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IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy

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Contents

Abbreviations

Term or abbreviations	Meaning or definition
AA	Annual Average
AC	Associated Countries
AgNPs	Silver (Ag) nano-particles
AMR	Antimicrobial Resistance
BAT	Best Available Techniques
BPR	Biocidal Products Regulation
BREF	Best Available Techniques Reference
BWD	Bathing Water Directive
CAS	Chemical Abstracts Service
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CIS	Common Implementation Strategy
CJEU	Court of Justice of the European Union
CLP	EU Regulation on Classification, Labelling and Packaging of chemical substances and mixtures to the Globally Harmonised System.
CMR	Carcinogenic, Mutagenic and Reprotoxic
DNSH	Do No Significant Harm
DSD	Dangerous Substances Directive
DSUP	Directive on Sustainable Use of Pesticides
DWD	Drinking Water Directive
DWS	Drinking Water Standard
EBM	Effect-Based Methods
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
EDC	Endocrine Disrupting Chemical
EEA	European Economic Area/European Environment Agency (Context specific)

Term or abbreviations	Meaning or definition
EINECS/EC numbers	European Inventory of Existing Commercial Chemical Substances number/European Community number
E-PRTR	European Pollutants Release and Transfer Register
EPR	Extended Producer Responsibility
EQS(D)	Environmental Quality Standards (Directive)
EU	European Union
FC	Fitness Check
FD	Floods Directive
FTE	Full-Time Equivalent
GAC	Granulated Activated Carbon (GAC)
GES	Generic Exposure Scenarios
GQA	General Quality Assessment test for groundwater chemical status
GWAAE	Groundwater Associated Aquatic Ecosystems
GWD	Groundwater Directive
GWDTE	Groundwater Dependent Terrestrial Ecosystems
GWQS	Groundwater Quality Standards
GWWL	Groundwater Watch List
IA	Impact Assessment
IED	Industrial Emissions Directive
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JRC	European Commission Joint Research Centre
LFR	List Facilitating the 6-yearly Review of GWD Annexes I and II
MAC	Maximum Allowable Concentration
MS	Member State(s)
MSFD	Marine Strategy Framework Directive
NAg	Nano-Silver (Ag)
ND	Nitrates Directive
NPV	Net Present Value

Term or abbreviations	Meaning or definition
nrMs	non-relevant Metabolites (pesticide degradation products)
OECD	Organisation for Economic Cooperation and Development
OPC	Open/Online Public Consultation
PACT	Public Activities Coordination Tool
PAH	Polyaromatic Hydrocarbon
PBDE	Polybrominated Diphenyl Ethers
PBT	Persistent, Bioaccumulative and Toxic
PC	Participating Countries
PCP	Personal Care Products
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
PFCA	Perfluorinated Carboxylic Acids
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate
PFOSA	Perfluorooctanesulfonamide
PHS	Priority Hazardous Substance
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No Effect Concentration
PoMs	Programmes of Measures
POP	Persistent Organic Pollutant
PRO	Producer Responsibility Organisations
PS	Priority Substance
RBMP	River Basin Management Plan
RBSP	River Basin Specific Pollutant
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RPF	Relative Potency Factor
RoHS	Restriction of Hazardous Substances
SCCS	Scientific Committee on Consumer Safety

Term or abbreviations	Meaning or definition
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SDG	Sustainable Development Goals
SSD	Sewage Sludge Directive
SUPD	Single-Use Plastics Directive
SVHC	Substance of Very High Concern
SWD	Staff Working Document
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
TV	Threshold Value
TWI	Tolerable Weekly Intake
vPvM	Very Persistent and Very Mobile
UWWTD	Urban Waste Water Treatment Directive
WB	Water Body
WFD	Water Framework Directive
WG	Working Group
WG GW	Working Group for Groundwater
WL	Watch List
WWTP	Wastewater Treatment Plant
ZPAP	Zero Pollution Action Plan

Glossary

Term or acronym	Meaning or definition
Antimicrobial Resistance (AMR)	AMR occurs when microbes (e.g. fungi and bacteria) transform over time and no longer respond to antimicrobial substances, in particular pharmaceuticals but also biocidal products and certain metals (e.g. silver). The main drivers of the development of drug-resistant pathogens are misuse and overuse of anti-microbials e.g. antibiotics, antivirals, antifungals and antiparasitics. AMR has been declared as one of the top 10 global public health threats facing humanity by the World Health Organization. (1)
Contaminants of emerging concern	According to the Organisation for Economic Co-operation and Development (OECD) “Contaminants of emerging concern” (CECs) comprise a vast array of contaminants that have only recently appeared in water, or that are of recent concern because they have

Term or acronym	Meaning or definition
	been detected at concentrations significantly higher than expected, or their risk to human and environmental health may not be fully understood. Examples include pharmaceuticals, industrial and household chemicals, personal care products, pesticides, manufactured nanomaterials, and their transformation products’. (2)
Do No Significant Harm (DNSH)	In the area of this initiative an activity is considered to be in line with the ‘do no significant harm’ to the sustainable use and protection of water and marine resources if it contributes to achieving and maintaining the good status or the good ecological potential of bodies of water, including surface water and groundwater, or to the good environmental status of marine waters.
Effect-Based Methods (EBM)	EBM are methods for detecting the presence of substances indirectly, i.e. without conducting conventional chemical analysis. They use biological test systems, which can be inside or outside a laboratory, and capture the presence of chemicals having the same biological effect, for example estrogenic activity or inhibition of photosynthesis.
Fitness Check of EU Water Law	Evaluation of WFD, Environmental Quality Standards Directive, Groundwater Directive and Floods Directive, published on 10 December 2019 (SWD(2019)439 final).
Groundwater	Water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.
Microplastics	Generally, microplastics are referred to as plastic fragments having at least one of their dimensions between 0.1 µm−5 mm in size. Note: according to the European Chemicals Agency (ECHA), ‘the term “micro-plastic” is not consistently defined, but is typically considered to refer to small, usually microscopic, solid particles consisting of a synthetic polymer. They are associated with long-term persistence in the environment, if released, as they are very resistant to (bio)degradation.’ The smallest particle size fractions are usually referred to as nanoplastics (3)
Micro-pollutants	Micro-pollutants are defined as synthetic or natural compounds released from point and nonpoint resources and which end up in the aquatic environments at low concentration (4), i.e. pollutants, which exist in very small traces in water (5). Most micro-pollutants are considered as “Contaminants of emerging concern” (see above).
Nanoplastics	Generally, nanoplastics are referred to as plastic fragments with at least one of their dimensions from 1 to 100 nm. Nanoplastic particles often present a colloidal behavior and are often unintentionally produced (i.e. from. the wear-and-tear, abrasion, degradation and the manufacturing of the plastic objects).
Pesticides	Pesticides can be described (with certain minor exceptions) as any substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest; any substances or mixtures of substances intended for use as a plant regulator, defoliant, or desiccant; any nitrogen stabilizers. (6)
PFAS	Per- and polyfluoroalkyl substances (PFAS) are a family of at least 4730 compounds containing carbon-fluorine bonds. Their lack of a chemically active group makes them very inert and highly resistant to degradation, both during their use andin the environment. Most PFAS are also easily transported in the environment covering long distances

Term or acronym	Meaning or definition
	away from their releasing point. PFAS have been frequently observed to contaminate groundwater, surface water and soil. Cleaning up polluted sites is technically difficult and costly. These substances are accumulating in the environment, drinking water and food. (7)
Pharmaceuticals	Pharmaceuticals (medicines, medications, drugs) are chemical substances used in the prevention, diagnosis or treatment of disease.
Precautionary principle	The precautionary principle is designed to assist with decision-making under uncertainty and is a core principle of EU environmental law, enshrined in Article 191(2) of the Treaty on the Functioning of the EU. The classic definition of 'a precautionary approach' comes from the 1992 Rio Declaration on Environment and Development, stating that: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (UNEP 1992)'. In cases where the precautionary principle was invoked this was done under the following conditions: 1) an established identification of potentially adverse effects; 2) evaluation of the scientific data available; 3) a (qualitative) assessment of the extent of scientific uncertainty.
Population Equivalent (p.e.)	1 p.e. describes the average water pollution load released by one person in one day The UWWTD definition: '1 p.e. (population equivalent)' means the organic biodegradable load having a five-day biochemical oxygen demand (BOD5) of 60 g of oxygen per day.' In the UWWTD IA, one p.e. includes on average 11.18 g/day for total Nitrogen, and 1.68 g/day for Phosphorus.
Priority (Hazardous) Substance (P(H)S)	Surface water pollutant listed in Annex X of the WFD (later superseded by Annex I to the EQSD) and for which measures have to be taken to reduce emissions. Among these, there are 'priority hazardous substances' which means substances identified as PBT or of equivalent concern and for which measures have to be taken to phase-out emissions completely.
River Basin Management Plan (RBMP)	River Basin Management Plans are the key tools for implementing the Water Framework Directive (WFD). They are drawn up after extensive public consultation and are valid for a six-year period. (8)
Surface water	Inland water, except groundwater, and transitional and coastal waters, as well as, with respect to chemical status, territorial waters.
TFEU	Treaty on the Functioning of the European Union Article 191(2) of the TFEU 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*".

Term or acronym	Meaning or definition
Watch List (WL)	For surface waters: Mandatory mechanism, established by the 2013 revision of the Environmental Quality Standards Directive (EQSD), to collect data from MS on surface water pollutants of potential EU-wide concern. For groundwaters: Voluntary mechanism, established in the CIS, to collect data from MS on groundwater pollutants of potential EU-wide concern.

1 1 INTRODUCTION: POLITICAL AND LEGAL CONTEXT

The European Green Deal (EGD) is Europe's growth strategy ensuring that by 2050 the EU is transformed into a climate neutral, clean and circular economy, optimising resource management while minimising pollution. Water is an essential resource and therefore an integral part of the EGD ambition and initiatives, building upon the EU's comprehensive and mature water law. Since the 1990s, significant progress has been achieved in improving water quality through the implementation of many EU laws regulating pollution sources[1]. By reducing pollution at source and by treating water before release into the environment, many past pollution problems were tackled successfully. However, the EU's water bodies are still at risk from certain hazardous substances, which can affect ecosystems and threaten human health. And new pollutants of concern are emerging.

This initiative is part of the Commission Work Programme 2022 and a key action in the Zero Pollution Action Plan (ZPAP)[2]. This initiative, like all EGD-initiatives, aims at ensuring that objectives are achieved in the most effective and least burdensome way, and comply with the 'do no significant harm' (DNSH) principle (see glossary for the water related details). It fine-tunes, updates and adapts existing legislation in the context of the EGD. Its focus is on defining the zero pollution ambition for water pollutants and thereby the level of protection for human health and natural ecosystems. The measures necessary to achieve this level of protection are addressed by several other, closely related, initiatives under the European Green Deal, e.g.[3]:

- The Biodiversity and Farm to Fork Strategies, which aim to reduce pesticide use, nutrient losses, and sales of antimicrobials (by 50%), as well as fertilizer use (by 20%) by 2030. Much of it is to be achieved by the ongoing revision of the Directive on the Sustainable Use of Pesticides. The upcoming review of Regulation (EC) No. 1107/2009[4] concerning the placing of plant protection products (PPPs) on the market in the European Union could also play a role.
- The EU Plastics Strategy and the upcoming EU microplastics initiative, which aim to deliver on the ZPAP target to reduce waste, plastic litter at sea (by 50%) and microplastics released into the environment (by 30%) by 2030;
- The Single Use Plastics Directive (SUPD) 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.
- The Circular Economy Action Plan, which announces in particular measures to reduce microplastics and the evaluation of the Sewage Sludge Directive (SSD), regulating the

[1] E.g. Urban Waste Water Treatment Directive, Industrial Emissions Directive and Nitrates Directive
[2] Specific commitment to 'Revise the EQSD and the GWD' (Action 10, Flagship 3)
[3] A comprehensive list of relevant actions also considered in the baseline assessment is available in Annex 5.
[4] A plant protection product ("pesticide") usually contains more than one component. The component that works against pests/plant diseases is called an "active substance". Active substances can be chemicals or micro-organisms. Active substances can only be approved for use in plant protection products if they fulfil the approval criteria that are laid down in Regulation (EC) No. 1107/2009.

quality of sludge used in agriculture; the new Regulation on minimum requirements for water reuse regulates the quality of waste water if used for agricultural irrigation[5].

- The Chemicals Strategy for Sustainability, which recognises that chemicals are essential for the well-being of modern society, but aims to better protect citizens and the environment against their possible hazardous properties;
- The 2019 Strategic Approach to Pharmaceuticals in the Environment (flowing directly from the 2013 revision of the EQSD) and the Pharmaceuticals Strategy for Europe, which both underline the environmental and potential health impacts of pollution from pharmaceutical residues and list a range of actions designed to tackle these challenges;
- The Industrial Emissions Directive, currently under revision, which regulates emissions from a large number of installations in the industrial and agricultural sector;
- Internationally, treaties such as the Stockholm Convention on Persistent Organic Pollutants and the Minamata Convention on Mercury prohibit or restrict the use of a number of the substances covered by this Impact Assessment. The EU, as a Party to these treaties, constantly ensure that EU legislation is kept in conformity with developments agreed in that context. Negotiations on a new global, legally binding instrument on plastics have been set in motion in 2022.
- This proposal is also consistent with the final report of the Conference on the Future of Europe and the explicit recommendations it contains from citizens on zero pollution in general and in particular the proposals on tackling pollution. Especially, the following final proposals are specifically relevant in this context:
  - Proposal 1.4 to: ‘Significantly reduce the use of chemical pesticides and fertilizers, in line with the existing targets, while still ensuring food security, and support for research to develop more sustainable and natural based alternatives’;
  - Proposal 2.7 to: ‘Protect water sources and combat river and ocean pollution, including through researching and fighting microplastic pollution’.

It will, however, ultimately be for Member States (MS) to put together the most cost-effective mix of measures to achieve the objectives set out by this initiative. This is set out in the WFD, 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. It aims to ensure that all surface and groundwater bodies achieve “good status” by a certain deadline and that there is no further deterioration of water quality. For a surface or groundwater water body (WB) to be classified in overall good status, both chemical status and either ecological or quantitative status, respectively, must be at least good. In particular, for surface waters, WFD Article 16(2) requires the establishment of a list of PS and priority hazardous substances (PHS) which present a significant risk to or via the aquatic environment. The first such list (constituting Annex X to the WFD) was established in 2001, and EQS were established in 2008 in the Environmental Quality Standards Directive (2008/105/EC - EQSD). The list was last revised in 2013 by Directive 2013/39/EU and currently contains 45 substances including industrial chemicals, pesticides, and metals.

