fork strategy.	Yes
Other pesticides	Glyphosate	Policy Option 1 (individual addition)	+++	-	+/-	++	++	+/-	Distance to target is large, noting that this substance is one of the highest volume pesticide actives in Europe. The EQS is based on risks to drinking water and humans given how widely it is used. Expect strong environmental benefits. The effectiveness and efficiency of listing predicts medium benefits on the grounds that better monitoring data could help characterise the issues more fully, but no specific coherence benefits identified.	Yes
	Nicosulforon	Policy Option 1 (individual addition)	+	+/-	+/-	++	++	+	Distance to target is small, primary concern could be application by boom-sprayers and spray drift. Assume small benefits to environment from listing. Improved monitoring data could help	Yes

Substances		Policy option	Environmental impacts	Economic	Social	Effectiveness	Efficiency	Coherence	Justification	Preferred option
									identify control options. Assume medium benefits for effectiveness and efficiency, and small benefits for coherence with farm to fork strategy.	
	Triclosan	Policy Option 1 (individual addition)	++	+/-	+/-	+++	+++	+++	Remaining use of triclosan is very limited, however, environmental persistence and impacts are a concern. Suggesting medium benefits for environment to better control the issues. The issues posed largely relate to existing environmental impacts, suggesting a listing in the EQSD could be appropriate and effective. Also adds coherence to the wider legislative landscape that has aimed to phase-out use.	Yes
PFAS		Policy Option 1 (individual addition)	++++	---	--	-	---	--	Approximately 6,000 PFAS substances exist. A total of 24 were identified as potential markers. In this case approaching them individually may be labour intensive and counter intuitive. Including negative coherence impacts for how these substances have been managed under the drinking water directive.	No
		Policy Option 2 (group addition)	++++	---	--	++	+++	+/-	Distance to target is large, with significant environmental concerns, suggesting strong environmental benefits for listing. Control and treatment options for WWTWs likely very costly, suggesting strong negative economic impacts. However, given that PFAS largely impacts the aquatic environment a group listing in the EQSD could be effective and a more efficient way to manage the issue than individual listings.	Yes

Substances	Policy option	Environmental impacts	Economic	Social	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Bisphenol A	Policy Option 1 (individual addition)	+++	+/-	+/-	+++	+++	+++	Distance to target is large, suggesting strongly positive benefits for environment with an EQSD listing. Within the wider legislative network controls are already in place under REACH and IED, but the issue may relate to in-use stocks. A listing in the EQSD would therefore have coherence benefits, and likely reflect strong positive aspects for effectiveness and efficiency in terms of tracking and controlling releases and concentrations within the aquatic environment.	Yes
Silver	Policy Option 1 (individual addition)	+	-	--	++	+/-	+/-	Distance to target was medium. While the direct environmental impacts on aquatic systems (e.g. toxicological effects) may be of smaller concern. The greater concern relates to nanoform or ionic silver and potential contributing to the growth of anti-microbial resistance. The diffuse nature of use and pathway to environment could pose challenges for control, while loss of some uses (e.g. biocidal) could have negative impacts for society. The issue is further complicated by naturally occurring silver, and the form of silver monitored for EQS. Therefore, a package of measures may be needed to help address releases, with key focus on source control (pre-treatment via onsite wastewater plants) or end of pipe treatment. - Assuming that between 1-5% UWWTPs would have to deploy reverse osmosis, costs for EU taxpayers would range between €2,184,600 and €109,230,000.	Yes

Substances	Policy option	Environmental impacts	Economic	Social	Effectivene	Efficiency	Coherence	Justification	Preferred option
								- Benefits /avoided costs of reducing AMR from silver are broadly comparable to those for AMR for antibiotics Assuming that the benefits of reducing silver related AMR range between 50% to 100% of the AMR costs for antibiotics, this results in EU-benefits of €42 to €84 billion.	

Benefits clearly outweigh the costs for:

- industrial chemicals—- PFAS
- pesticides (Glyphosate, Triclosan);
- neonicotinoid pesticides (Acetamiprid, Imidacloprid, Thiacloprid, Thiamethoxam);
- pyrethroid pesticides (Deltamethrin, Permethrin, Bifenthrin, Esfenvalerate);
- pharmaceuticals (Carbamazepine, Diclofenac);
- macrolide antibiotics (Azithromycin, Clarithromycin; Erythromycin);
- estrogenic hormones (17-Alpha-Ethinyl estradiol (EE2), 17-Beta estradiol (E2), Estrone (E1)).

The following substances have “balanced” impacts: Ibuprofen, Nicosulfuron, Clothianidin, Bisphenol A, and Silver and are suggested for inclusion.

9.1.2 *Option 2: Review 4 groups for potential 'family' EQS additions - Hormones (estrogens and macrolide antibiotics), PPPs, Pharmaceuticals, bisphenols.*

The second option also focusses on the candidate substances to add to the list of priority substances, but as groups. As indicated in Chapter 8, there can be good reasons to rationally consider the possibility of using grouping approaches when adding substances to the priority substance list. This option identified four possible groups – estrogenic hormones, macrolide antibiotics, neonicotinoid pesticides, pyrethroid pesticides (noting that the addition of PFAS as a group has already been confirmed and included as part of option 1).

-Table 9-2 provides the outcome of the impact assessment and balance of costs and benefits. As stated in section 8.4.2 there are a series of metrics which can strengthen of weaken the argument for whether a grouping approach is sensible and adds value to the way that the substances are managed. Based on the analysis of these metrics three out of the four possible grouping approaches (estrogens, neonicotinoids, and pyrethroids) have multiple problems which mean that in the balance of costs and benefits a grouping approach is not recommended.

The final possible grouping (macrolide antibiotics) showed a great deal of benefits for using a grouping approach, with the one major issue being the variation in potency. In this case the proposed EQS vary significantly (Azithromycin AA and MAC 0.019µg/l; Clarithromycin AA and MAC 0.13µg/l; Erythromycin AA and MAC 0.5µg/l). In this case the use of a relative potency factor (RPF) approach (similar to what has been proposed for PFAS) aligned to the equivalency of azithromycin could warrant further investigation. If this proved not possible/unfruitful, the variations in potency would suggest a single EQS entry would be unwise.

Note: the option to propose a group EQS for a larger subset of bisphenols, e.g. the most commonly used and detected bisphenols analogues like Bisphenol AF (BPAF), Bisphenol B (BPB), bisphenol D (BPD), Bisphenol F (BPF), Bisphenol S (BPS) and tetrabromobisphenol (TBBPA) etc.)[550], or for the total of all bisphenols was considered 'not yet feasible' based on scientific data currently available. Therefore, no further work was completed for that option. Nevertheless, it is noted that in 2022 ECHA and the MSs assessed a group of 148 bisphenols and recommended to restrict the use of 34 bisphenols due to their potential hormonal (endocrine disrupting) or reprotoxic effects. Three bisphenols (bisphenol A, bisphenol B and 2,2-bis(''-hydroxyphenyl)-4-methylpentane) have also already been identified as substances of very high concern (SVHCs) and SVHC identification is proposed for further bisphenols where sufficient information on hazards is already available. As also mentioned in chapter 8, ECHA considers assessing chemicals like bisphenols in groups a successful approach for regulatory action to avoid replacing one bisphenol with another that is just as harmful (regrettable substitution). Furthermore, German authorities prepared a proposal to restrict the use of BPA and other bisphenols with endocrine-disrupting properties for the environment[551]. Similarly, Belgian authorities prepared a proposal to restrict the use of BPS and Swedish authorities prepared a proposal to restrict the use of BPAF. Once there is

[550] https://www.sciencedirect.com/science/article/pii/S0048969721030849
[551] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea

greater clarity over bisphenols, and for which substances these proposals will collectively cover, ECHA and the European Commission will consider further needs for regulatory action on several other bisphenols. This might accelerate further work to derive a group total EQS for all bisphenols for surface and groundwaters as soon as sufficiently detailed scientific information becomes available.

Table 9-2 Option 2 options comparison and preferred option

Substance	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
		Cost	Benefits		
Estrogenic hormones	Possible incoherence issues linked to difference in potency	Incoherence issues could affect measure selection and negative cost impacts.	More consistent approach to managing selection of alternatives and substitution where needed.	Lack of granular data for E1, E2, EE2 in aquatic environment could lead to less effective management with negative societal consequences.	The potential costs outweigh the benefits. Grouping not recommended
Macrolide antibiotics	Greater coherence in the approach to AMR if grouped	Azithromycin has a greater distance to target, if grouped, would measures have to work to the worst member substance (i.e., greater unnecessary cost?)	Correlation on use, pathway to environment and measures, could mean cost savings is managed as a group	Greater coherence in the approach to AMR if grouped	Benefits could outweigh costs. But variation in potency an issue for investigation.
Neonicotinoids	Greater coherence in the approach to protection of pollinators if grouped	Variations in use, pathways, and measures. Grouping could create incoherence in measures and unnecessary costs.	No benefits identified.	Greater coherence in the approach to protection of pollinators if grouped	The potential costs outweigh the benefits. Grouping not recommended.
Pyrethroids	Uses and pathways to environment vary. Grouping could create coherence issues that would negatively impact environmental protections	Loss of granular (substance by substance) data impacts measure selection and effectiveness of measures.	Very limited alternatives, grouping approach could mean a more holistic approach avoiding regrettable substitution and associated costs.	No costs or benefits identified.	The potential costs outweigh the benefits. Grouping not recommended.

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances	Policy option	Environmental impacts	Economic	Social	Effectivene	Efficiency	Coherence	Justification	Preferred option
Estrogenic hormones 17-alpha-ethinyl-estradiol (EE2), 17-beta-estradiol (E2), estrone (E1)	Policy Option 2 (group addition)	+++	+/-	-	++	++++	--	The potency, pathway to environment, and treatment options vary significantly across the three substances. A group listing would likely have negative effects for coherence.	No
Macrolide antibiotics Azithromycin, Clarithromycin, Erythromycin	Policy Option 2 (group addition)	++	-	--	++	+++	++	The potency, and treatment options vary significantly across the three substances. A group listing would likely mean compromise on treatment and reduced effectiveness.	No
Neonicotinoid pesticides Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam	Policy Option 2 (group addition)	++	-	+/-	+	++	++	The regulatory status of the individual neonicotinoids varies. This means a group listing would mask some of the granular data and reduce both effectiveness and coherence.	No
Pyrethroid pesticides Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin	Policy Option 2 (group addition)	++++	--	-	+	+	++	The regulatory status of the four substances varies, as does the treatment options at WWTWs. Suggests a group listing would impact effective management, efficiency, and coherence negatively.	No

A grouping approach is not recommended.

9.1.3 *Option 3: Assess EQS for targeted set of high priority substances identified by the Commission and JRC*

Option 3 covers the **review and amendment of EQS for existing priority substances**. This is on the basis that the scientific data available has evolved since the original analysis and risk assessment for pre-existing EQS. Where the proposed EQS amendments reflect a robust and thorough investigation of the new and emerging science to re-appraise the EQS it can be expected that the proposed amendments already reflect environmental benefits to address the risks more appropriately. Equally where the proposed EQS amendments also include a relaxation of the thresholds where the existing threshold is deemed overly cautious, it is possible to see that there would also be economic benefits in the fact that measures may no longer be needed, and the resources can be reallocated in a more effective fashion to target other issues.

The current impact assessment has also recognised that for pre-existing EQS substances, there will be a distance to target based on the current situation (baseline) and based on the proposed EQS the distance target may remain unchanged, get bigger, or get smaller. -Table 9-3 provides the results of this impact assessment. Similarly, to option 1 the relative balance of costs and benefits resulted in three possible outcomes—- it has been possible for the benefits to outweigh the costs, the costs to outweigh the benefits, and the costs and benefits being balanced (i.e. a neutral result).

For the majority of the substances targeted for amendment of EQS the benefits outweigh the costs, either through greater environmental protections, or more accurate EQS allowing suitable prioritisation of risks and measures. For a smaller set of substances, the impact assessment draws a neutral result (chlorpyrifos, cypermethrin, mercury, nickel, and PAHs). This is because the revised EQS is significantly more stringent and will determine new measures are likely needed to help achieve good chemical status. However, based on the new risk assessment it can also be determined that the risks to date have been underestimated, and therefore the additional effort is warranted.

Based on the analysis of substances in the neutral category, the most uncertain will be nickel. The proposed EQS amendment is likely to create a new wave of exceedances, with potentially an extensive package of measures needed to achieve good chemical status. Given the potential uncertainties involved, this may be the one substance where, depending on the specific measures implemented, the costs might outweigh the benefits. However, the margins in this case are very tight and overall, the assessed balance of costs and benefits will be neutral.

Table 9-3 Option 3 options comparison and preferred option

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
Chlorpyrifos	**Medium**	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS is considerably lower than the existing one. Possible additional analytical costs. Where Chlorpyrifos is no longer approved, measures will likely target diffuse sources and legacy issues. Potential additional costs.	Limited economic benefits identified. Possible advances in analytical techniques could bring down the cost of analysis over time.	Improved protections for human health. Particularly given the recent nomination as a POP and issues around bioaccumulation.	Based on the review and reappraisal of EQS additional measures may be warranted. Costs likely consummate with risks. Option assessed as neutral (Medium cost / medium benefit)
Cypermethrin	Medium	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is more stringent. May need additional measures targeting timber treatment, including in-use stocks. Costs likely significant.	Avoided health costs for aquaculture and ecosystem services.	Improved environmental protections for ecosystem services.	Based on the review and reappraisal of EQS additional measures may be warranted. Costs likely consummate with risks. Option assessed as neutral (Medium cost / medium benefit)

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
Dicofol	Small	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is more stringent, but only a minor alteration to AA and biota. No expected additional costs.	Proposed EQS is more stringent, but only a minor alteration to AA and biota. No expected additional economic benefits.	No social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.
Diuron	**Medium**	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is significantly more stringent. Use as a pesticide and biocide has ceased. Additional measures likely to address industrial uses as restrictions / improved abatement. Also legacy issues from contaminated sites.	Potential innovation opportunity to remove use as an intermediate in manufacture of rubber products	Improved human health protections given diuron is an EDC	On the basis that new scientific evidence has been used to re-assess the EQS and risks understated. The benefits still outweigh the additional costs. Amendment is preferrable.
Heptachlor/ heptachlor oxide	Small	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS is less stringent. No additional costs expected.	The proposed EQS is less stringent, meaning resources can be reallocated and costs saved from measures no longer needed.	No specific social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
Hexachlorobenzene	Small	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS is less stringent. No additional costs expected.	The proposed EQS is less stringent, meaning resources can be reallocated and costs saved from measures no longer needed.	No specific social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.
Tributyltin	Medium	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is more stringent for biota. Given use has ceased. Likely measures include upgrade of WWTWs and natural attenuation. The costs of the former will be captured by the revised UWWT Directive.	Avoided health costs for aquaculture and ecosystem services.	No specific social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable in view of addressing concerns of Member States that the water EQS, included in the EQSD since 2008, is challenging to monitor while monitoring a different matrix would in their view be easier. The EQS allows set and EQS for

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
						biota or sediment provided it safeguards an equivalent level of protection.
Dioxins and furans	Medium	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Reduction in the proposed EQS for biota could lead to additional analytical costs. Limited scope for additional measures likely natural attenuation.	No economic benefits identified from amendment of the EQS.	Some additional society benefits in tackling environmental concentrations given bioaccumulation potential.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.
Fluoranthene	**Small**	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS is less stringent. No additional costs expected.	The proposed EQS is less stringent, meaning resources can be reallocated and costs saved from measures no longer needed.	No specific social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.
Hexachlorobutadiene	Small	Updated EQS based on new science and re-appraisal of risk, would	Proposed EQS is more stringent, likely to trigger some additional exceedances, but grouping will still be 'small'. Limited number of	No specific cost benefits identified.	Improved protections for human health. Particularly given	On the basis that new scientific evidence has been used to re-assess the

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
		provide more appropriate protections.	sources, which would target manufacturing and end-of-pipe. Costs are considered proportionate to the addressed risks.		HBCDD is a POP and issues around bioaccumulation.	EQS and no/limited impacts identified. Amendment is preferrable.
Nonyl Phenol	Small	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS has a more stringent AA and less stringent MAC. Primary issue is imported clothing. Expect end-of-pipe measures to address much of the issue.	No specific cost benefits identified.	Improved human health protections from additional controls. Improved ecosystem services.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable
PAHs	**Medium**	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS could be expected to trigger a new wave of exceedances, including promotion of the distance to target. Measures will likely need to target source-control on combustion and metallurgy and pathway disruption for run-off from road	No specific cost benefits identified.	Improved health protection from avoiding exposure to PAHs. Improved ecosystem services.	Based on the review and reappraisal of EQS additional measures may be warranted. Costs likely consummate with risks. Option assessed as neutral (High cost / high benefit)

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
			and field. Costs could be significant.			
PBDEs	Large	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	The proposed EQS is less stringent. No additional costs expected.	The proposed EQS is less stringent, meaning resources can be reallocated and costs saved from measures no longer needed.	No specific social impacts identified.	On the basis that new scientific evidence has been used to re-assess the EQS and no/limited impacts identified. Amendment is preferrable.
Mercury	Large	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Amendment of the EQS will likely trigger the need for additional source controls and pathway disruption. New measures are likely needed to help achieve good chemical status. However, based on the risk assessment it was concluded that the risks to date have been underestimated, and therefore the additional effort is warranted.	Avoided costs of health impacts for aquaculture. Avoided costs on impacts to ecosystem services	Greater human health protections on exposure to mercury as a chronic pollutant	The distance to target was already large with mercury responsible for the highest number of EQS failures. The amendment of biota EQS and addition of AA EQS will likely trigger a new wave of exceedances with significant cost for compliance. However, the benefits are equally as important.

Substance	Distance to target (bold and red denotes a change in group based on amended EQS)	Environmental impact	Economic Impact		Social impact	Preferred Option
			Cost	Benefits		
						Option assessed as balanced (High cost / high benefit)
Nickel	Medium	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is significantly more stringent and likely to trigger a wave of exceedances. Primarily measures will need to target source-controls (fossil fuel combustion, metal manufacture, basic organics, and surface treatments), pathway disruption (mine drainage), and end of pipe treatments. Depending on specific measures implemented and uncertainties involved the costs might outweigh the benefits, but margins are tight.	Avoided costs of health impacts for aquaculture. Avoided costs on impacts to ecosystem services	Greater human health protections on exposure to nickel as a chronic pollutant	The proposed amended EQS is likely to trigger a new wave of exceedances with application of extensive measures to achieve compliance. This will carry significant costs. However, based on the review of new evidence the benefits from avoiding impacts are also more significant than previously thought. Overall, the balance of costs and benefits of this option is assessed as neutral (High cost / high benefit)

The table below summarises the impacts of implementing the option, compared to the status quo.

	Substances	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Pesticides	Chlorpyrifos	+++	+/-	+	+++	+++	+++	The evolving science and nomination as a POP under the Stockholm Convention suggests that the proposed more strict EQS is appropriate. This would confer strong environmental benefits, while the further use of EQSD to support other legislation (particularly the POPs Regulation), would suggest strong benefits for effectiveness, efficiency, and coherence.	Yes
	Cypermethrin	+++	--	+	+++	++	+/-	Based on review of new evidence the proposed EQS are lower than the existing ones. This would fairly identify strong environmental benefits. Assume that existing EQS processes would still be highly effective. No specific new coherence benefits identified.	Yes
	Diuron	+++	-	+	+++	+++	+	Based on review of new evidence the proposed EQS are lower than the existing ones. This would fairly identify strong environmental benefits. Assume that existing EQS processes would still be highly effective. The approval of diuron as a pesticide ended in September 2020, so could expect some small coherence benefits from reducing the EQS.	Yes
	Dicofol	+/-	+	+/-	+/-	+/-	+/-	The proposed threshold for dicofol is higher than the existing one based on the review of data completed. The rates of exceedance are already low so would expect little impact for environment. Possibly some small economic benefits for being able to use analytical equipment with higher LOD.	Yes
	Hexachlorobenzene	+/-	+	+/-	-	+/-	+/-	The proposed threshold for hexachlorobenzene is higher than the existing one based on the review of data completed. The rates of exceedance are already low so would expect little impact for environment. Possibly some small economic benefits for being able to use analytical equipment with higher LOD.	Yes

	Substances	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	Heptachlor / Heptachlor epoxide	+/-	+	+/-	-	+/-	+/-	The proposed threshold for heptachlor is higher than the existing one based on the review of data completed. The rates of exceedance are already low so would expect little impact for environment. Possibly some small economic benefits for being able to use analytical equipment with higher LOD.	Yes
Industrial chemicals	Dioxins	+	-	+	+/-	+/-	++	The proposed biota threshold for dioxins is more strict based on review of the available evidence. Dioxins are already address by a range of legislation (particularly the POPs Regulation). Stricter controls would have coherence benefits with the aims of the POPs Regulation and provide environmental and societal benefits (food-chain) from a reduced EQS.	Yes
	Fluoranthene	+/-	+	+/-	+/-	+/-	+/-	The proposed threshold for fluoranthene is higher than the existing one based on the review of data completed. The rates of exceedance are already low so would expect little impact for environment. Possibly some small economic benefits for being able to use analytical equipment with higher LOD.	Yes
	Hexabromocyclo dodecane	+/-	+/-	+/-	+/-	+/-	+/-	Proposed amendment of the EQS is on new scientific data. This is reasonable on the basis that the EQS reflects the best evidence possible. However, in reality it will not have a material impact on environmental protections, economics, or society.	Yes
	Hexachlorobutad iene	++	+/-	+/-	+/-	+/-	+/-	The proposed amendment would lower the EQS based on review of new evidence. This would provide environmental benefits. The current distance to target is small but could be expected to include a wider number of waterbodies with exceedances. Assume the benefits would be medium positive.	Yes
	Nonyl phenol	+	+	+/-	+/-	+/-	+/-	The proposed amendment would lower the EQS based on review of new evidence. This would provide environmental benefits. The current distance to target is small but could be expected to include a wider number of waterbodies with exceedances. Assume the benefits would be medium positive.	Yes

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	PAHs	++	-	+	+/-	+/-	++	The proposed amendment would lower the EQS based on review of new evidence. The distance to target is already medium, and therefore there could be medium positive environmental benefits of the amendment. Given the potential for PAHs to bioaccumulate assume better controls would have societal benefits (food-chain). Where PAHs are a family also expect small negative economic benefits if more advance analysis is needed to achieve the LOD/LOQ.	Yes
	PBDEs	+	-	+	+	+/-	+	The proposed amendment would lower the EQS for biota (via secondary poisoning). The distance to target is already large, with other legislation listing proposals to also reduce critical thresholds. In particular the low POP content for waste under the POPs Regulation. Suggests that there will be small positive benefits for coherence, and societal (food-chain).	Yes
	Tributyltin	+	+/-	+/-	+	+/-	+/-	Based on new evidence, the proposed EQS is more strict than the existing one. Therefore, expect positive benefits for environment, and effectiveness of the EQSD.	Yes
Metals	Mercury	+++	--	++	+	+	+/-	The proposed amendment would add an annual average EQS (currently it only has a MAC). The distance to target is large, and greater control to manage the issues is needed. Assume that applying the annual average EQS would lead to strong environmental benefits on the basis that it provides more granularity. Medium benefits for society through improved protections, and small benefits for effectiveness and efficiency, in that adding an annual average EQS brings mercury into alignment with the other priority substances.	Yes
Metals	Nickel	++	--	+/-	+	+/-	+/-	The proposed amendments for nickel would lower both the AA and MAC EQS based on the review of new evidence. The existing distance to target is medium, with potentially more water bodies failing to meet good chemical status. Based on the evidence reviewed in deriving the amended EQS medium positive environmental benefits were indicated , and small benefits for improved effectiveness. Assume also negative economic impacts for greater use of controls and POMs.	Yes

All proposed amendments are preferred.

9.1.4 *Option 4 Review possible deselection of substances shortlisted by the COM following JRC deselection criteria approach.*

The final option within the surface water category relates to the potential **deselection of priority substances** that no longer present an EU-wide risk to the environment. The JRC and WG chemicals have defined robust selection criteria to help identify which substances may be candidates for deselection. This notes that deselection from the EU priority substance list does not preclude their further addition as river basin specific pollutants at national level where any identified risk still exists.

-Table 9-5 provides the outcome of the current impact assessment, which analysed the costs and benefits across the environment, economy, and social benefits and impacts. Based on this analysis the current study concurs with the work of the JRC and WG chemicals that the identified substances could be deselected from the priority substance list with the economic and environmental benefits outweighing any potential costs. This includes consideration of the risks of re-emergence/uptake in use increasing emissions in the future.

Table 9-4 Option 4 options comparison and preferred option

Substance	Environmental impact	Economic Impact		Social impact	Preferred Option
		Cost	Benefits		
Alachlor	Banned in the EU for many years, only 5 water bodies out of 97,000 exceed the EQS. Risk to environment is low.	Continued monitoring could be expected to utilise finite economic resources with more limited benefit.	Deselection could free up resources that can be reallocated emerging risks to better serve the environment. Cost savings €3.8 - €11.7 million Euro per year (monitoring of 5 substances).	While the health hazards of alachlor are clearly documented, risk of exposure is very low. Deselection would have limited /no impact on risk of exposure.	Based on the costs and benefits, it is concluded that deselection would have more benefits than costs.
Simazine	Banned in the EU for many years, only 4 water bodies out of 97,000 exceed the EQS. Risk to environment is low.			While the health hazards of simazine are clearly documented, risk of exposure is very low. Deselection would have limited /no impact on risk of exposure.	Based on the costs and benefits, it is concluded that deselection would have more benefits than costs.
Chlorfenvinphos	Banned in the EU for many years, only 6 water bodies out of 97,000 exceed the EQS. Risk to environment is low.			While the health hazards of chlorfenvinphos are clearly documented, risk of exposure is very low. Deselection would have limited /no impact on risk of exposure.	Based on the costs and benefits, it is concluded that deselection would have more benefits than costs.
Trichlorobenzenes	Use is ongoing and these substances are acutely toxic to the aquatic environment. However, the rate of exceedance are not very high, but deselection is questionable given the degree of risk they pose and their relevance for the MSFD. Could be possible to still maintain protections as a RBSP where needed.			For the substances targeted for deselection trichlorobenzenes are still in use, and monitoring could have societal benefits in tracking substance flows to protect exposure. Less monitoring would reduce the information available to assess exposure and decide on measures to reduce emissions, but MS should assess whether these substances	Based on the costs and benefits, it is concluded that deselection would have more costs than benefits .

Substance	Environmental impact	Economic Impact		Social impact	Preferred Option
		Cost	Benefits		
				should be designated and managed as RBSPs.	
Carbon tetrachloride	Still in use but, is not a POP. As identified under option 5, the rate of exceedances are extremely low and risk to environment is equally low. Possible to maintain protection by designating as a RBSP where needed.			While the health concerns for carbon tetrachloride are well founded. Related policy also controls and monitors exposure. Less monitoring would reduce the information available to assess exposure and decide on measures to reduce emissions, but MS should assess whether these substances should be designated and managed as RBSPs.	Based on the costs and benefits, it is concluded that deselection would have more benefits than costs.

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Pesticides	Alachlor	+/-	+	+	+	+	+/-	Alachlor fully meets the deselection criteria, which would assume no negative impacts for the environment if deselected. Small positive benefits in cost savings,	Yes

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
								as well as for society, effectiveness, and efficiency (redeployment of resources for other substances of concern).	
	Chlorfenvinphos	+/-	+	+	+	+	+/-	Chlorfenvinphos fully meets the deselection criteria, which would assume no negative impacts for the environment if deselected. Small positive benefits in cost savings, as well as for society, effectiveness, and efficiency (redeployment of resources for other substances of concern).	Yes
	Simazine	+/-	+	+	+	+	+/-	Simazine fully meets the deselection criteria, which would assume no negative impacts for the environment if deselected. Small positive benefits in cost savings, as well as for society, effectiveness, and efficiency (redeployment of resources for other substances of concern).	Yes
Industrial chemicals	Carbon tetrachloride	+/-	+	+	+	+	+/-	Carbon tetrachloride fully meets the deselection criteria, which would assume no negative impacts for the environment if deselected. Small positive benefits in cost savings, as well as for society, effectiveness, and efficiency (redeployment of resources for other substances of concern).	Yes
	Trichlorobenzenes	+/-	+	+	+	+	+/-	While trichlorobenzenes largely meet the deselection criteria (including very low rates of exceedance with the caveat that the EQS is likely 20+ years old), they are still actively in use. Based on the very low rates of exceedance deselection could be expected to have neutral impacts for the aquatic environment. It would also provide benefits in terms of cost savings and redeployment to other substances of concern. However, given the degree of risk they pose and their relevance for the	No

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
								MSFD their deselection is questionable. Another issue would be the loss in the time series and possibilities to monitor exceedances if releases increased in the future.	

There are two different categories that substances are falling into:

1) deselection would have more benefits than costs—- Alachlor, Simazine, Chlorfenvinphos (herbicides) and Carbon tetrachloride;

2) the costs and benefits are more balanced—- Trichlorobenzenes (solvents and chemical intermediates).

Consequently, trichlorobenzenes are not proposed for deselection.

9.1.5 *Option 5: Review the status of ''eight other pollutant'' added to the EQSD from the former dangerous substances directive (76/464/EEC) (which are not currently priority substances).*

This option explored the issues related to eight pollutants listed in Annex II of the EQSD with threshold values, which are not formally recognised as priority substances under Annex I. These eight substances relate to the DSD (which was the predecessor to the EQSD). Where these substances predate the EQSD, the threshold values quoted in Annex II are at least 15 years old, and likely close to 20+ years old, suggesting that they may no longer be based on the best scientific evidence available.

Therefore, a review was warranted to assess whether they should remain as they are, be removed from the EQSD entirely (on the understanding that they can still be addressed as river basin specific pollutants) or added fully to the priority substance list. For this last possibility it was recognised that the JRC have already completed an assessment of the eight substance as part of the work towards the deselection criteria (see section 8). This identified that one substance (carbon tetrachloride) could be a candidate for deselection (further covered here under option 4), while the remaining seven substances are not candidates for deselection. The main reasons for this are that the five pesticide substances (four Cyclodiene substances and DDT) are all recognised as POPs under the Stockholm Convention. The two remaining chloro-organic solvents, while not recognised as POPs, they do still have a small number of exceedances and some concerns that emissions may have risen in the last couple of years.

Therefore, for option 5, carbon tetrachloride can already be excluded and moved to option 4, and the remaining seven substances would either need to become full priority substances (including a re-evaluation of the EQS) or remain as they are. The current study has not included a critical analysis of the deselection criteria itself, but rather followed the conclusions reached from the JRC report in March 2022. Where tetrachloroethylene and trichloroethylene have so few exceedances it is hard to argue that an EU-wide risk is presented, while the benefits of adding them fully to the priority substance list may be present a narrower balance between costs and benefits. This assumes an increase in economic costs from increased monitoring frequency, but limited exceedances. The measures implemented (both alternative substances and end-of-pipe treatment) could be considered consummate to benefits of environmental protection.

For the five pesticide substances which are also POPs, all of the substances have been banned in the EU for a considerable period of time. Again, the number of exceedances are very low (<50 water bodies per annum across the EU27), with the measures likely to be linked primarily to natural attenuation or direct environmental interventions (e.g. dredging, capture and treat, etc). To be consist with the deselection criteria and wider EQS priority substance list, the argument could be made that they should be fully added to the priority substance list (with re-evaluation of the EQS) based on the fact that they are POPs.