The 2013 revision of the EQSD (Article 8(b)) introduced an obligation to establish a so-called watch list (WL) of substances for which EU-wide monitoring data are to be gathered to inform the review of the PS list. The first WL was established by Commission Implementing Decision (EU) 2015/495 and included macrolide antibiotics (Erythromycin, Clarithromycin

[5] Regulation (EU) 2020/741 on minimum requirements for water reuse: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0741

and Azithromycin, used to treat infections), estrogenic hormones (17-beta-estradiol (E2), and 17-alpha-ethinylestradiol (EE2), mainly used in contraception), neonicotinoid-pesticides (the insecticides Imidacloprid, Thiacloprid, Thiamethoxam, Clothianidin, Acetamiprid) and Diclofenac (an anti-inflammatory) were included in the first watch list. The list was updated in 2018 and 2020.

For groundwaters, pollutants of EU-wide concern and their quality standards are listed in Annex I to the Groundwater Directive (2006/118/EC - GWD) whereas MS have to consider setting national threshold values(TVs) for the substances listed in Annex II. Annex II substances are found only in a limited number of MS therefore no EU-wide action is needed. Both Annexes were last revised in 2014. Annex I currently includes nitrates and active substances in pesticides, incl. their metabolites, degradation, and reaction products, whereas Annex II contains 12 pollutants or pollution indicators. The 2014/80/EU Directive amending the GWD expressed the need to obtain information on additional substances posing a potential risk for groundwater (Recital 4). In response to this, in the context of the Common Implementation Strategy (CIS) supporting the implementation of the EU water acquis, a *voluntary* watch list mechanism for pollutants in groundwater was introduced. Under this Groundwater Watch List (GW WL) process, MS agreed to voluntarily collect data on groundwater pollutants of potential EU-wide concern, to support the identification of (emerging) pollutants for which groundwater quality standards or threshold values should be set. The "Voluntary Groundwater Watch List Concept & Methodology" (9) describes the identification process of substances to be put on the GW WL.

WFD Article 10 obliges MS to establish relevant emission limit values and ensure that all point and diffuse source emissions are controlled based on best available techniques (BAT). In addition, the EQSD and the GWD set out more precisely what 'good chemical status' means by defining the level of protection per pollutant and how it is assessed and monitored. .

Article 16(4) of the WFD requires the Commission to regularly review, at intervals of at least every four years, the list of PS that pose a risk to the aquatic environment, i.e. both surface and groundwaters. Specifically, for *surface water*, Article 8 of the EQSD requires the Commission to review Annex X of the WFD (the PS list), while, for *groundwaters*, Article 10 of the GWD requires the Commission to review every 6 years Annexes I and II of the GWD itself. The revision, and this impact assessment, also serve to report to the EP and Council, as referred to in Article 8 of the EQSD

In 2019, a Fitness Check (FC) evaluation of EU water legislation (10) was completed covering the WFD, as well as the EQSD and the GWD. The FC concluded[6] that, although the legislation is largely fit for purpose, there is room for improvement in relation to tackling chemical pollution. The obligation to review the lists of pollutants and their corresponding standards provides an opportunity to also introduce some of the improvements warranted by the FC. The changes considered by this initiative (see Chapter 5.4) are linked to the scope of the lists of substances, the updating process as well as related monitoring and reporting methods, which are all aimed at improving the regulatory response to emerging environmental and health risks. Conclusions of the FC related to the slow progress towards reaching WFD, EQSD and GWD objectives are not directly addressed by the proposed intervention and are instead being addressed, at this stage, by stepped up enforcement actions.

[6] Pages 120-121 ('emerging challenges') and 121-123 ('EQSD and GWD')

A possible revision of the lists of pollutants will also improve marine water quality and the quality of bathing waters[7]. There is also a direct link with soil health, in particular in relation to the protection of groundwaters. The proposal therefore feeds into the preparations of the new Soil Health Law foreseen for 2023. In line with the "A Europe fit for the Digital Age" Communication, the potential benefits of digitalisation will be further explored, as they are particularly relevant in the water sector. This will help reduce administrative burden.

Finally, the revision of the lists of pollutants directly contributes to achieving the Sustainable Development Goals (SDGs), specifically SDG 6 on ensuring the availability and sustainable management of water and sanitation for all[8], SDG 3 on ensuring healthy lives and promoting well-being[9], as well as SDG 14 on protecting life below water[10].

2 2 PROBLEM DEFINITION

Air, water and soil pollution affect human health and biodiversity. Pollution is transferred between different water compartments (from groundwater to lakes or rivers and from rivers to the marine environment) as well as different environmental compartments (air/water/soil). Tackling water pollution is therefore a cornerstone for achieving the Zero Pollution ambition. Water pollution is also one of the significant pressures affecting European surface and ground waters (11). This initiative addresses the identification of new pollutants of concern and adapts the existing lists of pollutants to the latest scientific and technological progress. This impact assessment does not address the – current – underachievement of the 'good chemical status' legal objective overall[11], which forms the object of the ongoing assessment, by the European Commission, of the 3rd River Basin Management Plans (RBMPs), covering the crucial 2021-2027 time-period and which all MS should have submitted by March 2022[12].

Box 1: Status of EU freshwater bodies as reported in 2nd River Basin Management Plans
The 2nd RBMP reporting showed that only 38% of EU surface water bodies are in good chemical status, while 46% are not achieving good status and the status of 16% is unknown (12). There are substantial differences between MS, as shown in Figure B1.1. Some report that over 90% of their surface water bodies are in good chemical status, while others report this for fewer than 10%.

[7] And thereby help in the review of the Marine Strategy Framework Directive (MSFD) and of the Bathing Water Directive.

[8] Specifically target 6.3: Improve water quality by reducing pollution and minimizing the release of hazardous chemicals and materials by 2030.

[9] Specifically target 3.9: Substantially reduce the number of deaths and illnesses from hazardous chemicals and water pollution and contamination by 2030.

[10] Specifically target 14.1: By 2025, prevent and significantly reduce marine pollution of all kinds, in particular from land-based activities, including marine debris and nutrient pollution.

11 Under the WFD, MS had time until 2015 to ensure good chemical status for their waterbodies, or until 2027 if achieving good status is disproportionally costly.

12 A total of 11 MS have reported their RBMPs by 5 September 2022.

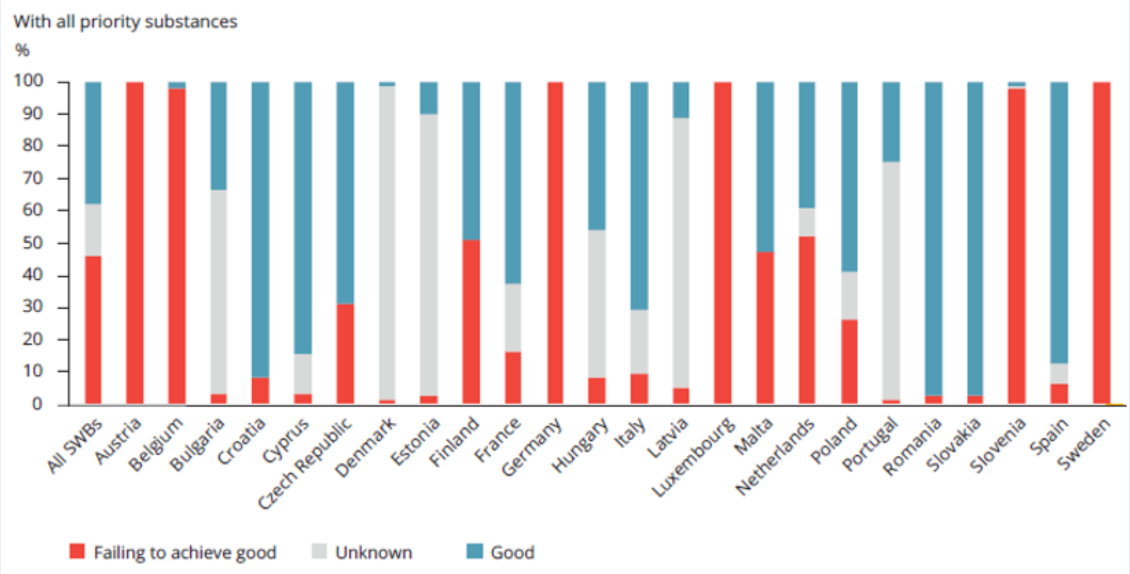

Figure B1.1: Chemical status of all surface water bodies for all priority substances per Member State (12)

As regards groundwater, the 2nd RBMP reporting showed that 75% of EU groundwater bodies are in good chemical status, while 24% are not achieving good status and only for 1% the status is unknown (12). There are substantial differences between MS, as shown in Figure B1.2. Some report that 100% of their groundwater bodies are in good chemical status, while others report this for 3%.

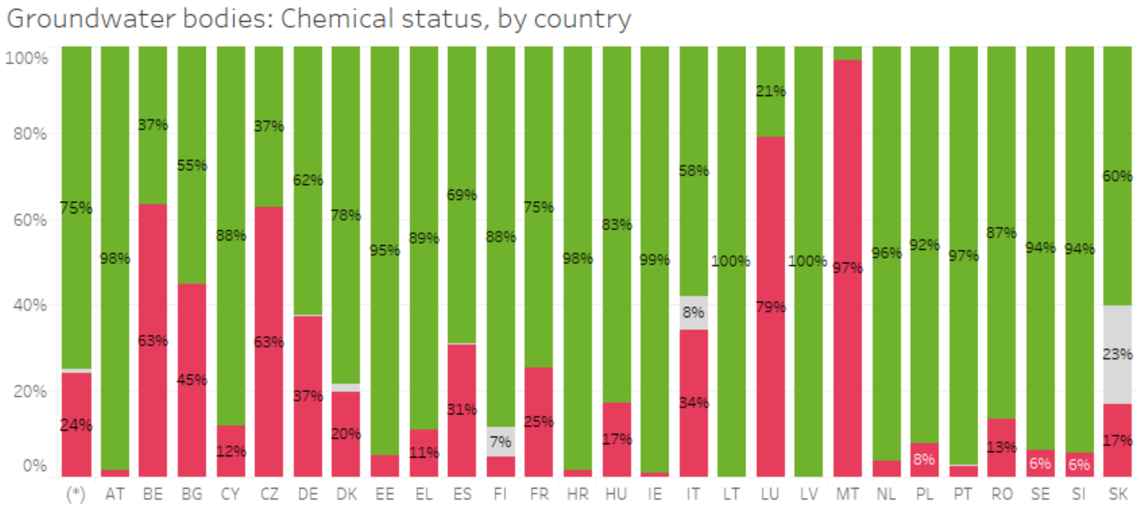

Figure B1.2: Chemical status of all Groundwater bodies per Member State (12)

2.1 2.1 What are the problems?

The problem definition rests mostly on the findings of the 2019 Fitness Check[13] (FC) related to chemical pollution, implementation, administrative simplification, and digitalisation. The key issue is that the current legislative scope does not sufficiently protect human health and ecosystems. In addition, several administrative and implementation impediments reduce the effectiveness of the legislation and raise the administrative burden of the legislation. The FC concluded that the key area to improve and to achieve better results is on chemicals. While there is evidence that the WFD, EQSD and GWD have led to reduced chemical pollution of

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

the EU's waters, the analysis points to three areas in which the current legislative framework is sub-optimal:

- the differences between the MS are much larger than what can be explained by national differences (variability in lists of local pollutants (river basin-specific pollutants and pollutants posing a risk to groundwater bodies) and the limit values they should not exceed);
- updating the list of PS (i.e. adding or removing substances and the corresponding quality standards) is a lengthy process, partly because it takes time to gather the necessary scientific evidence and partly because of the ordinary legislative procedure;
- the EQSD and GWD evaluate the risk to people and the environment based mainly on single substances, not taking into account the combined effects of mixtures, and inevitably cover only a tiny proportion of the substances present in the environment.

Figure 2.1.1 shows the "intervention logic" which links problem drivers, problems, consequences and specific objectives to the options under consideration. All policy options are expected to intervene at the driver and problem level. The intervention logic is the same both when single pollutants are considered and when their combination is at stake.

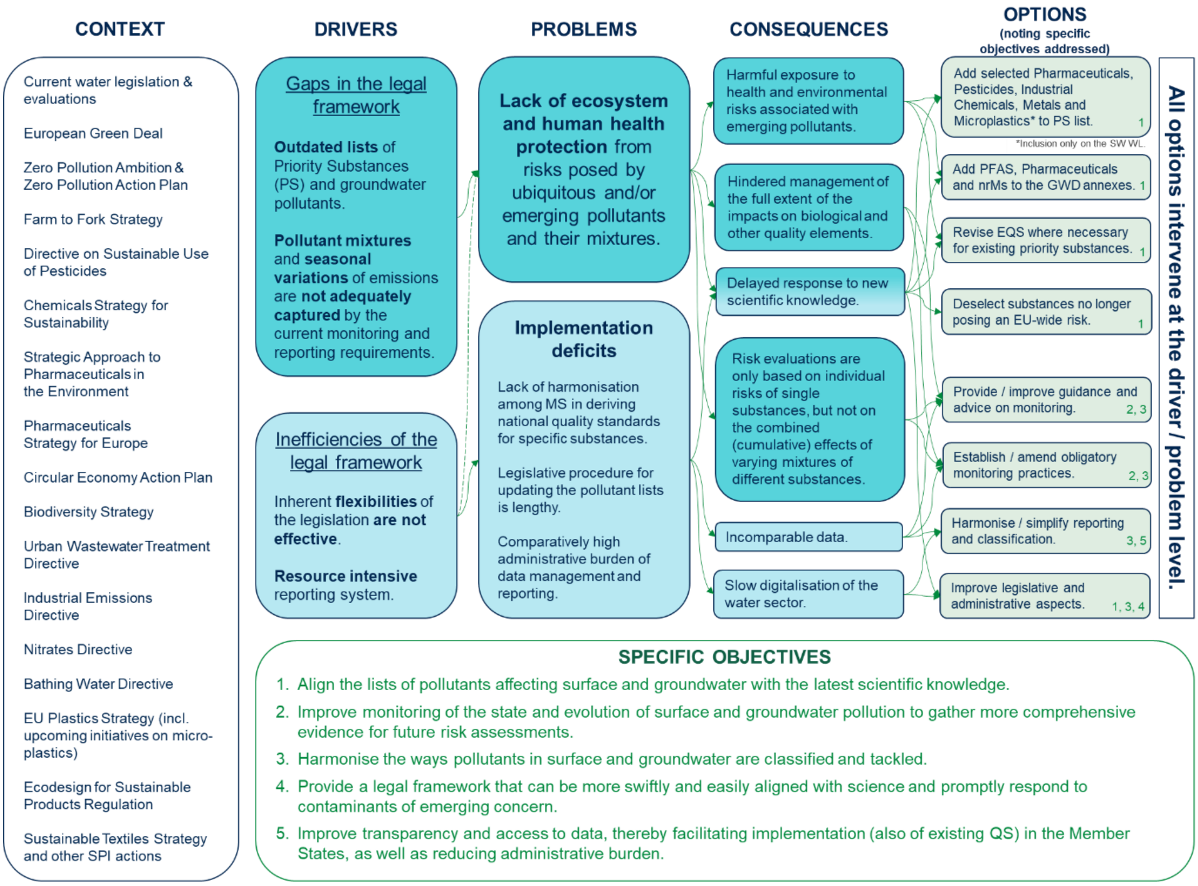

Figure 2.1.1: Intervention logic

2.1.1 2.1.1 Lack of ecosystem and human health protection from emerging risks

Emissions of pollutants in surface and groundwater are linked to agricultural production and animal farming activities (pesticides, pharmaceuticals, nutrients), industrial activities (emissions linked to production of various industrial pollutants), consumption and disposal of products containing pollutants (e.g. PFAS a.k.a. “forever chemicals”, or plasticizers), and also healthcare (increased consumption, partially due to ageing population). Numerous ubiquitous and emerging pollutants released from these anthropogenic sources continue to have detrimental effects on aquatic ecosystems, limit the services they provide (recreation, drinking water, etc.) and constitute a cause for concern for public health. Significant levels of concern regarding various surface and groundwater pollutants were also flagged during the consultation activities (see Box 2), indicating that more needs to be done to reduce their presence in the aquatic environment.

Box 2: Concerns regarding surface and groundwater pollutants expressed during consultation activities

In the Open Public Consultation (OPC) respondents were asked to rate their concern about the presence of various emerging pollutants in water bodies on a scale of 1 (not at all) to 5 (very much). For surface water, respondents were most concerned about pharmaceuticals (average score of 4.2; rated ≥4 by 72% of respondents) as well as pesticides (including biocides), substances released from household items (e.g. compounds from plastic products, flame retardants, detergents, disinfectants), and industrial chemicals (e.g. PFAS) (all scored 4.1 on average; rated ≥4 by 72%, 68% and 67% of respondents, respectively). A slightly lower, although still high, level of concern was expressed regarding metals and microplastics (both scored 3.9 on average; rated ≥4 by 63% and 59% of respondents respectively).

For groundwater, OPC respondents were most concerned about fertilisers (4.3; 71%) and pesticides (4.2; 76%), closely followed by industrial chemicals (incl. PFAS) (4.0; 64%), pharmaceuticals (3.9; 63%) substances released from household items and metals (3.8; 57%). Least concern was expressed regarding microplastics (3.5; 47%).

These substance groups were also of high importance to the water stakeholders and experts, as flagged in the Targeted Expert Consultation (TEC). Participants in the TEC were most concerned about individual pharmaceutical substances (61%), (micro)plastics (59%), PFAS (56%), neonicotinoid pesticides (55%) and pyrethroid pesticides (44%).

The current legislative scope covers 53 single substances or groups of substances for surface water and 14 for groundwater, including pesticides (their relevant metabolites, degradation and reaction products), various industrial chemicals (e.g. PAHs), (heavy) metals and other pollutants/indicators (e.g. nitrates and nitrites, ammonium, chloride) (see Annex 8 for the full lists). Out of the 21 currently listed pollutants considered under this initiative (see section 5.2.1), mercury, nickel, industrial chemicals PBDEs, PAHs (incl. Fluoranthene), Tributyltin and Nonylphenol are among the top 15 most frequently reported PS causing failure to achieve good chemical status in surface water bodies (12) and therefore remain highly relevant.

It should be noted that Member State a required to report they meet (pass) or do not meet (fail) quality standards, not the actual amount of pollutants, their geographical or sectoral sources, therefore, the EU-wide picture is of actual amounts (Table A11.2 in Annex 11) is incomplete.

Most of the currently listed pollutants had long been recognised as harmful to, or via, the aquatic environment; however, they are only a small subset of the thousands of chemicals found in water bodies. The problem is particularly apparent for PFAS, microplastics and pharmaceuticals. PFAS have been detected at more than 70% of the groundwater measuring points in EU MS (13); investigations reveal that existing thresholds are clearly exceeded at a considerable number of locations. Reported environmental concentrations and associated risks of microplastics are likely underestimated (14) because most studies fail to detect the smallest particles. Pharmaceutical contaminants are widely found in surface and ground waters (15) (16) (17), and several publications (18) (19) (20) (21) show that medicines, (ionic /nano) silver and antibiotic residues can have negative effects on aquatic organisms and/or contribute to antimicrobial resistance (AMR).

Box 3: PFAS

A main source of PFAS to humans and the environment is their production and use in industrial and professional installations, e.g. as production of fluoropolymers, use of fire-fighting foams, use in the production of textiles, paints and printing inks and food contact materials. Another source is the release from consumer products, such as textiles, polishing and cleaning products, cosmetics and food contact materials, during their use and at the end of their life. Analysis of sampled products showed that the most commonly detected PFASs in the samples collected in 2016 were PFOA followed by PFHxA/PFBA, PFDA.[14] PFAS can be released to the environment from industrial and municipal waste-water treatment plants, landfills, recycling and incineration plants and from re-use of contaminated sewage sludge. The number of sites potentially emitting PFAS has been estimated to be approximately 100 000 in Europe (25). PFAS pollution is found in surface and groundwater throughout Europe, sometimes in high concentrations, and is also detected in water, sediment and animals in all seas. Although PFAS-free solutions already exist, these chemicals are still unnecessarily added to many consumer products creating an irreversible toxic legacy within the EU.

Substances are considered for listing under the EQSD and the GWD based on the scientific assessment of their toxicity to humans and the aquatic environment, e.g. because they are directly toxic, limit organisms' ability to reproduce or because they bio-accumulate in food chains and have the potential to cause cancer. The key element of this evaluation is (eco)toxicological data on persistence, bioaccumulation, carcinogenicity, mutagenicity, reprotoxicity and endocrine disrupting potential of chemicals. Since the adoption of the existing EQSs in 2008 and 2013, new evidence has become available for some substances already on the Priority Substance (PS) list. This recognises that the scientific understanding has advanced considerably, and that the aquatic environment is not protected as well as it could be, either because the threshold is too high, thus underplaying the risk, or because it is too low, hence overplaying the risk and potentially drawing resources away from other, more harmful substances.

Furthermore, without addressing pollutant mixtures, ecosystem and human health protection will also remain inadequate. It is estimated that hundreds of chemical mixture combinations occur in water bodies throughout the EU (21). Significant pressures stem from the possible cumulative effects of pollutant mixtures, as these may be more toxic than individual compounds comprising the mix.

Finally, the occurrence of certain pollutants within water bodies, such as pesticides, can vary significantly dependent on, for example, seasonal economic activities. In agriculture, for example, specific application windows for certain pesticides can result in large temporal variations of levels in water bodies. Obtaining the peak concentration value is important for an adequate health and environmental risk assessment.

Box 4: Views on key regulatory issues contributing to surface and groundwater pollution expressed during consultation activities

During the Open Public Consultation (OPC), stakeholders considered the most important issues to be the lack of investment for emissions reduction and lack of incentives to take control measures (such as technological improvements) at the source of pollution (both with average score of 3.8 on a scale from 1 – not at all – to 5 – very much; rated ≥4 by 66% and 65% of respondents, respectively). Many respondents also felt that there was a lack of enforcement and implementation of existing legislation and lack of use of 'precautionary' and 'polluter pays' principles when assessing risks from new emerging substances (both with average score of 3.7; rated ≥4 by 62% of respondents).

[14] https://norden.diva-portal.org/smash/get/diva2:1118439/FULLTEXT01.pdf

2.1.2 2.1.2 Implementation deficits

The 2019 Fitness Check found that there is a trade-off between the flexibility of the Directives, which is needed to enable location-specific water management, and the complexity that this flexibility creates, which forms an impediment to enforceability and achieving better results. Lack of a harmonised approach among MS to derive EQSs for river basin-specific pollutants (RBSPs, which are identified by MS as 'locally' relevant pollutants, but do not pose an EU-wide risk) has resulted in significant differences in the number of identified substances and their corresponding EQS values. In addition, the differences between national quality standards (QS) set by MS for groundwater polluting substances under Annex II of the GWD are much larger than could be explained by national disparities in, for example, chemical use. In many cases, these variations occur due to various other factors, such as political will, resistance to change or insufficient technical capacity. The lack of harmonisation was found by the FC to render the comparison between MS difficult for substances in Annex II, thus hindering the assessment of EU-wide risks.

The administrative burden of data management and reporting, although not disproportionate given the breadth and complexity of the legislation and the need for it to underpin implementation and enforcement, remains comparatively high. Reporting systems require a very large amount of data and are resource-intensive, needing significant human and financial contributions. Moreover, because reporting only informs whether a water body (WB) is in good status or not, the insights into the magnitude of exceedances and the related 'distance to target' are severely limited. This leads to opaque decision-making processes on remediation and policy actions to improve water quality, as it is unclear if the most important problems and the biggest exceedances are tackled first. Moreover, the data are often outdated, also at EU level, which reduces the effectiveness of policy making.

Finally, updating the lists of pollutants affecting surface and groundwaters can only be done via the ordinary legislative procedure. Apart from being resource intensive and time-consuming, it could also be argued that, for what is essentially adapting to scientific progress, the ordinary legislative procedure is not the most adequate. The time lag between the initial risk assessment and subsequent legislative changes slows policy response to emerging environmental and human health risks.

Box 5: Progress in WFD implementation
The 6th WFD implementation report reveals improvements in knowledge and reporting on the WFD compared to the previous cycle[15]. MSThe trend of continuous decline of water quality has been stabilised and partly reversed. Although compliance with the WFD objectives is slowly increasing achieving full compliance with the objectives of EU water legislation before the end of the third cycle (in 2027) looks very challenging.

2.2 2.2 What are the problem drivers?

The problems described above are largely driven by gaps and inefficiencies of the legal framework. Findings of the 2019 FC of the WFD and the FD conclude that ubiquitous pollutants and/or contaminants of emerging concern, pollutant mixtures and seasonal variations of emissions are not adequately captured under the current legal scope; the existing flexibilities set out in the legislation are not effective and the reporting system is adequate but resource intensive.

[15] https://ec.europa.eu/environment//water/water-framework/impl_reports.htm

2.2.1 2.2.1 Gaps in the legal framework

2.2.1.1 Emerging pollutants

While current regulatory efforts focus on monitoring and assessing various legacy chemicals, many more anthropogenic chemicals detected in surface waters are currently not included in the list of priority (hazardous) substances (PS/PHS) set out in Annex I of the EQSD, or in the list of harmful substances in groundwater laid out in Annexes I & II of the GWD. The outdated status of the EU legal scope leads to risks for ecosystems and human health.

The technical process underpinning this impact assessment identified an EU-wide risk for 24 substances (or substance groups) for surface water and 3 groups for groundwater, highlighting the size of the scope gap. Data on the current levels of these pollutants in EU's water bodies are reported under the mandatory surface water and voluntary groundwater watchlist mechanisms, however, the picture is very fragmented, because only a few MS provide actual measured concentrations under the Surface Water Watch List, despite an obligation to do so. Existing concentration data have been submitted by 1 to 10 countries (see Table A11.1 in Annex 11), therefore, data are only available for each new pollutant from a limited number of countries. On request of the MS, this data has been anonymised, hence it is not possible to name which MS reported specific values. For groundwater the picture is also incomplete.

The delay of the process and the scope for identifying emerging pollutants is also of concern. The SW WL mechanism only addresses a limited number of emerging pollutants, meaning that the legislation is not up to date with the latest scientific knowledge. This leads to a delayed response or no response at all to health and environmental risks from emerging pollutants. Stakeholders support the SW WL, but have no consensus over necessary monitoring frequencies or the frequency of updating the list of PS with WL substances.

2.2.1.2 Pollutant mixtures

Current monitoring and reporting practices used under the WFD focus only on individual substances or groups of substances, and do not adequately capture pollutant mixtures. Individual chemicals may interact additively[16], synergistically[17] or antagonistically[18] with each other, and in some cases prove toxic at concentrations below those at which they are toxic on their own. Exposure to chemical mixtures does not necessarily translate into adverse biological effects, so that it is not always clear whether mitigation measures are needed. Thus, adequate monitoring and assessment strategies are essential to provide information on which mixtures are present and which have associated combined effects. This knowledge is key for adequate risk evaluations, as currently these are only based on individual risks of single substances, but not on the combined (cumulative) effects of varying mixtures of different substances. Chemical monitoring of a few selected individual chemicals is less informative for identifying the full extent of impacts on water quality, whilst the probability of overlooking significant risks is high (23).

[16] Additive interaction means the effect of two chemicals is equal to the sum of the effect of the two chemicals taken separately.
[17] Synergistic interaction means the effects of two chemicals taken together is greater than the sum of their separate effect at the same doses.
[18] Antagonistic interaction means that the effect of two chemicals is actually less than the sum of the effect of the two drugs taken independently of each other.

2.2.1.3 Seasonal variation of emissions

Another identified gap is that monitoring does not adequately capture, in some cases, seasonal variations of emissions. This applies to the monitoring of substances listed under the WFD/EQSD and the GWD as well as under the SW and GW WL mechanisms. The current once-per-year monitoring may miss annual peaks of, for example, pesticides with a specific application window used in agriculture. Consequently, risks may be underestimated and managing the full extent of the impacts on biological and other water quality elements is difficult. This is important for example with regard to mercury. Understanding spatial and temporal trends for mercury is crucial in assessing measures taken both at European and at global level. It is only by understanding the movement and interaction of mercury within our environment that this persistent problem can be tackled. This would also allow to monitor the effects of revised Best Available Technique (BAT) conclusions for large (coal) combustion plants, and an EU wide ban on dental amalgam.