The cost benefit analysis would conclude that there would be additional costs from increased frequency of monitoring, but that the rate of exceedances would remain very low. The implementation of measures would be limited given their legacy status, and primarily environmental benefits would be more accurate tracking of trends and coherence both within the EQSD and to related legislation.

-Table 9-5 provides the outcome of the impact assessment.

Table 9-5 Option 5 options comparison and preferred option

Substance	Environmental impact	Economic Impact		Social impact	Preferred Option
		Cost	Benefits		
Cyclodiene pesticides (aldrin, dieldrin, endrin, and isodrin)	All of the substances are listed as POPs but have been banned for many years. The rate of EQS exceedance suggests environmental risk is low, and benefits of continued monitoring may be limited.	The costs of monitoring and analysis are duly recognised. While these substances are not formerly priority substances the fact, they have an EQS warrants monitoring and analysis by MS.	Potential benefits if the substances are removed from the EQS to allow resources to be reallocated to other substances that may pose more emergent threats.	Greater coherence in the policy landscape could have societal benefits for how these substances are addressed.	For coherence with EQSD and deselection criteria consider addition.
DDT	Recognised POP under the Stockholm Convention with international concerns. However, use in EU has long since ceased and rate of exceedance is extremely low.	The costs of monitoring and analysis are duly recognised. While DDT is not formerly a priority substance the fact, they have an EQS warrants monitoring and analysis by MS.	Potential benefits if DDT was removed from the EQS to allow resources to be reallocated to other substances that may pose more emergent threats.	There is potential value in the monitoring time-series to support other work on tracking DDT, particularly imported foods.	For coherence with EQSD and deselection criteria consider addition.
Tetrachloroethylene	While tetrachloroethylene is in use and health concerns well founded. The monitoring data shows 6 water bodies out of 97,000 in exceedance. Even if the threshold is out of date and too high, the environmental risk is clearly very low.	The costs of monitoring and analysis are duly recognised. While tetrachloroethylene is not formerly a priority substance the fact, they have an EQS warrants monitoring and analysis by MS.	Potential benefits if tetrachloroethylene was removed from the EQS to allow resources to be reallocated to other substances that may pose more emergent threats.	The societal benefits of monitoring tetrachloroethylene within the water environment may be a valuable addition to help track emissions and possible human exposure via the environment.	For coherence with REACH and Solvent Emission Directive, consider addition
Trichloroethylene	While trichloroethylene is in use and health concerns well founded. The	The costs of monitoring and analysis are duly recognised.	Potential benefits if trichloroethylene was	The societal benefits of monitoring trichloroethylene within the water	For coherence with REACH and Solvent

Substance	Environmental impact	Economic Impact		Social impact	Preferred Option
		Cost	Benefits		
	monitoring data shows 3 water bodies out of 97,000 in exceedance. Even if the threshold is out of date and too high, the environmental risk is clearly very low.	While trichloroethylene is not formerly a priority substance the fact, they have an EQS warrants monitoring and analysis by MS.	removed from the EQS to allow resources to be reallocated to other substances that may pose more emergent threats.	environment may be a valuable addition to help track emissions and possible human exposure via the environment.	Emission Directive, consider addition.
Carbon tetrachloride	While carbon tetrachloride is in use and health concerns well founded. The monitoring data shows 1 water body out of 97,000 in exceedance. Even if the threshold is out of date and too high, the environmental risk is clearly very low.	The costs of monitoring and analysis are duly recognised. While carbon tetrachloride is not formerly a priority substance the fact, they have an EQS warrants monitoring and analysis by MS.	Potential benefits if carbon tetrachloride was removed from the EQS to allow resources to be reallocated to other substances that may pose more emergent threats.	The societal benefits of monitoring carbon tetrachloride within the water environment may be a valuable addition to help track emissions and possible human exposure via the environment.	See Option 4.

9.2 Groundwater options

9.2.1 *PFAS: Comparison of options and preferred option*

PFAS are listed as hazardous substances and their entry into groundwater should be prevented. Therefore, in principle the treatment of wastewater discharges to ground which then will percolate to groundwater (or indeed to surface water which may leach to groundwater), landfill leachate, and remediation of legacy pollution of contaminated soils and groundwater e.g. at industrial sites should be part of the baseline suite of measures. The review of the UWWTD and planned requirements for treatment of wastewater for micropollutants by 2030 and beyond means that wastewater treatment (which will include the treatment of some landfill leachate) will sit in the baseline.

Option 1c (addition to Annex II) provided the weakest protection of groundwater: given the likelihood of widespread detection of PFAS in groundwater and the societal and environmental impacts, European level action is needed to make a difference.

The distance to target for Options 1a, 1b, and 1d was close with a large number of locations likely to have an exceedance of the proposed GWQS across a large number of MS. The use of relevant potency factors under Option 1d means that for some PFAS the calculated GWQS is relatively high and for others very stringent, and this meant that in assessing the distance to target the outcome was in a similar range as for Options 1a and 1b. Therefore, the types of measures which would be implemented are likely to be similar, meaning costs and benefits sit with the same ranges.

The costs and energy use for capture and incineration / landfilling of biosolids and other wastes contaminated with PFAS are large, and these measures are unlikely to be used widely. These do not include the loss to the farming sector of relatively cheap soil improvers. The estimated costs of measures which may be adopted to control PFAS leaching to groundwater focus on the control of PFAS leaching from the source term already in the environment (i.e. restriction of use of PFAS in domestic products and the improved management of waste streams). The estimated benefits (avoided costs) of reducing low level exposure of populations through drinking water and food are of a higher order of magnitude compared to the estimated cost of restrictions of use of PFAS in manufacturing. Therefore, it is clear that the costs of restrictions on low level exposure to PFAS are outweighed by the benefits.

Options 1a and 1b were considered to align with the current DWD, Option 1b would not "future proof" the legislation in terms of the remaining PFAS substances, and were not considered protective enough of human health, based on the latest EFSA opinion[125] on tolerable intake. Although Option 1d does not follow the current DWD, there is an ambition to update the DWD as soon as possible with regards to the EFSA opinion. The need to use the latest scientific evidence is key and on this basis Option 1d is selected as the preferred option for PFAS.

The table below compares the impacts of implementing groundwater options for PFAS.

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
Option 1a PFAS (Group of 10) included in Annex I and assigned a GWQS of 0.10 µg/l (based on the drinking water standard for 20 identified PFAS - the 10 PFAS would be a subset of the 20)—- l Other options considered (Option 1 in the SWD)	Large scale, large magnitude (70% of reporting MS with exceedances at 75% of monitoring points)	Costs - €15-16 million (Europe) Benefits from the DWD implementation	Cost of remediation of legacy pollution (to tax payer where polluter pays principle cannot be enforced (e.g. soil remediation - €5 million to €760 million (one off cost at EU level)) Environmental PFAS remediation totalling €821 million to €170 billion (EEA/EU), with plausible best estimate of €10-20 billion. Restriction of use of PFAS in fire-fighting foams—- up to €390 million per year per substitute use (assume similar costs to other sectors) Cost of high temperature incineration of 10% of all biosolids €503-€755 million/yr (EU level). Cost of landfill of 10% of biosolids	Reduced energy costs and related process costs for wastewater treatment to tackle PFAS. Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for drinking water supply, agriculture (irrigation, livestock watering taken directly from a GWB) and industry (GAC treatment costs millions of € per site).. Lower production and maintenance costs through availability of cleaner raw potable groundwater.	Energy intensive measures including high temperature incineration of biosolids and other PFAS containing waste materials Loss of organic materials to spread to land by farming community	Reduced energy use for wastewater treatment to tackle PFAS. Lower risk of (irreversible) damage to natural resources such as groundwater and connected surface waters and ecosystems (i.e. reduced impact on sensitive water bodies such as wetlands and rivers, and fish); Reduced pollution of groundwater Increased knowledge and understanding of the risks of PFAS posed to the water environment. More data collected to understand the impact of these two PFAS Consistent approach to data collection at EU level.	Loss of organic materials to spread to land by farming community	Avoided illness / death through low level exposure through drinking water / food: in the EEA countries, health-related costs could reduce by up to €52-84 billion per year (based on 207.8 million population); A healthy river and lake ecosystem (fishing, swimming, etc). Sectors requiring a high quality of groundwater such as bottled water or aquaculture Clean raw groundwater for abstraction (for drinking water, irrigation, livestock watering) Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for agriculture and industry (GAC treatment costs € millions per site) Increased knowledge and understanding of the risks of PFAS posed to the water environment.	No - protects against current known PFAS but not future pollution.

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
			€201 million/yr (EU level). Capture of paper mill waste Landfill - €76.7 million/yr or high temperature incineration - €192 to €288 million/ yr.						
Option 1b All PFAS added as group to Annex I with a GWQS for "PFAS total" of 0.5 µg/l (again following the drinking water standard for PFAS total) l Option 2 in the SWD	Large scale, large magnitude (70% of reporting MS with exceedances at 75% of monitoring points)	€45-48 million Benefits from the DWD implementation and foreseen total PFAS methodology	As Option 1a with wider implementation as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	No–- GWQS not sufficiently precautionary / protective although it future proofs legislation
Option 1c All PFAS added as a group to Annex II for MS to consider for the development of a TV for specific substances posing a risk to GWBs l Option 3 in the SWD	Medium scale, large magnitude (35% of MS with 2.5% GWBs failing based on proxy substance)	Less than all other options Benefits from the DWD implementation	As Option 1a - but fewer sites to remediate Likely to focus on remediation rather that source control Cost of remediation of legacy pollution (to tax payer where polluter pays principle cannot be enforced)	As Option 1a but reduced consistency / less data collection	As Option 1a - but reduced extent	As Option 1a	As Option 1a but reduced extent	As Option 1a	No–- too variable and will not address pollution of groundwater at the Europe wide level
Option 1d PFAS (Group of 24 proposed as additions to the surface water Priority Substance list)	Large scale, large magnitude (90% of reporting MS	€45-48 million	As Option 1a with wider implementation as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a with wider impacts as covers all PFAS	As Option 1a	As Option 1a but improved targeting on more potent PFAS.	Yes Future proofed / human health focus

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
included in Annex I and assigned a GWQS of 4.4 ng/l PFOA equivalent; For PFAS substances not included on the PS list, the PFOA relevant potency factor (RPF) should be used to calculate the GWQS. If no RPF exists, then the RPF of PFOA should be assumed and a GWQS of 4.4 ng/l applied l Option 1 in the SWD	with exceedances at 68% of monitoring points)	Highest burden due to need to use RPFs Benefits from the DWD implementation							

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Option 1d: Policy Option 1 (Annex I addition as group of specific substances)	Soils +++/-- Carbon	--- costs of mitigation measures /+++ avoided costs DW and healthcare	++++	++	++++	++++	Carbon intensive remediation and reduced low-cost organic material for soils are negative, whilst improved ecosystem health and reduced soil pollution are environmental benefits. Economically the cost of disposal is high, but balances with the cost of avoided health treatment and drinking water treatment for the listed PFAS. Socially health impacts are very large, but this is only effective and efficient for the specific PFAS. Strong coherence with the DWD / EQSD.	Yes
Option 1b: Policy Option 2 (Annex I addition as group of all)	Soils ++++/ --- Carbon	---- costs of mitigation measures /++++ avoided costs DW and healthcare	+/-	+++	+++	+++	Carbon intensive remediation and reduced low cost organic material for soils are negative, whilst improved ecosystem health and reduced soil pollution are environmental benefits. Economically the cost of disposal is high, but balances with the cost of avoided health treatment and drinking water treatment for all PFAS. Socially health impacts are very large (more than Policy Option 1). Strong coherence with legislation but goes further.	No
Option 1c: Policy Option 3 (Annex II addition)	----	+/-	Health & Equine industry: -- AMR / Chronic ingestion: ++ Mineral water: ++	--	+/-	+	Environmentally effective only where included in GW risk is identified and will not provide the same level of protection at the Europe wide level. The ubiquitous nature of PFAS suggests that this will not be an effective policy option. Not coherent with other legislation.	No

9.2.2 *Pharmaceuticals: comparison of options and preferred option*

For pharmaceuticals the preference of the SCHEER, with agreement from stakeholder consultation, was to select option 2a (to add the two LFR pharmaceuticals to Annex I with recommended individual GWQS). This option has generally smaller costs than Option 2b (adding the two substances as a group). Option 2a will lead to a reduced pollution of groundwater and positive impact on shellfish and fisheries where groundwater inputs to rivers and estuaries are of considerable importance. Product substitution is considered as a viable option for Sulfathemoxazole, but less for Carbamazepine. MS will likely not take measures such as the treatment of biosolids only for these two pharmaceuticals as that would be disproportionately expensive but rather turn to 'Green Pharmacy' initiatives or other source control and pathway disruption measures.[552]

However, the GW WL process identified during the period of the SCHEER review, that there was enough evidence for primidone to be added to the LFR, although this was not formally done. In the March 2022, during the stakeholder workshop it was consulted Option 2c (adding all GW WL pharmaceuticals to Annex II), with the feedback that, apart from Primidone, for other pharmaceutical substances there was not enough evidence to be considered at this point. In the case of Primidone, due to the restricted timescale for consideration of a GWQS by the SCHEER, Option 2c was re-written as the addition of Primidone to Annex II. Based on the impact assessment, this option would not have a large impact neither on costs nor on benefits and, since it excludes addition to Annex I, it could be selected in addition to Option 2a.

[552] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6296717/#b1-cm-91-391

The table below shows the comparison of costs and benefits of groundwater options for addition of pharmaceuticals to the GWD Annexes.

Option	Distance to target	Economic Impacts			Environmental Impacts		Societal Impacts		
		Administrative burden	Costs of Measures	Benefits	Costs	Benefits	Costs	Benefits	Preferred option?
Option 2a Carbamazepine and Sulfamethoxazole added to Annex I and assigned GWQS of 0.5 and 0.1µg/l respectively - Option 1 in the SWD	Small scale, small magnitude (carbamazepine - 8% sites with exceedance reported by 37% of MS; sulfamethoxazole 0.43% of sites with exceedance reported by 12.5% of MS)	Costs of monitoring - €2 million (no significant additional administrative costs for risk / status assessments)	Generally smaller than 2b due to the focus on two substances. Product substitution viable for Sulfathemoxazole but unlikely for Carbamazepine—- costs associated with substitution of pharmaceuticals and availability of alternatives. Green Pharmacy initiatives in a small number of MS (<€1-10 million per MS) Treatment of biosolids / manures unlikely to be used due to being disproportionately expensive/ not coherent with energy / landfill policy	More data collected to understand the impact of these two pharmaceuticals. Consistent approach to data collection at EU level. Reduced pollution of groundwater	Impacts from substitution of other pharmaceuticals with increased production	As for Option 2b but with much reduced scale as only addressing two pollutants.	Restricting use could impact on health and well-being of people and animals where alternatives have side effects / different efficacy	Reduction in AMR likely to be small (mainly covered by baseline measures) Small increase in well-being from reduced risk of chronic ingestion in drinking water / improved ecosystem health. Positive impact on shellfish and fisheries where groundwater inputs to rivers and estuaries is significant	Yes (SCHEER preferred option, protective of human health and agreed with stakeholders)
Option 2b All pharmaceuticals added as a group to Annex I and assigned a G - WQS of 0.5 µg/l Option 2 in the SWD	Medium scale, medium magnitude (47% of reporting MS, with 50% of monitoring points with exceedances)	Costs of monitoring plus addition administrative costs €5.5 million to €11 million	Product substitution / ban use in animals (viable for Sulfathemoxazole but unlikely for Carbamazepine) - €140,000 average cost of alternative to carbamazepine in animals Returns program / Green Pharmacy initiatives - focused on two pharmaceuticals	More data collected for pharmaceuticals in groundwater leads to better understanding of risks Consistent approach to data collection at EU level. Future proofed legislation leads	Energy use to capture, store and destroy biosolids and animal manures to prevent leaching to groundwater	Reduced pollution of groundwater and connected aquatic ecosystems with reduced impact on sensitive habitats. Reduced treatment for drinking water reduces energy, carbon emissions and chemicals use (in the case of source control and	Restricting use could impact on the health and well-being of animals where alternatives have side effects / different efficacy	Reduction in AMR through control of Sulfamethoxazole is small in comparison to baseline measure of restricting prophylactic use in animals Small increase in well-being from reduced risk of chronic ingestion in drinking water / improved ecosystem health.	No - the GWQS is not protective of human health, and pharmaceuticals as a group have very different characteristics with no "total" pharmaceuticals analysis.

Option	Distance to target	Economic Impacts			Environmental Impacts		Societal Impacts		
		Administrative burden	Costs of Measures	Benefits	Costs	Benefits	Costs	Benefits	Preferred option?
			(less than €1-€10 million per MS) Treatment of biosolids / manures unlikely to be used due to being disproportionately expensive / not coherent with energy / landfill policy. Capture of biosolids - EU level €2 to 7500 billion to landfill or incinerate Capture and treatment of animal manures - EU level Treatment of wastewater (baseline measure - no cost)	to reduction in pharmaceuticals in groundwater and informs industry / permitting of new substances		pathway disruption measures). Increase reuse and recovery of pharmaceutical-free materials (e.g. use of sludge, treated wastewater). Increased knowledge and understanding of environmental behaviours of pharmaceuticals. Reduction in AMR likely to be small (mainly covered by baseline measures)—- Reduction in AMR through control of antibiotic use (costs avoided of €1.5 billion to the EU).	Capture of biosolids / incineration of manures has impact on farming sector with loss of low cost soil improver / fertiliser.	Benefits from impact on shellfish and fisheries where groundwater inputs to rivers and coastal estuaries is significant	
Option 2c All pharmaceuticals added as a group to Annex II—- guideline to include carbamazepine, sulfamethoxazole and primidone - Option 3 in the SWD.	Small scale, small magnitude (16% MS reporting detection of Primidone report an exceedance of suggested drinking water standard at 1% of monitoring points)	Costs negligible and absorbed into baseline. If all MS added Primidone via Annex II the additional costs would be half of Option 2a.	Returns program / Green Pharmacy initiatives - focused on two pharmaceuticals (less than 1-10 million per MS) Treatment of wastewater (baseline measure - no cost)	Unknown - likely to be much smaller scale than options 2a and 2b	As for Option 2b but scale depends on how far MS implement monitoring and measures	Specific risks to groundwater are investigated and dealt with locally rather than through EU wide schemes which may be too high level to be effective Monitoring data collected for at risk pharmaceuticals with a tailored approach	As for Option 2b but scale depends on how far MS implement monitoring and measures	As for Option 2b but scale depends on how far MS implement monitoring and measures	Yes, for Primidone

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Option 2a: Policy Option 1 (individual Annex I addition)	+	-	Health: --- Fisheries: + Mineral water: ++	-/+	+	+	Small scale environmental and economic impacts restricted to the listed substances. Social impact on health & Equine industry (restriction in use) versus potential for reduction in chronic ingestion and AMR. Effectiveness uncertain as human health may be more important than impacts. Coherence with aims of EU Green Deal reductions in AMR.	Yes
Option 2b: Policy Option 2 (Annex I addition as group of all)	+++	--	+/-	++	+++	+	Large scale environmental impact and moderate economic impact from investment in green pharmacy measures. Social impact human health and veterinary medicines (restriction in use) versus health benefits of reduction in chronic ingestion and AMR. Supported by returns schemes but effectiveness uncertain as human health may be more important than impacts. Coherence with aims of EU Green Deal reductions in AMR in soils.	No
Option 2c: Policy Option 3 (Annex II addition)	---	+/-	Farming: - Mineral water: ++	--	+/-	+	Little impact on reducing levels in GW across Europe and little change in terms of economic impact. Social impacts will be localised to where an issue has been identified.	Only for primidone

9.2.3 *nrMs of pesticides: comparison of options and preferred option*

The assessment of distance to target for nrMs was based on the extent of failure to achieve good status due to pesticides and their relevant metabolites, on the understanding that the additional impact of listing nrMs would follow a similar extent. As part of the baseline situation, most of the parent pesticide substances of the 16 nrMs identified as posing a widespread problem to groundwater at the European level are already banned. For the remaining parent pesticides, there are a number of strategies and legislation (e.g. the national action plans under the Sustainable Use of Pesticides Directive and the Farm to Fork ambition of reduced pesticide use) which will drive down permitted pesticide use at the European level. This suggests measures should already be in place over the next period which will continue to reduce the potential pollution of groundwater by nrMs.

The distance to target assessment suggests that Options 3b (all nrMs as a group in Annex I) and 3c (all nrMs as a group in Annex II) are unlikely to produce much change from the baseline situation where the approach is focused on specific GWBs or river basins. Based on published definitions, nrMs could be considered as non-hazardous substances and the GWD indicates that the concentrations of such pollutants should be limited in groundwater. The assessment of nrMs and stakeholder feedback suggests that all parties understand that the entry of these substances to groundwater (through control of emissions of the parent substance) needs to be limited as they are widely found in groundwater. Options 3b and 3c are likely to maintain the status quo with additional measures unlikely to extend outside the dynamic baseline.

Option 3a could be acceptable to MS and regulators as this follows the approach already taken, setting a GWQS which is just above those already set in some of the EU27. The DWD requires that MS set guideline values for nrMs and therefore Option 3a would close the loop, assuming that MS are most likely to select values close to or at the TVs already set for the GWD. This would also help to reduce the level of treatment needed for drinking water and reduce impacts on biota. However, this approach does not account for uncertainty around the effects of mixtures of substances or completely reduce the risk of potential impacts on groundwater biota which are likely to be more sensitive than humans. At the current point there are no specific Europe-wide actions taken by MS to protect groundwater biota.

Option 3d was proposed by SCHEER as following the precautionary principle to protect human health from the potential for mixture effects and to also be protective of groundwater biota. Given that the 16 nrMs are already detected in groundwater, there is a risk of further substances being detected in future at levels of concern. Therefore, Option 3e extends the more stringent GWQS to all nrMs of pesticides and hence future proofs the legislation, whilst following the precautionary principle with respect to mixture effects and protecting groundwater biota.

The cost of Option 3e has been identified by the pesticide industry as likely to lead to the revocation of authorisation for up to 20 pesticides, which would have an unacceptable impact on the farming sectors maintain food security.

It is not clear whether this assessment considers the ambition of the Farm to Fork strategy to reduce the use of hazardous pesticides by 50% by 2030, which is likely to help meeting the GWQS in Options 3d and 3e.

The table below depicts the additional impacts of implementing groundwater options, compared to the status quo for nrMs.

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
Option 3a nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 1 µg/l - Other options considered (Option 1) in the SWD.	Large scale, small magnitude (80% MS, exceedance at 29% MPs)	€4-5 million Costs of monitoring (no significant additional administrative costs for risk / status assessments)	Effectively results in a ban on use of approved parent pesticides (cost of alternative and possible loss of yield) - cost to industry product development, costs to farming sector of product substitution Cost of legacy pollution from landfill sites - average of €690,000 up to €77 million per site	Increased availability of clean raw groundwater for abstraction (for drinking water, irrigation, livestock watering). Avoided costs of (pre) treatment as a result of improved quality for potable water and process water for agriculture and industry More data collected for nrMs in groundwater leads to better understanding of risks Consistent approach to data collection at EU level. Better data for use during pesticide parent	Using substitutes that have an impact on other environmental compartments. Un-intentional impacts for example glyphosate is used to destroy cover crops, which are used to mitigate nutrients in run-off / leaching from agricultural fields over winter	Reduced risk of damage to natural resources such as groundwater and connected ecosystems Increased ecosystems services from groundwater biota not impacted by nrMs and cocktail effects Climate change impacts through reduced energy use (e.g. due to changes to wastewater and drinking water treatment processes) (in the case of source control and pathway disruption measures).	Costs to pesticide sector through loss of approved substances Increased data requirements could make gaining authorisation of new products more challenging Restrictions on use impact on farming sector and crop yields Substitute pesticides are available and can be cheaper or up to 100 times more costly that permitted parent pesticides	A healthy ecosystem (fishing, swimming, etc). Sectors requiring a high quality of groundwater such as bottled water or aquaculture Clean raw groundwater for abstraction (for drinking water, irrigation, livestock watering) Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for agriculture and industry Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment.	No - although likely to be closest to MS TVs this does not account for mixture effects and not protective of groundwater biota

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
				authorisation process					
Option 3b All nrMs added to Annex I as a group and assigned a group GWQS of 10 µg/l - Option 2 in the SWD.	Large scale, small magnitude (87% MS, exceedance 6% MPs)	€4-5 million Costs of monitoring (no significant additional administrative costs for risk / status assessments	Restrictions on use of parent pesticides across specific sensitive GWBs / drinking water protected areas (if not statutory may require compensation for lost crop yield)	Unlikely to lead to loss of parent pesticides.	Using substitutes that have an impact on other environmental compartments.	More data collected for nrMs in groundwater leads to better understanding of risks Consistent approach to data collection at EU level. Better data for use during pesticide parent authorisation process Future proof for other (unlisted) nrMs	Restrictions on use impact on farming sector and crop yields—-potential for cost increases	As above but only in restricted areas	No - maintains the status quo
Option 3c All nrMs added to Annex II for MS to consider for the development of a TV for substances that pose a risk to their GWBs - Option 3 in the SWD.	Medium scale, small magnitude (40% MS; 2% of GWBs fail)	Costs negligible and absorbed into baseline. Dependant on MS risks identified from nrMs	Inconsistent approach between MS Does not influence pesticide approval process	More data collected (but less than for Annex I listing)	Few additional costs (uncertain) as the extent of these impacts will depend on the TV adopted per MS	Under Option 3c the extent of these impacts will depend on the TV adopted. Could improve efficiency—-specific risks to groundwater are investigated and dealt with locally rather than through EU wide	Few additional costs	Limited programme of measures required	No (weakest option)

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
						schemes which may be too high level to be effective.			
Option 3d nrMs (Group of 16) added to Annex I as individual substances with a GWQS of 0.1 µg/l - Other options considered (Option 1) in the SWD.	Large scale, medium magnitude (93% MS, exceedance at 59% of MPs)	€4-5 million Costs of monitoring (no significant additional administrative costs for risk / status assessments	As Option 3a but more stringent: Costs to pesticide sector through loss of approved substances, costs of product development and product substitution to the farming sector. Substitute pesticides are available and can be cheaper (up to 3 times) or up to 100 times more costly than permitted parent pesticides. Increased data requirements could make gaining authorisation of new products more challenging.	As Option 3a	As Option 3a but more stringent	As Option 3a plus Reduced impacts on groundwater biota Consistent approach to data collection at EU level and improved knowledge (more data collected) on nrMs in groundwater leading to better understanding of risks. Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment. Improved knowledge and better data for use during pesticide parent authorisation process.	As Option 3a but more stringent	As Option 3a	No - does not future proof legislation

Option	Distance to target	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
			Costs	Benefits	Costs	Benefits	Costs	Benefits	
Option 3e All nrMs added to Annex I as individual substances with a GWQS of 0.1 µg/l - Option 1 in the SWD.	Large scale, medium magnitude (93% MS; exceedance at 59% of MPs)	€4-5 million Costs of monitoring (no significant additional administrative costs for risk / status assessments	As Option 3a but with future proofing	As option 3a	As option 3a	As option 3d	As option 3a	As option 3a	Yes–- future proofs legislation, with precaution for mixture effects

The table below summarises the impacts of implementing the option, compared to the status quo.

Substances	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Option 3e: Policy Option 1 (individual Annex I addition)	++	-	Farming: - Mineral water: +++	++	++++	+++	Environmental impacts include reduced drinking water treatment, healthier GW ecosystems (and services such a denitrification). Economic impacts will be the costs of finding new parent products and legacy clean up. Social impacts will include the challenge to pesticide industry and farming for authorisations and restriction of use, whilst the water bottling and fisheries sectors will benefit. Efficient for group identified. Coherent with EU Green Deal but goes beyond DWD.	Yes
Option 3b: Policy Option 2 (Annex I addition as group of all)	+++	--	+/-	+++	+	+++	Environmental impacts include reduced drinking water treatment, healthier GW ecosystems (and services such a denitrification). Economic impacts will be the costs of finding new parent products and legacy clean up. Social impacts will include the challenge to pesticide industry and farming for authorisations and restriction of use, whilst the water bottling and fisheries sectors will benefit. Efficiency is uncertain due to the GW timelag. Coherent with EU Green Deal but goes beyond DWD.	No
Option 3c: Policy Option 3 (Annex II addition)	----	+/-	+/-	--	+/-	+++	Small impact on reducing levels at European scale means environmental impacts are low with minimal change to investment in analysis and mitigation measures. Localised social impacts where used is restricted. Coherent with the DWD but not with the EU Green Deal. Option is ineffective and inefficient at dealing with the issue at the EU scale.	No

9.3 Monitoring, reporting and administrative streamlining options (Complementary options)

The table below depicts the additional impacts of implementing the aforementioned options, compared to the status quo. The options presented are not mutually exclusive, and can co-exist. As illustrated in the previous chapters, the proposed policy options have significantly different economic, environmental and social impacts. An overall assessment of the impacts is summarised below, whereby the options were categorised as having (overall): no impact; positive impacts; negative impacts; or neutral impacts.

Following this, the options have been categorised based on their level of ambition, which is a reflection of the benefits weighted against the potential costs. Options are classed into three categories of ambition level:

Low ambition: Reflects options that have a low positive impact. The option may either have a low or high cost, but its return on investment in terms of benefits is low. Options in this category are most often based on clarifying key concepts and providing more information to support implementation, such as guidance documents or sharing of best-practices. Since the options are non-binding, their implementation often remains voluntary and actual beneficial impacts may remain low.

Medium ambition: These options can have a significant positive impact, as they would be binding. However, they are often either associated with high costs that either not outweighed by the benefits, or the return on investment take substantial time and is therefore at risk due to uncertainty of the success of up-take and implementation. Nonetheless, these options have high potential to be impactful and can possibly be considered at a later stage for further revisions of the Directives.

High ambition: Options with high ambition are marked by their significant positive environmental and social impact that they can have. While the options can be associated to high initial costs, their implementation would quickly show significant benefits to environmental and social protection and conservation. The options will usually affect a large range of stakeholders, thus having the ability to trigger change in economic and social behaviour, as well as protective measures implementation.

The table below indicates the ambition level of each option, based on the previous assessments.