2.2.2 2.2.2 Inefficiencies of the legal framework

2.2.2.1 Flexibility

Surface and groundwater pollution is a problem in many parts of Europe[19], even if the gravity and the exact type of pollutants vary between river basins. Although part of this divergence can be explained by the different natural, geological and hydromorphological conditions of each river basin, an important contribution comes from anthropogenic activities (from agriculture, industry, urban areas or other human activities), whose impact on the status of waters may be of different magnitude and last for variable time lengths. The legislation takes this fact into account by setting common standards for EU-relevant pollutants while leaving MS the freedom to set river basin specific standards for other pollutants, which play a role locally or regionally, but not per se EU-wide. Therefore, limited guidance for setting national chemical quality standards for RBSPs is prescribed in the WFD (Annex V section 1.2.6). This inherent flexibility has however resulted in poor comparability of the EQS values between MSs for RBSPs[20] and the corresponding monitoring schemes and regulatory measures. Furthermore, the contrasting methodologies used to select RBSPs also result in inconsistent identification of relevant substances. The FC concluded that 'this is an instance where the flexibility left to the MS has led to sub-optimal results'.

Similarly, the GWD allows considerable flexibility for MS when setting national threshold values (TVs) for the pollutants that are only relevant in some MS and therefore listed in Annex II. The process usually takes into consideration receptors, risks, and pollutant background levels. The inherent flexibility provided in the GWD has resulted in largely varied ranges of TVs across the EU[21]. For pollutants/indicators with at least 10 nationally established TVs, the differences range from a factor of 1 to 50. Some of these variations are logical, as they depend on the natural background levels determined by the geological nature of the area, but others depend exclusively on the methodologies used to set the TVs. The FC therefore concluded that the 'national' thresholds route does not work effectively, thus justifying harmonised EU action. Moreover, the voluntary nature of the Groundwater Watch

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[19] Of the 146,460 surface water bodies in Europe, 31% is affected by atmospheric pollution, 33% by diffuse sources and 15% by point sources (EEA).

[20] Surface water: Standard types and threshold values for RBSPs [table] and Surface water: Standard types and threshold values for RBSP [country overview]

List (GW WL) limits the evidence gathered of pollutants present in groundwater bodies, ultimately limiting the development of groundwater regulation and the establishment of TVs.

<u>Substances no longer found</u>

Emissions of some currently listed substances have decreased or ceased and the scientific consensus (considering legal bans of substances and actual measurements of the concerned substances) indicates that there may no longer be an EU-wide threat to surface water quality from some such substances. It stands to reason that the small numbers of MSs reporting failures, and the exceedances being of a very limited magnitude, that it is justifiable that these substances are candidates to be proposed for deselection as they no longer pose an EU-wide risks.

2.2.2.2 Resource intensity

The existing legal framework for updating the lists of pollutants is partially built on the Watch List system and occurs on a 6-year review cycle. Substances which are identified as having a significant EU-wide risk are then considered as candidates for the next review of the PS list. However, the noted time lag between revisions and simultaneous delay in obtaining conclusive data makes it challenging to have an up-to-date legislative alignment with science and a quick response to relevant health and environmental risks.

Furthermore, the reporting and data sharing system set up under EU water legislation could be improved via simplification and automation. Monitoring techniques utilising satellite data, automated sensing technologies, citizen science and smartphone applications are still under-implemented in some MS. Although progress has been made towards further digitalisation of monitoring and reporting, the potential is still far from exploited.

Box 6: Views on ways to improve policy effectiveness expressed during consultation activities
During the OPC, the vast majority of stakeholders supported all improvements listed in the questionnaire. Improved collection of data on new pollutants in a harmonised format via a common information platform was considered the most essential (average score of 4.2 on a scale from 1 – not at all – to 5 – very much; rated ≥4 by 77% of respondents). More swift updates of GWD Annexes (average score of 3.7; rated ≥4 by 62% of respondents) and of the priority substance list (average score of 3.6; rated ≥4 by 58% of respondents) were considered overall less important in future strategies to address pollution.

2.3 2.3 How likely is the problem to persist?

The problem of an insufficient level of protection of the ecosystem and human health is overall likely to persist. The dynamic baseline scenario (Chapter 0) shows that, despite the implementation of existing legislation and planned new initiatives that address the problem of pollution at source, pathway and end-of-pipe (IED and UWWTD revisions, PFAS ban, SUPD revision, etc.), there continues to be a need to track actual progress and identify pollutants of emerging concern also at the level of surface and groundwater bodies. Consequently, revising the EU water legislation is necessary to better protect the aquatic environment and public health from risks related to (emerging) toxic pollutants and their mixtures. All mentioned groups of pollutants have common problems that arise from legislation not being up to date with science, as well as a lack of harmonisation, inconsistent implementation, and burdensome data management due to lack of adaptation to digital progress.

2.3.1 2.3.1 Persisting industrial substances and PFAS pollution

In the past decade, scientists identified several industrial substances that act as environmental contaminants with estrogen-like properties including, dicofol, nonylphenols, PCBs, endosulfan and Bisphenol-A. Endocrine disruptors are e.g. found in food containers, plastics, furniture, toys, carpeting and cosmetics. Estrogenic hormones and endocrine disrupting chemicals (EDCs) are detected at polluting levels in surface waters, e.g. sites close to waste water treatment facilities, and in groundwater at various sites globally. There is evidence of a causal relationship between estrogens in the environment and breast cancer and prostate cancer. Estrogens also perturb fish physiology and can affect reproductive development in both domestic and wild animals (24).

The group of Per- and polyfluoroalkyl substances (PFAS) is extremely prevalent in Europe's water. Some PFAS are classified as Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB)[22]. The persistence, mobility and bio accumulative nature of PFAS leads to negative effects for human health and biodiversity. The bio-accumulative effects are e.g. illustrated by the results of an EU LIFE project which showed that Per-fluoro-octane sulfonic acid (PFOS, one of the many PFAS substances, used in stain repellents, impregnation agents for textiles, paper, and leather; in wax, polishes, paints, varnishes, cleaning products for general use, in metal surfaces, and carpets) concentrations in the livers of top predators are severely elevated compared to those present in the fish they eat.

Apart from PFAS used in firefighting foam, PFAS emissions from coatings of carpets, clothes, furniture, and paper (incl. food packaging), land spreading of residues from the paper industry, car wash facilities, etc. will continue to cause water related environmental and health concerns. Many countries[23] currently deal with a myriad of PFAS related problems at national level, e.g. by introducing PFAS restrictions and/or purification measures. The increasing number of national measures underlines the need to urgently adopt EU-wide harmonised quality standards. To avoid shifting the problem by substituting one PFAS substance by another, a quality standard must be set for PFAS substances as a group. This is particularly important for substances like (ultra)short-chain per-alkyl acid (such as trifluoroacetic acid - TFA) of which very little toxicological data are yet available, but which are rising and are expected to entail the same human health risks as other PFAS substances.

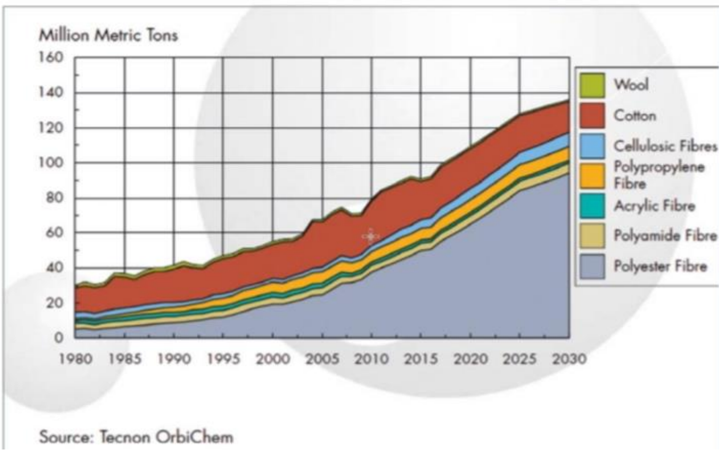
The harmful effects and persistence of PFAS are well-known; thus, several EU policies and initiatives already partly tackle PFAS pollution, such as the European Chemicals Agency (ECHA) proposal, under the Chemical Strategy for Sustainability, to ban forever chemicals like PFAS from firefighting foams (26).

2.3.2 2.3.2 Persisting microplastics pollution

[22] Perfluorohexane sulphonic acid (PFHxS) and its salts, perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and its salts, nonadecafluorodecanoic acid (PFDA) and its salts (https://echa.europa.eu/candidate-list-table)

[23] Countries like BE, DE, DK, ES, FR, IT, NL, SE and UK introduced (drinking water) standards up to a maximum 2 ng/l for PFAS substances. Also, Denmark introduced a national ban on PFAS in food packaging.

Microplastic pollution is omnipresent. Microplastics are detected in 80% of our livestock feed, blood, milk and meat (27), and is also present in human blood (28). Microplastic pollution spreads across borders, regions, species and ecosystems. An OECD report (29) echoes the scale of the problem, indicating that "microplastics have been observed in all surface waters and sediments of EU lakes (30) and rivers, as well as in drinking water". Scientists find microplastics practically in every water sample from EU lakes and rivers. Studies from 2016 on the annual amounts of plastics entering surface and groundwater report numbers between 1.15-2.41 million metric tons (31), whereas recent studies from 2021 already rate the global annual plastic input at between 9-23 million metric tons (14) (32) (33). In the absence of action, the amount of plastic waste entering aquatic ecosystems could triple (34) to around 53 million tonnes per year by 2030 (32) and quadruple by 2050. Recent research showed that 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 (35). 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 (14). 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 (36), 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 (see Chapter 0 and Annex 4). 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. For unintentional releases of microplastics from tyre wear, JRC estimates show a 16% increase in driving mileages from passenger road transport by 2030 and 30% for by 2050. Freight transport mileage is estimated to increase by 33% by 2030 and 55% by 2050 (37). Climate change effects, e.g. more frequent heavy rainfall events, will exacerbate the problems linked with releases of those microplastics via urban runoff and storm water overflows (SWO), which the upcoming revision of the UWWTD aims to at least partly reduce. Also, projections for unintentional releases from textile fibre foresee a 50% increase by 2030 under a business-as-usual scenario (see Figure 2.3.1).



2.3.3 2.3.3 Persisting pharmaceuticals pollution

Pharmaceutical products (mainly medicinal products, but also other personal care products) can act as environmental contaminants (38) (39) (40) (41) (42).

Personal Care Products (PCPs)

Personal Care Products (PCPs), including disinfectants, conservation agents, fragrances and UV screens, contain substances that are problematic in the aquatic environment such as silver, triclosan, microplastics and PFAS. Like pharmaceuticals, PCPs are designed to maximise their biological activity at low concentrations and produce a prolonged action. The major point source for PCPs are waste water treatment plants. Partially effective, the effluent of waste water treatment plants does contain PCP residues, subsequently reaching surface and groundwater.

Pharmaceuticals

Approximately more than 100,000 tons of medicinal products are consumed every year by human patients, the European Union (EU) market being the second biggest consumer in the world after the United States of America (USA) (43) (44). Moreover, 559 active pharmaceutical ingredients are found in environmental sectors such as surface water, groundwater, soil etc.

Some pharmaceuticals degrade relatively slowly, and their constant use can lead to continuous environmental releases exceeding degradation rates. While the EU has a proactive approach to reduce antibiotic use in animals as growth promotors / feed additives and preventive use (45), the projected worldwide increase in the use of antibiotics in feed used for rearing livestock animals (67% by 2030 compared to 2015 levels) (18) could nullify progress or even potentially aggravate the problem. Ageing populations will also lead to an increased use of pharmaceutical products increasing sales of medication 'over the counter', and a higher demand for control of health risks for vulnerable age groups. In Germany, pharmaceutical usage is projected to increase by 43-67% by 2045 as a result (from a baseline of 2015). It is estimated that around 8-10% of pharmaceutical substances in the environment originate from improperly disposed medicines - flushed down the toilet, poured into drains, or otherwise disposed inappropriately in household waste by patients or even by medical institutions (46) (47). Increasing awareness amongst citizens across the EU can therefore lead to a change in behaviour that can make a substantial difference; a fact recognised under EU waste policy. On top of the emissions from unused medicines, between 30-90% of the active ingredients in pharmaceuticals are excreted unchanged after consumption (48), and enter the environment via sewage treatment works[24]. Alongside metabolites and degradation products, they contaminate water and soil, threatening wildlife and human health. Incorrect disposal of unwanted drugs and pollution from pharmaceutical manufacturing plants further compounds the problem. In Portugal, 1% of the solid waste produced originates from the medicine sector (49).

Since conventional wastewater treatment plants are not equipped to fully remove pharmaceuticals from wastewater, concentrations of active pharmaceutical ingredients in soils, biota, sediments, surface water, groundwater and drinking water are likely to increase, and thus action at EU level is necessary. The IA underpinning the upcoming revision of the UWWTD states that pharmaceuticals represent a large share of potentially harmful substances found in wastewater, corresponding to the toxic environmental load of 264 million

[24] https://www.pharmaceutical-technology.com/comment/commentgreen-pharma-the-growing-demand-for-environmentally-friendly-drugs-5937344/

population equivalent (p.e.). Over half of this amount (158 million p.e.) comes from centralised treatment plants, with the rest emitted by other sources. Pharmaceutical pollution is also tackled via other EU policies[25] and initiatives such as the EU Strategic Approach to Pharmaceuticals in the Environment which proposed over 30 actions across the life cycle of pharmaceuticals (see Box 6 for a state of implementation).

Box 7: Status of the implementation of the Strategic Approach to Pharmaceuticals in the Environment

The EQSD, through article 8c of the amended Directive of 2013, required the development of a Strategic Approach to Pharmaceuticals in the Environment. Since its adoption in 2019, good progress has been made in implementing the 33 actions it contains (see Figure B1.1), with some being well advanced or already completed. Most notably, the possible revision of Urban Waste Water Treatment Directive (UWWTD) to address the increasing problem of micro-pollutants, is scheduled for adoption by the Commission this year. The introduction of new pharmaceuticals in the Surface Water Watch List[26], will increase knowledge about presence of pharmaceuticals in water. Within the same time frame, the revision of the pharmaceutical legislation, should lead to more effective Environmental Risk Assessment of pharmaceuticals. In addition, the EU is funding research projects on pharmaceuticals in the environment, e.g. support for the manufacturing of greener pharmaceuticals.

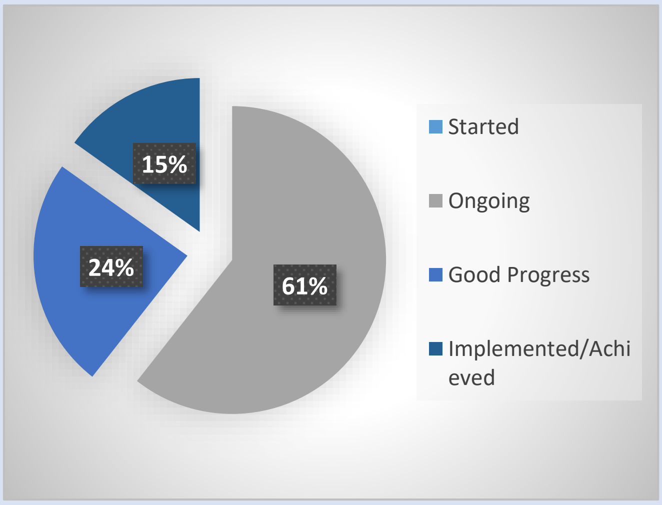


Figure B6.1: Status of actions under the Strategic Approach to Pharmaceuticals in the Environment

2.3.4 2.3.4 Persisting pollution from metals

Silver is a rare but naturally occurring metal, often found deposited as a mineral ore in association with other elements. Emissions from smelting operations, manufacture and disposal of certain photographic and electrical supplies, coal combustion, and cloud seeding are some of the anthropogenic sources of silver in the biosphere (CICADS, 2002). Silver is registered under the REACH Regulation and is manufactured in and /or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum[27], whereas ECHA

[25] Examples of EU legislation are mentioned in (124) and include Regulation (EC) No. 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents; 2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, etc.

[26] Commission Implementing Decision (EU) 2022/1307 of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council EUR-Lex - 32022D1307 - EN - EUR-Lex (europa.eu)

[27] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/40a35be9-f2e1-4221-b12b-4d3c3f8fcb9d

information from 2018 indicates that the current manufacture and use of silver amounts to between 100,000 – 1,000,000 tonnes /year[28]. The use of silver is steadily increasing (year-on-year increases vary between 5-13% in recent years)[29].

This substance is used in the following products: 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. 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 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). A number of silver substances are under evaluation under the Biocides Regulation (EU) No 528/2012 (BPR) . Some of the biocidal product types under which the substances are notified require the deliberate release of silver into water in order to exert the claimed effects, for example for human hygiene, disinfection of food and feed areas, disinfection of drinking water or the prevention of pathogens in cooling systems. Other applications may result in release of silver into the environment via the sewage system or when exposed to rain outdoor, for example preservation of paints or preservation of fibre, leather, rubber and polymerised materials.

When evaluating the end-of-life phase of silver containing products, it is assumed that their waste management (recycling, wastewater treatment, landfilling, and incineration) is similar to conventional products. Consequently, silver content in non-recycled waste ultimately ends up in the environment, as waste in landfills, emissions from wastewater treatment plants, or as residual waste from incineration plants.

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).

[28] 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

[29] https://www.silverinstitute.org/silver-supply-demand/

Scientific evidence 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[30]. Consequently, they are important as a 'last' resort for treating infections with multi-resistant bacteria[31]. 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[32]. 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.

An OECD project focusing on availability of vitro methods for the assessment of the genotoxic potential of nanomaterials, by specific testing of nanomaterials in a stepwise approach, evaluated the uptake of selected representative nanomaterials and their in vitro cytotoxicity. For silver it was demonstrated that silver NMs induced cytotoxicity to various degrees depending on the sensitivity of the used cell line [33]. While resistance to ionic silver is recognised for many years, many scientific studies also demonstrate increasing bacterial resistance to silver. Some resistance related mutations in bacteria are uniquely associated with resistance to NAg, while others are protective against both NAg and ionic silver. These mutations continued to be detected after the silver exposure had stopped, indicating that heritable resistance characteristics continue to spread even after discontinued silver use. This shows that silver cross-resistance occurs, and indicates the importance of avoiding heritable silver resistance. Avoiding Ag-resistance is extra relevant as scientific evidence demonstrates that, bacteria pre-exposed to sublethal dose of silver also exhibited increased resistance toward antibiotics (ampicillin and Pen-Strep) with the half maximal inhibitory concentration (IC50) elevated by 3 to 13-fold[34]. Scientific evidence of silver-driven co-selection of antibiotic resistance determinants is mounting and indicates that an increasing development of resistance to silver will additionally increase the resistance to other antibiotics. Consequently, it is of utmost importance to avoid (further) antibiotic resistances from emerging through the process of co-selection[35], e.g. by reserving the use of silver based antimicrobials only for treating infections[36], in order to preserve its efficacy.

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[30] 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

[31] 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/

[32] 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

[33] In vitro cytotoxicity and cellular uptake evaluation gold, silica and silver nanoparticles in five different cell lines: Caco-2, A549, CHO, V79 and TK6; Bogni Alessia et.al., 2022: https://publications.jrc.ec.europa.eu/repository/handle/JRC120791

[34] Mechanisms of antibiotic resistance in bacteria mediated by silver nanoparticles; Chitrada Kaweeteerawat, et.al., Journal of toxicological environmental health 2017; 80 p.1276-1289 https://pubmed.ncbi.nlm.nih.gov/29020531/

[35] 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

[36] Heritable nanosilver resistance in priority pathogen: a unique genetic adaptation and comparison with ionic silver and antibiotics: Elizabeth Valentin et.al. Nanoscale, 28 January 2020 p.2384-2392: https://pubmed.ncbi.nlm.nih.gov/31930233/

The widespread over-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 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. 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[37].

2.3.5 2.3.5 Persisting pesticide (incl. nrMs) pollution

Use of pesticides in Europe has not decreased in recent years. In 2019 almost 350,000 tonnes of herbicides were sold in Europe, for use in the agricultural sector. The continued high level of sales is consistent with measurements of high levels of pesticides in EU surface and groundwater bodies.

In 2021 the EEA assessed pesticide levels in surface and groundwaters between 2013 and 2019. The findings showed that one or more pesticides or their metabolites were detected above their effect threshold at 13-30% of all surface water monitoring sites each year. Exceedances were mainly caused by the insecticides imidacloprid and malathion in surface waters, and the herbicides MCPA, metolachlor and metazachlor. Exceedances of one or more pesticides were detected at between 3% and 7% of groundwater monitoring sites, mainly by atrazine and its metabolites (50). Atrazine, no longer approved for use continued to be found in groundwater due to its persistence.

Exceedance rates of more than 30% were reported in 13 out of 29 countries for surface waters and in one out of 22 countries for groundwater. High exceedance rates were mainly reported at monitoring sites in small and medium-sized rivers.

Pesticides and pesticide degradation products (often classed either as 'relevant metabolites', 'metabolites of no concern' or 'non-relevant metabolites', nrMs)[38], have been identified (51) in many surface water and groundwater bodies across the EU. New nrMs are emerging, whilst concentrations of known nrMs are increasing. Also, the impact of cocktail effects on (ground)water quality, i.e. from mixtures of various substances (incl. nrMs), remains unaddressed in the absence of EU action. Monitoring results from recent SW WL show increasing concentrations of pesticides across the EU. For groundwater ecosystems the

[37] 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-

[38] Sanco guidance (45), which is linked to the pesticide authorization regulation (EC 1107/2009), provides the following definitions:
Relevant metabolite as "a metabolite for which there is reason to assume that it has comparable intrinsic properties as the active substance in terms of its biological target activity, or that it has certain toxicological properties that are considered severe and unacceptable with regard to the decision-making criteria described in the text."
Metabolite of no concern as "a) CO_2 or an inorganic compound, not containing a heavy metal; or (b) 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) 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."
Non-relevant metabolite as "a metabolite which does not meet the criteria for "relevant metabolites" or that for "metabolites of no concern".
Some MS do not differentiate between nrM and relevant metabolites and consider all pesticide metabolites as "relevant metabolites".

situation is also worrying as they are generally more vulnerable to pollutants than freshwater ecosystems due to slower biological and physical degradation processes combined with longer residence times for water. This results in prolonged exposure times for groundwater flora and fauna due to longer persistence of chemicals. Also, given the great difficulty to restore contaminated groundwater bodies, an increased protection of groundwater ecosystems is essential. Although pesticide emissions are expected to be partly tackled by upcoming EU initiatives like the revision of the EU Sustainable Use of Pesticides Directive (SUPD), their combined anticipated effect in short- to medium-term is modest (an expected emissions reduction by 10-30% at best; see Chapter 0 and Annex 4) due to legacy pollution, the use of substitutes and stocks.

2.3.6 2.3.6 Implementation deficits

Most problems referred to under implementation deficits (Chapter 2.1.2) are intimately linked to the existing EU legislation and, therefore, certain to persist without changes made to it, or non-legislative measures with the same effect such as voluntary higher frequency reporting by MS. Issues linked to monitoring, reporting and the processing of data are a mixture of requirements of EU legislation and voluntary practices developed over the years. While incremental improvements (e.g. facilitating correct and efficient reporting) are continuously made, the implementation deficits will by and large persist if no further initiative is taken.

2.3.7 2.3.7 Best practice to reduce water pollution at EU level

The evaluations of the Industrial Emissions Directive (IED) and the EU Pollution Release and Transfer Register (E-PRTR) concluded that industrial installations covered by the IED /E-PRTR, account for about 20% of pollutant emissions by mass to water (52). Consequently, an effective implementation of the IED and E_PRTR, leads to reduced impacts on human health and the environment through lower emissions to air, water and soil, reduced waste generation and higher resource efficiency. Figure 3-7 from this evaluation shows that, for a number of pollutants, an absolute decoupling of the total mass emissions to water from industry Gross Value Added (GVA) took place. There is a visible declining trend for heavy metals (Cd, Hg and Pb). In the case of Nitrogen (N), Phosphorous (P) and Total Organic Carbon (TOC) releases have declined since 2007 as well, although to a lesser extent. At the same time, figure 3-8 of the same evaluation also shows that, based on 2017 data, despite the significant reductions seen to date in emissions from industrial activities, they still contribute a significant proportion of total EU emissions for some important pollutants.

3 3 WHY SHOULD THE EU ACT?

3.1 3.1 Legal basis

The WFD, EQSD and GWD are based on Article 192(1) of the Treaty on the Functioning of the European Union (TFEU) and so will be the revision proposal. Article 191(2) of the TFEU states policies shall be based on the precautionary, the polluter pays and the preventive action principles (see glossary). As recently re-affirmed by the Zero Pollution Action Plan and the zero-pollution hierarchy explained therein, further action needs to be taken according to these key provisions. While water quality standards for pollutants are science-based (see Chapter 5.1), the application of the precautionary principle is particularly pertinent for the pollutant groups of microplastics, PFAS and nrMs. According to the TFEU, the EU shares competences with MS to regulate environment and health in the field of water, while considering the principles of necessity, subsidiarity and proportionality.

Also, WFD Article 7(3) contains an obligation for MS to ensure the necessary protection for water bodies to avoid a deterioration of their quality and reducing the level of purification treatment required in the production of drinking water. This includes setting stricter values at EU level to ensure harmonised implementation of this requirement and contribute to compliance with the revised DWD. Finally, EU water legislation includes review clauses that enable the revision of the relevant annexes to adjust to technical progress and ensure that a high level of protection is maintained. Currently, the WFD Article 16(4) stipulates the Commission's obligation to review, every 6 years, the list of PS that pose a risk to the aquatic environment. Specifically, for surface water, the requirement to review Annex X of the WFD (the PS list) is enshrined in Article 8 of the EQSD; while, for groundwater, Article 10 of the GWD requires a review of Annexes I and II every 6 years.

3.2 3.2 Subsidiarity: Necessity of EU action

Surface and groundwater bodies in the EU are polluted by a range of different contaminants, ranging from residues of pharmaceuticals, pesticides, microplastics, industrial chemicals, metals, residues from products used domestically, and nutrients. While existing EU policies contribute to reducing the emissions at source as well as at pathways, only the setting of sufficiently strict environmental quality standards allows to check whether, across the EU, surface and groundwater pollution levels remain below concentrations harmful to the environment and/or human health – subject to proper monitoring and implementation by MS.

The potential for long-term and irreversible risks to 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.

Measures to be taken to reduce the presence of the listed pollutants are often a combination of EU (e.g. EU product bans or operating standards) and local action (e.g. industrial emission limits or waste water plant operating conditions adjusted to local circumstances). Addressing pollution without action at international level would in many cases be prohibitively expensive, especially for downstream countries. Therefore, action at EU level is of paramount importance. 60% of European river basin districts are international (either shared between MS or between a MS and a 3rd country) and the WFD made cooperation between countries sharing a basin within the EU mandatory. Pollution often finds its source in part or entirely in one country, making international cooperation essential to reduce pollution in a cost-efficient manner. Substances listed under the legislation automatically become part of the mandatory cooperation (for intra-EU river basins) or of the "endeavours" (for river basins shared with non-EU countries) MS are required to make according to WFD Article 13.

A failure to address risks from emerging pollutants swiftly via EU wide quality standards can lead to incorrect risk assessments for groups of substances regulated at EU level. This also leads to an underestimation of human health and environmental risks associated to certain groups of substances of very high concern. Finally, if unaddressed, the cumbersome reporting and a lack of data sharing between different legislative areas and between countries will continue to lead to potentially delayed and inefficient policy measures.

Box 7: Views on the relevance of EU water legislation expressed during consultation activities
OPC respondents considered the water directives and regulations highly relevant for environmental protection (average score of 4.2 on a scale from 1 – not at all – to 5 – very much), agriculture sector, wastewater treatment and health protection (each scored at 4.1), and biodiversity protection (4.0), with the relevance deemed highest at EU level (4.3) for all these areas. Overall, the directives were not seen as relevant for the circular economy (3.6), particularly at a local level (3.3).

3.3 3.3 Subsidiarity: Added value of EU action

The 2019 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. Experts interviewed during the FC consultation highlighted the power of a long-term binding policy target and the fact that the Directives' level of ambition is higher than what could have been expected without them. Additionally, stakeholders consulted for this Impact Assessment considered imposing stringent standards at EU level to be more effective in addressing surface and groundwater pollution than action at national level (see Box 8).