Option	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
Option 1a: Develop guidelines on applying innovative methods in monitoring procedures, including continuous/automated monitoring techniques	Neutral impact: depending on the measures that will be described in the document	Limited cost (≤€500,000) to develop the guidance document. Other costs to MS depend on uptake of measures	Likely to have positive social impacts depending on uptake of measure	Depending on uptake of measures
Option 1b: Follow-up to improve existing guidelines in view of setting application ‘trigger values’ in practice to improve monitoring of groups/mixtures of pollutants by using effect-based methods (EBMs), and trigger values	Neutral impact: depending on the measures that will be described in the document	Limited cost (≤€500,000) to develop the guidance document. Uptake of EBM would improve cost-efficiency of monitoring. Increased costs for control source pollutants by industry due to improved monitoring accuracy.	Likely to have positive social impacts depending on uptake of measure.	Depending on uptake of measures
Option 1c: Develop a harmonised measurement and monitoring methodology and guidance for microplastics, as a basis for mandatory MS reporting on microplastics and a future listing under EQSD/GWD	Positive impact in the longer run, allowing for monitoring and ultimately regulating microplastics levels in water.	Limited cost (≤€500,000) to develop the guidance document.	In the longer run, positive health impacts from preventing exposure to microplastics, as well as reduction of costs of water treatment downstream.	Benefits clearly outweigh costs
Option 1d: Develop guidelines on sampling frequency for priority substances (PS) and river basin specific pollutants (RBSPs)	Neutral impact: depending on the measures that will be described in the document	Limited cost (≤€500,000)to develop the guidance document. Other costs to MS depend on uptake of measures	Likely to have positive social depend on uptake of measure	Depending on uptake of measures
Option 1e: Provide a repository for sharing best-practices from MSs regarding available monitoring techniques, and foster cooperation to implement these	Possible positive impacts, but depending on uptake of knowledge and implemented actions	Minimal economic costs, with significant benefits to knowledge sharing and innovation	Likely to have positive social impacts through more accurate monitoring.	Benefits could outweigh initial costs due to knowledge sharing and development

Option	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
Option 2a: Include an obligation in the EQSD to use EBMs to monitor estrogens	Significant benefits to the environment through garnering a greater understanding of threats and occurrence of estrogen exceedances	Relatively minor additional costs borne by MSs. Costs likely to be further reduced following standardisation of laboratory analysis in the future. But possible measures to be taken due to monitoring results may be substantial	Likely to have positive impacts on human health by allowing better targeting of policy measures	Benefits on human health and the aquatic environment likely to outweigh economic costs
Option 2b: Establish an obligatory groundwater watchlist analogous to that of surface waters and drinking water, and provide guidance as necessary on the monitoring of the listed substances	Positive impacts due to better decision-making processes regarding substances posing risks and better comparability of data	Additional cost for monitoring and reporting, balanced by benefits of more comparable and coherent data to implement efficient measures to improve groundwater status	Neutral impacts	Benefits through enhanced data comparability and cohesion out-weigh costs of monitoring
Option 2c: Improve the monitoring and review cycle of the surface water watch list so that there is more time to process the data before revising the list	Neutral impacts as they depend on the actions implemented (i.e. which substances added to Priority Substance list), but expected to be positive	Neutral impacts due to administrative costs for additional and more frequent monitoring, compensated by decrease in frequency of updating the list	Neutral impacts	Significant environmental benefits and reduced reporting burden likely to outweigh the possible costs of monitoring frequency- yet this is dependent on the measures implemented following enhanced monitoring procedures
Option 3a: Establish an automated delivery mechanism for the EQSD and the WFD to ensure easy access at short intervals to monitoring/status data to streamline and reduce efforts associated with current reporting, and to allow access to raw monitoring data.	Positive impacts by improving accessibility of spatial/temporal knowledge for more effective actions	Initial cost for aligning data and establishing harvesting mechanisms, but outweighed by benefits of data-sharing and long-term cost savings for reduced reporting	Positive impacts due to accessibility of information	Significant benefits in the long run, however substantial cost implications involved

Option	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
Option 3b: Introduce a reference list (repository of standards) of environmental quality standards for the RBSPs as an Annex to the EQSD and modify Annex V of WFD section 1.2.6 (*Procedure for the setting of chemical quality standards by MS*) accordingly, and incorporate RBSPs into the assessment of chemical status for surface waters	Positive impact through harmonization of EU-wide standards allowing more effective measures	Negative impact due to agreeing on RBSPs EQSs likely leading to substantial costs for MS for implementation of monitoring and costs for economic actors taking measures where necessary	Positive impacts for social well-being and health, providing equal standard of water resource across EU	Significant environmental and social benefits outweigh the possible costs incurred by MS and economic actors
Option 4a: Use annex in the EQSD instead of Annex X to the WFD to define the list of Priority Substances, and consider a provision to update it by comitology or delegated acts	Positive impact due to quicker actions to address new substances	Neutral impact due to cost of measures to be taken by economic actors and minor costs associated to delegated acts, but balanced by stimulating innovation and possible improvement in market competitiveness	Positive impacts as innovation and research will lead to possible employment opportunities	Significant environmental, economic, and social benefits that out-weigh possible costs
Option 4b: Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of PS/PHS ***Pesticides****: Aldrin, Dieldrin, Endrin, Isodrin, DDT (all to PHS)* ***Industrial chemicals****: Tetrachloroethylene, Trichloroethylene (to PHS)* *Note: Carbon tetrachloride is deselected under surface water option 4, hence is not considered here.*	The cyclodiene pesticides Aldrin, Dieldrin are suspected to be Carcinogenic and recognised as POP. Endrin is recognised as POP and toxic for the nervous system. Isodrin is very toxic to aquatic life with long lasting effects. For DDT, the isomer 111 -trichloro -22 bis (p–- chlorophenyl) ethane is recognised as POP and is suspected to be carcinogenic. DDTs are also known endocrine disruptors. Tetrachloroethylene and Trichloroethylene are mutagenic and carcinogenic.	Minor additional compliance costs (extremely low current exceedances).	The societal benefits of monitoring tetrachloroethylene and trichloroethylene within the water environment may be a valuable addition to help track emissions and possible human exposure via the environment.	Benefits outweigh the costs.

Option	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
	The rate of EQS exceedance suggests environmental risk is low. Greater coherence in the policy landscape would have societal benefits for how these substances are addressed.			
Option 4c: Change the status of some existing PS to that of PHS where it fulfils the criteria of the POP Regulation and/or Article 57 of REACH Regulation ***Industrial chemicals***: *1,2-Dichloroethane, Fluoranthene, Octylphenol, Pentachlorophenol* ***Metals***: *Lead*	Greater coherence in the policy landscape would have environmental benefits for how these substances are addressed.	No costs - administrative change only.	Greater coherence in the policy landscape would have societal benefits for how these substances are addressed.	Benefits outweigh the costs

The table below summarises the impacts of implementing the monitoring, reporting and administrative streamlining options, compared to the status quo. The options presented are not mutually exclusive.

Policy option	Sub-option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Option 1: Provide / improve guidance and advice on monitoring	**a)** Guidelines on applying innovative methods.	+/-	+/-	+	+/-	+/-	++++	Impacts on environment / economy neutral as depending on uptake from MS. Similarly, effectiveness and efficiency will depend on the extent of investment and uptake. Option coherent with provisions of WFD	No
	b) Improve existing guidelines on EBMS.	+/-	+/-	+	+/-	+/-	++++	As above	Yes
	c) Harmonised monitoring methodology and guidance for microplastics.	+/-	+/-	+	+/-	+/-	++++	As above	Yes
	d) Guidelines on sampling frequency for PS and RBSPs.	+/-	+/-	+	+/-	+/-	++++	As above	No
	e) Repository for sharing best available monitoring technique practices MS.	+	++	++	+/-	+/-	++++	Impacts on environment / economy and social positive as it enables knowledge sharing. Efficiency positive as long term benefits outweigh investment due to savings in unsuccessful approaches. Effectiveness depends on use of MS. Coherent with WFD	No
Option 2: Establish / amend obligatory monitoring practices	**a)** Obligation in EQSD to use EBMs to monitor estrogens.	+++	-	+++	++++	+/-	++++	Economic impacts high but benefits to environmental and society significant. Effectiveness very high, whereas the cost/benefit ratio means a neutral rating. Coherent with WFD	Yes
	b) Obligatory Groundwater Watch List mechanism.	+++	-	+/-	++++	++	++++	Obligation for monitoring would inquire costs, but have significant environmental benefits in short term, and likely social in long term. Effectiveness and efficiency very positive as monitoring stations already in place. Option coherent with WFD	Yes
	c) Improve monitoring and review cycle of Surface Water Watch List	++	+/-	+/-	++	+	++++	Significant environmental benefits and reduced reporting burden likely outweigh possible costs of monitoring. As such, effectiveness considered medium. Efficiency small positive as administrative costs are compensated by decrease in frequency of updating list. Option coherent with WFD	Yes
Option 3: Harmonise reporting and classification	**a)** Harmonised digital reporting / automated data delivery mechanism.	+	-	+	+++	+	++++	Significant benefits in the long run, however substantial cost implications involved. As such, the effectiveness is high but the efficiency remains positive, but small as the benefits would outweigh cost but only through time. The option is coherent with provisions of the WFD	Yes

Policy option	Sub-option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	b) Reference list of EQS for RBSPs and incorporate RBSPs into assessment of chemical status	+/-	--	+++	+++	++	++++	Negative impact due to substantial costs MS for implementation and costs for economic actors taking measures. However, positive impacts through harmonization allowing more effective measures and providing equal standard of water resource leads to high effectiveness. Benefits will outweigh costs thus efficiency also positive.	Yes
Option 4: Legislative and administrative aspects	**a)** Update lists of SW and GW pollutants by delegated acts.	+++	+/-	+++	+	+++	++++	Cost of measures to be taken and minor costs associated to delegated acts but balanced by stimulating innovation and possible improvement in competitiveness. Environmental and social impacts very positive leading to positive efficiency rating. Effectiveness will depend on which pollutants are actually integrated.	Yes
	b) Change status of 'eight other pollutants' to that of PS/PHS.	+	-	++	++	++	++++	Five of eight other pollutants are POPs under Stockholm Convention, therefore option increases consistency and improve efficiency and effectiveness with their management. Three other substances are solvents with known CMR properties, for which water protection currently not addressed. Addition tri and tetrachloroethylene would have strong coherence benefits to REACH and solvent emissions directive.	Yes, except carbon tetrachloride (see SW option 4)
	c) Change status some existing PS to that of PHS.	n/a	n/a	n/a			++++	PHS status coherent as follows: **PCP** (to become PHS along with other POP under Stockholm Convention); **Fluoranthene** (grouped with other PAHs recognised as POPs under the Convention on Long-Range Transboundary Air Pollution). **Lead** (other metals of similar class are already PHS); **1,2 dichloroethane** ('sufficient concern at community level' as in REACH); the **two Octylphenol** substances (coherence REACH and sufficient concern at community level)	Yes

The analyses have packaged the options into three categories, based on their ambitions in terms of positive impacts and associated costs. The target of complementary options was to revise the Directives and their functioning in the most impactful manner. As such, the high ambition package reflects those options that are of most relevance. The assessment therefore recommends the following as preferred options:

- ✓ Option **1b**: Improve existing EBM guidelines to improve monitoring of groups/mixtures of pollutants by using EBMs, and **1c**: Develop a harmonised measurement standard and guidance for microplastics in water as a basis for MS reporting and a future listing under EQSD and GWD.
- ✓ Option **2a**: Include an obligation in the EQSD to use EBMs to monitor estrogens; **2b**: Establish an obligatory Groundwater Watch List analogous to that of surface waters and drinking water and provide guidance on the monitoring of the listed substances; and **2c**: Improve the monitoring and review cycle of the Surface Water Watch List so that there is more time to process the data before revising the list.
- ✓ Option **3a:** Establish automated data delivery mechanism to ensure easy access at short intervals to monitoring/status data to streamline and reduce efforts associated with current reporting, and to allow access to raw monitoring data; **3b:** Introduce a repository of environmental quality standards for the RBSPs as an Annex to the EQSD, and incorporate RBSPs into the assessment of surface waters' chemical status.
- ✓ Option **4a**: Use EQSD instead of WFD to define the list of Priority Substances, and update the lists of SW and GW pollutants by Comitology or delegated acts; **4b**: Change the status of Aldrin, Dieldrin, Endrin, Isodrin, DDT, Tetrachloroethylene and Trichloroethylene from 'other pollutants' to that of Priority Substances; **4c** Change the status of 1,2 dichloroethane, fluoranthene, lead, octylphenol ethoxylates and pentachlorophenol to that of Priority Hazardous Substances.

10 Summary of preferred options

The preferred policy options are aggregated in the table below. The package of all surface and groundwater options and the digitalisation, administrative streamlining and better risk management options marked as preferred in the preceding chapter.

Table 10-1: Preferred policy initiatives

Surface water		
<u>Option 1:</u> Addition to PS list as an individual substance with EQS set for each individually	**24 individual substances:** 17-Beta estradiol (E2); Acetamiprid; Azithromycin; Bifenthrin; Bisphenol A; Carbamazepine; Clarithromycin; Clothianidin; Deltamethrin; Diclofenac; Erythromycin; Esfenvalerate; Estrone (E1); Ethinyl estradiol (EE2); Glyphosate; Ibuprofen; Imidacloprid; Nicosulfuron; Permethrin; Silver; Thiacloprid; Thiamethoxam; Triclosan, Silver	
<u>Option 2:</u> Addition to PS list as a group with EQS set for "total" and/or "sum of"	PFAS (sum of 24 named substances)	
<u>Option 3:</u> Amendment of existing EQS	**14 substances to more stringent:** Chlorpyrifos; Cypermethrin; Dicofol; Dioxins; Diuron; Fluoranthene; Hexabromocyclododecane (HBCDD); Hexachlorobutadiene; Mercury; Nickel; Nonyl Phenol; PAHs; PBDEs; Tributyltin **2 substances to less stringent:** Heptachlor/heptachlor epoxide; Hexachlorobenzene,	
<u>Option 4:</u> Deselection	**4 substances:** Alachlor; Carbon tetrachloride; Chlorfenvinphos; Simazine	
<u>Option 5:</u> Change the status of the 'eight other pollutants' added to the EQSD from the former Dangerous Substances Directive (76/464/EEC) to that of priority substances	Change the status of Aldrin, Dieldrin, Endrin, Isodrin, DDT, Tetrachloroethylene and Trichloroethylene from 'other pollutants' to that of Priority Substances.	
Groundwater		
<u>Option 1:</u> Addition to Annex I with GW QS set for each individually	**Option 2a: 2 pharmaceutical substances:** Carbamazepine and Sulfamethoxazole Option 3e: All nrMs with individual GW QS of 0.1 µg/l	
<u>Option 2:</u> Addition to Annex I with GW QS set for "total" and/or "sum of"	Option 1d: PFAS (sum of 24 named substances)	
<u>Option 3:</u> Addition to Annex II	**Option 2c: 1 substance:** Primidone	
Monitoring, reporting and administrative streamlining		
<u>Option 1:</u> Provide guidance and advice on monitoring	b	Improve existing EBM guidelines to improve monitoring of groups/mixtures of pollutants by using EBMs. .

Surface water		
	c	Develop a harmonised measurement standard and guidance for microplastics in water as a basis for MS reporting and a future listing under EQSD and GWD.
<u>Option 2:</u> Establish/amend obligatory monitoring practices	a	Include an obligation in the EQSD to use EBMs to monitor estrogens.
	b	Establish an obligatory Groundwater Watch List analogous to that of surface waters and drinking water and provide guidance on the monitoring of the listed substances.
	c	Improve the monitoring and review cycle of the Surface Water Watch List so that there is more time to process the data before revising the list.
<u>Option 3:</u> Harmonise reporting and classification	a	Establish automated data delivery mechanism to ensure easy access at short intervals to monitoring/status data to streamline and reduce efforts associated with current reporting, and to allow access to raw monitoring data.
	b	Introduce a repository of environmental quality standards for the RBSPs as an Annex to the EQSD, and incorporate RBSPs into the assessment of surface waters' chemical status.
<u>Option 4:</u> Legislative and administrative aspects	a	Use EQSD instead of WFD to define the list of Priority Substances, and update the lists of SW and GW pollutants by Comitology or delegated acts.
	b	Change the status of Aldrin, Dieldrin, Endrin, Isodrin, DDT, Tetrachloroethylene and Trichloroethylene from 'other pollutants' to that of Priority Substances.
	c	Change the status of 1,2 dichloroethane, fluoranthene, lead, octylphenol ethoxylates and pentachlorophenol to that of Priority Hazardous Substances.

11 How would the actual impacts be monitored and evaluated?

As highlighted in the Better Regulation guidelines, it is important to consider, from the impact assessment stage how to monitor the measures to ensure that the general and specific objectives are achieved in an effective and efficient manner. The WFD along with its daughter-Directives the EQSD and GWD represent one of the most comprehensive and ambitious legislations of EU water policy. The Fitness Check of the WFD showed that its form is generally fit for purpose and has been successful in setting up a governance framework. This includes a key role in slowing down the deterioration of water quality status and reducing chemical pollution. Nonetheless, it was also found that the costs of implementation have been significant for MSs, and the implementation significantly delayed. As part of the revision of the Directives it is important that a balance is struck between improving water bodies' status while not causing significant cost burdens, and further delays in implementation.

Overall, the monitoring and reporting obligations through the WFD will remain the key indicators to track progress against the objectives of this revision. For surface and groundwater, the timeliness, and the completeness of reporting, broken down by MS, pressure source and pollutants, will be the main tools to evaluate and continuously monitor progress. However, more frequent periodic (and obligatory) reporting and sharing of information by MSs will be needed to complement the current reporting cycles in place in order to successfully evaluate progress. The voluntary nature of the groundwater watch-list has also meant that MS can delay or chose not to implement monitoring of substances included in this list, thereby delaying monitoring and reporting of risk.

In the current format, information regarding status of water bodies is slow to reach the public domain. For example, most data in the 2018 EEA State of Water report dates back to 2013 or 2014 and this, at the time of writing this report, still provides the most up to date information publicly available at EU level. It needs to be acknowledged that the data collection surrounding the assessment of (chemical and ecological) good status of water bodies is dependent on many different data points, and thus requires time. However, a greater uptake and implementation of modern monitoring and reporting systems, and digitalization of the water sector can enable these overviews to be generated in shorter timeframes than currently.

Additional indicators could be established to be reviewed and analysed as part of the implementation and evaluation of the revised Directive. These indicators could be developed in cooperation with the EEA considering the agency's expertise with the data being reported under the WFD, WISE database and hosting of the repository under ReportNet. Examples of indicators could include:

- Harmonization of EQSs for RBSPs;
- Adoption of EBM monitoring standards;
- Monitoring of selected pollutants of emerging concern's pressure in surface and groundwaters;
- Raw data completeness checks.

The European Commission should continue to work alongside Member States and with the relevant stakeholders to monitor implementation and management of surface and ground-water substances. The Working Group Chemical and Working Group Groundwater represents an excellent source of knowledge and information exchange with Member States and key stakeholders. Feedback can also be obtained from other stakeholder groups on the wider impacts of the revised legislation, and could be done during the course of the next review cycle.

Appendix A Groundwater watch list review

Review of the GWWL Process and Recommendations

The technical work for the GW WL is led by the subgroups of experts and members of the Working Group (WG) Groundwater under the Common Implementation Strategy (CIS) for the WFD.[553]. A review of the GW WL process was undertaken based on a review of reports, meeting minutes and presentations publicly available on CIRCABC and interviews with lead members of the GW WL subtask group. The aim was to better understand the context of decisions made in the development of the methodology.

In this review the key elements of the GWWL process were compared to the equivalent surface water watch list for the Priority Substance list (under the EQSD) in the GWWL methodology report. Here, this comparison of the two watch list approaches has been expanded to include additional elements, an assessment of the strengths and weaknesses of the GWWL process, feedback from the interviews of GW WL subtask group members and to suggest possible improvements which could be made. The outcomes of the review are shown in the table below.

553 https://circabc.europa.eu/w/browse/a53f1d54-0cd9-4de6-b370-2cbb14004986

Table —-1 Review of the GWWL process

Element	Surface water watch list (for comparison)	Groundwater watch list	Strengths of the GWWL	Weakness of the GWWL	Feedback from interviews
Purpose of the watch list as set out in legislation	To gather EU-wide monitoring data to support future prioritisation exercises (i.e. the priority substances list)	To increase the availability of monitoring data on substances posing a risk or potential risk to GWBs and, therefore, to identify substances for which GWQS or TVs should be set	Both WL have the same purpose, which is to gather through monitoring to inform decisions on whether substance should be formally listed.	Voluntary so relies on participating countries (PC) collecting sufficient information to inform decision-making	Voluntary process enables rapid decision making.
Method development and the process	Technical work is carried out by the Joint Research Council (JRC), with input from CIS WG Chemicals and is reviewed every two years. Proposals must pass the WFD Regulatory Committee before adoption.	The GWWL process was developed by CIS WG GW with approval from the Strategic Coordination Group.	Voluntary process gives flexibility in timing and addition of substances to WL without need for regulatory committee checks.	Lack of expertise in WG GW on the specialist subjects of toxicology / ecotoxicology. Lack of data on leaching potential of new and emerging substances means that this element of the process was not assessed Six-yearly cycle of review of the GWD annexes is too long to address rapidly emerging substances	Expertise from other groups has been sought for example from the NORMAN network. Due to the lack of information on substance properties and their behaviour in the subsurface, the leaching potential analysis was only attempted for PFAS. The GWWL process has subsequently relied solely on the detection of substances in groundwater as criteria for selection or removal MS have the option to assign TVs for substances putting groundwater at risk so the six yearly cycle of review is not so restrictive for groundwater, although the level of protection is likely to vary between countries.
Monitoring / Reporting	Obligatory	Voluntary	Voluntary nature means that PCs which are unable to implement monitoring (e.g. due to economic factors) can share data and experience from those countries which are able to put monitoring in place.	There is a risk of low participation / monitoring due to the voluntary nature of the GW WL Risk of bias in the datasets used to support the GWWL process as only PCs provided data	All MS, Participating Countries (PC) and Associated Countries (AC) were consulted on the design of the process and were asked to provide analytical data from their groundwater monitoring programmes for review and analysis during subsequent studies. A high level of participation was reported (29 countries contributed to the latest nrM review with 17 providing monitoring data). Where countries have not participated fully it is typically due to a lack of data. Although there is bias in data provision (some countries will have a larger /longer dataset, some are not able to participate due to the costs etc.) it was felt that there was sufficient data provided to give a representative picture of the situation across a significant part of Europe. The criteria for inclusion of substances on the LFR follows that for the surface water priority substances list with respect to having minimum requirements for frequency of detection and number of PCs and provides a sufficient threshold for inclusion on LFR.
Setting of water quality standards based on WL outputs	EQSs are set in the Priority Substances Directive during the six year review of the Priority Substance list, and applied across the EU. MS can identify substances as river basin-specific pollutants and set national standards.	MS should consider setting TVs for substances identified as posing a risk to achieving WFD objectives. Formal recognition for inclusion in Annex I and II occurs during the six yearly review of the GWD.	Flexibility to add and remove substances to GWWL without the need for legislative changes. MS can use Annex II approach to set TVs for any substances posing risk to GWBs between review cycles of the GWD Annexes.	Risk that MS will not set TVs for substances which are not specified in Annex II. WG GW does not include experts in ecotoxicology or toxicology, and therefore may not be able to access relevant information on the leaching potential and hazard assessment part of the GWWL process	Some PC have already set TVs for new and emerging substances based on human health studies or environment quality standards at the national level, or on EU-wide guidance (e.g. SANCO). It was assumed that these TVs were developed using national expert input. These values have been used in identifying suggested GWQS for the update to the GWD Annexes.
Selection of substances for GWWL process		Substance groups (by chemical property or use) were selected through review of REACH and other data sources. The order of GWWL process application was prioritised by WG GW based on the level of concern for the substance in groundwater	Substances are selected by MS and should therefore focus on the most pressing issues	Substances are grouped by chemical properties or usage, which does not help in understanding the leaching potential or hazard	Grouping of substances was done by usage group or chemical group, as this was the easiest way of communicating the types of substances. Grouping of substances can be useful, especially when considering the review of the GWD Annexes, as addition of groups of substances rather than individuals avoids the need for updates to legislation and also complies with the precautionary principle[554].

[554] The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high. According to the EU Court of Justice 'the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.

In general, the voluntary GW WL process provides more flexibility in identifying substances of concern for which more data should be collected, compared to the Surface Water Watch list. Although the process is voluntary there has been a high level of participation (around 70% of MS) and the approach fulfils the aims set out in the GWD 2014 amendment.[555]

Some recommendations for potential improvements to the GWWL process include:

- Improved data collection on, and better sharing of data of, leaching potential of substances (e.g. with the chemicals industry and research organisations) should be undertaken to understand the potential risk that a substance poses to groundwater;
- Increased participation in the process. Some MS currently have a low level of participation, leading to a bias in data provision towards north-west European countries. Economic factors most likely play a key part due to lack of analytical capability or funding for sampling programmes. The value of participation should be demonstrated in terms of benefits outweighing costs (e.g. versus dealing with human health issues or greater depollution efforts in the future).
- Accounting for variations in substance use across different MS. There are likely to be differences in use patterns because of differences in climate and crops grown (nrMs); medical practise (pharmaceuticals) and due to differences in sewage provision and industry locations (PFAS, pharmaceuticals). Linking substances on the GWWL to use patterns would provide a better estimate of risk at the EU level;
- The reasons for listing a substance should be clearly stated and the expected outcome considered in advance to provide the evidence to MS that would help to support inclusion in monitoring programmes.
- Increased input from experts in toxicology and ecotoxicology would help to better quantify the risk and provide a more robust evidence base for risk of substances in groundwater. This could help to increase participation.
- Be forward looking. The process has, to date, relied on groundwater monitoring data. However, for a substance to be widespread in groundwater it must have been used for many years. It would be important to anticipate future groundwater emerging substances based on their properties and ensure that this is taken into account in assessing risks to groundwater as part of the GWWL for instance through modelling and more detailed data assessment, i.e., the assessment of data should be wider than just the number of detections, it should also consider trends in the data.
- Ensure coherence with other directives where possible for example with the updates to the EQSD and DWD.
- Gather feedback from MS on their risk assessments / likely impact of the GW WL and LFR substances on status for use in the review of the annexes.

[555] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0080&from=EN

Appendix B Information on emissions of List Facilitating Review (LFR) substances

Overview of current situation

The substances proposed for inclusion in the LFR by GW WL group, and their corresponding quality standards were validated by the WG GW. By analogy with the SW process, the resulting proposals for including them in the Annexes to the GWD were independently reviewed by scientists of the Scientific Committee on Health and Environmental Emerging Risks (SCHEER). The substances identified were: pharmaceuticals, PFAS and degradation products of pesticides which do not have the same properties as the parent substance and whose toxicity is unknown (referred to as non-relevant Metabolites (nrMs)), as outlined below.

In order to understand the current status of GWBs, the number of GWBs at risk of failing to meet good chemical status and the level of exceedance in regard to PFAS, pharmaceuticals and nrMs needs to be defined. Unlike the surface water situation, a Europe-wide assessment of the risk to groundwater from PFAS, nrMs and pharmaceuticals does not yet exist. Although a small number of MS have carried out a risk assessment, other MS do not have sufficient monitoring data to do so. The data provided by MS for the GW WL process, which was used to identify the presence of Europe-wide pollution, was under condition of anonymity, as some data may be owned by third parties. The data was provided with no spatial information and consequently it can only be used to identify the frequency of detection with concentration ranges in groundwater.
Therefore, in order to assess the baseline status of groundwater for the pollutant in the LFR, analysis of the following datasets was carried out:

- Emission data was collated and reviewed for each group of LFR substances (source locations of chemical production and industrial, agricultural, amenity and domestic use)
- Pathways to groundwater including environmental fate information;
- The most recent reported status of GWBs (2nd River Basin Management Plans) was checked to identify the chemicals leading to failure with similar emission characteristics, and environmental fate along pathways to groundwater – referred to as proxy substances hereafter;
- The GW WL reported frequency of different concentrations of the reported LFR substances (note that GW WL results were supplied as concentration ranges, rather than actual values);

Finally, an assessment of the likely Europe-wide current day status of GWBs with respect to the LFR pollutants is made. As stated previously, the lack of a Europe-wide risk assessment based on monitoring data for the LFR pollutants means that an estimation of the likely current day risk and status of GWBs is needed to understand how the problem would evolve. To estimate the proportion of the circa 13746 GWBs reported on by the EU27 which are potentially at risk of being at poor status due to LFR pollutants, the following assumptions were made:

- The majority of MS will set a TVs based on the current day DWS as this is the most commonly used criteria for TV setting. Although there are EQS for PFAS (PFOA and PFOS), pharmaceuticals and pesticide metabolites this is less likely to be used unless the GWB supports an aquatic ecosystem.
- The most likely used chemical status test would be the General Chemical Assessment (GCA)[556] test (the remaining tests are not relevant or would need more detailed datasets).

The emissions, pathways and detection in groundwater were used to estimate the scale of pollution and whether this would trigger a failure of the GCA test. Estimates were benchmarked by comparison to the number of GWBs at risk for substances with similar emissions, pathways and environmental fate which are listed in the GWD Annexes or lead to poor status of GWBs.

For the substances added to the LFR, the baseline situation, in terms of production, use and emissions, is in most cases subject to significant uncertainty. Several measures, including legislation and voluntary programmes, are already in place that will or may have an impact on the use and emissions of some of the substances in the coming years, and therefore on their concentrations in groundwater.

PFAS Emission, pathways and detection in groundwater

PFAS are a large family of thousands of synthetic chemicals that are widely used throughout society and found in the environment. They contain strong carbon-fluorine bonds that resist degradation. Despite their use over many decades they have emerged as groundwater pollutants more recently and are identified as such due to their high mobility, persistence and toxicity through bioaccumulation. Their persistence means that they will be present in groundwater for many years. There are also concerns around the cumulative impact of the presence of mixtures of many similar substances.

PFAS European emissions

Developed in the 1930s, PFAS have since been used in a wide range of applications including; fire-fighting foams, as surfactants, as coatings (food packaging, paints, photographic processes, ski wax, clothing), in hydraulic fluids, polishes, non-stick coatings, stain resistance and in pesticides. As a result of their widespread use in textiles and food packaging industry they are likely to be present in domestic wastewater, sludges and landfilled waste. They are also deposited on the land-surface through aerial particulates from stack emissions. The specific PFAS on the LFR include manufactured PFAS, such as PFOS and PFBS but also substances that are likely to result from degradation of parent compounds.

[556] The general chemical assessment (GCA) identifies significant pollution and requires that the pollutant(s) must be present at sufficient number of monitoring points to indicate either that the entire GWB is at risk (average concentrations exceed GWQS or TV) or that a significant proportion of the GWB is at risk (defined in CIS Guidance 18 as 20% or more of the area of a GWB).

PFAS are manufactured in a small number of locations in Europe and although they will be present at these manufacturing sites, their specific manufacture in the EU is restricted through the Stockholm Convention on persistent organic pollutants (POPs). As concern has risen around human health impacts, the use of some PFAS compounds has been restricted or banned. POPs Regulation (2019/1021/EU) implements the Stockholm Convention on POPs and bans/restricts the manufacturing, marketing and use of POPs in the EU (applicable to PFOS, PFOA, PFHxS). PFOS and PFOA are listed under Annex A (full ban) and so are restricted globally and PFHxS has also been approved for listing under Annex A. Several PFAS (incl. PFOA, PFECA and ADONA) are not permitted for use in food contact materials under the Food Contact Materials Legislation (EC1935/2004) and Commission Regulation (10/2011) on plastic materials and articles intended to come into contact with food. Therefore, the production or import within the EU of several PFAS on the LFR is currently restricted or banned. However, as PFAS are persistent they will continue to be in circulation in products and further releases to the environment will take place and the main source is likely to already be in the environment. PFAS will also be present within many environmental media where they can migrate into groundwater within recharge.

PFAS pathways to groundwater

The widespread use of PFAS in domestic and industrial settings leads to entry to groundwater via many pathways including:

- direct emissions to ground (biosolid (including anaerobic digestate) and paper / industrial process sludge spreading to agricultural land, landfill disposal, sewage effluent discharges to ground);
- diffuse emissions from use of PFAS products (ski wax, personal care products, waterproof clothing, food packaging etc) and aerial deposition of particulates leaching to groundwater;
- unintended emissions (fire-fighting foams, industrial use such as in chrome plating); and
- leakage from surface water (wastewater effluent discharges or aerial deposition).