Box 8: Views on effective strategies to address surface and groundwater pollution expressed during consultation activities
During the OPC, stakeholders were asked to rate from 1 (not at all) to 5 (very much) the effectiveness of certain strategies in addressing surface and groundwater pollution. "Regulation of the application and use of pesticides and biocides" (average rating of 4.3, rated ≥4 by 74% of respondents) was considered to be the most effective, closely followed by "Regulations at EU level to ensure pollutant presence and exceedance are minimised through stringent standards", "Regulation of emissions from UWWTPs" and "Point source-based pollution control through regulation (legally binding)" (average rating of 4.2, rated ≥4 by 79%, 74% and 72% of respondents respectively). "Regulations at MS level to ensure pollutant presence and exceedance are minimised through stringent standards" were viewed to be less effective (average rating of 4.0, rated ≥4 by 68%)..

Specifically in relation to pollutants, the legislation distinguishes between substances most appropriately legislated at EU level and those to be regulated at river basin or groundwater basin level. The substances considered for addition to the pollutant lists belong to the first category as they raise an EU-wide concern (see Chapter 5.1.1 for explanation of how these are selected). This revision process also identified a small number of existing PS that are no longer considered substances of EU-wide concern, but which might still need to be addressed at national level as (RBSPs). Those substances are covered under surface water policy option 4 (possible deselection). For the latter, it supports a mechanism transferring former EU EQSs to an EU-wide repository of standards, to be applied if the substances are identified as RBSPs, to safeguard a harmonised approach to the extent possible, and thus contribute to maintaining a level playing field between MSs.

Market authorisation and risk assessment of many of the substances concerned takes place at EU level (e.g. pharmaceuticals, pesticides, industrial chemicals) even if national procedures co-exist, providing for a harmonised and cost-efficient approach, as well as a level playing field to those who sell and use the substances.

4 4 OBJECTIVES: WHAT IS TO BE ACHIEVED?

Having regard to the accelerated need to reduce the presence of toxic chemicals in water in light of the on-going triple planetary crisis (climate change, biodiversity and pollution), the aim of this regulatory intervention is to update the lists of substances and their quality standards set in the Annexes of the EQSD and GWD,whilst clarifying their importance for future drafting and assessments of RBMPs and modernising the modalities to keep them in pace with scientific and technological developments. .

4.1 4.1 General objectives

Taking into account the overarching objective of EU water policy, the general objectives of this initiative are t**o increase the protection of EU citizens and natural ecosystems** in line with the Biodiversity Strategy and the Zero Pollution ambition embedded in the European Green Deal, and **to increase effectiveness and reduce administrative burden** of the legislation, hence facilitating a quicker response to emerging risks. Both of these are long-term aims that will see limited positive progress without further action under EU water legislation. Whilst implementation of other EU and international policies can and will contribute to lowering the emerging risks to or via the aquatic environment (see dynamic baseline assessment in section 0 and Annex 4), none of the other initiatives can guarantee an adequate level of protection is achieved, hence rendering action under EU water legislation essential.

4.2 4.2 Specific objectives

The specific objectives represent the short-to-medium-term goals set to achieve the general objectives of this revision, and bring closer the overall aim of EU water legislation described above. The planned EU intervention would have the following specific 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.

Because these objectives aim to address specific shortcomings of the WFD, EQSD and GWD identified by the Fitness Check, they will not be influenced by other policy initiatives considered under the dynamic baseline (see section 0 and Annex 4).

5 5 WHAT ARE THE AVAILABLE POLICY OPTIONS?

The policy options were derived taking into account the identified problems and objectives as described in Chapters 2 and 4, respectively. The intervention logic, introduced in Chapter 2, explains how the main options are expected to address the problems, their drivers and consequences while delivering on the specific objectives.

This chapter outlines the methodology used to select candidate substances and set their quality standards (QS), describes the baseline in case of no legislative action in the field of water policy, and presents the policy options identified for consideration.

5.1 5.1 Methodology to select substances and set the quality standards

This section summarises the key elements of the technical processes carried out to prioritise substances for listing under EU water legislation and derive their respective QSs. Further details can be found in Annexes 4 and 5 of this impact assessment.

5.1.1 5.1.1 Substance selection

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.

There is an urgent need to address microplastics at source in view of the ever increasing loads of microplastics in EU surface and groundwater. A ban on the intentional use of microplastics in products, including fertilisers, cosmetics, detergents would prevent the release of 500,000 tonnes of microplastics into the environment over a 20-year period. Because of that, microplastics were considered but were not taken further as candidate PS because there is too little data to perform an actual risk assessment. Consequently, gaps in relation to the measurement, monitoring and data collection of the actual concentrations of microplastics in surface and groundwaters need to be addressed first, to allow setting an actual EQS in a second stage.

The prioritisation process for groundwater serves as a basis for the determination of substances to be selected either for the voluntary Groundwater Watch List (GW WL), or for the List Facilitating the Review (LFR) of Annexes I and II of the GWD. The GW WL provides a list of substances that MS should consider adding to their monitoring programmes on the basis that these pollutants may present an obstacle to the achievement of the environmental objectives of the WFD. This is key to obtaining data for new or emerging pollutants, feeding into the development of the GWD. Under the umbrella of the Working Group Groundwater (WG GW), the sub-group on the voluntary GW WL has contributed to assessing data provided by the participating countries and the subsequent compilation of the LFR for this initiative. Pollutants on the LFR go through the quality standard derivation process as described below and are then included in the impact assessment. The process resulted in a group of 10 PFAS, 2 individual pharmaceuticals and a group of 16 nrM substances being selected (22).

It should be stressed that the prioritisation of substances for listing is based on the conclusion that they pose a risk at EU level, i.e. in all or most MS. The monitoring required as a result of the substances proposed for listing will inform future revisions of the lists. In this context, it should also be noted that the initiative considers various improvements to the monitoring regime (see Section 5.2.3), thereby improving future data availability.

5.1.2 5.1.2 Setting the limit values

The derivation of quality standards for selected substances (or 'quality standards derivation process') follows scientific methods and is subject to several rounds of scrutiny, as illustrated in Figure 5.1.1. 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 (53) 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.

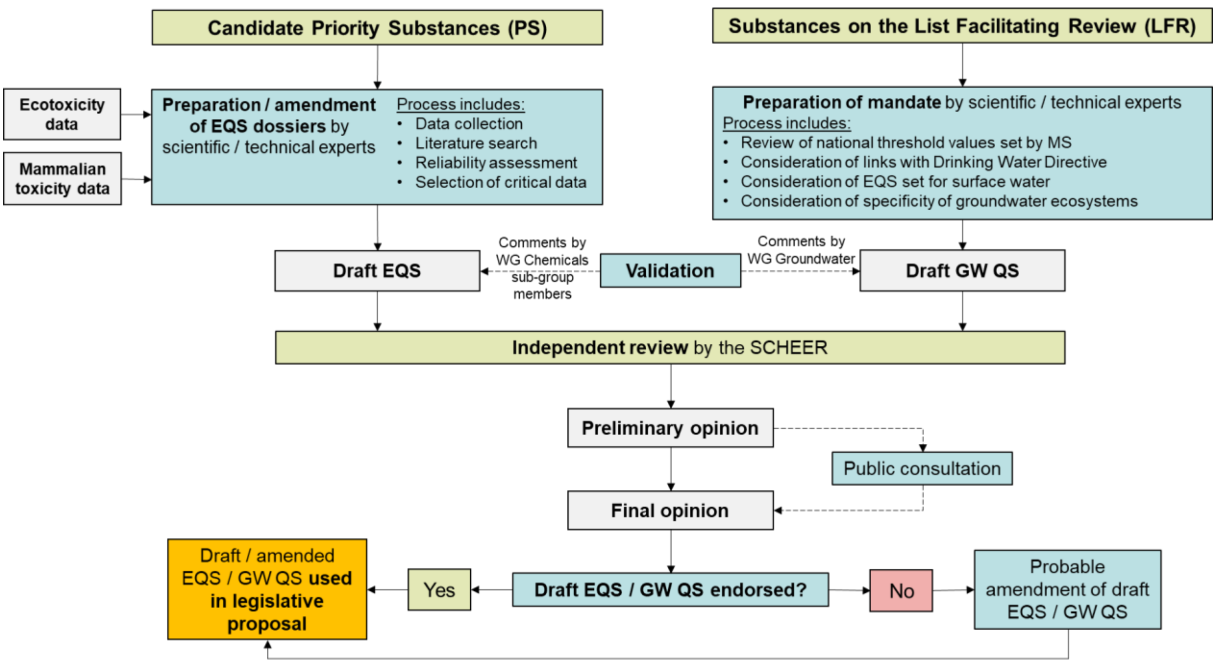


Figure 5.1.1: Process of setting limit values for surface water and groundwater pollutants

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, available at this point in time (September 2022). QS for substances for which no preliminary or final opinions are available, are based on the dossier prepared by the Commission for SCHEER. The QS for these substances are denoted by square brackets throughout the Impact Assessment and the Proposal. As opinions arrive, square brackets will be removed.

What is the baseline from which options are assessed?

The baseline describes a situation where no further changes would be introduced in policies directly affecting EU water quality (i.e. the WFD, EQSD and GWD). In designing the baseline, it is assumed that the identified problems would remain, although their scale would be impacted by external trends influenced by existing and upcoming policy interventions (e.g. possible chemical substitution of a banned substance) and other non-policy drivers (e.g. demographic developments). The dynamic baseline therefore reflects the likely changes to emissions and, by proxy, environmental concentrations in a "business-as-usual" scenario.

To understand how the policy landscape will change the baseline situation, each candidate substance was assessed against each relevant EU and international policy instrument, indicating the expected range of impact on emissions. The outcome of this exercise is provided in Table 5.1.1.

For many of the substances, efforts are already being made under other legislation which might have a beneficial impact for the aquatic environment. This includes initiatives like the review of the industrial emissions directive (IED) and the UWWTD, as well as upcoming EU initiatives on micro-plastics and PFAS. The most significant of these is for PFAS, which have been a core focus within the EU Green Deal and are reflected across a basket of legislation (most notably the upcoming REACH initiative to ban non-essential uses). The Pharmaceutical Strategy should address issues with many pharmaceuticals, however, for non-prescription medicines like ibuprofen data gaps are larger and controls look weaker, suggesting emissions will continue to grow in line with affluence, availability, and an ageing population. The continuous implementation of the existing Programmes of Measures (PoMs) under the WFD as well as the target under Farm to Fork Strategy to limit use of hazardous pesticides will likely reduce pesticide releases to the environment. These could have synergistic benefits for the candidate PS that are pesticides and their non-relevant metabolites. Only five parent pesticides of the 16 nrMs listed in the LFR are still authorised: glyphosate, metazachlor, flufenacet, dimethachlor, and fluopicolide. The bans already in place for the other parent pesticides of the remaining nrMs are expected to entail, over time, significant reductions in the concentrations of nrMs in groundwater. A detailed overview of the dynamic baseline and the expected contribution of EU initiatives for pollutants is included in Tables A4.1 and A4.2 in Annex 4.

For four candidate PSs as well as five substances considered for EQS amendment, no significant decrease or increase in emissions (+/- ≤10%) was found, even in the presence of other key policies aiming to drive down emissions. The 'no change' outcome is the product of complex issues, such as multiple pathways to the environment, other drivers, or legacy issues which are likely to prevent real change in emissions to water before 2030 and therefore necessitating additional measures by MS if their water bodies fail to meet the standards set. For all five existing PS that have been proposed for deselection, the baseline is also considered to be no change in the current situation. This is because three of these chemicals are banned for many years, and emissions of the other two appear to be stable for years.

Table 5.1.1: Outcomes of the dynamic baseline assessment

Policy option	Significant reduction (30% - ≤50%)	Some reduction (10% - ≤30%)	No change (≤10%)
Substances considered for addition to PS list / GWD Annexes	Pharmaceuticals: Macrolide antibiotics (azithromycin, clarithromycin, erythromycin) Industrial chemicals: PFAS	Pharmaceuticals: Diclofenac, Carbamazepine, estrogenic hormones (E1, E2, EE2) Pesticides: Neonicotinoids (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam), Pyrethroids (Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin), Nicosulfuron, nrMs Industrial chemicals: Microplastics Metals: Silver	Pharmaceuticals: Ibuprofen Pesticides: Triclosan, Glyphosate Industrial chemicals: Bisphenol A
Substances considered for amendment of existing EQS	Metals: Mercury	Pesticides: Chlorpyrifos, Cypermethrin, Diuron, Tributyltin Industrial chemicals: PAHs, Nonylphenol, PBDEs Metals: Nickel	Pesticides: Dicofol, Heptachlor / Heptachlor oxide, Hexachlorobenzene Industrial chemicals: Dioxins, Fluoranthene, Hexachlorobutadiene, HBCDD
Substances considered for deselection from PS list			Pesticides: Alachlor, Chlorfenvinphos, Simazine Industrial chemicals: Carbon tetrachloride and Trichlorobenzenes

Note: Baseline assessment does not account for the revisions of the UWWTD and SSD as these were premature at the time of analysis.

The dynamic baseline reflects emission rates to water and does not consider the persistence or residence time in different environmental compartments, which would have a further impact on ambient concentrations. Furthermore, physical properties and environmental fate will vary substance by substance, adding uncertainty to this analysis. However, consideration of emission control under existing or upcoming policy interventions helps understand whether we could expect the ambient concentrations in water to go up, down, or remain broadly similar to current levels.

5.2 5.2 Description of the policy options

5.2.1 5.2.1 Surface water policy options

Based on the problem definition for surface water and to address specific objective 1 of this initiative, a total of four policy options were identified (listed in Table 5.2.1 below) that **add substances** to the existing PS list, **change environmental quality standards** or **deselect (remove) currently listed substances**. Policy options 1 and 2 focus on the listing of new candidate substances, i.e. if and how (e.g. individually or as groups[39]) they should be listed, therefore constituting an "either-or" selection as they represent different approaches for the same candidate substances. Policy options 3 and 4, on the other hand, are independent of all other options and the choice there is only whether, for each of the substances involved, the respective option should be implemented. The recommended EQSs for each substance or group of substances under Options 1, 2 and 3 are listed in Annex 8.

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 priority hazardous substances (PHS) since the regime of possible measures is different. Measures for PS are mainly aimed at reducing emissions in view of complying with the EQS values, whereas measures for PHS are aimed at phasing out emissions entirely. From all the candidate substances under consideration, only PFAS and Bisphenol A (BPA) meet the criteria for PHS status.