To date large scale groundwater pollution requiring remediation has been identified as due to the use of fire-fighting foams at airfields and fire training stations, and from landfill waste from industries using PFAS.

Emissions via soils have been shown to lead to shorter chain PFAS reaching groundwater as longer chain substances are absorbed by soil particles until the absorption capacity is exhausted, after which also the longer chain substances will reach groundwater. This leads to longer lag-times for detection in groundwater and means that it is a matter of time until PFAS substances that are already found in surface water will appear in groundwater through both natural and artificial aquifer recharge. The persistent nature of PFAS and long residence time in some aquifers means that they are key groundwater pollutants already, or likely to become key groundwater pollutants in the future.

PFAS detection in European groundwater

PFAS have been detected in groundwater in many MS[557]. Data reviewed through the GW WL process from 11 PC included only around 30 reliably reported from an initial target list of 52 PFAS substances. Within this group, 10 PFAS substances met the criteria for inclusion on the LFR (present in more than 10 locations in more than 4 PC). A further three PFAS remain on the GW WL because insufficient information was identified to justify their inclusion on the LFR. Results of the GW WL review are set out in Table B-1 and indicate the widespread nature of the PFAS detections.

Table B-1 PFAS detected in groundwater in more than 4 PC and at more than 10 sites

No of MS/AC	Acronym	No. of sites monitored	No. of sites >LOQ	>LOQ in %	PC with detections
6	PFOSA	1715	22	1.3	4
7	PFUnA	2598	39	1.5	6
7	PFDoA	2830	62	2.2	6
8	PFDA	2945	173	5.9	7
8	PFNA	3752	195	5.2	7
5	PFBA	1189	552	46.4	5
7	PFBS	2209	577	26.1	5
7	PFPeA	2452	701	28.6	7
9	PFHpA	4224	817	19.3	8
8	PFHxS	2328	873	37.5	7
9	PFHxA	4662	1175	25.2	8
11	PFOS	6971	1435	20.6	11
11	PFOA	6429	1553	24.2	11

The 10 PFAS identified by the GWWL and put forward in the LFR are presented in Table B-2. A further two PFAS remain on the GWWL because insufficient information was identified to justify their inclusion on the LFR. These were: Perfluorododecanoic Acid (PFDoA); and Perfluoroundecanoic Acid (PFUnA).

Table B-2 PFAS substances on the List Facilitating Review and GWWL

Substance Name	Acronym	CAS #	Status
Perfluorooctane Sulfonate	PFOS	1763-23-1	LFR
Perfluorooctanoic Acid	PFOA	335-67-1	LFR
Perfluorohexanoic Acid	PFHxA	307-24-4	LFR
Perfluoroheptanoic Acid	PFHpA	375-85-9	LFR
Perfluorohexane Sulfonate	PFHxS	432-50-8	LFR
Perfluorobutane Sulfonate	PFBS	375-73-5	LFR
Perfluorodecanoic Acid	PFDA	335-76-2	LFR
Perfluorononanoic Acid	PFNA	375-95-1	LFR

[557] Voluntary Groundwater Watch List Process Study on Per- and Polyfluoroalkyl substances (PFAS) –Monitoring Data Collection and Initial Analysis –Draft V.2.3 / 23. February 2020

Substance Name	Acronym	CAS #	Status
Perfluoropentanoic Acid	PFPeA	2706-90-3	LFR
Perfluorobutanoic Acid	PFBA	375-22-4	LFR
Perfluorododecanoic Acid	PFDoA	2058-94-8	GWWL
Perfluoroundecanoic Acid	PFUnA	307-55-1	GWWL

PFAS predicted baseline GWB Risk and Status

To estimate the number of GWBs potentially at risk of being at poor status due to PFAS pollution it was assumed that the majority of MS would set a TV for PFAS based on the current day DWS[558]. Various Member States[559] have also set very strict national levels for groundwater (used for the abstraction of drinking water) or drinking water, e.g. a maximum of 2 nanograms per litre for the total sum of the PFAS, based on the 2020 scientific EFSA opinion[560] on the harmfulness of PFAS.

For PFAS the there is no direct comparison with the existing Annex I substances or the minimum list of substances listed in Annex II of the GWD. The only substances which may behave in a similar manner are the chlorinated solvents (tetra and trichloroethene) in that they are persistent and mobile organic pollutants. However, the main sources for chlorinated solvents in groundwater are leaks and spills at industrial sites and dry cleaners, rather than chronic emissions through sewage disposal or airfields. Additionally, the diffuse sources of PFAS (land spreading, aerial deposition) will not be matched. Therefore, PFAS pollution could follow patterns similar to these chlorinated solvents but may be as widespread as pesticide pollution (land spreading of man-made chemicals) due to the wide range of source terms and pathways to groundwater.

Based on the large number of sources pathways to groundwater, plus known persistence and the reported detection by 40% of MS at around 25% of monitoring points (for PFOA) provided for the GW WL it is likely that PFAS will lead to a number of failures of the GCA test. An estimate of the likely number could sit close to the impact of pesticides i.e. 2.5% of GWBs with 38%. However, this assumes that all MS would set TVs for PFAS under Annex II, and therefore under the current GWD, the picture for PFAS could be closer to that for Tetrachloroethylene (0.9% GWBs at poor status and 35% of MS reporting a problem).

Table B-3 Benchmarking for PFAS GWB current day risk and status

Substance leading to RBC2 GWB failure	GWBs failing (No.)	MS reporting failures (No.)	Characteristics of pollutant	Relevance to PFAS
Nitrate	8.2% (1137)	96% (25)	Emissions: widespread agricultural use and human wastewater, and is naturally occurring (organic matter breakdown). Pathway: persistent GWQS 50 mg/l – human health based (relatively	Gives a worst case for any new listed substance (based on current knowledge) due to widespread use and persistent behaviour. PFAS likely to have a lower impact on

[558] Sum of 20 PFAS with a limit of 0.1 µg/l, and a proposed Total PFAS limit of 0.5 µg/l.
[559] https://tox.dhi.dk/en/news/news/article/danish-epa-more-tough-on-pfas-in-drinking-water/
[560] https://www.efsa.europa.eu/en/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake

Substance leading to RBC2 GWB failure	GWBs failing (No.)	MS reporting failures (No.)	Characteristics of pollutant	Relevance to PFAS
			high compared to man-made chemicals i.e. 0.5ug/l total pesticides)	GWBs due to relatively smaller area of emissions.
Total Pesticides (including metabolites)	2.5% (341)	38% (10)	Emissions: widely used in agriculture sector but also in amenity use Pathway: some legacy pesticides can be persistent, permitted substances typically have low persistence in soils but once in groundwater can persist. GWQS 0.1µg/l individual substance, 0.5µg/l sum of all.	Similar scale of emissions / group of chemicals but with different characteristics and pathways to groundwater.
Tetrachloroethylene (PCE)	0.9% (123)	35% (9)	Emissions: An industrial chemical, widely used in the past for engineering / manufacturing works / dry cleaning, typically linked to point sources Pathway: persistent in aerobic groundwater systems GWQS: Annex II substance so MS set TV which may be based on the DWS of 10µg/l (sum with TCE)	Relevance due to industrial source, but PCE does not have as many pathways to the environment as it is not expected to be in domestic wastewater / sludge.

Pharmaceuticals Emission, pathways and detection in groundwater

Pharmaceuticals European emissions

Pharmaceuticals are a broad group of substances used for human health purposes as well as veterinary medicines and belong to many different chemical groups. Pharmaceuticals have been used for many years, even centuries in some cases. The two pharmaceuticals on the LFR are Carbamazepine and Sulfamethoxazole.

Carbamazepine is an anticonvulsant medication used primarily in the treatment of epilepsy and neuropathic pain caused by diabetes/condition called trigeminal neuralia. It may also be used to treat bipolar disorder. There are several suppliers /manufacturers and exporters in the EU including in Germany, Poland and Portugal. The route of administration appears to be oral only in the form of tablets and by prescription only. It is also less used as a veterinary medicine to treat seizures (epilepsy), chronic pain (primarily nerve pain), to treat aggression, to treat head shaking in horses although its use has decreased[561]. The number of people with epilepsy in the EU (6 million[562]) is likely to far outweigh the number of horses with headshaking (circa 5 million tame horses in the EU of which 1%[563] are estimated to have photic head shaking symptoms i.e. 50,000 cases). Therefore, the main emission route will be through human prescribed use.

Sulfamethoxazole is an antibiotic used to treat bacterial infections such as urinary tract infections, bronchitis, and prostatitis. As a veterinary medicine it is commonly used as an

[561] Carbamazepine | VCA Animal Hospitals (vcahospitals.com)
[562] euro_report.pdf (who.int)
[563] Trigeminal-mediated headshaking in horses: prevalence, impact, and management strategies (nih.gov)

antibiotic in combination as Sulfamethoxazole/Trimethoprim. It is used for cats, dogs, birds, reptiles, and small mammals to treat certain infections such as bladder and prostate infections, Nocardia infections, or parasitic infections. It has been used prophylactically in livestock to prevent infections in herds and subsequently detected in manures and their anaerobic digestates which are spread to land, potentially resulting in increased antimicrobial resistance of soils[564]. The introduction of restrictions in 2019 on prophylactic use of veterinary medicines in livestock husbandry is likely to reduce this later source term. One manufacturer of sulfamethoxazole is identified in the EU (Italy).

A further 9 substances were put on the GW WL so that more information could be collected on their distribution in groundwater. These were: Clopidol, Crotamiton, Amidozoic acid, Sulfadiazin, Primidone, Sotalol, Ibuprofen, Erythromycin and Clarithromycin. In 2022 at the WG GW meeting and the final stakeholder workshop of this project it was indicated that there was sufficient evidence available to support the inclusion of Primidone (a beta blocker) on the LFR. This group includes antibiotics, painkillers, antipruritics, anti-epileptics and beta blockers[565] all of which are likely to enter groundwater from human, domestic pet and agricultural livestock waste (including wastewater and manure and biosolids spreading to land).

Pharmaceuticals pathways to European groundwater

The European Union Strategic Approach to Pharmaceuticals in the Environment[566] identifies that the largest source of pharmaceuticals entering the environment is through their use. The main pathways to groundwater will therefore differ depending upon whether human or veterinary use is involved. It also states that "the chemical and/or metabolic stability of some pharmaceuticals means that up to 90% of the active ingredient is excreted (or washed off) in its original form. Wastewater treatment varies in its ability to eliminate pharmaceutical residues[567], depending upon the substance and the level of treatment; in some cases, substantial amounts are removed, in others, only a small percentage; but even the best, most expensive, current treatments are not 100% effective. The release of veterinary medicines to the environment tends to come from untreated diffuse sources such as the spreading of manure." However, recent

[564] Dissipation of the antibiotic sulfamethoxazole in a soil amended with anaerobically digested cattle manure - PubMed (nih.gov)

[565] Crotamiton is an anti-parasite medicine for parasites that live or lay eggs in skin. Amidozoic Acid is a contrast agent used during X-rays or computer tomography to visualize veins, the urinary system, spleen, and joints. Sulfadiazin is an antibiotic used to treat toxoplasmosis. Primidone is a barbiturate used to treat seizures and tremors. Sotalol is a beta blocker used to treat and prevent abnormal heart rhythms. Ibuprofen is an anti-inflammatory for treating pain, fever, and inflammation. Erythromycin is an antibiotic for the treatment of a number of bacterial infections including respiratory tract infections, skin infections, chlamydia infections, pelvic inflammatory disease, and syphilis. Clarithromycin is an antibiotic used to treat bacterial infections. This includes strep throat, pneumonia, skin infections, Heliobacter pylori infection, and Lyme disease.

[566] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE European Union Strategic Approach to Pharmaceuticals in the Environment COM(2019) 128final

[567] Metabolites (conversion products) may have lower biological activity (see case studies in http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm) but may, e.g. if conjugated, be converted back to the parent pharmaceutical during sewage treatment, or have similar biological activity.

The main routes for all pharmaceuticals to groundwater are through sewage effluent discharge (including excreted pharmaceuticals and unused products disposed of to the sewage system despite the existence of collection schemes) and spreading of animal manure. Other pathways include:

- the discharge of effluent from manufacturing plants;
- the spreading of sewage sludge containing pharmaceuticals removed from waste water;
- grazing livestock and spreading of manures / digestates to land;
- the treatment of pets with run-off from excreta or washed off topical applications;
- improper disposal into landfill of unused pharmaceuticals and contaminated waste;
- recharge from surface water containing pharmaceuticals from wastewater discharge.

Pharmaceuticals detection in European groundwater

For the GW WL process, 13 PC provided groundwater datasets for review. The review found around 300 pharmaceutical substances have been monitored by PCs but only a small number of these were detected in more than 4 countries. Only 2 pharmaceuticals, Sulfamethoxazole and Carbamazepine, were present in both four or more PC and at 10 more sites in each of these countries and were put forward on the LFR. A further 9 substances were put on the GW WL so that more information could be collected on their distribution in groundwater. These were: Clopidol, Crotamiton, Amidozoic acid, Sulfadiazin, Primidone, Sotalol, Ibuprofen, Erythromycin and Clarithromycin. In 2022 at the WG GW meeting and the final stakeholder workshop of this project it was indicated that there was sufficient evidence available to support the inclusion of Primidone (a beta blocker) on the LFR. This was discussed at WG GW Plenary in March 2022 and also in the 2nd Stakeholder Workshop in March 2022. In addition, the proposed Option 3 includes adding 8 further pharmaceuticals from the GW WL to Annex II for consideration by MS.

Pharmaceuticals predicted current day risk and GWB status

Pharmaceutical pathways to groundwater are mainly limited to wastewater streams and the spreading of animal manures and biosolids derived from the wastewater treatment regime. Depending on their individual properties, these substances may preferentially partition into the solid or liquid phases (i.e. be retained in sewage sludge and biosolids or the effluent[568]). The pathway from land spreading of biosolids and manures is likely to provide a diffuse source of pollution to groundwater, whilst wastewater discharges to ground or surface water are more likely to provide point sources of pollution. Following the benchmarking approach, pharmaceuticals could be compared to current day GWB status of parameters such as boron, ammonium or phosphate which are indicators or sewage and listed on Annex II, although the latter two will have a number of other sources (Table B-4). Based on this assessment the probable number of GWBs at poor status and MS reporting failures due to pharmaceuticals is likely to be low: probably less than 1% of GWBs and perhaps up to 10% of MS reporting a failure.

[568] Mejías, C. Martin, J., Santos, J. L., Aparicio, I., & Alonson, E., 2021. Occurrence of pharmaceuticals and their metabolites in sewage sludge and soil: A review on their distribution and environmental risk assessment. Trends in Environmental Analytical Chemistry 30 (2021) e00125.

Table B-4 Benchmarking for GWB status due to pharmaceuticals

Substance leading to RBMP2 GWB failure	GWBs failing (No.)	MS reporting failures (No.)	Characteristics of pollutant	Relevance to Pharmaceuticals
Ammonium	1.9% (265)	58% (15)	Emissions: Indicator of sewage, contaminated land and denitrification of nitrate (latter may be natural background) Pathway: rapidly transformed to nitrate in aerobic conditions so failure of GWBs suggests large source term or anaerobic conditions. GWQS: Annex II substance and TV may use DWS 0.5mg/l	An indicator of sewage and animal manure inputs, but has a higher DWS (100 times). Probably overstates pharmaceutical status as ammonium is linked to most landfills, and to some contaminated land sites.
Boron	0.12% (17)	8% (2)	Emissions: naturally occurring but also an indicator of domestic sewage GWQS - Annex II substance with high TV (DWS is 1 mg/l. Boron occurs naturally).	An indicator of sewage but biased to only 2 MS and has a much higher DWS
Phosphate	0.2% (33)	19% (5)	Emissions: use in agricultural and high levels in wastewater discharges Pathway: could demonstrate surface water pathway connection	An indicator of sewage but biased to only 5 MS. No DWS.

nrMs Emission, pathways and detection in groundwater

Pesticides are used for the purposes of plant protection primarily in agriculture but also for amenity use. They constitute a wide range of organic chemicals. Pesticides released to the environment breakdown (metabolise) to new compounds (metabolites). The metabolites of pesticides are grouped into: (1) relevant metabolites, (2) non-relevant metabolites (nrMs) and (3) metabolite of no concern. A relevant metabolite is one for which there is reason to assume that it has comparable intrinsic properties as the active substance and as such is treated like the parent pesticide for the purposes of regulation. A metabolite of no concern is considered to be harmless. Non-relevant metabolite do not meet the criteria to be considered either relevant metabolites or metabolites of no concern and therefore need to be considered.

Non-relevant metabolites from pesticides (nrMs) are not manufactured products, forming in the water environment through degradation of a parent pesticide compound (see Table 7-4). The pathway to groundwater is depends on the use / release of the parent compound. The predominant parent compound use is for plant protection by the agricultural sector as herbicides or fungicides, but may include amenity purposes and as a biocide. The parent compounds Tolylfluanid and Dichlofluanid are fungicides that are registered as biocides. N,N-Dimethylsulfamid (DMS) and Chlortalonil-SA are also fungicides. The majority of parent compounds are not approved for use in the EU (Table 11-6). Whilst the source term for nrMs is most likely to be diffuse from the leaching of the parent product, point sources of nrMs will also occur from leakages around pesticide handling areas (equipment washing) and accidental spills or illegal storage of banned parent substances.

The SANCO guidance[31] sets out a five step process for assessment of the relevance of metabolites, ending with a refined risk assessment for substances in groundwater identified as nrMs. The guidance is designed for use by organisations applying for authorisation of substances under EC 1107/209[569] (the plant protection products regulations) and building a body of evidence which will then be reviewed by rapporteur MS and EFSA. New authorisations of substances listed under EC 1107/209 are valid for 10 years, whilst renewed authorisations can be granted for up to 15 years. The review of authorised substances is expected to include new data / modelling. For the parent compounds of LFR nrMs not approved for use in the EU the presence of their metabolites is likely to be related to historical use leading to a legacy issue, although illegal use cannot be ruled out. Some of the parent compounds have not been authorised for use for many years, such as atrazine, indicating the persistence of the nrM and / or the parent compound.

Table B-5 Non relevant metabolites on the List Facilitating Review

nRM substance	CAS	Parent Compound	Use	Status (EU pesticides database)[570]
Desphenylchloridazon (metabolite B)	6339-19-1	Chloridazon	Herbicide	Not approved (EC1107/2009)
Methyl-desphenyl-chloridazon (Metabolite B1)	17254-80-7	Chloridazon	Herbicide	Not approved (EC1107/2009)
2,6-Dichlorbenzamid (2,6-D, BAM, M01, AE C653711)	2008-58-4	Dichlobenil Fluopicolide	Herbicide Fungicide	Not approved (EC1107/2009) Approved
Aminomethylphosphonic acid	1066-51-9	Glyphosate	Herbicide	Approved
Metazachlor-acid (OXA) (BH 479-4)	1231244-60-2	Metazachlor	Herbicide	Approved
Metazachlor ESA Metazachlor-SA (BH 479- 8) (Metazachlorsulfone acid, Metazachlorsulfonic acid (ESA)	172960-62-2	Metazachlor	Herbicide	Approved
Atrazine-2-hydroxy	2163-68-0	Atrazine	Herbicide	Not approved since 2004
N,N-Dimethylsulfamid (DMS)	3984-14-3	Tolylfluanid, Dichlofluanid	Fungicide	Not approved (EC 1107/2009)
s-Metolachlor-acid, (OXA, CGA 51202, CGA 351916)	152019-73-3	S-metolachlor	Herbicide	Not Approved (EC 1107/2009)
Chlorthalonil-SA (R417888 or VIS-01 / M12) (Chlortalonilsulfone acid)	1418095-02-9	Chlorothalonil	Fungicide	Not registered
Metolachlor-Ethanesulfonic acid (ESA, CGA 380168, CGA 354743)	171118-09-5	S-metolachlor	Herbicide	Not Approved (EC 1107/2009)

569 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
570 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

nRM substance	CAS	Parent Compound	Use	Status (EU pesticides database)[570]
Dimethenamid-ESA	205939-58-8	Dimethenamid	Herbicide	Not approved
Flufenacet-sulfonic acid (ESA) 201668-32-8		Flufenacet	Herbicide	Approved
Alachlor-t-sulfonic-acid (ESA)	142363-53-9	Alachlor	Herbicide	Not approved
S-Metolachlor NOA 413173 or VIS-01 (Chlortalonilsulfone acid) Metabolite	1418095-19-8	Chlorothalonil , S-metolachlor	Herbicide	Not registered Not Approved (EC 1107/2009)
Dimethachlor CGA 369873 1418095-08-5		Dimethachlor	Herbicide	Approved

NrMs pathways to groundwater

The main pathway to groundwater for nrMs is mainly the leaching from soils following use of parent pesticides and transport downwards in recharging water to groundwater either as the parent compound or as the metabolite.

nrMs detection in European groundwater

Through the GW WL process, 17 countries provided groundwater data on the nrM compounds for review. The data indicate that nrMs were widely detected in European groundwater above limits of quantification (LoQ). The nrM monitoring results show 16 substances were detected in four or more PC and at 10 or more sites in each of these countries. These substances fulfilled the criteria for addition to the LFR. From the assessment, WGGW concluded that there is enough evidence of a Europe-wide presence of nrMs in groundwater. Therefore, these 16 nrMs were put forward in a LFR and it was recommended that other nrMs are not added to the GWWL.

nrMs predicted current day risk and GWB status

Given the source of nrMs, the obvious worst case scenario for the likely current day impact on GWB status would be the number of GWB that fail due to pesticide pollution. As the TVs that would be set at the current day are unlikely to be lower than the pesticide GWQS (based on reported TVs used by MS for nrMs) the number of reported fails is likely to be smaller than for total pesticides or the individual parent substance (Table B-6), especially as some failures for pesticides are likely to be for substances without nrMs on the LFR. The estimated impact on current day status is likely to be between 0.5 and 2% of GWBs with up to 40% of MS reporting a failure.

Table B-6 Benchmarking for GWB status due to nrMs of pesticides

Substance leading to RBC2 GWB failure	GWBs failing (No.)	MS reporting failures (No.)	Characteristics of pollutant	Relevance to nrMs
Total Pesticides (including metabolites)	2.5% (341)	38% (10)	Emissions: widely used in agriculture sector but also in amenity use Pathway: some legacy pesticides can be	Includes the parent products so could provide worst case.

Substance leading to RBC2 GWB failure	GWBs failing (No.)	MS reporting failures (No.)	Characteristics of pollutant	Relevance to nrMs
			persistent, permitted substances typically have low persistence in soils but once in groundwater can persist. GWQS 0.1µg/l individual substance, 0.5µg/l sum of all.	
Alachlor		4% (1)	Parent products or relevant metabolites of LFR nrMs	Includes the parent products and some metabolites so could provide a reasonable worst case impact.
Alachlor ESA	0.5% (63)	4% (1)		
Alachlor OA		4% (1)		
Atrazine	0.4% (55)	27% (7)		
Chloridazon		4% (1)		
Deisopropyldeethylatrazine	0.1% (12)	8% (2)		
Desethylatrazine	0.5% (69)	19% (5)		
Desisopropylatrazine				
Glyphosate		8% (2)		
Metazachlor ESA	0.4% (58)	4% (1)		
Metolachlor	0.1% (14)	12% (3)		
Metolachlor ESA		12% (3)		

Regulatory Landscape

The main existing regulatory measures which are applicable to prevent groundwater pollution from the substances put forward on the LFR are summarised in Table 7-1. For each measure the general implications and specific impact on relevant substances are identified. In the final column of the table, the feedback from Comission experts on progress with implementation of specific regulations and strategies along with expert judgement have been used to qualitatively assess the likely impact of these measures on the dynamic baseline for groundwater. This assessment is given in terms of a positive (i.e. reduces observed concentrations in groundwater) or negative impact (may lead to increased concentrations or even deterioration of status). It is important to note the prevent and limit requirements of the GWD listed in the table which already require that controls on the entry of PFAS and likely nrMs into groundwater should be controlled.

Appendix C Review of surface water substances

Methodology to select substances and set the quality standards

Identification of new substances to consider listing is based on the risk to or via the aquatic environment. The risk assessment follows the criteria set out in WFD Article 16(2) and includes, as a minimum, weighing of:

- the intrinsic hazard of the substance concerned, and in particular its aquatic ecotoxicity and human toxicity via aquatic exposure routes;
- evidence from monitoring of widespread environmental contamination; and
- other proven factors indicating the possibility of wide-spread environmental contamination, such as production / use volumes of a substance, and use patterns.

The prioritisation process for surface water serves as a basis for the determination of substances either to be selected as candidate PS, RBSPs or for inclusion on the SW WL. Introduced by the amendment of EQSD in 2013, the SW WL has so far resulted in the adoption of three Commission implementing decisions establishing a list of substances for Union-wide monitoring in the field of water policy. Under the SW WL, emerging substances are monitored at selected EU representative monitoring stations for at least 12 months, and up to 4 years. Monitoring data for pollutants listed in the first two Commission implementing decisions have been used to derive the candidate PS list for this initiative. The candidate PS indicate the pollutants for which an EU-wide risk has been established, warranting an EQS derivation and impact assessment. This process resulted in 24 individual substances and a group of 24 PFAS being selected

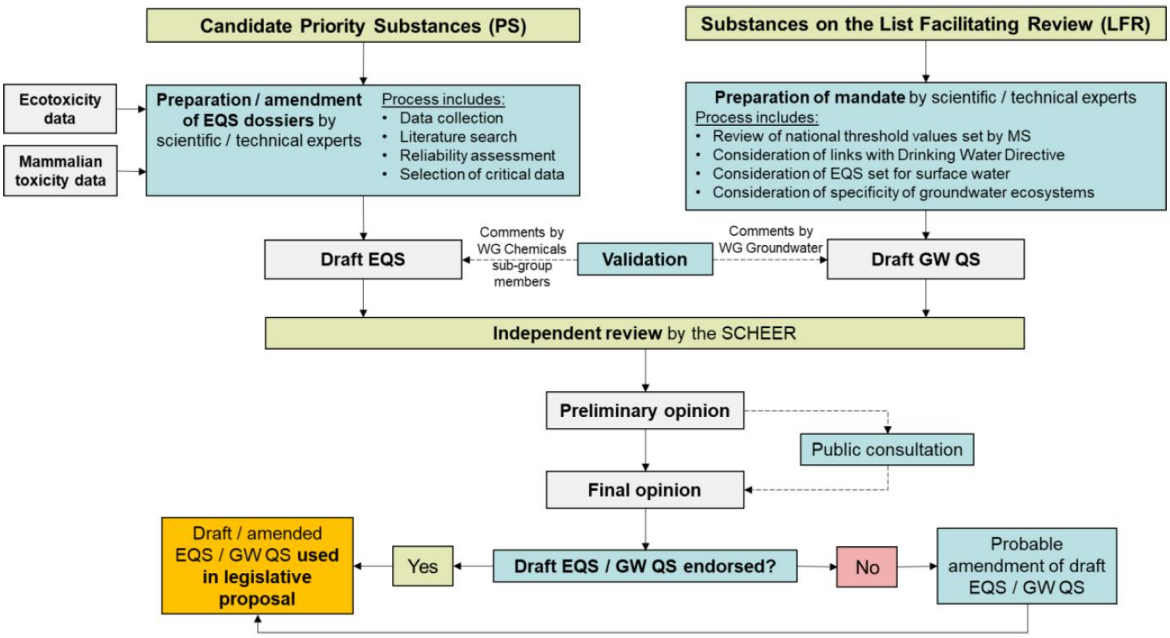
Derivation of quality standards for selected substances

The derivation of quality standards for selected substances (or ‘quality standards derivation process’) follows scientific methods and is subject to several rounds of scrutiny. The technical process of threshold derivation for surface and groundwater pollutants is carried out by the JRC in collaboration with subgroups of experts and rapporteurs. The approach used to set the limit values for candidate PS is based on a Technical Guidance Document on Deriving EQS developed in 2018. It starts with collecting (eco)toxicity data from EU official reports, stakeholder inputs and peer-reviewed studies. Then the scientific papers are evaluated for reliability and a selection of critical data for EQS derivation is made. For substances on the LFR of the GWD, the QSs are drafted considering specificity of groundwater ecosystems, any national threshold values (TVs) set by MS, links with the Drinking Water Directive and EQS set for surface water.

In those cases where Quantified monitoring samples plus non-quantified samples when ½ LOQ ≤ PNEC (or EQS). Sc3 is a more relevant data scenario for making a risk assessment according the sub-group on review (SG-R) of the priority substances list (Carvalho et al., 2016).

The support studies and draft quality standards are subject to quality control and validation by the experts of Common Implementation Strategy (CIS) working groups (WG). Comments received are addressed by the JRC and the derived QSs are submitted for an independent review by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The SCHEER considers whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS; and whether the most critical EQS (in terms of impact on environment/health) has been correctly identified. Values endorsed by the SCHEER are used in the impact assessment and the legislative proposal. The impact assessment incorporates the preliminary or final opinions on each of the substances /groups of substances.

The support studies and draft quality standards are subject to quality control and validation by the experts of Common Implementation Strategy (CIS) working groups (WG). Comments received are addressed by the JRC and the derived QSs are submitted for an independent review by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The SCHEER considers whether the EQS have been correctly and appropriately derived, in the light of the available information and the TGD-EQS; and whether the most critical EQS (in terms of impact on environment/health) has been correctly identified. Values endorsed by the SCHEER are used in the impact assessment and the legislative proposal. The process is summarised in the figure below.



The impact assessment incorporates the preliminary or final opinions on each of the substances / groups of substances, available until the proposal was adopted by the College (October 2022) others will need to be aligned where needed in cooperation with the European Parliament and the Council.

The details of each substance, uses, and reasons for concern as an EU-wide risk are summarised in -Table C-1.