Table 5.2.1: Surface water policy options

Policy option	Description	List of substances
Policy option 1:	***Additions***. Include each candidate priority substance **individually** 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*:*** 24 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***. Include candidate priority substances **as groups of substances where appropriate.** 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.	**Pesticides:** Chlorpyrifos, Cypermethrin, Diuron, Dicofol, Hexachlorobenzene, Heptachlor/Heptachlor epoxide **Industrial chemicals:** Dioxins, Fluoranthene, Hexabromocyclododecane, Hexachlorobutadiene, Nonyl phenol, PAHs (*consisting of following 5 PAHs: Benzo(a)pyrene (marker for other compounds); Benzo(b)fluoranthene; Benzo(k)fluoranthene; Benzo(g,h,i)perylene; Indeno(1,2,3-CD)pyrene*), PBDEs, Tributyltin **Metals:** Mercury, Nickel
Policy Option 4:	***Deselection.*** Remove substances from the list following agreed deselection criteria.	**Pesticides:** Alachlor, Chlorfenvinphos, Simazine **Industrial chemicals:** Carbon tetrachloride and

[39] This covered the possible grouping of the three estrogenic substances, three macrolide antibiotics, five neonicotinoid pesticides, four pyrethroid pesticides and 24 PFAS substances. Also including pesticides as a group in surface waters is considered as part of option 2, with a group standard of 0.5 µg/l, i.e. corresponding to that in the GWD and the DWD.

Policy option	Description	List of substances
		Trichlorobenzenes

It should be noted that the legislation currently provides MS with a period of time to comply with the newly listed substances and the modified TVs, going beyond the 2027 deadline for achieving good chemical status set in the WFD. For revised surface water EQS this additional time was set[40] at 6 years (2021, plus 12 more years in case of technical infeasibility or disproportionate cost). For new surface water substances, it is 12 years (2027, plus 12 more years in case of technical infeasibility or disproportionate cost).

Box 9: Views on surface water options expressed during consultation activities
Option 1: Overall agreement for including all candidate substances on the Priority Substance list, with ≥55% of TEC respondents supporting listing PFAS, BPA, Diclofenac, Carbamazepine and Ibuprofen.
Option 2: Clear preference for PFAS and slight preference for macrolide antibiotics to be added as groups rather than individually.
Option 3: More stringent EQS values were supported for Chlorpyrifos, Diuron (AA/MAC) and PAHs (biota); whereas current AA/MAC EQS for Nickel and biota EQS for Mercury, Hexachlorobenzene and Hexachlorobutadiene were considered correct. Views that EQS should be less stringent for Heptachlor/heptachlor epoxide (MAC) and PBDEs (biota) were expressed.
Option 4: ≥50% of TEC respondents saw no EU-wide risk for Alachlor, Chlorfenvinphos and Simazine.

5.2.2 5.2.2 Groundwater policy options

Three policy options have been developed to address the pollution of groundwater by PFAS, pharmaceuticals and nrMs. The major policy choice is whether to add these emerging contaminants to Annex I (as individual substances or groups) or Annex II of the GWD. Additions to Annex I must be accompanied by an EU-wide groundwater quality standard (currently covered are nitrates, pesticides and their relevant metabolites), whilst substances added to Annex II must be considered by MS during the risk assessment phase of river basin management planning, and appropriate TVs set at national level.

The options, listed in Table 5.2.2, represent an "either-or" choice for each of the substances (or groups of substances), which are assessed independently of each other under each option. The SCHEER endorsed quality standards are based on available (eco)toxicological data, harmonised with surface water quality standards in several cases, and, where necessary, the precautionary principle. All of the options address specific objective 1 of this initiative.

Table 5.2.2: Groundwater policy options

Policy option	Description	List of substances
Policy Option 1	**Add** LFR substances **to GWD Annex I individually or as a group of specific chemicals**, and assign an individual or a "sum of" EU-wide GW QS respectively.	**Industrial chemicals:** PFAS (Group of 24 as for surface water) **Pharmaceuticals:** Carbamazepine and Sulfamethoxazole **Pesticides:** All nrMs
Policy Option 2	**Add** LFR substances **to GWD Annex I as groups of all**, and assign an EU-	**Industrial chemicals:** All PFAS **All Pharmaceuticals**

[40] At the most recent revision, in 2013; for groundwater the current initiative is the first revision.

Policy option	Description	List of substances
	wide GW QS for the group "total".	**Pesticides:** All nrMs
Policy Option 3	**Add** LFR substances **to GWD Annex II** for MS to consider setting a TV for specific substances posing a risk to groundwater bodies (GWBs).	**Industrial chemicals:** All PFAS **All Pharmaceuticals**, Carbemazepine and Sulfamethoxazole are included in the minimum list of pollutants (part B). Additionally, as a guideline, a reference to the GWWL is added, which includes nine pharmaceuticals **Pesticides:** All nrMs

Box 10: Views on groundwater options expressed during consultation activities

PFAS addition to Annex I was most strongly supported in the targeted expert survey. Listing a limited number of named PFAS was favoured by 49% of respondents, whereas 19% preferred including all PFAS with a group 'total' standard.

The general consensus for pharmaceuticals was to include them in Annex I (individually - 33% of TEC respondents; all as a group – 18%). Annex II listing was favoured by 27% of respondents.

Most TEC participants endorsed inclusion of nrMs in Annex I (46% favoured listing a limited number of named nrMs with individual QSs, whereas 13% preferred including all nrMs with a group 'total' standard). Annex II listing was supported by 23% of respondents. Contrasting views on the quality standards were expressed during all consultation activities, with industry stakeholders preferring less stringent QS, and MS and drinking water sector representatives noting the widespread presence of nrMs in groundwater and urging stricter regulation at EU level.

5.2.3 5.2.3 Monitoring, reporting and administrative streamlining options

To address specific objectives 2 to 5 of this initiative, 15 discrete actions were identified. These were categorised into four groups of policy options based on their subject matter (e.g. monitoring, reporting) and nature (e.g. voluntary, legislative). Table 5.2.3 lists the four policy options and the respective specific sub-options considered under each. The four thematic policy options are not mutually exclusive and all the (sub)options can be implemented in combination with each other within and across these groupings. All these (sub)options are complement the surface and groundwater-specific options described above.

Providing / improving guidance and advice on monitoring, including Effect Based Methods (EBMs), modern instruments, digital techniques etc., is necessary to address the significant pressures stemming from emerging pollutants (such as microplastics) and possible cumulative effects of pollutant mixtures. 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 like setting an EQS/GW QS. In addition, there are a range of innovative monitoring techniques, including automated sensing technologies, which could provide important insights into pollutant levels, but which are yet to be commonly adopted. Improved sharing of knowledge and best-practices among MS may help facilitate wider implementation of such innovative methods.

Establishing / amending existing obligatory monitoring practices is needed to gather more specific evidence on the evolution of pollution. Mandatory monitoring would help fill the existing data gaps (e.g. on the combined effects of estrogenic substances, emerging pollutants in groundwater, seasonal variations of emissions in surface waters) and inform future risk assessments.

Actions to *harmonise / simplify reporting and classification* would improve transparency and access to data as well as reduce the administrative burden of MS in the medium and long term.

Box 11: Which kind of information are stakeholders interested in?

During the OPC, the majority of respondents indicated a need for access to more information for all of the items listed in the questionnaire (i.e. average rating ≥3.5 on a scale from 1 – not at all – to 5 – very much). Stakeholders expressed the most interest (average score of 4.2) in information on the presence and concentration of individual/groups of pollutants (rated ≥4 by 80% of respondents) as well as sources, nature and associated risks of pollutants (rated ≥4 by 79% of respondents).

The *legislative and administrative changes* are needed to enable more effectiveness, efficiency, coherence, responsiveness and flexibility in the legislation.

Table 5.2.3: Policy options related to monitoring, reporting and administrative streamlining

Policy Option	Description	List of sub-options	Objective addressed
Policy Option 1	Provide / improve guidance and advice on monitoring	a) Develop guidelines on applying innovative methods in monitoring procedures, including continuous/automated monitoring techniques.	Specific objective 2
		b) Follow-up to improve existing guidelines on EBMS in view of setting application 'trigger values' in practice to improve monitoring of groups/mixtures of pollutants by using EBMs, and trigger values.	
		c) 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.	Specific objectives 2, 3
		d) Develop guidelines on sampling frequency for PS and RBSPs.	Specific objective 2
		e) Provide a repository for sharing best practices from MS regarding available monitoring techniques, and foster cooperation to implement these.	
Policy Option 2	Establish / amend obligatory monitoring practices	a) Include an obligation in the EQSD to use EBMs to monitor estrogens.	
		b) 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.	Specific objectives 2, 3
		c) Improve the monitoring and review cycle of the SW WL so that there is more time to process the data before revising the list. *Suggested improvements consist of a) increasing the monitoring frequency for pollutants with seasonal emission patterns (e.g. pesticides); b) extending the obligatory monitoring period from 12 to 24 months; and c) increasing the review frequency from 24 to 36 months (by modifying WFD Article 8b).*	Specific objective 2
Policy Option 3	Harmonise / simplify reporting and classification	a) 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.	Specific objective 5
		b) 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	Specific objectives 3, 5
Policy Option 4	Legislative and administrative aspects	a) 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.	Specific objective 4
		b) 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*	Specific objective 3
		c) 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	Specific objective 1

[41] The maximum number of substances that can be included for monitoring might differ for the surface and the groundwater watch lists.

5.3 5.3 Options discarded at an early stage

For the identification of possible policy measures, a two-step approach was used. In a first step, a wide range of possible measures were identified. For each problem, different solutions were envisaged, ranging from soft approaches - mainly based on non-binding guidance to MS - up to stricter regulatory measures. In a second step, based on a 'feasibility' screening, a selected number of possible policy measures were retained for further analysis.

The option of not updating other aspects of this legislation that are not directly linked to chemical pollution was discarded early on, given the outcomes of the FC and the political commitment not to seek a change in the WFD in the short run. Also rejected was the option in relation to targeted substances to directly ban certain pharmaceuticals, pesticides or other chemicals. In all these cases the EU has a well-functioning system of risk-screening before market authorisation for their intended use. Therefore, while possibly effective from an environmental standpoint, these options would be inconsistent with the established policy approaches. As regards substitutes for potential new substances, the impact assessment did not consider substitutes that are over 3.5 times more costly than the original substance, as beyond this price difference they are no longer regarded as a realistic substitute (substitutes considered are detailed in Annex 10).

6 6 WHAT ARE THE IMPACTS OF THE POLICY OPTIONS AND WHO WILL BE AFFECTED?

This section describes the impact assessment methodology, discusses the impacts of policy options and stakeholders particularly affected by them. The assessment of the addition or removal of substances or groups of substances selected through the methodology described in Chapter 5.1 has been based on the distance to target, including application of the dynamic baseline, and an assessment of additional measures that might be needed to achieve the recommended quality standards (listed in Annex 8).

Note that EU water legislation does not specify exact measures to be taken to reach a given water quality standard. Therefore, the **assessment of possible costs and benefits** of policy options **is based on the potential measures that MS might take** because of this initiative, **additionally to the existing measures and any requirements imposed by other EU legislation**.

It is not possible, in this impact assessment, to identify the isolated cost and benefit of listing substances since this will depend on measures chosen by MS and on distance to target in the concerned water bodies. Moreover, water legislation works in sync with other legislation (waste water treatment, source control, international requirements, etc). Figures in this section and in section 8 are therefore often related to estimated costs / benefits from groups of substances with similar characteristics or effect (eg cost of removing all PFAS, or all health effects of hormone disturbing chemicals) but are not to be understood as costs and benefits solely associated with this initiative.

A more detailed overview of impacts, for each of the surface water and groundwater options, can be found in Annex 9.

Box 12: Implications of listing a substance under the water legislation
For **surface water**, MS might need to: • Monitor concentrations to obtain representative information of the water body and its chemical status. • In case of EQS exceedances MS must act (source control measures take priority over others). • If a substance is persistent, mobile and toxic (PMT) and/or very persistent, very mobile (vPvM) and thus also bio-accumulates, then it is classified as priority hazardous substance (PHS). • For priority substances (PS) MS must implement measures to progressively reduce pollution, for PHS MS must implement measures to cease or phase out emissions completely. • Include new substances in the national inventory of emissions, containing a timetable for cessation or phase-out, and reduction. For **groundwater**, MS might need to: • Implement measures necessary to lower concentrations of any pollutant in groundwater and therefore progressively reduce pollution. • Take all measures necessary to prevent inputs into groundwater of any hazardous substances covered by the groundwater quality standards in Annexes I and II of the GWD.

6.1 6.1 Impact assessment methodology

6.1.1 6.1.1 Distance to target

An important factor to understand the impacts of adding new substances to the lists of pollutants or amending existing EQS values is the 'distance to target'. This refers to the size of the gap between the baseline situation and the target considered within the policy option. The indicative assessment of the potential exceedances above the envisaged limit values helps evaluate the likely extent of measures required to address the issue.

The 'distance to target' assessment followed a two-step process. First, the substances considered under each option were assigned to groups (large / medium / small) based on the predicted geographic scale (i.e. how many water bodies might fail chemical status; how many MS might need to take measures) and the magnitude (i.e. how far above the thresholds do concentrations rise) of the current gap. The general criteria for these groupings is shown in Table 6.1.1 with further caveats (e.g. specificities for SW and GW assessment) explained in Annex 4.

Table 6.1.1: General scale and magnitude criteria for the distance to target assessment

Distance to target group	Scale criteria (based on monitoring data)	Magnitude criteria (based on exceedances compared to new quality standards)
Small	Predicted exceedances in ≤33% of MS	Mean monitored concentrations ≥0 and ≤33% over the new QS
Medium	Predicted exceedances in >33 and ≤66% of MS	Mean monitored concentrations >33 and ≤66% over the new QS
Large	Predicted exceedances in >66% of MS	Mean monitored concentrations >66% over the new QS

There is currently not enough detailed information to allow the distance to target to be determined for each Member State vis-à-vis each substance or group of substances under consideration. Indeed, the monitoring data underpinning such measurement (typically gathered from the SW WL, the GW WL and the WFD reporting) are in a number of cases incomplete. In such cases, extrapolation considering authorisation, use and emission data, and expert judgement are used to obtain an indication of the existing scale and magnitude of pollution (see Annex 4 for details).