Summary of details of each substance, uses, and reasons for concern as an EU-wide risk

Table C-1 Overview for substances of concern covered by the current study

Options	Substance	Type/Use	Concern
Additions	17 alpha-ethinylestradiol (EE2)	Pharmaceutical: synthetic steroid hormone used mainly in oral contraceptives. No production data available. Approx 32 million women in EU use EE2-based contraception. Approximately additional 700 kg of synthetic estrogens (EE2) are discharged globally per year[571].	Endocrine disruptive; prolonged exposure to low concentrations of EE2 has been shown to cause sex changes, alterations in reproductive capacity, and ultimately population collapse in fish (Kidd et al, 2007)
Additions	17 beta-estradiol (E2)	Steroid hormone: excreted naturally (approx 90%) in human and livestock urine but also (<10%) as a result of pharmaceutical use (of which 90% from HRT).	Endocrine disruptive; chronic studies show effects on sexual development and fecundity in fish.
Additions	Estrone (E1)	Steroid hormone: Natural and synthetic. In humans taken as hormone replacement therapy to treat estrogen deficiency but has veterinary uses. 30,000 kg of natural steroidal estrogens (E1, E2, and E3) are discharge from humans per year and annual estrogen discharge by livestock is 83,000 kg per year[572].	Endocrine disruptor, reproductive toxin: Has been shown to cause feminisation of male fish (albeit to a lesser extent than E2 and EE2)[573].
Additions	Azithromycin	Antibiotics: Macrolide, used to treat infections in humans but also used as an antimicrobial for food-producing animals and in horses. Human consumption of macrolides is highest in Greece[574].	The discharge of azithromycin can increase the risk of developing antimicrobial resistance[575].
Additions	Clarithromycin	Antibiotics: Macrolide, used in humans to treat infections including pharyngitis and tonsillitis. Human consumption of macrolides is highest in Greece[576].	Resistance to clarithromycin has been shown to occur in waste water[577].
Additions	Erythromycin	Antibiotics: Macrolide, used in humans to treat infections including respiratory tract infections and chlamydia, while also having veterinary uses. Human consumption of macrolides is highest in Greece[578].	Resistance to erythromycin has been shown to occur in waste water[579].
Additions	Diclofenac	Pharmaceutical: NSAID used to treat pain and inflammation such as the symptoms of osteoarthritis and rheumatoid arthritis in both humans and	Toxic - Reproductive toxicity, osmoregulatory distruption, generation of oxidative stress,

571 https://www.researchgate.net/publication/311675096_Environmental_impact_of_estrogens_on_human_animal_and_plant_life_A_critical_review/link/5853c3d408ae95fd8e1fbe6a/download
572 https://www.researchgate.net/publication/311675096_Environmental_impact_of_estrogens_on_human_animal_and_plant_life_A_critical_review/link/5853c3d408ae95fd8e1fbe6a/download
573 https://pubs.acs.org/doi/10.1021/acs.est.7b00606
574 https://www.ecdc.europa.eu/en/antimicrobial-consumption/database/geographical-distribution
575 https://pubmed.ncbi.nlm.nih.gov/30622075/
576 https://www.ecdc.europa.eu/en/antimicrobial-consumption/database/geographical-distribution
577 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6884605/
578 https://www.ecdc.europa.eu/en/antimicrobial-consumption/database/geographical-distribution
579 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0119403

Options	Substance	Type/Use	Concern
		animals. Of Member States in the study, Germany had the highest consumption (>1,000 mg/inh/y)[580]	genotoxicity[581] as well as the production of further emerging contaminants[582].
Additions	Carbamazepine	Pharmaceutical: Treatment for epilepsy (seizure control), treatment for specific causes of nerve pain and occasionally bipolar disorder. Less commonly used, for similar purposes, in veterinary medicine. The most authorisations of carbamazepine (in accordance with Article 57(2) of Regulation (EC) No. 726/2004) are in Germany, Romania and the Netherlands[583].	Carbamazepine has been shown to disturb the normal growth and development of exposed fish embryos and larvae[584].
Additions	Ibuprofen	Pharmaceutical: NSAID used as a painkiller and to treat inflammation in both humans and animals. Germany has the largest number of authorisations of ibuprofen (in accordance with Article 57(2) of Regulation (EC) No. 726/2004)[585].	Ibuprofen has been shown to cause acute toxicity in a variety of aquatic organisms (algae, plants, crustaceans and fish)[586].
Additions	Nicosulfuron	Pesticide: Used as herbicide and authorised as a Plant Protection Product to control annual grass weeds in maize crops. Pesticide sales in the EU27 in 2019 (Sulfonylurea herbicides, which includes nicosulfuron, and 23 other herbicides) indicate highest consumption in Romania (30%), France (26%) and Germany (19%)[587].	Nicosulfuron has been shown to be toxic, persistent and bioaccumulative. In particular, nicosulfuron has been shown to be toxic to phytoplankton in aquatic ecosystems[588].
Additions	Acetamiprid	Pesticide: Amenity use, agricultural use and use in the control of insects in the urban environment. France has banned the use of acetampirid in plant protection products and seed treatments. 2019 Pesticide sales (Pyridylmethylamine insectidies total including Acetamiprid) indicate higher sales in Romania (30%), Poland (14%) and Germany (12%)[589].	Poses a toxicity risk to aquatic organisms in particular aquatic invertebrates[590].
Additions	Clothianidin	Pesticide: Professional insecticide used in the control of insect populations such as cockroaches. Also used indoors in domestic premises. Pesticide sales in 2019 (Nitroguanidine Insecticides including	Low soil binding, high soil persistence, and high water solubilit with both lethal and sublethal effects on aquatic organisms at environmental concentrations[592][593].

580 https://link.springer.com/article/10.1007/s11356-016-6503-x
581 https://www.researchgate.net/publication/324862625_Diclofenac_in_the_marine_environment_A_review_of_its_occurrence_and_effects/link/5b3e53df4585150d23000efa/download
582 https://pubmed.ncbi.nlm.nih.gov/27649472/
583 Public data from Article 57 database | European Medicines Agency (europa.eu)
584 https://pubmed.ncbi.nlm.nih.gov/27386877/
585 Public data from Article 57 database | European Medicines Agency (europa.eu)
586 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6063337/
587 https://ec.europa.eu/eurostat/databrowser/view/AEI_FM_SALPEST09__custom_1090183/default/table?lang=en
588 https://hal.archives-ouvertes.fr/hal-00655976/document
589 https://ec.europa.eu/eurostat/databrowser/view/AEI_FM_SALPEST09__custom_1081452/default/table?lang=en
590 https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-099050_15-Mar-02.pdf
592
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0174171#:~:text=Neonicotinoids%20pose%20a%20risk%20to,invertebrates%20at%20field%20relevant%20concentrations.
593 https://link.springer.com/article/10.1007/s11356-017-1125-5

Options	Substance	Type/Use	Concern
		Clothianidin) were highest in Hungary (47% of EU27 sales), Denmark (18%) and Romania (19%)[591].	
Additions	Imidacloprid	Pesticide: Ceased manufacture. Previously used for both professional (e.g. agriculture or fly control) and domestic uses (e.g. cockroach control). Additional uses in veterinary medicine (e.g. flea treatment). 2019 Pesticide sales (Pyridylmethylamine insectidies total including Imidacloprid) indicate higher sales in Romania (30%), Poland (14%) and Germany (12%)[594].	Imidacloprid is a neonicotinoid, which is a group that is neurotoxic to a range of organisms. Runoff, leaching and spray drift have lead to the exposure of aquatic organisms to imidacloprid and their subsequent decline e.g. exposure of macroinvertebrates following application leads to a decline in their populations[595].
Additions	Thiacloprid	Pesticide: Approval as a biocide has expired. Previously used in agriculture (noteably with sugar beet) as a biocide. 2019 Pesticide sales (Pyridylmethylamine insectidies total including Thiacloprid) indicate higher sales in Romania (30%), Poland (14%) and Germany (12%)[596].	Carcinogenic, reproductive toxin and endocrine disruptor: Thiacloprid is a neonicotinoid, which is a group that is neurotoxic to a range of organisms. Runoff, leaching and spray drift as well as the moderate persistence of the chemical have lead to the exposure of aquatic organisms to thiacloprid and the subsequent decline in their populations[597].
Additions	Thiamethoxam	Pesticide: Approval expired as a Plant Protection Product in 2019. Authorised use only as an insecticide, in permanent greenhouses or for the treatment of seeds in permanent greenhouses[598].	Thiamethoxam is a neonicotinoid, which is a group that is neurotoxic to a range of organisms. Runoff, leaching and spray drift have lead to the exposure of aquatic organisms to thiamethoxam and the subsequent decline in their populations e.g. exposure of invertebrates leads to a decline in their populations[599]
Additions	Bifenthrin	Pesticide: Approved for use as an active substance in biocides/wood preservative. However, no existing authorisations are in place in any MS. Authorisations in Austria, Denmark, France, Germany, Netherlands and Sweden ended in 2020 (either expired or cancelled)[600]	Bifenthrin has been shown to be persistent (often binding to substrate due to its hydrophobic nature), bioaccumulative, toxic, carcinogenic and an endocrine distruptor (estrogenic activity in fish species)[601].

591 https://ec.europa.eu/eurostat/databrowser/view/AEI_FM_SALPEST09__custom_1082578/default/table?lang=en
594 https://ec.europa.eu/eurostat/databrowser/view/AEI_FM_SALPEST09__custom_1081452/default/table?lang=en
595
https://www.researchgate.net/publication/340588507_Ecological_risks_of_imidacloprid_to_aquatic_species_in_the_Netherlands_Measured_and_estimated_concentrations_compared_to_species_sensitivity_distributions/link/5fc9f871a6fdcc697bdb979d/download
596 https://ec.europa.eu/eurostat/databrowser/view/AEI_FM_SALPEST09__custom_1081452/default/table?lang=en
597 https://www.mdpi.com/2077-1312/8/10/801/pdf
598 https://echa.europa.eu/ann-approved-act-subs-plant-prot-prods?p_p_id=eucleflegislationlist_WAR_euclefportlet&p_p_lifecycle=0&p_p_col_id=column-1&p_p_col_count=1
599 https://link.springer.com/article/10.1007/s11356-017-1125-5
600 https://echa.europa.eu/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/8/PT08
601 https://www.researchgate.net/publication/334315401_Toxicity_of_nanoencapsulated_bifenthrin_on_rainbow_trout_Oncorhynchus_mykiss

Options	Substance	Type/Use	Concern
Additions	Deltamethrin	Pesticide: Approved as a biocidal active substance in Plant Protection Products, and authorised at national level in all 27 MS[602]. Approval expires 31/10/2021. Only uses as an insecticide are authorised. Existing emergency authorisations in EE, SI, FR, FR[603].	Deltamethrin is a synthetic pyrethroid which has been shown to be bioaccumulative and an endocrine distruptor in aquatic organisms[604]. Relatively low toxicity to birds and earthworms but toxic to mammals, aquatic organisms and honey bees[605].
Additions	Esfenvalerate	Pesticide: Approved as a plant protection product until 31/12/2022. Authorised at national level in AT, BE, BG, CY, CZ, DE, EL, ES, FI, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SE AND SK (21 of 27 MS). Not authorised in DK, EE, LT, SI, LV and MT. Approval as a biocidal active substance is no longer supported in use as an insecticide, acaricide and products to control other arthropods[606].	Esfenvalerate is a synthetic pyrethroid which is both bioaccumulative and toxic to aquatic organisms e.g. aquatic invertebrates[607].
Additions	Permethrin	Pesticide: Not approved as a Plant Protection Product. Approved as a biocide as a wood preservative until 2026. Authorised in 129 biocidal products in all MS, except Malta, as well as at Union level. Approved as a biocide for insecticides, acaricides and products to control other arthropods[608].	Permethrin is a insecticide which has been shown to be persistent in the environment and to increase the mortality of aquatic invertibrates[609].
Additions	Glyphosate	Pesticide: Approved active substance for plant protection products. Authorised in AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK (26 of 27 MS). Conflicting views on Luxembourg authorisation. Emergency authorisation currently in place in BE to control an outbreak of water primrose[610].	Glyphosate has been shown to be toxic to both aquatic invertebrates and fish as well as increasing mortality within communities of aquatic plants[611].
Additions	Triclosan	Pesticide: Cease manufacture. Previously, there was only one European registrant that registered a production of 100-1000 tonnes in 2015, and updated this to 10-100 tonnes in 2016[612].	Triclosan has the potential to be toxic to aquatic organisms[613]. It is also know to pose a risk as an endocrine disruptor and to play a role in carcinogenesis[614].

[602] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=602
[603] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home
[604] https://pubmed.ncbi.nlm.nih.gov/31394255/
[605] http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/205.htm
[606] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=84
[607] https://www.sciencedirect.com/science/article/abs/pii/S0048969721034215
[608] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/1342/PT08
[609] https://www.researchgate.net/publication/283158322_Toxicological_effects_of_pyrethroids_on_non-target_aquatic_insects
[610] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/rest/pppapi/emergAuthAPI/authorisationsPDF/3147
[611] https://www.researchgate.net/publication/331044852_Ecotoxicology_of_Glyphosate-Based_Herbicides_on_Aquatic_Environment
[612] https://www2.mst.dk/Udgiv/publications/2016/12/978-87-93529-47-2.pdf
[613] https://echa.europa.eu/da/registration-dossier/-/registered-dossier/12675/6/2/2
[614] https://springerplus.springeropen.com/articles/10.1186/s40064-016-3287-x

Options	Substance	Type/Use	Concern
Additions	PFAS	Industrial: PFAS chemicals are used in a wide range of applications including textiles, cosmetics, ski treatment, industrial chemicals, lubricants and greases, and firefighting foams to name a few. There is minimal quantifiable information on PFAS uses available at a higher level of disaggregation.	All PFAS, such as PFOS, are toxic to aquatic organisms and have the potential to induce adverse effects on the endocrine system fish, mammals and other organisms[615].
Additions	Bisphenol A	Industrial: The primary use of BPA (75% of total use) is in the manufacture of polycarbonate, used in the manufacture of a wide range of products. Following this, 17% of total use is in epoxy resins[616][617].	Shown to be toxic (exhibiting genotoxicity, cytotoxicity and neurotoxicity), a reproductive toxin and an endocrine disruptor[618].
Additions	Microplastics	Disposed (mirco)plastics originate from both industrial and domestic/household use[619]. Microplastics (MPs) are defined by [17] as "synthetic solid particles or polymeric matrices, with regular or irregular shape and with size ranging from 1 µm to 5 mm, of either primary or secondary manufacturing origin, which are insoluble in water." Plastic particles smaller than 5 millimetres are generally considered to be microplastic. Some studies have identified plastic particles as small as 10 nanometres (or 0.00001 millimetres). Since plastics are non-biodegradable, they will likely continue degrading into even smaller pieces even past 10nm. Microplastics can contain two types of chemicals: (i) additives and polymeric raw materials (e.g. monomers or oligomers) originating from the plastics, and (ii) chemicals absorbed from the surrounding ambience[620]. Because plastics are particularly sensitive to the degrading action of light, UV radiation and heat, the stabilizers, have the function of preventing the thermal decomposition during the processing, as well as the oxidation and the consequent breaking of the polymeric chains (using phenols and aromatic amines). They mainly consist of organic or inorganic cadmium, barium, or lead salts [22]	Many plastic additives are substances of (high) concern that are classified as hazardous according to the EU regulation on classification and labelling [27], but are presently still widely used in everyday products as regular ingredients. Among these chemicals, many routinely used to make plastics are dangerous. Bisphenol A (BPA), phthalates, as well as some of the brominated flame retardants, that are used to make household products and food packaging, have been proven to be endocrine disruptors that can damage human health if ingested or inhaled [30].[623] The combination of various kind of polymers of different sizes and shapes that are joined to the action of a large amount of additives that originate from plastics results in a cocktail of contaminants that not only alter the nature of plastic but can leach into the air, water, food, and, potentially, human body tissue during their use or their disposal, thus exposing us to several chemicals together.

[615] Substance reports
[616] HBM4EU policy brief (internal, not published), and refs therein
[617] Fischer, Benedikt., Milunov, Milos., Floredo, Yvonne., Hofbauer, Peter., Joas, Anke. 2014. "Final report to the Federal Environment Agency (Germany): Identification of relevant emission pathways to the environment and quantification of environmental exposure for Bisphenol A." Project No. (FKZ) 360 01 063. Report No. (UBA-FB) 001933/E.
[618] https://www.researchgate.net/publication/347391539_Occurrence_toxicity_and_ecological_risk_of_Bisphenol_A_analogues_in_aquatic_environment_-_A_review/link/5fe1f87845851553a0df9a02/download
[619] https://www.nwwac.org/_fileupload/Papers%20and%20Presentations/2019/NWWAC&MAC%20Plastics%20Workshop/10%20Microplastic%20and%20Human%20Health.pdf
[620] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7068600/
623 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7068600/

Options	Substance	Type/Use	Concern
		Soluble or insoluble dyes are organic or inorganic substances in the form of fine powders that give the polymer the desired color; the soluble dyes maintain the transparency of the plastic, while the insoluble ones (pigments) cover it to make it opaque. Many inorganic pigments contain heavy metals, while organic pigments include various chromophoric families like azo pigments, phthalocyanine pigments, anthraquinone chromophores, and various other chromophores [23]. Lubricants and anti-adhesives are substances that facilitate the processing of plastic materials, improving their flow characteristics. They consist of calcium or magnesium stearates [24]. Flame retardants have the function of cooling or protecting a material in the event of a fire by preventing the oxidation of flammable gases or by forming a layer of ash. They are products that contain, for example, chlorine and bromine, which release by the action of the flame; phosphorus, which favours the transformation into coal; and aluminium hydroxide, which generates water vapour and CO2 at 200 °C [24]. The additives, in almost all cases, are not chemically bound to the plastic polymer; only some flame retardants are polymerized with plastic molecules, becoming part of the polymeric chain [18]. Though these additives improve the properties of polymeric products, many of them are toxic, and their potential for the contamination of soil, air and water is high [18]. Studies on their impact on aquatic organisms with which they come into contact through macro and microplastics ingestion are numerous, but many are also still ongoing [25,26]. Some examples out of many are a study on microplastics in seafood and the resulting implications on human health[621], and a study on microplastic pollution and human health[622].	For example, there is some evidence that microplastics can absorb toxic chemicals and then release them in an animal's digestive systems. This would obviously be bad for our health. There is evidence that potentially-toxic plastic nanoparticles may be able to migrate through the intestinal wall during digestion. Whether they then enter the blood stream is not yet fully clear, however, but it is likely. If inhaled or ingested, microplastics may accumulate and exert localized particle toxicity by inducing or enhancing an immune response. Chemical toxicity could occur due to the localized leaching of component monomers, endogenous additives, and adsorbed environmental pollutants. Chronic exposure is anticipated to be of greater concern due to the accumulative effect that could occur. This is expected to be dose-dependent, and a robust evidence-base of exposure levels is currently lacking. Although there is potential for microplastics to impact human health, assessing current exposure levels and burdens is key[624]. Another study demonstrated that nanoplastic particles lodged in the brains of fish affected their behaviour. The study found that plastic particles made fish eat slower and explore their surroundings less. It is likely that these results can partly be extrapolated to human health, additional

[621] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6132564/
622 https://www.scientificamerican.com/article/from-fish-to-humans-a-microplastic-invasion-may-be-taking-a-toll/?sf196831995=1 and https://www.niehs.nih.gov/research/supported/translational/peph/podcasts/2020/june22_microplastics/index.cfm
624 https://pubmed.ncbi.nlm.nih.gov/28531345/

Options	Substance	Type/Use	Concern
			evidence is desirable and needed to assess if and how nanoplastics penetrate brain tissue in humans, let alone affect behaviour.
Additions	Silver	Metal: Main uses in photography, imaging, electronics and electrical applications[625], silver for biocides in medical applications, food processing, food preservation, paper, wood preservation, textiles, and consumer products as well as soldering products[626]. The EU country importing the most silver in 2018 was Germany, followed by Italy, France, Netherlands, and Spain[627].	The free silver ion has been shown to be toxic to aquatic organisms following uptake primarily via the gills and gut[628]. Nanoform of silver may contribute towards anti-micorbial resistance[629].
Amendment to EQS	Chlorpyrifos	Organophosphate pesticide no longer used as a plant protection products or biocide; banned in the EU. Previous emergency authorisations in 2019 for use on corn, sunflower and rapeseed against moths and larvae[630].	Use has led to contamination of environmental compartments and disruption of biogeochemical cycles. Causes neurotoxicity, and immunological and psychological effects in humans and ecosystems[631].
Amendment to EQS	Dioxins	Generated as unintentional pollutants from a range of sources such as manufacture of metals (particularly secondary metal manufacture), incineration of waste, accidental fires (buildings and vehicles), and as a contaminant in some chloro-organic chemicals (e.g. PCBs)[632].	Toxic, bioaccumulative and persistent; Dioxins are known to be highly toxic, carcinogenic, cause reproductive and developmental problems, interfere with hormones, and damage the immune system[633].
Amendment to EQS	Diuron	Herbicide that is not approved in the EU as a plant protection product or biocide. Application for approval in progress for use as a biocidal active substance for film preservatives and construction material preservatives[634,635].	Carcinogenic to humans and slightly toxic to mammals and birds and moderately/highly toxic to aquatic organisms[636].

625 https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620170404
626 https://healthy-living.org/~rxsilver/DiRienzo-Silver.pdf
627 https://www.statista.com/statistics/1114919/silver-imports-distribution-globally-by-country/
628 Draft EQS dossier
629 Bacterial resistance to silver nanoparticles and how to overcome it; Aleš Panáček, Libor Kvítek, Monika Smékalová, Nature nanoparticles, 2018, volume 13 p.65-71: https://www.nature.com/articles/s41565-017-0013-y
630 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home
631 https://www.sciencedirect.com/science/article/pii/S0301479719303512?via%3Dihub
632 https://www.tandfonline.com/doi/full/10.1080/10962247.2015.1058869
633 https://www.epa.gov/dioxin/learn-about-dioxin#:~:text=Dioxins%20are%20highly%20toxic%20and,the%20fatty%20tissue%20of%20animals%20.
634 https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/260.htm
635 https://echa.europa.eu/information-on-chemicals/biocidal-active-substances?p_p_id=dissactivesubstances_WAR_dissactivesubstancesportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3&_dissactivesubstances_WAR_dissactivesubstancesportlet_javax.portlet.action=dissActiveSubstancesAction
636 https://wsdot.wa.gov/sites/default/files/2008/01/25/Herbicides-factsheet-Diuron.pdf

Options	Substance	Type/Use	Concern
Amendment to EQS	Fluoranthene	Fluoranthene is a member of the polyaromatic hydrocarbon family. While PAHs more generally do not have commercial uses and tend to be present as an unintentional byproduct of fossil fuels, fluoranthene has had some limited application as a pesticide and within metal treatment.[637]	Carcinogenic and mutagenic.
Amendment to EQS	PAHs	Polyaromatic hydrocarbons are (PAHs) are a family of organic chemicals strongly associated with fossil fuels. As a group they do not have a recognised commercial value, but are unintentionally included within solid fossil fuels and petroleum based products. The majority of emissions are to air from combustion activities. The major pathways to water are from deposition of atmospheric emissions, and via WWTPs, although note partitioning is mainly to suspended solids or sludge.	As a family the physical properties vary between family members as do the hazards. However, a number of PAH substances have been identified as carcinogenic, with potential mutagenic and endocrine disrupting properties.
Amendment to EQS	Heptachlor/Heptachlor oxide	Insecticide - not approved as an active ubstance in plant protection products and banned as a biocide within the EU. No emergency authorisations[638].	Classified as a possible carcinogen, reproductive/developmental toxicity, other acute/chronic toxicity and classified as a persistent organic pollutant[639,640].
Amendment to EQS/Deselection	Hexachlorobenzene	Pesticide and formed as a byproduct during the manufacture of other chemicals[641]. Banned in the EU as a pesticide and is not approved as a biocide. Otherwise, can be used as a seed dressing and as a wood-preserving agent among other uses[642,643].	Presumed to be carcinogenic - probable carcinogen. Also shows chronic toxicity and reproductive/developmental effects have been demonstrated in animal studies[644].
Amendment to EQS/Deselection	Hexachlorobutadiene	Industrial chemical previously used intentionally in as a solvent in chemical products for textiles and as a pesticide among other uses. More recently, released unintentionally during chemical manufacturing[645,646,647].	Identified as toxic, bioaccumulative, persistent (the Stockholm Convention risk profile states half-life in air is 1 year which suggests that long range transport is possible), mutagenic, carcinogenic and has an Equivalent Level of Concern[648].

[637] https://pubchem.ncbi.nlm.nih.gov/compound/Fluoranthene#section=Uses
[638] https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/378.htm
[639] https://www.epa.gov/sites/default/files/2016-09/documents/heptachlor.pdf
[640] https://echa.europa.eu/da/substance-information/-/substanceinfo/100.000.876
[641] https://www.epa.gov/sites/default/files/2016-09/documents/hexachlorobenzene.pdf
[642] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1021&from=EN
[643] http://ec.europa.eu/social/BlobServlet?docId=10173&langId=en
[644] https://www.epa.gov/sites/default/files/2016-09/documents/hexachlorobenzene.pdf
[645] https://www.eurochlor.org/wp-content/uploads/2019/04/sd5-hexachlorobutadiene-final.pdf
[646] https://link.springer.com/content/pdf/10.1007/s11783-020-1352-8.pdf
[647] https://utslappisiffror.naturvardsverket.se/en/Substances/Chlorinated-organic-substances/Hexachlorobutadiene/
[648] Risk profile for hexachlorobutadiene under Stockholm Convention

Options	Substance	Type/Use	Concern
Amendment to EQS	Mercury	Metal; In Europe emissions of mercury have been most commonly associated with coal combustion. Elemental mercury has been commonly used in electrical equipment, medical and laboratory equipment and dental amalgams and is present naturally[649, 650].	Neurotoxicity is one of the primary concerns of mercury exposure. Toxicity of mercury also known to have other neurological, renal, gastrointestinal, genetic, cardiovascular and developmental effects in organisms – reproductive problems in birds are a concern[651].
Amendment to EQS	Nickel	Metal; Natural and anthropogenic sources. Anthropogenic uses in metal, chemical and food processing industries (e.g. in catalysts and pigments), with the largest use in stainless steel production. Less significant sources of nickel include dental /orthopaedic implants, kitchen utensils and jewelry[652].	Nickel is a toxic and carcinogenic environmental and occupational pollutant[653].
Amendment to EQS	Nonyl phenol	Industrial chemical; Previously in the EU, used in paints, pesticides, imported textiles, and personal care products (often intermediates in the manufacture of other chemical compounds). However, since 2003 the production and majority of uses of nonylphenols was restricted[654].	Persistent, bioaccumulative, highly toxic to aquatic organisms and is known to cause the feminisation of fish[655].
Amendment to EQS	PBDEs	Industrial chemical used as flame-retardants primarily in plastics (especially electricals), textiles, sealants, adhesives, and coatings used for construction[656] Use of lower order homologues was banned internationally in 2004, and use of DecaBDE should have ceased by 2021.	Capable of bioaccumulation and biomagnification in food chains. Toxic to aquatic organisms and humans, potential endocrine disruptors, reproductive toxins, neurodevelopmental toxins, and possible effects on the thyroid system[657].
Amendment to EQS	Tributyltin	Industrial chemical; Banned in the EU, but previously used as an antifouling paints on ships and boats[658].	Tributyltin is toxic to aquatic organisms[659].
Deselection	Alachlor	Pesticide; Not approved as an active substance in PPP and not approved as a biocide - Banned as a herbicide in the EU since 2006.	Alachlor is an animal carcinogen with potential as a human carcinogen[660].

649 https://www.eea.europa.eu/data-and-maps/indicators/eea32-heavy-metal-hm-emissions-1/assessment-10
650 HBM4EU policy brief (internal, not published), and refs therein
651 https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/2020-01/ard-28.pdf
652 https://people.wou.edu/~taylors/es420_med_geo/med_geo/Nikel_2006_Env_Nickel_Toxicology.pdf
653 https://onlinelibrary.wiley.com/doi/full/10.1111/bcpt.12689
654 https://www.eea.europa.eu/publications/chemicals-in-european-waters/download
655 https://pubmed.ncbi.nlm.nih.gov/18282600/
656 UNEP - Risk Management Evaluation for DecaBDE
657 https://consult.environment-agency.gov.uk/environment-and-business/challenges-and-choices/user_uploads/polybrominated-diphenyl-ethers-pressure-rbmp-2021.pdf
658 https://www.sciencedirect.com/science/article/pii/S0301479708002624
659 https://www.frontiersin.org/articles/10.3389/fmars.2019.00633/full
660 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6136926/

Options	Substance	Type/Use	Concern
Deselection	Chlorfenvinphos	Insecticide; Not approved for use in the EU.Used elsewhere to control insects such as ticks, livestock flies, mites, root flies, rootworms, beetles and leafhopers[661].	Highly toxic to birds, honeybees and aquatic invertebrates and moderately toxic to fish and earthworms[662].
Deselection	Simazine	Pesticide; Not approved for use as a plant protection product or as a biocide[663].	Classified as "not likely to be carcinogenic to humans"[664] and
Deselection	Benzene	Industrial chemical; Used in the manufacture of plastics, raw materials for detergents, synthetic rubber, dyes, Resins, plant protection products and other chemicals[665].	Benzene is mutagenic/genotoxic and carcinogenic leading to cancers such as leukemia and diseases such as aplastic anaemia[666].
Deselection/ Change of status	Carbon tetrachloride	Industrial chemical; used as an intermediate in the manufacture of chemicals such as rubber and polymers as well as hydrofluoroolefins[667]. Use in applications such as aerosols and refrigerant gases was phased out in the mid-1990s[668].	Toxic and carcinogenic to both humans and animals[669] and an ozone-depleting chemical[670].
Change of status	Aldrin	Pesticide; Banned in the EU for more than 40 years. Was used as a pesticide for soil applications (e.g. to protect roots of plants from termites)[671] and potentially to protect wooden structures from termites.	Toxic (including neurological and reproductive effects[672]), persistent, bioaccumulative, carcinogenic and with an Equivalent Level of Concern.
Change of status	Dieldrin	Pesticide; Banned in the EU for more than 40 years. It is often referenced together with aldrin, in part because aldrin degrades into dieldrin. Previously used as a pesticide for soil applications (e.g. to protect roots of plants from termites)[673] and potentially to protect wooden structures from termites.	Toxic (including neurological and reproductive effects[674]), persistent, bioaccumulative, carcinogenic and with an Equivalent Level of Concern.
Change of status	Endrin	Pesticide; Banned in the EU as of 1991 but it was severly restricted in the EU as of 1979 (79/117/EEC)[675,676]. Previously used in backpack	Toxic (neuro-, hepatic, renal, respiratory, cardiovascular, endocrine, immuno-, reproductive and developmental toxicities),

661 https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/138.htm
662 http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/138.htm
663 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=1136
664 https://www.epa.gov/sites/default/files/2019-12/documents/simazine_pid_signed.pdf
665 https://echa.europa.eu/documents/10162/be2a96a7-40f6-40d7-81e5-b8c3f948efc2
666 https://www.who.int/ipcs/features/benzene.pdf
667 https://www.chlorinated-solvents.eu/uses-and-benefits/uses/technology/
668 https://www.eurochlor.org/term/carbon-tetrachloride/
669 https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=195&toxid=35
670 https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2018GL079500#:~:text=Carbon%20tetrachloride%20(CCl4)%20is,uses%20was%20banned%20from%202010.
671 http://www.inchem.org/documents/ehc/ehc/ehc91.htm
672 https://www.atsdr.cdc.gov/toxguides/toxguide-1.pdf
673 http://www.inchem.org/documents/ehc/ehc/ehc91.htm
674 https://www.atsdr.cdc.gov/toxguides/toxguide-1.pdf
675 ATSDR - US Toxicological profile for Endrin
676 https://www.pan-europe.info/old/Archive/About%20pesticides/Banned%20and%20authorised.htm

Options	Substance	Type/Use	Concern
		sprayers for orchards, in crop dusting for vegetables and as a rodenticide[677,678].	persistent, bioaccumulative and with an Equivalent Level of Concern[679].
Change of status	Isodrin	Pesticide; Isodrin is co-produced with aldrin at approx 3.5% isodrin; 90.5% aldrin, and 6% other fractions[680].	Very toxic to both aquatic organisms and humans[681].
Change of status	DDT	DDT was a general broad spectrum insecticide with a very wide set of applications[682] but was very heavily restricted in the EU from 1979[683]. It was banned outright from 1983 onwards[684]. However, it was permitted to be used (and still used) as an intermediate for the manufacture of dicofol until 2006[685].	Toxic (also with reproductive effects), persistent, bioaccumulative, carcinogenic and with an Equivalent Level of Concern. Toxic effects have been observed in a range of birds and aquatic organisms[686].
Change of status	Tetrachloroethylene	Industrial chemical; Applications include dry cleaning, industrial textile treatment, metal surface cleaning, catalyst regeneration, applications within oil refineries and as a chemical intermediate in the manufacture of fluoropolymers[687].	Toxic (shown to have reproductive/developmental effects) and carcinogenic[688].

677 http://www.inchem.org/documents/ehc/ehc/ehc130.htm
678 ATSDR - US Toxicological profile for Endrin
679 https://www.atsdr.cdc.gov/toxprofiles/tp89.pdf
680 USEPA Toxicological profile for aldrin/endrin
681 https://utslappisiffror.naturvardsverket.se/en/Substances/Pesticides/Isodrin/
682 http://www.inchem.org/documents/pims/chemical/pim127.htm]
683 https://ec.europa.eu/commission/presscorner/detail/en/MEMO_03_219
684 https://ec.europa.eu/commission/presscorner/detail/en/MEMO_03_219
685 UNEP - Dicofol risk profile
686 http://npic.orst.edu/factsheets/archive/ddttech.pdf
687 https://www.chlorinated-solvents.eu/products/perchloroethylene-per/
688 https://www.epa.gov/sites/default/files/2016-09/documents/tetrachloroethylene.pdf

Appendix D Monitoring data

The European Environment Agency (EEA) WISE database contains information on the status, quality, quantity and emissions to of Europe's rivers, lakes, groundwater bodies, transitional, coastal, and marine waters[689] . The 'Waterbase – Water Quality ICM' dataset contains time series of chemicals in rivers, lakes, groundwater, transitional, coastal, and marine waters, with spatial object identifiers as reported through WFD and WISE. **-Table 4-2** contains a summary of the aggregated dataset (Part 2 of the Waterbase- Water Quality ICM) for selected substances. Data has been extracted for surface water bodies only (river water, lake water and transitional). As the dataset was already aggregated (rather than individual concentration data), the 'minimum value' represents the minimum value of the minimum values in the dataset, the 'maximum value' presents the maximum of the maximum values, and the 'mean' is the mean of the means presented in the dataset. Data has only been extracted for the EU-27.

Note: Many Member States measure the 'presence' of substances (meaning measured concentrations reliably confirming exceedances of the limit of quantification (LoQ)[690], without quantifying the exact level of exceedance however). This is often due to the use of analytical methods suitable for 'quick screening' but less precise. To still be able to use those 'non-quantified' sample data for risk analysis purposes, the dossiers provide the following a scenario to consider the use of those so called 'censor data' (non-quantified samples)', and the scale of risk based on monitoring. The risk assessments in all substance dossiers use the same statistical approach as documented and used by EFSA and USA EPA to perform basic statistics on the concentration data derived from those data. It is based on the following data scenario which was considered as the most appropriate scenario for making a risk assessment according the WG Chemicals / sub-group on review (SG-R) of the priority substances list. This scenario considers quantified monitoring samples and non-quantified samples only when ½ Limit of Quantification (LoQ) ≤ Predicted No-Effect Concentration (PNEC) or EQS, thus avoiding any non-confirmed exceedances. The sub-group on review (SG-R) of the priority substances list confirmed this to be the most relevant scenario to assess whether the substance poses a risk at EU-level[691]. This scenario avoids excluding data collected as non-quantified while minimising artificial exceedances.

[689] European Environment Agency. (2021). *Waterbase – Water Quality ICM*. https://www.eea.europa.eu/data-and-maps/data/waterbase-water-quality-icm-1
[690] LoQ is the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are also met. The LoQ may be equivalent to the Limit of Detection (LoD) or it could be a higher concentration. Often, the LoD defined as 3 × standard deviation of the blank, and at the LoQ defined as 10 × standard deviation of the blank.
[691] Carvalho RN, Marinov D, Loos R, Napierska D, Chirico N, Lettieri T. 2016. Monitoring-based exercise: second review of the priority substances list under the Water Framework Directive, Available at https://circabc.europa.eu/w/browse/52c8d8d3-906c-48b5-a75e-53013702b20a

Table D-1 Summary table of aggregated data from the European Environment Agency (WISE and WFD) for SW Water bodies only (River Water, Lake Water and Transitional)

Substance	Minimum Value	Maximum Value	Mean	Unit(s)	Countries covered	River bodies covered	Number of data entries (aggregated)	Year of data
Estrone (E1)	0.0003	24.49	1.59	ug/L	CZ, ES	RW	65	2013-2019
17-eta-estradiol (E2)	0.0003	0.0033	0.000945	ug/L	CZ, RO	RW	55	2013-2019
Ethylestradiol (EE2)	0.00005	0.005	0.000882	ug/L	CZ, RO	RW	55	2013-2019
Diclofenac	0.005	3998	15.1	ug/L	CZ, DE, ES, LU, RO	LW, RW	1517	2009-2019
Azithromycin	0.01	3145.38	41.5	ug/L	CZ, ES	LW, RW	317	2015-2019
Clarithromycin	0.01	391	15.4	ug/L	CZ, ES, DE	LW, RW	576	2015-2019
Erythromycin	0.01	200	17.2	ug/L	CZ, DE, ES	LW, RW	473	2010-2019
Carbamazepine	0.005	1.85	0.0531	ug/L	CZ, DE, ES, LU, NL	LW, RW	1017	2007-2019
Ibuprofen	0.005	10	0.0740	ug/L	CZ, DE	LW, RW	933	2009-2019
Nicosulfuron	0.00206	3	0.0160	ug/L	DE	LW, RW, TW	215	2016-2019
Acetamiprid	0.000195	0.0644	0.0055	Ug/l	N/A	N/A	N/A	N/A
Clothianidin	0.005	25	1.45	ug/L	CZ, ES, SE	LW, RW	697	2012-2019
Imidacloprid	0.00005	400	2.83	ug/L	CZ, DE, ES, IT, NL, SE	LW, RW, TW	1463	2011-2019
Thiacloprid	0.0005	88	1.02	ug/L	CZ, ES, FI, IT, SE	LW, RW	1235	2011-2019

Substance	Minimum Value	Maximum Value	Mean	Unit(s)	Countries covered	River bodies covered	Number of data entries (aggregated)	Year of data
Thiamethoxam	0.0005	2.7135	0.0437	ug/L	N/A	N/A	N/A	N/A
Bifenthrin	0.0338	0.436	0.1125	ug/l	N/A	N/A	N/A	N/A
Deltamethrin	0.001	0.19	0.0535	ug/l	N/A	N/A	N/A	N/A
Esfenvalerate	0.004	0.1495	0.0430	ug/l	N/A	N/A	N/A	N/A
Permethrin	0.0005	20	0.162	ug/L	CZ, FI, FR, IT, SE	LW, RW, TW	1656	2002-2019
Glyphosate	0.001	790	0.525	ug/L	CZ, DE, ES, FI, FR, IE, IT, NL, SE, SK	LW, RW, TW	3948	2006-2019
Triclosan	0.0001	0.458	0.0142	ug/L	CZ, DE	LW, RW, TW	858	2010-2019
PFOA and PFOS and its derivatives	0.00003	120	0.288	ug/L	CZ, DE, ES, FR, IT	LW, RW, TW	2324	2010-2019
Bisphenol A	0.0005	1300	0.623	ug/L	CZ, DE, ES, FI, IT, LT, SK	LW, RW	1193	2007-2019
Silver	0.003	25	0.524	ug/L	CZ, DE, FR, IE, IT, LU, NL, PL, RO	LW, RW, TW	2566	1999-2019
Chlorpyrifos	0	500	0.187	ug/L	AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SK	LW, RW, TW	18193	2000-2019
Cypermethrin	<LOQ	0.01	0.0864	Ug/l	ES, CZ, DE, FR	RW		
Dicofol	<LOQ	<LOQ	<LOQ	Ug/l	CY, CZ, DE, ES, FR, IT	RW		

Substance	Minimum Value	Maximum Value	Mean	Unit(s)	Countries covered	River bodies covered	Number of data entries (aggregated)	Year of data
Dioxins including dioxin-like PCBs only 2,3,7,8 - Tetrachlorodibenzo-p dioxin, TCDD	0	580	0.843	ug/L and ug{TEQ}/kg	BE, BG, CY, DE, EL, ES, FR, HR, IT, IU, NL, RO, SK,	LW, RW, TW	10066	2003-2019
Diuron	0	2295	0.390	ug/L	AT, BE, CY, CZ, DE, DL, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK	LW, RW, TW	17579	1991-2019
Fluoranthene	0	5350	0.552	ug/L	AT, BE, BG, CY, CZ, DE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK	LW, RW, TW	16590	1991-2019
Heptachlor and Heptachlor epoxide	0	20	0.546	ug/L	BE, CY, CZ, DE, EL, ES, FI, FR, HR, IT, LT, NL, PT, SK	LW, RW, TW	14585	1996-2019
Hexabromocyclododecane	<LOQ	0.056	0.0001	ug/l	CZ, DE	RW		
Hexachlorobenzene	0	1000	0.123	ug/L	AT, BE, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LV, LU, MT, NL, PL, PT, RO, SK	LW, RW, TW	16689	1980-2019
Hexachlorobutadiene	0	100	0.530	ug/L	AT, BE, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, RO, SK	LW, RW, TW	14034	1994-2019
Mercury	0	5800	3.54	ug/L	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SK	LW, RW, TW	27626	1975-2019

Substance	Minimum Value	Maximum Value	Mean	Unit(s)	Countries covered	River bodies covered	Number of data entries (aggregated)	Year of data
Nickel	0	2000000	672	ug/L	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SK	LW, RW, TW	33864	1975-2019
Nonylphenol and nonylphenol ethoxylates (NP + NPEs)	0.005	0.15	0.0863	ug/L	DE	LW	4	2013
PAHs (Benzo(a)pyrene; Benzo(b)fluoranthene; Benzo(g,h,i)perylene; Benzo(k)fluoranthene; Indeno(1,2,3-cd)pyrene)	0	2180	0.221	ug/L	AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK	LW, RW, TW	79594	1991-2019
Poly brominated diphenyl ethers (Brominated diphenylethers congener numbers 28, 47, 99, 100, 153 and 154; Pentabromodiphenylether)	0	5	0.0465	ug/L	DE, ES, FR, LU, MT, PL, SK	LW, RW, TW	1825	2004-2019
Tributyltin	0	100	0.261	ug/L	BE, CZ, DE, ES, FR, LU, MT, NL, PL, SK	LW, RW, TW	4166	2005-2019

Data was downloaded on 14 July 2021 in CSV format. https://www.eea.europa.eu/data-and-maps/data/waterbase-water-quality-icm-1 (Part 2 CSV files)

Appendix E Rationale underpinning the dynamic baseline - Surface Waters

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
WFD - Programme of measures	No pharmaceutical substances currently included in the PS list. Primary point of release will be UWWT. Assume existing PoMs will be ineffective and have no impact. **NO IMPACT**	similar issue as oestrogenic - however, see strategy for pharmaceuticals where anti-microbial resistance may be an important driver for existing action. **NO IMPACT**	same response as oestrogenics. **NO IMPACT**
Revised Drinking Water Directive (adopted by the European Parliament in December 2020)	While the new directive reinforces quality standards beyond the WHO level, pharmaceuticals are not covered by Annex I. evidence about oestrogenics in drinking water are still emerging so the picture is inconclusive. Assume no impact. **NO IMPACT**	antibiotics are not covered by Annex I so no obligation to monitor or control concentrations. Assume no impact. **NO IMPACT**	similar case as the other pharmaceuticals. **NO IMPACT**
*Revised Urban wastewater treatment Directive (**NOTE**: The impact assessment for the UWWTD is ongoing and therefore unclear specifically how the directive will be amended. This row is included for context only and not used in the ranking for the dynamic baseline)*	*The IA talks about additional focus on micropollutants and the use of EPR to fund tertiary treatment upgrades across Europe. This would have very significant impacts for emissions. However, the associated costs are equally significant, and therefore it's unclear what the final position may be. But could see a significant emissions reduction.*	*The IA also has a key focus on AMR and the release of low concentration anti-biotics as being part of the driver for AMR. It's possible that the revised UWWT would therefore be a key component with specific targets. This suggests a significant emissions reduction. However, costs and practical implementation may be an issue.*	*In terms of pharmaceuticals, oestrogenics and AMR tends to grab the headlines. Its less clear what importance would be attached to other pharmaceuticals. However, upgrades in tertiary treatment would also be likely to have an impact here, so we could expect some emission minimisation at least.*

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
Revised sewage sludge directive (NOTE: the evaluation of the SSD is ongoing, with preliminary results now available. However, as the process is at earlier stage (I.e., IA has not commenced), this row is included for context only and not used in the ranking for the dynamic baseline).	*The evaluation has highlighted that the list of substances for quality standards in the SSD are limited and may need expansion. Unclear which additional substances might be included. This could limit the disposal of sludge to land and loss to environment.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*	*the issue of AMR is of key importance, and therefore it could be argued that the antibiotics may have a stronger case for inclusion in any sludge quality standards. This could result in some emission minimisation. Note that if sludge cannot be placed on land it creates other practical issues.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*	*similar comments to the other pharmaceuticals.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*
Plant Protection Products Regulation	N/A	N/A	N/A
Biocidal Products Regulation	N/A	N/A	N/A
REACH Regulation	N/A	N/A	N/A
CLP Regulation	N/A	N/A	N/A
Other legislation related to metals	N/A	N/A	N/A
Pharmaceutical legislation	E1 and E2 are naturally produced, as well as manufactured for hormone replacement. EE2 is used in the contraceptive pill. Approvals in place for all substances. The legislation itself is unlikely to further impact emission minimisation. But see the pharmaceutical strategy also. **NO IMPACT (see Pharma strategy)**	the antibiotics covered by this category are already approved under the pharmaceutical legislation. Only a limited number of antibiotics exist, with trends in how they are used/prescribed. Challenging to predict such trends but assume developments under the legislation directly will have little or no impact.	Similar to the other pharmaceutical categories there are already approvals in place. One possible issue is that ibuprofen is a non-prescription medication, data on usage rates and possible increase is less well documented. May be the case that use of this substance will increase depending on GDP, ageing population, and availability of medicine.

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
		NO IMPACT (see Pharma strategy)	**Diclofenac and Carbamazepine - NO IMPACT.** Ibuprofen - EMISSIONS MAY INCREASE
Further legislation related to metals	N/A	N/A	N/A
Industrial emissions directive	the pharmaceutical strategy comments that pharmaceuticals should be considered as KEI for water emissions when considering BAT and in particular the update to dairy farming. However, to date inclusion and consideration of impacts for water has been variable with few BAT conclusions linked to water. Assume benefits under IED would be linked to pharma strategy. SOME EMISSION MINIMISATION	The wider consideration of antibiotics under IED including binding BAT conclusions would be driven by the pharmaceutical strategy using the IED as the delivery method. Any improvement is contingent on the success of the strategy noting that BAT conclusions for water are more limited than for air. SOME EMISSION MINIMISATION	Same points as for other pharmaceuticals. SOME EMISSION MINISATION
Persistent organic pollutants regulation	Unlikely to be included as POP. **NO IMPACT**	Unlikely to be included as a POP. **NO IMPACT**	Unlikely to be included as a POP. **NO IMPACT**
Waste legislation	Based on our review control of pharmaceutical waste was something of gap. The issue of wastes / unused pharma will be tackled more by the pharmaceutical strategy. Assume no impact.	same comment	same comment

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
	NO IMPACT.	NO IMPACT	NO IMPACT
European Green deal:			
i) farm to fork strategy	N/A	The strategy comments aims for more strict controls on use of antibiotics for imported meat products. This would force non-EU meat producers to comply with EU standards under the recently agreed veterinary medicinal products regulation. This could limit emissions to water during processing and from human population. SOME EMISSIONS MINISATION	N/A
ii) Biodiversity to 2030 strategy	The strategy aims to identify a larger EU-wide network of protected land, which could have increased actions for protection against a range of substances including oestrogenic substances, particularly given the EDC effects. Could assume some emission minimisation SOME EMISSION MINIMISATION	Same comments as oestrogenics SOME EMISSION MINIMISATION	Same comments as oestrogenics SOME EMISSION MINIMISATION
iii) strategy for sustainable use of chemicals	defers to pharmaceuticals strategy	defers to pharmaceuticals strategy	defers to pharmaceuticals strategy

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
iv) strategy for pharmaceuticals	The strategy does include aims to discuss with pharma companies EPR. Possible recognition that management is likely to be via end of pipe, and costs for UWWT plants will be significant. The strategy is relatively ill-defined on timescales and achievable targets, it details a set of aspirations and steps to help achieve them, but it is less clear on the wider impact and by when. The changes for human health related medicines are still developing however the risk assessment focus is on human health not the environment. If some emission change is achieved, reduction is expected to be less than 10%. **NO IMPACT**	The strategy aims to improve the understanding around use, release, and impacts in the environment for pharmaceuticals. The issue of AMR is at the forefront of the strategy and will include greater visibility and control on use of antibiotics within veterinary settings. It also includes fostering greater ties with the WHO to find practical solutions for the problems identified by the strategy. The aims of the strategy are relatively broad with less hard detail on implementation and timelines (e.g. see the farm to fork aspiration for 50% less pesticide use by 2030, no such deadlines in the pharma strategy). However, should have positive impacts for emission minimisation. In particular for veterinary uses as pre-emptive use of antibiotics for farmed animals was banned as of 2019, and strict targets and reporting in place to drive down use to only essential. would expect a big drop in emissions. **SIGNIFICANT EMISSION MINIMISATION**	Less clear on how quickly things will be achieved. The main issue is around over non-prescription medicines which have less control. In particular it's foreseeable that with increased disposable income, ageing population, and availability there would be increased use of medicines such as ibuprofen in coming years. Suspect there would be positive impacts for carbamazepine and diclofenac, through greater control in use and awareness of environmental impacts. No impact for ibuprofen confirmed during consultation which commented that any potential increase in use and therefore increase in emissions is overly simplistic. Carbamazepine and diclofenac : **SOME EMISSIONS MINIMISATION** Ibuprofen: **NO IMPACT**
v) Sustainable use of pesticides	**N/A**	**N/A**	**N/A**
vi) EU Biodiversity Strategy & the EU Pollinators initiative	**NO IMPACT**	**NO IMPACT**	**NO IMPACT**

	Pharmaceuticals		
	Oestrogenic substances	Macrolide antibiotics	Other substances
Summary	The primary releases of oestrogenics will be from grazing animals and humans via UWWTPs. The existing PoMs are likely to be ineffective. No specific greater controls identified under evolving legislation. The pharmaceutical strategy does however provide some positive efforts to limit environmental impacts, however, no timescales are indicated and the subject remains contentious. The baseline would assume some limited improvement, but equally it's possible that under BAU rate of release would be unchanged without intervention.	Importance of AMR as an issue will be a key driver to progress. It is listed as a key aim of the pharmaceutical strategy and there is the option to use IED as a vehicle to add regulatory force to help drive improvements, particularly agricultural use of anti-biotics. However, as with oestrogenics it is a controversial issue and how much headway can be made, particularly with competing food security issues is less clear. But would assume under the baseline to see at least some tangible improvement even without intervention.	The issue of other pharmaceuticals is more challenging to assess. The existing PoMs are likely to be ineffective as they do not address the issue directly. Limited additional controls expected under evolving pharma legislation, and while anti-biotics are likely to take a key focus under IED other pharma may not. The pharmaceutical strategy is likely to have beneficial impacts, but for non-prescription medicines there is really only a watching brief to fill knowledge gaps and monitoring. use of such medicine is increasing, so would expect emissions of ibuprofen to get worse if unchecked.
Rating (+ + significant emission minimisation) (+ some emission minimisation) (**0** no impact) (- some emission increase) (- - significant emission increase)	+ Some emissions minimisation	++ Significant emissions minimisation	+ Some emissions minimisation (carbamazepine and diclofenac) 0 No Impact (ibuprofen)

* Pharmaceuticals - Oestrogenics (EE2, E2, E1)

pharmaceuticals - macrolide antibiotics (azithromycin; clarithromycin; erythromycin)

pharmaceuticals - other substances (diclofenac, carbamazepine, ibuprofen)

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances
WFD - Programme of measures	Assume that some of PoMs addressing wide-dispersive use of pesticides may also benefit release minimisation indirectly. But impacts likely to be variable. Note uses as biocides unlikely to be covered by PoMs. SOME EMISSION MINISATION	same response as neonicotinoids SOME EMISSION MINISATION	same response as neonicotinoids SOME EMISSION MINISATION
Revised Drinking Water Directive (adopted by the European Parliament in December 2020)	The targets for pesticides in the revised DWD are unchanged for pesticides. Much of the focus in the new DWD is about access to clean drinking water. It's possible that this would reduce exposure indirectly and that has consequence for secondary emissions. However, very hard to quantify. Overall, would assume no impact to limited impact in some geographies. **NO IMPACT**	same comments as for other pesticides **NO IMPACT**	same comments as for other pesticides **NO IMPACT**
*Revised Urban wastewater treatment Directive (**NOTE**: The impact assessment for the UWWTD is ongoing and therefore unclear specifically how the directive will be amended. This row is included for context only and not used in the ranking for the dynamic baseline)*	*The IA has provided a significant focus on micropollutants, AMR, PFAS, and endocrine disrupting chemicals. Pesticides have not been included directly, with the possibility that emissions from use are more significant than via UWWT. Therefore, would assume limited to no impact on emissions from changes to the UWWTD.*	*Similar to the other pesticides, assume no impact from revision of the UWWTD*	*Similar to the other pesticides, assume no impact from revision of the UWWTD*

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances
Revised sewage sludge directive (NOTE: the evaluation of the SSD is ongoing, with preliminary results now available. However, as the process is at earlier stage (I.e., IA has not commenced), this row is included for context only and not used in the ranking for the dynamic baseline).	*As commented for UWWTD, pesticides may be of lower importance for wastewater and therefore by proxy for sewage sludge. It is therefore unclear whether the revised SSD would have impact for pesticides or not.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*	*Same comment as neonicotinoids.*	*Same comment as neonicotinoids.*
Plant Protection Products Regulation	Some of the neonicotinoids are already no longer approved for use, while acetamiprid is approved until 2033. Note that a number of emergency authorisations are in place. Additional protection of surface water unlikely to improve under BAU against PPP but see also the farm to fork strategy. **NO IMPACT (see farm to fork)**	Two family members not approved for use in the EU, while the other two have active approvals which expire shortly. Protection of surface water 'may' improve if the active substances aren't renewed. For the purposes of the dynamic baseline assume they will be renewed, meaning no impact on water protection under PPP, but see also farm to fork. **NO IMPACT (see farm to fork)**	The two substances in this group have active approvals which expire in the coming 12-18 months. Assume they will be renewed and that PPP will have no further impacts for water protection in the dynamic baseline but see also farm to fork. **NO IMPACT (see farm to fork)**
Biocidal Products Regulation	All of the neonicotinoids except one have active approvals spanning several years. Furthermore, farm to fork will not address these uses. Assume no impact on emission minimisation. **NO IMPACT**	For the four pyrethroids, one has no use as a biocide, one more is subject to substitution and the remaining two have approvals spanning several years. Assume under BAU that there would be some positive impacts for emission minimisation related to substitution of bifenthrin. **SOME EMISSION MINISATION**	Glyphosate and nicosulfuron do not have applications as biocides. The use of triclosan as a biocide is already not permitted. **NO IMPACT**
REACH Regulation	N/A	N/A	N/A

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances
CLP Regulation	N/A	N/A	N/A
Other legislation on metals	**NO IMPACT**	**NO IMPACT**	**NO IMPACT**
Pharmaceutical legislation	N/A	N/A	N/A
Further legislation related to metals	N/A	N/A	N/A
Industrial emissions directive	Manufacture of pesticides is not directly covered by the IED, although the intermediary steps are likely to be covered. Consideration of environmental releases and impacts is more likely to be covered by PPP. Assume no further improved control. **NO IMPACT**	Same comment as neonicotinoids. **NO IMPACT**	Same comment as neonicotinoids. **NO IMPACT**
Persistent organic pollutants regulation	None of these substances have been identified as POPs.	None of these substances have been identified as POPs.	None of these substances have been identified as POPs.
Waste legislation	wastes from pesticides would already be classified as hazardous. However, revisions to the waste framework may strengthen the implementation. Very challenging to comment on how things will develop so assume no impact for water protection as default. **NO IMPACT**	same comment **NO IMPACT**	same comment **NO IMPACT**
European Green deal:			

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances
i) farm to fork strategy	The strategy aims to reduce the use of more environmentally hazardous pesticides by 50% by 2030. Hazardous is defined as those active substances that meet the cut-off criteria as set out in points 3.6.2. to 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009. It could be assumed there would be reduced use of neonicotinoids under the strategy. However, note the ongoing use via emergency authorisations. It is less clear how successful this aim will be but could assume it will have a limiting effect. During consultation it was highlighted that these pesticides are already banned or heavily restricted, it is then unlikely for further restriction to come into place. **NO IMPACT**	The strategy targets the reduced use of hazardous pesticides by 50% by 2030. May impact the neonicotinoids more substantially. The strategy does include a wider aim for reduced reliance on pesticides but without a deadline date. I suspect the overall farm to fork strategy would have additional positive impacts for emission minimisation, but the magnitude may be less dramatic than some of the other candidate PS. Consultation detailed that two of these substances are banned and other two are candidate list substances. Emission reduction borderline between no impact and some minimisation. **SOME EMISSIONS MINIMISATION**	Glyphosate has picked up a lot of attention in recent years with the pesticide renewal in 2020, however the consultation indicated that rules on glyphosate are unlikely to change. Nicosulfuron emissions will reduce with this initiative.. **NO IMPACT**
ii) Biodiversity to 2030 strategy	The strategy aims to identify a larger EU-wide network of protected land, which could have increased actions for protection against a range of substances including pesticide substances, particularly given the wide dispersive use. Could assume some emission minimisation **SOME EMISSION MINIMISATION**	Same comments as neonicotinoids **SOME EMISSION MINIMISATION**	Same comments as neonicotinoids **SOME EMISSION MINIMISATION**
iii) strategy for sustainable use of chemicals	N/A	N/A	N/A
iv) strategy for pharmaceuticals	N/A	N/A	N/A
v) Sustainable use of pesticides	50% reductions by 2030 based on Zero Pollution Action Plan (ZPAP), The ambitious target is challenging to achieve and consultation indicated it is aspirational. Furthermore the target will	50% reductions by 2030 based on Zero Pollution Action Plan (ZPAP), The ambitious target is challenging to achieve and consultation indicated it is aspirational.	50% reductions by 2030 based on Zero Pollution Action Plan (ZPAP), The ambitious target is challenging to achieve and consultation indicated it is aspirational. Furthermore the

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances
	need to be national and EU legislation to be directly regulated. SIGNIFICANT EMISSIONS MINIMISATION	Furthermore the target will need to be national and EU legislation to be directly regulated. SIGNIFICANT EMISSIONS MINIMISATION	target will need to be national and EU legislation to be directly regulated. SIGNIFICANT EMISSIONS MINIMISATION
vi) EU Biodiversity Strategy & the EU Pollinators initiative	**NO IMPACT**	**NO IMPACT**	**NO IMPACT**
Summary	For the PoMs that address the wide-dispersive use of pesticides there could be some synergistic benefits to reducing emissions and environmental concentrations of neonicotinoids. But it can be crop/application specific. The biggest impact is likely to come from the farm to fork strategy and aims to reduce reliance on pesticides more generally. However, note that the PPP has revoked the approval for some neonics and they are still in use via emergency authorisations, which reflects the scale of the challenge. There could be improvements in releases and environmental concentrations under the dynamic baseline but suspect it would vary geographically and the impact may be less dramatic than a "50% reduction" first suggests.	Similar issue for the pyrethroids, as a family of pesticides that have been in use for many years and one of the biggest families (by sales) used by farmers. The 50% reduction target by 2030 means these pesticides 'may' avoid the hazardous pesticide tag and therefore the requirements could be less stringent. Based on the analysis of everything else in the rows above we conclude an outcome between no impact and limited benefits.	Nicosulfuron, glyphosate and triclosan. Triclosan has no use as a pesticide and use as a biocide is no longer permitted. Therefore, emissions from active use should have ceased already. The above legislation and strategies will not improve upon that. For nicosulfuron and glyphosate the strategy to reduce pesticide use should help, and there has been lengthy debates and reviews on continued use of glyphosate, but could expect the emissions under BAU could fall.
Rating (+ + significant emission minimisation) (+ some emission minimisation) (**0** no impact) (- some emission increase) (- - significant emission increase)	**+ Some emissions minimisation**	**+ Some emissions minimisation**	**+ Some emissions minimisation (nicosulfuron)** **0 No impact (triclosan and glyphosate)**

* Pharmaceuticals - Oestrogenics (EE2, E2, E1)

	Pesticides		
	Neonicotinoids	Pyrethroids	Other substances

pharmaceuticals - macrolide antibiotics (azithromycin; clarithromycin; erythromycin)

pharmaceuticals - other substances (diclofenac, carbamazepine, ibuprofen)

Pesticides - neonicotinoids (acetamiprid, clothanidin, imidacloprid, thiacloprid, thiamethoxam)

Pesticides - pyrethroids (bifenthrin, deltamethrin, esfenvalerate, permethrin)

pesticides - other substances (nicosulfuron, glyphosate, Triclosan)

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
WFD - Programme of measures	Existing PoMs are unlikely to target the sources of silver correctly. Note in some cases further issues with naturally occurring concentrations. Assume existing PoMs have no impact. **NO IMPACT**	Existing PoMs for PFOS would be likely to have beneficial impacts against other PFAS. However, note the very broad set of uses for PFAS. It is unlikely that all major pathways to environment are appropriately covered. Therefore, there may be some minimisation of releases from existing PoMs, but benefits would be limited. **SOME EMISSION MINISATION**	Existing PoMs are unlikely to target the sources of BPA correctly. Assume existing PoMs have no impact. **NO IMPACT**
Revised Drinking Water Directive (adopted by the European Parliament in December 2020)	Silver is not listed under Annex I. no obligations to monitor or control. Therefore, assume no impact from the revised legislation on emissions. **NO IMPACT**	PFAS has now been added to Annex I with quality thresholds. Analytical standards are in the process of being developed in 2021. This would suggest greater control on the flow of material and cycling within the water chain. How significant an impact is hard to comment, but as part of the wider set of approaches should have a positive impact. **SOME EMISSION MINIMISATION**	A new standard for bisphenol A has been added to Annex I. This would improve monitoring and control of bisphenol A. This should have a positive impact for cycling of BPA within the water cycle. **SOME EMISSION MINIMISATION**

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
*Revised Urban wastewater treatment Directive (**NOTE**: The impact assessment for the UWWTD is ongoing and therefore unclear specifically how the directive will be amended. This row is included for context only and not used in the ranking for the dynamic baseline)*	*Metals are often one of the sets of substances that are easier to treat within standard wastewater processes. Note however this usually involves partitioning into sludge. For the revised UWWT directive, it may be the case that further improvements on managing metals such as silver see less marked changes than some of the other candidate PS here. Assume some emission minimisation.*	*PFAS is a set of chemicals that has drawn particular attention in the IA. Given the strong focus on PFAS within the European Green Deal, its foreseeable that PFAS would be given key importance and targets within the revised directive. Treatment of PFAS however is challenging and the very low concentrations associated with negative environmental effects, could mean it is a real challenge for many wastewater operators to address PFAS without very significant cost and practical issues. Therefore, would assume SOME emissions minimisation, but how much is harder to quantify.*	*The IA refers to treatment of micropollutants. BPA could fall into this category along with many others. The upgrade to tertiary treatment would have positive impacts, but we have seen the varying physical properties of chemicals means a suite of measures are needed to give good overall coverage. Is that possible in practice? assume some emission minimisation.*
Revised sewage sludge directive (NOTE: the evaluation of the SSD is ongoing, with preliminary results now available. However, as the process is at earlier stage (I.e., IA has not commenced), this row is included for context only and not used in the ranking for the dynamic baseline).	*the existing quality standards for SSD largely cover metals. It could be possible that silver would therefore more likely to be added to the list. Metals partition more readily into sludge during wastewater treatment than many other chemicals. Justification for the addition however could be complex given similar issues seen for surface water.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*	*There has been very significant focus and efforts to address the issues posed by PFAS. Possible addition of PFAS to many of the related environmental legislation would suggest that there is a high likelihood that PFAS would be added to the SSD. However, the mechanics of that addition (given that PFAS is a family of 6,000 chemicals) is less clear. Also, the low concentrations at which PFAS can generate effects, may pose problematic issues for practical implementation (i.e., existing background concentration + concentration in the sludge), i.e., it could mean the majority of sludge cannot be placed on land.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*	*the evaluation has highlighted that the list of substances with quality standards is limited and likely needs expansion. Which additional substances are added is unclear, and therefore challenging to comment on BPA directly.* *The consultation confirmed that there are many different drivers for sludge application, it is difficult to determine the direction of change.*
Plant Protection Products Regulation	N/A	N/A	N/A

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
Biocidal Products Regulation	Review of silver (in nanoform) for use in drinking water is ongoing. Depending on the developments of the review, further measures could limit exposure and release of silver SOME EMISSION MINISATION	N/A	N/A
REACH Regulation	Review of endocrine properties is ongoing under biocidal products. Under REACH it could lead to further restrictions but challenging to predict. Assume no direct impact via REACH. **NO IMPACT**	A REACH restriction for PFAS is currently being prepared. Based on the outcome of that process it could be expected that there would be a significant reduction in use and emissions, with only critical use remaining and all non-essential used being phased out. SIGNIFICANT EMISSION MINIMISATION	Controls are already in place under REACH, including identification of BPA as an SVHC and restrictions on use. Expect that these controls will increase use in other bisphenol species. Listing as an SVHC should promote substitution so use and release would decline albeit more slowly without addition to PS list. SOME EMISSION MINIMISATION
CLP Regulation	N/A	N/A	N/A
Other legislation on metals	**NO IMPACT**	**NO IMPACT**	**NO IMPACT**
Pharmaceutical legislation	N/A	N/A	N/A
Further legislation related to metals	The majority of the legislation covered here focuses on mercury and nickel. Likely to have only limited impact for silver directly. **NO IMPACT.**	N/A	N/A

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
Industrial emissions directive	Silver is covered by the BREF on non-ferrous metals. However, specific consideration of emissions to water and BAT-conclusions in line with the risk identified by the nomination for PS listing is less clear. Likely greater control on releases is unlikely. assume no impact. **NO IMPACT.**	PFAS would be covered by multiple IED economic categories. Further efforts to control emissions and development of BAT conclusions related to PFAS would likely be associated with the large volume organic chemicals (last updated in 2017). It may also appear under the manufacture of organic fine chemicals last updated in 2006. Updates to BREFs occur once every 10-15 years. It's possible with the increased focus on PFAS that update of the organic fine chemicals BREF could include additional controls to limit release. Assume that IED would address this issue in the short-medium term future. The consultation identified that PFAS are mentioned in the Textiles BREF. The consultation also detailed that it is difficult to say what change to the baseline will occur in the next 10 years. **SOME EMISSION MINISATION**	Manufacture of BPA specifically is not included under IED, although it will fall into the economic categories covered by IED. There was a BAT conclusion developed for BPA as part of the 2017 update of the large volume organic chemicals BREF. It could be expected that this will help limit emissions going forward. However, it depends on how MS implement and enforce this. **SOME EMISSION MINISATION**
Persistent organic pollutants regulation	Unlikely to be included as a POP. N/A	PFOS and PFOA already added as POPs. PFHxS likely to be added soon. Growing pressure and possibility of additional PFAS substances being nominated and added. Consultation confirmed that POP classification for PFOS and PFOA limits emissions. Borderline no impact but optimistic outlook assumed. **SOME EMISSION MINISATION**	This substance 'may' meet at least some of the criteria to be considered a POP. But it has not been nominated under the Stockholm Convention or POPs Regulation. Assume no impact. **NO IMPACT**
Waste legislation	the revision of the waste framework and inclusion of SCIP database should improve traceability. This could limit emissions to water over time, but very hard to comment on the magnitude of the impact. **SOME EMISSION MINIMISATION**	Same comments here as for silver. The SCIP database could help better track PFAS in articles, improved landfill monitoring and reporting. How significantly these efforts will reduce releases is far less clear. But could assume some improvement on current levels of control. **SOME EMISSION MINIMISATION**	Use of BPA is already restricted from a number of applications. The SCIP database could be useful, but its less clear how significant the impacts would be for things like poly carbonate. To maintain continuity, assume no impact. **NO IMPACT.**

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
European Green deal:			
i) farm to fork strategy	N/A	N/A	N/A
ii) Biodiversity to 2030 strategy	The strategy aims to identify a larger EU-wide network of protected land. However, of the candidate PS, based on other ongoing work and fact that silver is a naturally occurring substances. The strategy may have less impact for this substance specifically. Therefore, assume no impact **NO IMPACT**	PFAS is of high priority and impacts on land and water have been identified. The main issue will be around concentrations and monitoring capabilities, but it is possible to see that the biodiversity strategy may also address PFAS like many other legislation and initiatives in this list. **SOME EMISSION MINIMISATION**	BPA is already restricted under REACH and included within the IED as a KEI. If there is expansion of protection zones that could have an impact for release and tighter controls on releases. **SOME EMISSION MINIMISATION**
iii) strategy for sustainable use of chemicals	Silver comes in a variety of forms and is also a naturally occurring element. The strategy does aim to promote one substance, one assessment and wider cohesion across the chemicals acquis, which could result in greater control and improved management of use, waste, and recycling. However, the positive impacts may be smaller and somewhere between No impact and minimal positive impact. Consultation confirmed only speculative change is foreseen. **NO IMPACT**	PFAS is a specific targeted element of the sustainable strategy. This includes phase-out for all PFAS use in the EU other than essential uses for society. It also includes developing new monitoring methodologies, strategies and aims to support remediation where needed. The high priority for which the EU has placed on PFAS could expect significant additional controls and steps to limit emissions. Consultation detailed that most significant change will be delivered through REACH not this initiative. **NO IMPACT**	The strategy aims to strengthen the circular economy and work towards a non-toxic environment. This could strengthen the cause for total phase-out of BPA and substitution. Although that is likely to see a transition to other Bisphenol family members. The strategy overall does promote greater control and awareness for emissions. But much of the emission will come from in-use stocks which are less impacted by the strategy. Consultation confirmed only speculative change is foreseen. **NO IMPACT**

	Metals	Industrial chemicals	
	Silver	PFAS	Bisphenol A
iv) strategy for pharmaceuticals	N/A	N/A	N/A
v) Sustainable use of pesticides	N/A	N/A	N/A
vi) EU Biodiversity Strategy & the EU Pollinators initiative	**NO IMPACT**	**NO IMPACT**	**NO IMPACT**
Summary	Challenging to define conclusion. Due in part to the fact that silver is a naturally occurring element and chemically exists in a number of forms. The nanoform of silver is under review within the BPR in terms of impacts for drinking water. But more broadly silver sits within generic approaches to improving implementation under several legislation. Based on the review of the above legislation and strategies the likely impacts for environmental release to surface water and environmental concentrations are likely to be very limited. On that basis assume no impact on emissions.	There is a large volume of work ongoing to target and reduce both use and emissions of PFAS. It is front and centre within the chemicals strategy and being treated as very high priority within the EU. Would expect very significant changes in the next 10 years and an equally substantial fall in emissions to environment. Monitoring is needed to track that progress and that alone might be justification for an EQS listing. but even without listing would expect big improvements.	Restrictions already in place for a range of BPA applications. A BAT conclusion was included in the 2017 update of the large volume organic chemicals BREF. That could help limit emissions to water. The primary use of BPA is in the manufacture of polycarbonate and epoxy resins, so manufacture could be a key point of release, alongside the in-use emissions (particularly water pipes). Based on the above, without further intervention the use (and therefore emission and environmental concentrations) would decline over time irrespective, but an EQS listing could help speed things up.
Rating (+ + significant emission minimisation) (+ some emission minimisation) (**0** no impact) (- some emission increase) (- - significant emission increase)	**0 No impact**	**++ Significant emissions minimisation**	**+ Some emissions minimisation**

Appendix F Data on groundwater pollutants – use, monitoring and baseline

Key trends in use and pollution and how these might evolve without action are considered as part of the dynamic baseline for this impact assessment. The timescale over which this assessment is made is around 10-20 years based on the typical timescale for impacts of mitigation measures for moderately persistent pollutants to be seen in groundwater.

For the substances added to the LFR, the baseline situation, in terms of production, use and emissions, is in most cases subject to significant uncertainty. Policy measures already in place (i.e. legislation, strategies and voluntary programmes) will or may have an impact on the use and emissions of some of the substances in the coming years, and therefore on their concentrations in groundwater. Available information on the main uses of PFAS, pharmaceuticals and approved nrM parent compounds, and their production volumes is presented below.

PFAS are a large family of thousands of synthetic chemicals that are widely used throughout society and found in the environment. They contain strong carbon-fluorine bonds that resist degradation. PFAS were developed in the 1930s and since then have been used in a wide range of applications including; fire-fighting foams, as surfactants, as coatings (food packaging, paints, photographic processes, ski wax, clothing), in hydraulic fluids, polishes, non-stick coatings, stain resistance and in pesticides. As a result of their widespread use in textiles and food packaging industry they are likely to be present in domestic wastewater, sludges and landfilled waste. They are also deposited on the land-surface through aerial particulates. The specific PFAS on the LFR include manufactured PFAS, such as PFOS and PFBS but also substances that are likely to result from degradation of parent compounds.

Although PFAS will be present at manufacturing sites, their specific manufacture in the EU is restricted through the Stockholm Convention on persistent organic pollutants (POPs). POPs Regulation (2019/1021/EU) implements the Stockholm Convention on POPs and bans/restricts the manufacturing, marketing and use of POPs in the EU (applicable to PFOS, PFOA, PFHxS). PFOS and PFOA are listed under Annex A (full ban) and so are restricted globally and PFHxS has also been approved for listing under Annex A. Several PFAS (incl. PFOA, PFECA and ADONA) are not permitted for use in food contact materials under the Food Contact Materials Legislation (EC1935/2004) and Commission Regulation (10/2011) on plastic materials and articles intended to come into contact with food. Therefore, the production or import within the EU of several PFAS on the LFR is currently restricted or banned. However, as PFAS are persistent they will continue to be in circulation in products and further releases to the environment will take place. PFAS will also be present within many environmental media where they can migrate into groundwater within recharge.

Pharmaceuticals are a broad group of substances used for human health purposes as well as veterinary medicines and belong to many different chemical groups. Pharmaceuticals have been used for many years, even centuries in some cases. The principal routes for pharmaceutical to groundwater is via sewage discharges to ground as a result of disposal of unused substances and excretion. They may also be present at manufacturing sites and in landfills. The use of many pharmaceuticals is controlled via prescription. The two pharmaceuticals on the LFR are:

- Carbamazepine: is an anticonvulsant medication used primarily in the treatment of epilepsy and neuropathic pain caused by diabetes/condition called trigeminal neuralia. It may also be used to treat bipolar disorder. The route of administration appears to be oral only in the form of tablets and by prescription only. It is also less used as a veterinary medicine to treat seizures (epilepsy), chronic pain (primarily nerve pain), to treat aggression, to treat head shaking in horses. There are several suppliers /manufacturers and exporters in the EU including in Germany, Poland and Portugal.
- Sulfamethoxazole: is an antibiotic used for bacterial infections such as urinary tract infections, bronchitis, and prostatitis. As a veterinary medicine it is commonly used as an antibiotic in combination as Sulfamethoxazole/Trimethoprim. It is used for cats, dogs, birds, reptiles, and small mammals to treat certain infections such as bladder and prostate infections, Nocardia infections, or parasitic infections. One manufacturer is identified in the EU (Italy).

A further set of pharmaceuticals were identified for inclusion on the GWWL but were not found in groundwater at a sufficient frequency to justify inclusion on the LFR. These cover a wide range of uses.

Pesticides are used for the purposes of plant protection primarily in agriculture but also for amenity use. They constitute a wide range of organic chemicals. Pesticides released to the environment breakdown (metabolise) to new compounds (metabolites). The metabolites of pesticides are grouped into: (1) relevant metabolites, (2) non-relevant metabolites (nrMs) and (3) metabolite of no concern. A relevant metabolite is one for which there is reason to assume that it has comparable intrinsic properties as the active substance and as such is treated like the parent pesticide for the purposes of regulation. A metabolite of no concern is considered to be harmless. Non-relevant metabolite do not meet the criteria to be considered either relevant metabolites or metabolites of no concern and therefore need to be considered.

Non-relevant metabolites from pesticides (nrMs) are not manufactured products, forming in the water environment through degradation of a parent pesticide compound (see Table 7-4). The pathway to groundwater is depends on the use / release of the parent compound. The predominant parent compound use is for plant protection by the agricultural sector as herbicides or fungicides, but may include amenity purposes and as a biocide. The parent compounds Tolylfluanid and Dichlofluanid are fungicides that are registered as biocides. N,N-Dimethylsulfamid (DMS) and Chlortalonil-SA are also fungicides. The majority of parent compounds are not approved for use in the EU. The SANCO guidance[31] sets out a five step process for assessment of the relevance of metabolites, ending with a refined risk assessment for substances in groundwater identified as nrMs. The guidance is designed for use by organisations applying for authorisation of substances under EC 1107/209[1] (the plant protection products regulations) and building a body of evidence which will then be reviewed by rapporteur MS and EFSA. New authorisations of substances listed under EC 1107/209 are valid for 10 years, whilst renewed authorisations can be granted for up to 15 years. The review of authorised substances is expected to include new data / modelling.

Monitoring

The addition of PFAS, pharmaceuticals and nrMs to the GW WL and subsequently to the LFR, has triggered the expansion of their monitoring in groundwater. Despite the voluntary nature of the process the rate of participation in the GW WL process was significant, yet does not include all MS. The provision of monitoring data for GW WL review varied between pollutant groups as follows: pharmaceuticals (13 countries), PFAS (11 countries) and nrMs (17 countries). From these groups, 10 PFAS, 2 pharmaceuticals and 16 nrMs were put forward on the LFR. A brief review of the data as used during the GWWL process to give an indication of the level of pollution, is presented below by pollutant group.

PFAS

Despite their use over many decades they have emerged as groundwater pollutants more recently and are identified as such due to their high mobility, persistence and toxicity through bioaccumulation. Their persistence means that they will be present in groundwater for many years. There are also concerns around the cumulative impact of the presence of mixtures of many similar substances. Their widespread use leads to entry to groundwater via many pathways including: leaching from materials used for land spreading, wastewater discharges; in runoff following aerial deposition; and landfill (use / environmental fate data to be developed for DFR). As concern has risen around human health impacts, the use of some PFAS compounds has been restricted or banned. In many instances, however, the replacement shorter chain PFAS are also persistent and mobile in groundwater, as well as toxic. PFAS have been detected in groundwater in many MS [225]. Data reviewed through the GW WL process from 11 PC included only around 30 reliably reported from an initial target list of 52 PFAS substances. Within this group, 10 PFAS substances met the criteria for inclusion on the LFR (present in more than 10 locations in more than 4 PC). Results of the GW WL review are set out in Table F-1 and indicate the widespread nature of the PFAS detections.

Table F-1 PFAS detected in groundwater in more than 4 PC and at more than 10 sites

No of MS/AC	Acronym	No. of sites monitored	No. of sites >LOQ	>LOQ in %	PC with detections
6	PFOSA	1715	22	1.3	4
7	PFUnA	2598	39	1.5	6
7	PFDoA	2830	62	2.2	6
8	PFDA	2945	173	5.9	7
8	PFNA	3752	195	5.2	7
5	PFBA	1189	552	46.4	5
7	PFBS	2209	577	26.1	5
7	PFPeA	2452	701	28.6	7
9	PFHpA	4224	817	19.3	8

No of MS/AC	Acronym	No. of sites monitored	No. of sites >LOQ	>LOQ in %	PC with detections
8	PFHxS	2328	873	37.5	7
9	PFHxA	4662	1175	25.2	8
11	PFOS	6971	1435	20.6	11
11	PFOA	6429	1553	24.2	11

The 10 PFAS identified by the GWWL and put forward in the LFR are presented in Table F-2. A further two PFAS remain on the GWWL because insufficient information was identified to justify their inclusion on the LFR. These were: Perfluorododecanoic Acid (PFDoA); and Perfluoroundecanoic Acid (PFUnA).

Table F-2. PFAS substances on the List Facilitating Review and GWWL

Substance Name	Acronym	CAS #	Status
Perfluorooctane Sulfonate	PFOS	1763-23-1	LFR
Perfluorooctanoic Acid	PFOA	335-67-1	LFR
Perfluorohexanoic Acid	PFHxA	307-24-4	LFR
Perfluoroheptanoic Acid	PFHpA	375-85-9	LFR
Perfluorohexane Sulfonate	PFHxS	432-50-8	LFR
Perfluorobutane Sulfonate	PFBS	375-73-5	LFR
Perfluorodecanoic Acid	PFDA	335-76-2	LFR
Perfluorononanoic Acid	PFNA	375-95-1	LFR
Perfluoropentanoic Acid	PFPeA	2706-90-3	LFR
Perfluorobutanoic Acid	PFBA	375-22-4	LFR
Perfluorododecanoic Acid	PFDoA	2058-94-8	GWWL
Perfluoroundecanoic Acid	PFUnA	307-55-1	GWWL

Pharmaceuticals

The European Union Strategic Approach to Pharmaceuticals in the Environment[692] identifies that the largest source of pharmaceuticals entering the environment is through their use. The route to groundwater will differ depending upon whether human or veterinary use is involved. It also states that “the chemical and/or metabolic stability of some pharmaceuticals means that up to 90% of the active ingredient is excreted (or washed off) in its original form. Wastewater treatment varies in its ability to eliminate pharmaceutical residues[693], depending upon the substance and the level of treatment; in some cases, substantial amounts are removed, in others, only a small percentage; but even the best,

692 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE European Union Strategic Approach to Pharmaceuticals in the Environment COM(2019) 128final

693 Metabolites (conversion products) may have lower biological activity (see case studies in http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm) but may, e.g. if conjugated, be converted back to the parent pharmaceutical during sewage treatment, or have similar biological activity

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en most expensive, current treatments are not 100% effective. The release of veterinary medicines to the environment tends to come from untreated diffuse sources such as the spreading of manure."

The main pathways for pharmaceuticals to groundwater are through sewage effluent discharge (including excreted pharmaceuticals and unused products disposed of to the sewage system despite the existence of collection schemes) and spreading of animal manure. Other pathways include:

- the discharge of effluent from manufacturing plants;
- the spreading of sewage sludge containing pharmaceuticals removed from waste water;
- grazing livestock;
- the treatment of pets;
- improper disposal into landfill of unused pharmaceuticals and contaminated waste;
- recharge from surface water containing pharmaceuticals from wastewater discharge.

For the GW WL process, 13 PC provided groundwater datasets for review. The review found around 300 pharmaceutical substances have been monitored by PCs but only a small number of these were detected in more than 4 countries. Only 2 pharmaceuticals, Sulfamethoxazole and Carbamazepine, were present in both four or more PC and at 10 more sites in each of these countries and were put forward on the LFR. A further 9 substances were put on the GW WL so that more information could be collected on their distribution in groundwater. These were: Clopidol, Crotamiton, Amidozoic acid, Sulfadiazin, Primidone, Sotalol, Ibuprofen, Erythromycin and Clarithromycin.

Non-relevant metabolites from pesticides

The primary pathway to groundwater for nrMs is likely to be leaching from soils following use of parent pesticides and transport downwards in recharging water to groundwater either as the parent compound or as the metabolite. Through the GW WL process, 17 countries provided groundwater data on the nrM compounds for review. The data indicate that nrMs were widely detected in European groundwater above limits of quantification (LoQ). The nrM monitoring results show 16 substances were detected in four or more PC and at 10 or more sites in each of these countries. These substances fulfilled the criteria for addition to the LFR. From the assessment, WGGW concluded that there is enough evidence of a Europe-wide presence of nrMs in groundwater. Therefore, these 16 nrMs were put forward in a LFR and it was recommended that other nrMs are not added to the GWWL.

Several of the parent compounds of LFR substances are not approved for use in the EU, which means that the presence of their metabolites is likely to be related to historical use leading to a legacy issue, although illegal use cannot be ruled out. Some of the parent compounds have not been authorised for use for many years, such as atrazine, indicating the persistence of the nrM and / or the parent compound.

Table F-3. Non relevant metabolites on the List Facilitating Review

nRM substance	CAS	Parent Compound	Use	Status (EU pesticides database)[694]
Desphenylchloridazon (metabolite B)	6339-19-1	Chloridazon	Herbicide	Not approved (EC1107/2009)
Methyl-desphenyl-chloridazon (Metabolite B1)	17254-80-7	Chloridazon	Herbicide	Not approved (EC1107/2009)
2,6-Dichlorbenzamid (2,6-D, BAM, M01, AE C653711)	2008-58-4	Dichlobenil Fluopicolide	Herbicide Fungicide	Not approved (EC1107/2009) Approved
Aminomethylphosphonic acid	1066-51-9	Glyphosate	Herbicide	Approved
Metazachlor-acid (OXA) (BH 479-4)	1231244-60-2	Metazachlor	Herbicide	Approved
Metazachlor ESA Metazachlor-SA (BH 479- 8) (Metazachlorsulfone acid, Metazachlorsulfonic acid (ESA)	172960-62-2	Metazachlor	Herbicide	Approved
Atrazine-2-hydroxy	2163-68-0	Atrazine	Herbicide	Not approved since 2004
N,N-Dimethylsulfamid (DMS)	3984-14-3	Tolylfluanid, Dichlofluanid	Fungicide	Not approved (EC 1107/2009)
s-Metolachlor-acid, (OXA, CGA 51202, CGA 351916)	152019-73-3	S-metolachlor	Herbicide	Approved
Chlortalonil-SA (R417888 or VIS-01 / M12) (Chlortalonilsulfone acid)	1418095-02-9	Chlortalonil	Fungicide	Not registered
Metolachlor-Sulfonsäure (ESA, CGA 380168, CGA 354743)	171118-09-5	S-metolachlor	Herbicide	Approved
Metolachlor ESA (Metolachlor-SA (CGA354743)	171118-09-5*	Metolachlor	Herbicide	Not approved
Dimethenamid-ESA	205939-58-8	Dimethenamid	Herbicide	Not approved
Flufenacet-sulfonic acid (ESA) 201668-32-8		Flufenacet	Herbicide	Approved
Alachlor-t-sulfonic-acid (ESA)	142363-53-9	Alachlor	Herbicide	Not approved
S-Metolachlor NOA 413173 or VIS-01 (Chlortalonilsulfone acid) Metabolite	1418095-19-8	Chlortalonil, S-metolachlor	Herbicide	Not registered Approved
Dimethachlor CGA 369873 1418095-08-5		Dimethachlor	Herbicide	Approved

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

694 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

Appendix G Possible alternatives to the candidate priority/priority hazardous substances

The table below provides a non-exhaustive analysis of possible alternatives to the candidate priority/priority hazardous substances.

Substance name	Type of Pesticide	Pesticide	Biocide	Alternatives
Nicosulfuron	Herbicide	Y	N	Mesotrione; Glyphosate; Tembotrione
Acetamiprid	Insecticide	Y	Y	Avermectin, Copper compounds, diacyl-hydrazine, diamide, etofenprox, flonicamid, fludioxonil, spinosad, spirotetramat, sulfur, tebufenozide, Chlorantraniliprole
Clothianidin	Insecticide	NA	Y	Pyriproxyfen
Imidacloprid	Insecticide	NA	Y	No alternatives identified
Thiacloprid	Insecticide	NA	NA	Same alternatives to acetamiprid
Thiamethoxam	Insecticide	NA	Y	Same alternatives to acetamiprid
Bifenthrin	Insecticide	NA	Y	Cypermethrin
Deltamethrin	Insecticide	Y	Y	Pirimicarb, pirimiphos-methyl, lambda-cyhalothrin
Esfenvalerate	Insecticide	Y	NA	Lambda-cyhalothrin
Permethrin	Insecticide	NA	Y	Other pyrethroids primarily cypermethrin
Glyphosate	Herbicide	Y	N	Diflufenican, chlorotoluron, Metribuzin, oxyfluorfen, florasulam, MCPA, 2,4 D Dicamba, Clethodim, propaquinzafop

Substance name	Type of Pesticide	Pesticide	Biocide	Alternatives
				Bifenox, chlorpropham, penoxsulam, Isoxaben, propyzamide, Bentazone, caprylic acid
Triclosan	Antibacterial / antifungal	NA	Y	benzalkonium chloride, benzethonium chloride, chloroxylenol, chlorhexidine

Key: Y = Yes; N = No, NA = No longer approved.

Appendix H Possible sectors identified for impacts of measures

Possible measures to identify and subsequently limit emissions of PS, PHS and LFR of GWD substances to identify costs and benefits (the possible burden)

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
Public sector (incl. Member State competent water authorities and Public Health sector)													
General: Inclusion in national Programme of measures	X	X	X	x	x	X	x	x	x	x	x	x	x
General: Revision of environmental permits under the EU IED regime and/or national permitting and licensing regimes	X		X	x	x	x	x	x	X	x	x	x	x
General: Inclusion of emissions sources in inventory of emissions	X	X	X	X	x	x	x	x	x	x	x	x	x
Improving seasonal monitoring to quantify run-off	X	X		x	x	x							
PEST/BIO: Restrict the use of pesticides/biocides in sensitive areas / drinking water protection areas and buffer strips along water courses/ during particular seasons (e.g. via	X		X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
provisions of the Sustainable Use of Pesticides Directive and/or Plant Protection Products Regulation (PPPR) and/or CLP legislation))													
PEST/BIO: Partial ban/restriction on the use of a pesticide/ biocide (e.g. professional vs non-professional uses/ particular sectors/ applications (e.g. gel, brush on applications))	X	X	X	X	X	X							
PEST/BIO: Restrict sale of plant protection products only to authorised professional and holding a valid training certificate	X		X	X	X	X							
PEST/BIO: Complete or partial ban the use of a pesticide/ biocide	X	X	Both	X	X	X							
PEST/BIO: Requirements on use (e.g. requirement to use the most efficient application techniques; to limit release to water; to retain and treat water used e.g. to wash down stables, horse carts, mobile transport; to	X		X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
establish buffer strips, plant hedges along waterbodies etc.)													
PEST/BIO: Increased (more stringent) requirements on quality of direct discharges from manufacturing sites through permitting	X		X	X	X	X							
PEST/BIO: Include listed PS / PHS in National Action Plan (NAP) for the sustainable use of pesticides	X	X	X	X	X	X							
PHARMA: Introducing more stringent conditions for putting a pharmaceutical on the market	X		X				X	X	X				
PHARMA: Promoting use and prescription of environmentally-friendly pharmaceutical alternatives	X	X	X				X	X	X				
PHARMA: Green Public Procurement	X	X	X				X	X	X				
PHARMA: Eco-labelling of high-risk OTC pharmaceutical products	X		X				X	X	X				
PHARMA: Changing OTC medicine to prescriptive medicine only, improving diagnostics and reducing prescriptions	X		X					X	X				

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids [Note 1]	Pyrethroids [Note 2]	Others [Note 3]	Macrolide antibiotics [Note 4]	Estrogens [Note 5]	Others [Note 6]	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
PHARMA: Ban on individual pharmaceutical substances (either general, or use specific (human/ veterinary))	X	X	X				X	X	X				
PHARMA: Increased requirements on quality of direct discharges from manufacturing sites and other hot spots (e.g. hospitals, care homes)	X		X				X	X	X				
PHARMA: Public sector - improved on-site wastewater treatment at hot-spots (e.g. hospitals, care homes) (adsorption, advanced oxidation, biological, membrane and other treatment processes)	X		X				X	X	X				
PHARMA/ IND/MET: Public sector - cleaning up legacy contaminated sites (e.g. former manufacturing sites, landfills)	X	X	X	x	x							X	X
IND/MET: Restrict the use of individual substances (sector/use/content)	X		X							X	X	X	X

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
IND/MET: Complete ban of all non-essential production and uses (incl. in EU Sustainable Chemicals Strategy)	X	X	X							X	X	X	X
IND/MET: Increased requirements on quality of direct discharges from manufacturing sites	X		X							X	X	X	X
MET: Further restrictions on use of raw materials (e.g. on coal-fired power plants and coal use (Hg), Ni content in tobacco etc.)	X	X											X
MET: Public sector - Improved treatment of effluent from disused/abandoned mines	X	X											X
Industry: Producers / Manufacturers													
PHARMA: Improved processes for pharmaceutical production	X		X				X	X	X				
PHARMA: Innovation in green pharmacy, extended producer responsibility schemes, use of ecolabels	X	X	X				X	X	X				
PHARMA: Providing advice to consumers on proper disposal of	X		X				X	X	X				

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
discarded/expired pharmaceuticals (human and veterinary use)													
PEST/BIO, PHARMA, IND, MET: Improved on-site wastewater treatment (adsorption, advanced oxidation, biological, membrane and other treatment processes)	X		X	X	X	X	X	X	X	X	X	X	X
IND/MET: improved manufacturing processes, raw materials resulting in lower discharges	X		X		x	x				X	X	X	X
PEST/BIO, PHARMA, IND, MET: Substitution of PS and PHS by less harmful alternatives	X	X	X	X	X	X	X	X	X	X	X	X	X
Consumers / society													
PEST/BIO: Improve correct and safe disposal of old and obsolete plant protection products (including instructions use and proper disposal of discarded products on packaging)	X	X	X	X	X	X	X	X	X				
PEST/BIO: Use of drift reducing technology in all field crops, and regular cleansing of machinery and	X		X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
equipment in line with instructions to minimise spills and accidental losses													
IND: Use of alternative products, not containing PS/PHS	X	X	X							X	X	X	
PHARMA: Use of environmentally friendly alternatives where possible (human and domestic veterinary use)	X	X	X				X	X	X				
PHARMA: Improved adherence to the advice on appropriate unused/ expired medicine disposal	X		X				X	X	X				
Retailers / Advisory services													
PEST/BIO: Promote training and advisory systems for alternative pest - control techniques and the better implementation of Integrated Pest Management (IPM)	X	X	X	X	X	X							
PEST/BIO: Set-up and use of independent farm advisory services to provide advice on the safe (Human health) and environmentally responsible use of pesticides	X	X	X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
PEST/BIO: Provide training to professional pesticide users, distributors and advisers including, e.g. potential possibilities for crop rotation at regional level, a reduced rate of application; reduced number of applications; partial applications; spot application.	X		X	X	X	X							
PEST/BIO: Improve guidance to users of pesticides and biocides on end-of-life disposal	X		X	X	X	X							
PHARMA: Increasing variability of drugs dosages in standard packaging to allow for easier individual tailored dosages	X		X				X	X	X	x	x		
PHARMA: Promoting use of environmentally-friendly alternatives (where available)	X	X	X				X	X	X				
PHARMA: Improving take-back schemes and promoting appropriate disposal of discarded/ expired medicines	X		X				X	X	X				
MET: Improve guidance on disposal of products containing substance	X		X										X

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			**Pharmaceuticals**			**Industrial substances**			**Metals**
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
Water industry: Water companies and wastewater companies													
PHARMA, BIO, IND, MET: Improved public wastewater treatment (possibly requiring extended producer responsibility (EPR))	X	X	X	X	X	X	X	X	X	X	X	X	X
PHARMA, BIO, IND, MET: Improved sludge management and treatment and restriction of spreading of waste to land as fertiliser.	X		X	X	X	X	X	X	X	X	X	X	X
PHARMA, BIO, IND, MET: Measures to address stormwater overflows	X		X	X	X		X	X	X	X	X	X	X
Agriculture: Farmers / agricultural installations													
PEST/BIO: Improve application, use of, and risk from pesticides	X		X	X	X	X							
PEST/BIO: Increase the use of less hazardous and non-chemical alternatives to chemical pesticides for pest control (substitution)	X	X	X	X	X	X							
PEST/BIO: Increase the application and enforcement of integrated pest management (IPM)	X	X	X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
PEST/BIO: Minimise loss of spray drift through improved application equipment	X		X	X	X	X							
PEST/BIO: Improve implementation of IPM rules at farm level	X		X	X	X	X							
PEST/BIO: Restrict and/or prohibit aerial application of pesticides / biocides in certain (sensitive) areas	X		X	X	X	X							
PEST/BIO: Improve storage, disposal and handling at farm level	X		X	X	X	X							
PEST/BIO: Restrict use of pesticides in sensitive areas / drinking water protection areas and buffer strips (e.g. 10 meter along water courses, or set back area around boreholes and wells)	X		X	X	X	X							
PEST/BIO: Improve general requirements for the storage and use of plant protection products for professional use and of application equipment in professional use	X		X	X	X	X							

Description possible policy measures by groups of stakeholders	Identified as PS	Identified as PHS	GWD LFR	Substance group									
				Pesticides /biocides			Pharmaceuticals			Industrial substances			Metals
				Neonicotinoids Note 1	Pyrethroids Note 2	Others Note 3	Macrolide antibiotics Note 4	Estrogens Note 5	Others Note 6	PFAS	Bisphenol-A	Other (existing)	Silver, Nickel, Mercury
PEST/BIO: Improved wastewater/run-off treatment (e.g. biobed reactors, constructed wetlands, reed beds)	X		X	X	X	X							
PHARMA: Use of environmentally friendly alternatives where possible (veterinary use)	X	X	X				X	X	X				
PHARM/ IND: Restriction on spreading of animal manures, or anaerobic digestate from biosolids and animal manures, or waste from paper manufacture process	X	X	X			X	X			X			
PHARMA: Improved land management and land drainage (to reduce run-off from veterinary use and natural load)	X		X				X	X	X				

Note 1: Pesticides - neonicotinoids (acetamiprid, clothanidin, imidacloprid, thiacloprid, thiamethoxam)

Note 2: Pesticides - pyrethroids (bifenthrin, deltamethrin, esfenvalerate, permethrin)

Note 3: Pesticides - other substances (nicosulfuron, glyphosate, Triclosan, Fluopicolide, Flufenacet, Dimethachlor, metazochlor)

Note 4: Pharmaceuticals - macrolide antibiotics (azithromycin; clarithromycin; erythromycin, sulfamethoxazole)

Note 5: Pharmaceuticals - Oestrogenics (EE2, E2, E1)

Note 6: Pharmaceuticals - other substances (diclofenac, carbamazepine, ibuprofen, clopidol, crotamiton, amidozoic acid, sulfadiazin, primidone, sotalol)

Appendix I Possible policy measures to identify and subsequently limit emissions of PS and PHS respectively to identify costs and benefits (the possible burden)

	Pharmaceuticals	Pesticides	Industrial Chemicals	Metals
Industry	Manufacture	Manufacture	***Bisphenol A***	Mining
	Agriculture - farmyard animals /meat producing - natural/drug use	Pesticides - Agriculture - fruits & veg/grains/potatoes and legumes/professional greenhouses	Manufacturing - Primary	Manufacture - smelting / remelting
	Agriculture - Equines - natural/drug use	Pesticides - Agriculture - Emergency authorisations	Manufacturing - Poly carbonate	Power generation - coal
	Veterinary - domestic	Pesticides - Amenity uses (e.g. parks, pavements, etc)	Manufacturing - epoxy resins, paints, and polishes	Electronics - soldering
	Hospital applications	Biocides - veterinary - agricultural uses (e.g. sheep)	***PFAS***	Adhesives and sealants
	Wastewater treatment works	Biocides - veterinary - domestic uses (e.g. cats and dogs)	Manufacturing	Biocidal products - solids
	Energy from waste (incineration)	Biocides - professional - outdoor/indoor/directly to timer applications	Fire-fighting	Biocidal applications - liquids
		Biocides - amateur - outdoor/indoor/directly to timer applications	Textiles, furniture	Textile applications - incl. jewellery
		Wastewater treatment works	Paper and cardboard - food packaging	Lubricants and greases
			Construction	Pharmaceutical manufacture
			Automotive	Wastewater treatment works
			Electronics - incl. cabling	
			Personal care products	
			Plant protection products	
			Aviation	
			Medical applications	
			Water distribution - pipes	
			Wastewater treatment works	
Social	Health impacts:	Food related impacts:	Loss of consumer items/articles	Loss of consumer items/articles
	i) quality of life effects (loss of medication/less effective medication)	i) loss of crop yields	Choice of consumer items/articles	Choice of consumer items/articles
	ii) loss of life	ii) food security issues	Infrastructure - range of issues	Infrastructure - adhesives, sealants, lubricants, greases
		iii) food pricing issues	Petroleum industry - safety - firefighting	Potential health impacts from loss of biocidal applications
	Additional pressures on health services	Infrastructure - timber	Impacts for social and health care where PFAS is used	Agri/horticultural impacts - loss of biocidal applications

	Pharmaceuticals	Pesticides	Industrial Chemicals	Metals
	Loss of worker days to other businesses	Pet care - health of pets	Possible impacts for food production	
	Alternatives - cost, efficacy, emissions, env. Impact			
Environment	Landfill	Landfill	Landfill	Naturally occurring
	Legacy sites of former manufacture	Legacy sites of former manufacture	Current sites of manufacture	Landfill
		Spray drift	Diffuse from automotive	Legacy sits of former manufacture
			Diffuse from construction	
			Legacy concentrations already in water	

Appendix J Long list of measures - Groundwaters

Table J-.1 Long-list of measures for PFAS

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Wastewater treatment: Microfiltration with ceramic membrane	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	unknown (reported impacts on clean water only)	unknown	unknown	high	uncertainty over effectiveness. Does not destroy PFAS	no - no discharge to GW permitted (prevent requirements)
Wastewater treatment: Nanofiltration with ceramic membrane	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	unknown (reported impacts on clean water only)	unknown	unknown	high	uncertainty over effectiveness. Does not destroy PFAS	no - no discharge to GW permitted (prevent requirements)
Wastewater treatment: Coagulation	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	low	unknown	unknown	high	low effectiveness	no - no discharge to GW permitted (prevent requirements)
Wastewater treatment: GAC	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	high	low	unknown	high	PFAS removed but not destroyed - GAC cannot be regenerated needs to be incinerated for destruction	no - no discharge to GW permitted (prevent requirements)

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Wastewater treatment: Anion exchange processes	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	unknown (reported impacts on clean water only)	unknown	unknown	high	Effective in concentrating PFAS but does not destroy it - so waste must then be dealt with	no - no discharge to GW permitted (prevent requirements)
Wastewater treatment: Reverse osmosis (RO)	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	high	low (energy consumption)	moderate	high	Effective in concentrating PFAS but does not destroy it - so waste must then be dealt with	no - no discharge to GW permitted (prevent requirements)
Wastewater treatment: Advanced oxidation processes	End of pipe - WWT	Polluting industry or water industry	Construction and operation of plant	high	unknown (reported impacts on clean water only)	unknown	unknown	high	uncertainty over effectiveness. Does not destroy PFAS	no - no discharge to GW permitted (prevent requirements)
Improved returning program	End-of-pipe	Government, other	Administrative / disposal	moderate (uncertain)	low to moderate - no information on returns programmes	high	moderate - requires returns infrastructure	high	Products too numerous / diffuse for realistic program	No
Ensure that national returns programs are implemented (if nonexistent)	End-of-pipe	Government, other	Administrative / disposal	moderate (uncertain)	low to moderate - no information on returns programmes	high	moderate - requires returns infrastructure	high	Products too numerous / diffuse for realistic program	No

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Ensure adequate treatment during manufacturing if effluent discharge is direct	End-of-pipe	Polluting industry	Construction and operation of plant	moderate to high	moderate - baseline restrictions on use will limit future effectiveness of measure	moderate	moderate	high	Low. Will eliminate some future emissions but not affect PFAS already emitted	No - baseline
Separate WW networks	End-of-pipe - WWT	Government, water industry	Construction and operation of plant	high	moderate	moderate	moderate	high	Potential to eliminate PFAS from high emission areas but will not affect more diffuse emissions in most GWBs	No - baseline
Water safety planning	Other	Government, water industry	Administrative	moderate	low	high	low	low	Low. WSP already in place	No -baseline
Harness new innovations in water quality monitoring, modelling, scenario development and risk assessment	Other	Government	R&D costs	unknown	low - no destruction or removal of PFAS	high	high	high	No does not result in destruction or removal of PFAS	No - baseline
Centralised database with regulatory oversight to share ERAs and environmental	Other	Government	Administrative	low	low - no destruction or removal of PFAS	high	high	high	No does not result in destruction or	No - baseline

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
monitoring data of APIs									removal of PFAS	
Control of times in which sludge can be applied to land	Source control	Polluting industry	Additional storage	moderate - requires increased sludge storage facilities	low - does not prevent emissions	moderate	high	high	Limited as it does not limit emissions or result in destruction of PFAS - as they are persistent they will enter soil anyway	No - not effective
Extended producers responsibility schemes	Source control	Polluting industry	Administrative	moderate	low	high	low	low	PFAS have been used in a wide range of products including imported products so could be hard to enforce.	No - baseline
Soil remediation	Source control	Polluting industry / government	Remediation of soils	high	moderate	low	low	moderate	Remediation may be required to remove soils that are a secondary source of PFAS. Treatment of soils is likely to be by high temperature incineration	Yes

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Groundwater remediation	Source control	Polluting industry / government	Remediation of groundwater	low - GW remediation is generally energy intensive and slow	Low	low (high energy requirements)	low	moderate	Remediation will be required to remove groundwater that is a secondary source of PFAS using one of the wastewater techniques set out above.	Yes
Capture of biosolids for treatment.	Source control - WWT	Polluting industry	Treatment of biosolids	High	high	low (high energy requirements)	low	low	Treatment likely to consist of high temperature incineration (high cost, high CO2 emissions) but does destroy PFAS, or landfilling of waste.	Yes
Improved sludge management (industrial waste e.g. paper mills)	Source control - WWT	Polluting industry	Treatment of sludge	moderate	moderate	moderate	moderate	high	Sludge is a potential source of PFAS - so potentially effective	Yes
Guidance on proper use of PFAS containing products which could be spread to land	Source control (Behavioural)	Government	Administrative	Low	low - limited evidence that emissions are due to improper use	low	high	high	Limited effectiveness because lack of evidence that emissions are due to improper use	Yes

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
									or poor practice / large amount of PFAS already released	
Guidance on proper disposal	Source control (Behavioural)	Government	Administrative	Low	low	high	high	high	Lack of evidence that improper disposal is a significant pathway. No enforcement means compliance with guidance is voluntary	No
Increased penalties for improper disposal	Source control (Behavioural)	Polluting industry, society	Administrative	Low	low - limited evidence that improper disposal is a significant source	high	low	high	Insufficient evidence that ongoing improper disposal is a significant emission	No - baseline
Cease production and use of products containing PFAS	Source control (production)	Polluting industry	Cost of alternatives	moderate to high	will reduce future emissions but does nothing for already released substance	high	moderate	moderate to high		No as restrictions already in place

Measure	Type of measure	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Ban use	Source control (production)	Society	Cost of alternatives	High	will reduce future emissions but does nothing for already released substance	high	moderate - not all uses can be eliminated straight away and some uses the alternatives carry high risks (e.g. chrome plating risk to uses)	moderate to high	Significant restrictions already in use and substitution has already taken place in some areas	No - restrictions already in place and likely to be triggered through other mechanisms
Increased requirements on industrial discharges	Source control (production)	Polluting industry	Administrative	moderate	moderate - some industrial discharges are potentially significant emissions but restrictions on use will limit future effectiveness	moderate	moderate	high	Will eliminate some future emissions but will not affect PFAS already emitted - restrictions on use will limit overall effectiveness Limited number of sites affected. Sites already controlled under IED and will be covered by extended producer responsibility	No - baseline

Table J-.2 Long list of measures for Pharmaceuticals

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Separate wastewater networks for health care	End-of-pipe - WWT	Y	Y	Y	Government, water industry	Construction and operation of plant	Low	low - unless use is restricted	high	low - requires separate infrastructure	low - due to impracticality - would require drug users to stay in one place	Not suitable due to impracticality of implementation at scale and need to restrict where drug is administered and used	No - would require restriction of patients to healthcare setting.
Treatment of wastewater: Ozonation	End-of-pipe - WWT	Y	Y	Y	Water industry, Society	Construction and operation of plant	moderate to high	moderate - carbamazepine moderate - sulfamethoxazole high - primidone	high	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: UV photodegradation	End-of-pipe - WWT	Y	N	Y	Water industry, Society	Construction and operation of plant	moderate to high	moderate sulfamethoxazole low - primidone	high	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Fenton process	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	Low - sulfamethaxoazole High carbamazepine	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Treatment of wastewater: GAC	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	moderate - sulfamethoxazole High carbamazepine	low	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Flocculation	End-of-pipe - WWT	Y	N	N	Water industry, Society	Construction and operation of plant	moderate to high	low - sulfamethoxazole	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Constructed wetlands	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	moderate sulfamethoxazole low carbamazepine	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Biofiltration	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	moderate sulfamethoxazole	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Bank filtration	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	moderate sulfamethoxazole low carbamazepine	moderate	moderate	moderate	requires further evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Ultrafiltration	End-of-pipe - WWT	Y	N	N	Water industry, Society	Construction and operation of plant	moderate to high	moderate sulfamethoxazole	moderate	moderate	moderate	requires further evaluation of effectiveness	No - baseline under UWWTD by 2030

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Treatment of wastewater: Nanofiltration	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	moderate to high	high - sulfamethoxazole low to high carbamazepine	moderate	moderate	moderate	requires further evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Chlorination	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	high	low sulfamethoxazole low - carbamazepine	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Chlorine dioxide	End-of-pipe - WWT	Y	Y	N	Water industry, Society	Construction and operation of plant	high	high - sulfamethoxazole low carbamazepine	moderate	moderate	low - untested on WW	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: Membrane techniques (incl reverse osmosis)	End-of-pipe - WWT	Y	N	N	Water industry, Society	Construction and operation of plant	high	high - sulfamethoxazole high carbamazepine	low	moderate- generates waste stream	moderate	moderate - proven technology	No - baseline under UWWTD by 2030
Treatment of wastewater: MBR	End-of-pipe - WWT	Y	N	N	Water industry, Society	Construction and operation of plant	high	high - sulfamethoxazole	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Treatment of wastewater: Sand filter	End-of-pipe - WWT	Y	N	N	Water industry, Society	Construction and operation of plant	moderate to high	high - sulfamethoxazole	moderate	moderate	moderate	moderate - but requires evaluation of effectiveness	No - baseline under UWWTD by 2030
Treatment of wastewater: PAC (powdered activated carbon)	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	high - carbamazepine	low	moderate	moderate	effective but high cost	No - baseline under UWWTD by 2030
Treatment of wastewater: UV photodegradation	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	moderate - carbamazepine	moderate	moderate	moderate	effective	No - baseline under UWWTD by 2030
Treatment of wastewater: Photo-fenton	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	High carbamazepine	low	moderate	moderate	effective	No - baseline under UWWTD by 2030
Treatment of wastewater: Whole-cell white rot fungi	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	low to high (uncertain) carbamazepine	low	moderate	moderate	Uncertain / unproven	No - baseline under UWWTD by 2030
Treatment of wastewater: Extracellular enzymes	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	low carbamazepine	moderate	moderate	moderate	Uncertain / unproven	No - baseline under UWWTD by 2030

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Treatment of wastewater: MBR	End-of-pipe - WWT	N	Y	N	Water industry, Society	Construction and operation of plant	high	low to moderate (uncertain) carbamazepine	moderate	moderate	moderate	Uncertain / unproven	No - baseline under UWWTD by 2030
Legislation and standardised methodology for ERA and incorporation into benefit-risk assessment of pharmaceutical marketing authorisation	Source control	Y	Y	Y	Government	Administrative / Testing	high	moderate	moderate	high	moderate	Only applies to new authorisations so will not affect existing drugs	no – does not apply here as no re-approvals process for existing substances.
Water safety planning to reduce risk to drinking water	Source control	Y	Y	Y	Government, water industry	Administrative	low	Low	high	high	high	WSP are / should be routinely updated to monitor and eliminate or mitigate risks to drinking water	No - baseline
Harness innovations in water quality monitoring, modelling, scenario development and risk assessment to reduce risk to drinking water	Source control	Y	Y	Y	Government		moderate	uncertain	high	uncertain	high	Insufficient information to evaluate	No - baseline

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Capture of manure for treatment	Source control (animals)	Y	Y	Y	Polluting industry	Manure treatment (uncertain of if this exists)	Uncertain - will depend on what happens to manure	moderate - does not eliminate emissions (and not the only source of emissions)	high	Low - complex system	Moderate -	Possible if animals under treatment can be segregated - benefit is hard to quantify unlikely to significantly reduce emissions.	No - uncertain that a technically feasible method to treat and remove pharmaceuticals exists.
Ban use in all animals	Source control (animals)	Y	Y	Y	Polluting industry, society	Relative cost of alternative	Low (but depends on cost of alternatives)	Moderate	low	Low unless equivalent alternatives	Low unless equivalent alternatives	Potentially cost-effective where suitable alternatives exist - requires changes to prescribing practice / guidance to doctors	Yes for two LFR
Ban use in agricultural animals	Source control (animals)	Y	Y	Y	Polluting industry	Relative cost of alternative	Low (but depends on cost of alternatives)	Moderate	low	Low unless equivalent alternatives	Low unless equivalent alternatives	Unlikely to be acceptable without a suitable alternative	Yes for two LFR
Ban use in pets	Source control (animals)	Y	Y	Y	Society	Relative cost of alternative	Low (but depends on cost of alternatives)	Moderate	low	Low unless equivalent alternatives	Low unless equivalent alternatives	Unlikely to be acceptable without a suitable alternative	No - unlikely to be a major source - mainly linked to urban areas / run-off

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Land management measures such as fencing out of animals and use of buffer strips	Source control (animals)	Y	Y	Y	Polluting industry	Cost of buffer strips	low due to limited benefit for GW	low as emissions not eliminated		moderate - requires additional effort	low -	Limited effectiveness as it does not eliminate emissions and moderate costs suggest unlikely to be adopted - only effective for surface water	no
Alterations to field/stable drainage	Source control (animals)	Y	Y	Y	Polluting industry	Cost of new drainage	Moderate - (requirement for fencing / drainage)	low as emissions not eliminated		moderate - requires additional effort	low -	Limited effectiveness as it does not eliminate emissions and moderate costs suggest unlikely to be adopted only effective for surface water	no
Guidance to stable owners	Source control (animals)	N	Y	N	Polluting industry	Administrative	high	Low	high	high	moderate	Low effectiveness - does not eliminate emissions	no - unclear effectiveness
Reduce stocking density of agricultural animals	Source control (animals)	Y	Y	Y	Polluting industry	Reduced yield	Moderate	low as emissions not eliminated		moderate - requires additional effort	low -	Limited effectiveness as it does not eliminate emissions and moderate costs suggest unlikely to be adopted unless supported by payments	no - Baseline in AMR strategy (1)

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Improved hygiene standards in health facilities, stable management and livestock handling	Source control (animals)	Y	N	N	Polluting industry	Training and guidance	high	low - does not eliminate emission		high	moderate	It is not clear that lack of hygiene is a significant factor in emissions	no - Baseline in AMR strategy (1)
Improved stock control	Source control (animals)	Y	Y	Y	Polluting industry	Administrative	high	low - does not eliminate emissions from use		high	high	low - as most emissions are through use	no - Baseline in AMR strategy (1)
Reduce number of prescriptions / improved diagnostics	Source control (prescribing)	Y	Y	Y	Society	Administrative	High	moderate - does not eliminate all emissions from use	high	moderate	high - part of AMR strategy aims (sulfamethoxazole)	Potential to be highly effective	no - Baseline in AMR strategy (1) and Smart Prescribing
Ban use in people	Source control (prescribing)	Y	Y	Y	Society	Relative cost of alternative	Low (uncertain). Costs potentially high if no suitable alternatives	high	low - may affect rights to health	Low unless equivalent alternatives	Low unless equivalent alternatives	Unlikely to be acceptable without a suitable alternative (risk to people outweigh risks to groundwater)	No - conflict with human right to effective medicine
Provide guidance on proper disposal	Source control (prescribing)	Y	Y	Y	Government	Administrative	High	moderate - potential to reduce emissions	high	high	high	Will have beneficial impact but hard to quantify does not reduce emissions from use	Yes

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Improved returns program for unused drugs	Source control (prescribing)	Y	Y	Y	Government, other	Admin and disposal	High	moderate	high	high proven to work (e.g. France, Sweden)	high	only removes unused drugs - which may not be a major emission but has been suggested by stakeholder and could form part of pharmaceuticals strategy	Yes
Establish national returns programs (if non existent)	Source control (prescribing)	Y	Y	Y	Government, other	Admin and disposal	High	moderate not likely to be mandatory - does not eliminate emissions from use	high	Proven to work	high	limited effectiveness as it only removes unused drugs - no evidence that this is a significant emission	yes (combined with above)
Ensure pharmacies send 100% of waste to incineration	Source control (prescribing)	Y	Y	Y	Government, other	Admin and disposal	High	moderate unless mandatory - does not eliminate used / excreted drugs from wastewater system - more effective as part of returns program	high	Moderate Potentially complex system to administer	moderate	limited effectiveness as it only removes unused drugs no evidence that this is a significant emission	No - not effective as main pathway through wastewater rather than landfill.
Increased penalties for improper disposal	Source control (prescribing)	Y	Y	Y	Polluting industry, society	Administrative	Moderate -	low - improper disposal may not be an issue	moderate	low	low	Lack of evidence that improper disposal is a significant emission	No - baseline

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Innovation in green pharmacy - allow medicine experts to promote prudent use and correct disposal of pharma -	Source control (prescribing)	Y	Y	Y	Polluting industry	Administrative	high	moderate (uncertain)	high	uncertain	high	Uncertain effectiveness	yes - but combined with measure 7 and 8 on returns programmes
Green public procurement with environmental criteria	Source control (prescribing)	Y	Y	Y	Government	Administrative	High	low - not that relevant to pharma	high	low	high	No concrete proposals so unlikely to be of use in next 6 years	no - baseline-Pharmaceuticals Strategy
Eco-labelling of high-risk over-the-counter pharmaceutical products to improve consumer choice selection and awareness	Source control (prescribing)	Y	Y	Y	Polluting industry	Administrative	High	n/a	high	n/a	n/a	not an over-the-counter drug	not for LFR pharmaceuticals - yes for all pharmaceuticals
Improved human and animal health and well-being to reduce drug use	Source control (prescribing)	Y	Y	Y	Polluting industry, society	Training and guidance	High	high	high	high	high	No direct link to groundwater	no

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Personalised medicines, vaccinations, targeted delivery mechanism to reduce drug use	Source control (prescribing)	Y	Y	Y	Polluting industry	Cost of alternative	High (uncertain)	moderate (uncertain)	high	uncertain	uncertain	Too much uncertainty to evaluate	no
Use of alternative substances with lower environmental risk	Source control (prescribing)	Y	Y	Y	Polluting industry, society	Cost of alternative	High	moderate (unknown)depends on whether alternative is as effective	high	high	high	Potential for alternatives to be future problems	no - requires detailed knowledge of the suitability of alternatives
Tailoring drug dosage/providing a range of package sizes	Source control (prescribing)	Y	Y	Y	Polluting industry	Training and guidance	High	moderate - does not eliminate emissions from use	high	high	high	low - as most emissions are through use	yes
Cease production and use of products containing substance	Source control (production)	Y	Y	Y	Polluting industry	Relative cost of alternative	Low to high (uncertain) depends on cost of alternatives	High - eliminates future emissions		Depends on whether alternatives are available	Low if other forms of treatment are less effective	Unlikely to be viable unless a suitable alternative already exists	No
Improved processes for pharmaceutical production	Source control (production)	Y	Y	Y	Polluting industry	Construction and operation	Moderate (uncertain)	Low as few production facilities / controlled environment - no evidence that they are source of emissions	high	moderate	moderate	Limited due to small number of manufacturing sites. Cost low due to limited no. of sites	no - unlikely to be a large source term

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Increased requirements on industrial discharges	Source control (production)	Y	Y	Y	Polluting industry	Construction and operation	Moderate (uncertain)	low as few production facilities	high	moderate	moderate	Limited due to small number of manufacturing sites. Cost low due to limited no. of sites	no - unlikely to be a large source term
Ensure adequate treatment during manufacturing if effluent discharge is direct	Source control (production)	Y	Y	Y	Polluting industry	Construction and operation of plant	moderate	low as few production facilities / controlled environment		moderate	high	Limited due to small number of manufacturing sites	no - unlikely to be a large source term and no direct discharge to groundwater
More stringent conditions for placing a pharmaceutical on the market that is of high-risk to the environment	Source control (production)	Y	Y	Y	Government, polluting industry	Admin. Testing	high	high	high	low	high	Only applies to new authorisations so will not affect existing drugs. Addressed by pharmaceutical strategy	No - baseline
Environmental criteria for Good Manufacturing Practices, effluent discharge limits and disclosure of pharmaceutical wastewater discharge from supply chains	Source control (production)	Y	Y	Y	Polluting industry	Admin, testing	moderate	low as few production facilities / controlled environment	high	moderate	high	Limited due to small number of manufacturing sites	no

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Cost classification (who pays)	Main cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Extended producers responsibility schemes	Source control (production)	Y	Y	Y	Polluting industry	Disposal fees	moderate	low	high	low	high	Unclear extent to which this would work when most of the source is people	no - only a small number of sites which are likely to have their own wastewater treatment works.
Centralised database with regulatory oversight to share ERAs and environmental monitoring data of APIs	Source control (production)	Y	Y	Y	Government	Administrative	moderate	low - does not eliminate emissions	high	n/a	n/a	not applicable to a single product	No - baseline
Improved sludge management at wastewater treatment works	Source control (WWT)	Y	Y	Y	Polluting industry	Construction and operation of plant	moderate to high	moderate - potentially eliminates some emissions (uncertain) but not all as some from private systems	high	moderate	moderate	moderate - but requires evaluation of effectiveness	yes but unclear what is needed - substances sorbed to sludge may not be leachable at high concentrations.
Control of times in which sludge can be used	Source control WWT	Y	Y	Y	Polluting industry		Low - moderate	low as does not limit emissions	high	moderate - requires sludge storage	low -	Potentially effective as part of overall sludge management package - can limit leaching of pollutants to groundwater	No

Table J-.3 Long list of measures for currently authorised parent pesticides of nrMs

Measure	Type of measure	Cost classification (who pays)	Cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Ban / restrict agricultural uses of parent pesticide (use substitute)	Source control	Polluting industry, Society	Use of alternative	Moderate - cost of alternative	High (eliminates emission)	High	low	low	high - eliminates emission	Yes
ban / restrict non-professional use of the parent pesticide	Source control	Polluting industry, Society	Use of alternative Need to hire professionals	Low - non professional use limited in extent	Low - non professional use is relatively small area	High	low	low	low - limited use	no - not a significant source term and glyphosate is the main active permitted parent available.
ban / restrict all outdoor use of the parent pesticide	Source control	Polluting industry, Society	Use of alternative	Low (reduced crop yield)	High (eliminates emission)	High	low	low	high - eliminates emission	no - not cost effective
ban / restrict non-agricultural use of the parent pesticide	Source control	Polluting industry, Society	Use of alternative	Moderate	Low - non agricultural use is relatively small area	High	low	low	moderate - SUD includes a prohibition on use in parks and other public access space and in sensitive areas	no - baseline as part of SUD pesticides
Restrictions on parent pesticide in specific areas (e.g. sensitive GWBs)	Source control	Polluting industry	Use of alternative	High	Moderate	High	low	low	moderate - SUD includes a prohibition on use in parks and other public access space and in sensitive areas	yes - in baseline / available as voluntary measure. Use a WPZ for a statutory measure?

Measure	Type of measure	Cost classification (who pays)	Cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Advice and support for integrated pest management (IPM)	Source control	Polluting industry, society	Use of alternative pest management options	Moderate - potentially cost neutral / cost-beneficial	High (eliminates emission)	High	low	low	moderate - SUD promotes IPM	no - in baseline
Approval and promotion of bio-herbicides as alternatives to parent pesticide	Source control	Polluting industry, other	Use of alternative substitute	Low	High	High	low	low	moderate - SUD promotes lower toxicity alternatives	no - in baseline
Crop risk insurance for integrated pest management (IPM)	Source control	Polluting industry, other	Cost of insurance	Low	High	High	low	low	low - can result in increased use of pesticide	no - can lead to increases in use of pesticides
Parent pesticide reduction through private assurance schemes	Source control	Polluting industry	???	Low	High	High	low	low	???	no - not assured that pesticide us reduction is part of the scheme - likely to be part of baseline.
Installation herbicide handling areas with separate water drainage systems	Source control	Polluting industry	Construction of handling area	Moderate	High	High	low	low	low - not specific to LFR substances will only address this source	no - point sources are less likely to be the main source of nrMs. More likely to be diffuse from application to crops.
Stricter requirements on aquatic releases for sites of manufacture through environmental permitting.	Source control	Polluting industry	Cost of treatment / facilities	Moderate	High	High	low	low	low - baseline requirements under IED will be in place already	no

Measure	Type of measure	Cost classification (who pays)	Cost elements	Efficiency (CB)	Effectiveness	Coherence	Practicality	Stakeholder acceptability	Overall effectiveness and suitability	Short-listed
Ensure disposal is convenient and easy to access	Source control	Government	Admin costs / disposal costs	Low	High	High	low	low	low - disposal is part of baseline	no
Ensure suitable timing of pesticide applications relative to rainfall and soil moisture	Source control	Polluting industry	Admin / training costs - baseline	Low	High	High	low	low	low - good practice is part of baseline	no
Improve guidance to users of pesticide on end-of-life disposal	Source control	Government	Admin costs	Low	High	High	low	low	low - guidance already exists	no
Prohibit use of aerial spraying	Source control	Polluting industry, Society	Baseline	Low	High	High	low	low	moderate - SUD NAP should include prohibition of aerial spraying	no - method of application not relevant for GW
Restrict seasons in which pesticide can be applied	Source control	Polluting industry, Society	Baseline	Low	High	High	low	low	low - requires further evidence that this will be effective	no - baseline / good practise
Use of the most efficient application techniques,	Source control	polluting industry	Cost of additional equipment	High	High	High	low	low	low - no evidence this is a pathway	no - baseline

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of the European Union