Secondly, the dynamic baseline assessment (described in Chapter 0) was taken into account to reflect the expected change in emissions due to other (policy) drivers. The final **distance to target**, therefore, **reflects the additional EU-wide effort that may be required to tackle the pollution caused by the candidate substances**. Where there are no EU-wide measures introduced by other policy initiatives, MS will have to take action nationally, and the (large / medium / small) distance to target indicates the average relative effort required to tackle the relevant substances. Results of the distance to target assessment are presented in dedicated surface and groundwater sections below.

6.1.1.1 Surface water

The distance to target for surface water Option 1 (addition to PS list individually) and Option 2 (addition to PS list as groups) has been determined using a combination of monitoring data gathered from the SW WL and the assessment conducted within the EQS dossiers. The baseline situation is represented by the current concentrations measured in surface water, whereas the target is the value considered protective of human health and the aquatic ecosystem (i.e. the scientifically recommended EQS; see Annex 8).

An overall relatively **large** distance to target was estimated for 3 pharmaceuticals (17 alpha-ethinylestradiol (EE2), Diclofenac, Carbamazepine), Silver, 5 pesticides (Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin, Glyphosate) and 2 industrial chemicals (PFAS, Bisphenol A).

An overall **medium** distance to target was estimated for 4 pharmaceuticals (17 beta-estradiol (E2), Estrone (E1), Azithromycin, Ibuprofen), 2 pesticides (Imidacloprid and Triclosan) and 1 metal (silver and its compounds).

An overall **small** distance to target was estimated for 2 pharmaceuticals (Clarithromycin, Erythromycin), and 5 pesticides (Acetamiprid, Clothianidin, Thiacloprid, Thiamethoxam and Nicosulfuron).

A slightly amended approach was used to assess the distance to target for surface water Option 3 (EQS amendment), because the impact assessment looked at possible additional efforts required to tackle these substances once their EQS is amended. The baseline situation is, therefore, represented by the current gap between concentrations measured in surface water and existing EQS, whereas the target is the new scientifically recommended EQS.

The scale and magnitude of the current gap has been determined using a combination of monitoring data gathered from the WFD reporting and the assessment conducted within the EQS dossiers. Then, based on the new recommended EQS (where available, see Annex 8) and guidance from the JRC, an assessment has been made as to whether the size of the gap would increase, decrease, or stay the same following EQS amendment. Afterwards, as for other policy options, the impacts of the dynamic baseline (see Chapter 0) were taken into account to re-group substances.

An overall relatively **large** distance to target was estimated for 1 industrial chemical group (PBDEs) and 2 metals (Mercury, Nickel).

An overall **medium** distance to target was estimated for 4 pesticides (Chlorpyrifos, Cypermethrin, Diuron, Tributyltin) and 2 industrial chemical groups (Dioxins and furans, PAHs).

An overall **small** distance to target was estimated for 3 pesticides (Dicofol, Heptachlor / Heptachlor epoxide, Hexachlorobenzene) and 3 industrial chemicals (Fluoranthene, Hexachlorobutadiene, Nonylphenol).

6.1.1.2 Groundwater

Unlike the surface water situation, an EU-wide monitoring network of emerging groundwater pollutants does not exist. Therefore, the likely current day status of groundwater bodies (GWBs) with respect to the LFR pollutants is needed to understand how much effort might be required to reach the targets proposed by the various policy options. This baseline assessment was made by reviewing the most recent reported status of GWBs (i.e. 2nd River Basin Management Plans covering the 2015-2021 period) and the chemicals leading to failure with similar emission characteristics and environmental fate along pathways to groundwater. The scale was represented by % of MS likely to report failure, whereas the magnitude was defined as the level of exceedance above TVs already used by MS for the proxy substances.

Then, the expected distance to target was assessed based on expert judgement and the indication of the likely level of exceedance over the potential PFAS, pharmaceuticals and nrMs TVs. The level of exceedance is estimated by calculating the proportion of monitoring locations and MS reporting concentrations above the targets stipulated in the policy options. Afterwards, the impacts of the dynamic baseline (see Chapter 0) and the lag-time of groundwater ecosystems were taken into account to adjust the grouping. For example, although PFAS emissions are expected to reduce significantly due to other policy interventions, this will be reflected in groundwater concentrations much later, therefore having no impact on distance to target before 2030.

An overall relatively **large** distance to target was estimated for PFAS under all options as well as nrMs under Option 1 (all individually in Annex I).

An overall **medium** distance to target was estimated for pharmaceuticals under Option 2 (group of all in Annex I), and nrMs under Option 2 and Option 3 (addition in Annex II).

An overall **small** distance to target was estimated for pharmaceuticals under Option 1 (carbamazepine and sulfamethoxazole in Annex I) and Option 3 (group in Annex II, considering Primidone).

6.1.2 6.1.2 General considerations for all surface and groundwater options

Impacts of the policy options related to the (de)listing of surface water and groundwater substances are dependent on the specific measures taken to reduce the presence of pollutants. Measures come in four groups: source control (e.g. substitution, bans, emission prevention at production stage), pathway disruption (physical barriers preventing/reducing pollution to surface and ground-waters), end-of-pipe[42] (in this case treatment measures

[42] End-of-pipe treatment indicates the separate treatment of the generated pollutants before entering the environment. This usually occurs either directly after the production process and/or after the use phase.

preventing/reducing pollution at the waste water stage) and finally monitoring and risk attenuation at water bodies' level.

Key sectors likely to be impacted by groups of measures were identified. In many cases, the same measures are effective for addressing multiple substances in a complementary fashion. The importance of different measure categories varies depending on the substance. Table 6.1.2 provides a quick reference for how the measure categories relate to the substance categories. Then, an overview of stakeholders possibly impacted by the implementation of identified measures is presented in .

Table 6.1.2: **Overview of measure categories and substance categories**

Control Option	Pharmaceuticals	Pesticides		Industrial chemicals	Metals
		Plant Protection Products	Biocides		
Intervention at source	✓	✓	✓	✓	✓
Pathway disruption	✓*	✓		✓***	✓
End-of-pipe	✓		✓	✓	✓
Risk containment, monitoring, and natural attenuation		✓**		✓	

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

Table 6.1.3: Overview of stakeholders likely impacted by measures identified (surface and groundwater)

Pharmaceuticals	Pesticides (incl. nrMs)	Industrial Chemicals (incl. PFAS)	Metals
Pharmaceutical and Personal Care Products manufacturers and distributors (ranging from SMEs to multinationals) (EPR)	Pesticide manufacturers and distributors	Manufacturing e.g. of raw chemicals, clothing, cosmetics textiles, printing	Mining operations sector
Healthcare sector	Healthcare sector	Manufacturing and use of chemicals, disinfectants (multiple sectors)	Manufacturing industries – particularly smelting and use in electronics / automotive.
Farmers and veterinary applications – farmed animals and horses	Farmers (ranging from SMEs to multinationals) and landowners	Infrastructure and roads	Healthcare sector e.g. biocidal applications
Society - costs to consumers/	Veterinary applications – particularly biocides, farmed animals and domestic pets	Society - costs to consumers	Society - costs to consumers
Wastewater and drinking water companies (mainly SMEs)	Society - costs to consumers	Wastewater and drinking water companies (mainly SMEs)	Wastewater and drinking water companies (mainly SMEs)
Member State Authorities – guidance and enforcement	Wastewater companies (biocides) (EPR) and drinking water companies	Member State Authorities – guidance and permitting	Member State Authorities – mine drainage and landfill

Pharmaceuticals	Pesticides (incl. nrMs)	Industrial Chemicals (incl. PFAS)	Metals
			sites.
	Member State Authorities – guidance and enforcement	Waste disposal (Landfill)	

6.2 6.2 Surface water – impacts of policy options

This section provides a summary of the associated environmental, economic and social impacts of individual policy options. The evaluations of the Industrial Emissions Directive (IED) and the EU Pollution Release and Transfer Register (E-PRTR), pieces of legislation with which the WFD interacts strongly, notably on water management, concluded that industrial installations, covered by the IED /E-PRTR, account for about 20% of pollutant emissions by mass to water this includes among others the main groups of pollutants covered by this evaluation (pharmaceuticals, industrial substances, and metals). For pesticides the picture is different since the main emitter of those substances is the agricultural sector who is the end-user of the products produced by industry.

6.2.1 6.2.1 Policy option 1 – listing candidate PS individually

Option 1 applies to all substance categories (industrial/pharmaceuticals/pesticides/metals).

<u>Industrial chemicals (PFAS and Bisphenol-A)</u>

Important sources of PFAS emissions are the primary manufacturers of manufacturers of fluorochemicals and/or fluoropolymers, as well as cardboard and paper mills producing PFAS coated paper for a myriad of applications. The number of PFAS production sites in Europe is between 12 and 25 plants (25). Also, based on Eurostat data on the basis of NACE codes, nine additional industrial activities where PFAS are likely used (textiles, leather, carpets, paper, paints and varnishes, cleaning products, metal treatments, car washes, plastic/resins/rubber) were identified. Also, regarding environmental discharges from paper mills, it is estimated that a “typical” paper mill that produces 825 tons of PFAS-coated paper per day and discharges 98.4 million liters of water per day which release more than 100,000 ppt of PFAS in the wastewater effluent (55). Consequently, paper mill companies estimated a release of 43 to 102 kg of PFAS per day in their wastewater[43]. With 743 EU paper mills (56) this results in daily PFAS emissions between 31 to 76 tonnes. Companies also state that for 10 kg of PFAS going from the manufacturing process into wastewater treatment, 9 kg end up in biosolids and 1 kg is released into surface waters (57). That means the amount of PFAS ending up in sludges across the EU ranges from 310 to 760 tonnes/day. PFAS can only be effectively removed from wastewater by reverse osmosis with operating costs of €0.4 /litre. A cost model calculating the capital costs for building PFAS drinking water remediation resulted in baseline capital cost of $712,752 plus $2,070,142 per million gallons/day (MGD) which is simplified to $2 million per MGD which equals €520/m3/day. Measures at source would thus avoid costs at least €39.4 million EU-wide related to a complete removal of PFAS

[43] Information obtained by EDF through a Freedom of Information Act request to the US Food and Drug Administration for PFAS used to produce PFAS coated paper and board which is among others used for food contact applications.

from paper mills effluents/sludges. Note: the EU has comparatively limited information on (industrial) point sources of PFAS emissions from production and manufacturing sites because many industrial installations do not have to monitor PFAS under their discharge permits. Consequently, US information (58) (59) (60) (61) was used.

In 2018, a car wash facility in the US state of New Hampshire was cited as one of the sources of PFAS contamination in wells serving several nearby towns (62). Investigators tested wells on the car wash property and found levels for PFAS higher than expected – up to 158.8 ppt, compared to the USEPA lifetime advisory level of 70 ppt. The facility will be required to take measures to prevent the contamination from continuing. According to the International Car Wash Association 79,000 car wash facilities are operating in Europe. These are likely to be SMEs employing less than 250 workers (63). It is not known how many of these use products containing PFAS.

The industrial chemical Bisphenol-A (BPA), is produced in large quantities for use primarily in the production of polycarbonate plastics. It is found in various products including shatterproof windows, eyewear, water bottles, and epoxy resins that coat some metal food cans, bottle tops, and water supply pipes. For the environment, contaminated landfill leachate is an important source for both SW and GW. Consequently, an improved capture of landfill leachate combined with wastewater treatment could prevent in the order of 246MT of leachate being emitted. Annual costs associated to this measure are estimated to amount around €103.7 million, with an assumed 25-year asset lifetime. Avoided economic health related costs for avoided BPA exposure in relation to childhood obesity are estimated to amount to around €1831[44] million (64). Recent findings from EHCA (65) also support a further restriction of BPA emissions. For human health, BPA in food and beverages accounts for the majority of daily human exposure. BPA can leach into food from the protective internal epoxy resin coatings of canned foods and from consumer products such as polycarbonate tableware, food storage containers, water bottles, and baby bottles. Lowering human health risks comes at little to no costs, since exposure can be easily limited by behavioural changes such as not microwaving polycarbonate plastic food containers, reducing the use of canned foods, and when possible, opt for glass, porcelain or stainless steel containers, particularly for hot food or liquids and finally choosing to use (baby) bottles that are BPA free.

Pharmaceuticals

Source control measures like restricting/reducing the use of candidate pharmaceuticals within the human population, e.g. by substituting the most harmful pharmaceuticals by less harmful alternatives (greening pharmacy), or by changing from over-the-counter to prescription-only systems, will be important to limiting their emissions. Additionally, the management of unused, expired medicines /medicine containers to prevent the substance entering wastewater systems and/or landfills (see Box 13) could also be improved. Furthermore, new EU Ecolabel criteria for cosmetics and animal-care products (adopted in October 2021) offer proof to consumers that they purchase products with MSverified environmental excellence, along the

[44] Based on an exchange rate of 1 EUR = 1.09 USD

entire life cycle[45]. Price impact for consumers will be limited since alternatives to listed substances are available at little or no additional cost.

The use of pathway disruption measures like buffer strips (costs €160 per hectare) or natural constructed wetlands (costs €43.7 per m^3) are identified as potential cost-effective measures for reducing the entry of estrone (E1) and 17-beta estradiol (E2) into the environment. Under a worst-case scenario, a maximum of 5% of all pastoral farmland would be assumed to require measures (buffer strip /constructed wetland / additional fencing. End of pipe measures directly relate to the revision of the UWWTD. The costs to remove micro-pollutants from waste water under that legislation are shown in Table 6.2.1: Overview of measure categories and substance categories.

Table 6.2.1: Overview of measure categories and substance categories

Preferred option in the UWWTD revision SWD	Costs (Million €/year)	Toxic load avoided (p.e.)	Avoided Toxic load in areas at risk (p.e.)	Additional GHG (Million t CO_2e/year)
All plants >100 k p.e. + plants 10 k to 100 k in areas at 'risk'[46]	1 185.51	68 198	41 836	0 to 4.97

As regards pharmaceuticals, depending on policy measures at national level, choice of specific medication may be limited through different prescription policy.

For carbamazepine, diclofenac and ibuprofen a range of (cheaper) alternatives exist. Technical challenges related to manufacturing and supply chains (increasing supply of alternatives), and issues related to the prescription of alternatives exist for some substances. Also, for specific individual patients the substitution of specific medicines might not be feasible and could thus limit the impact on emission reductions. For veterinary uses, pathway disruption could also help reduce diffuse emissions to surface water.

End of pipe measures to remove pharmaceuticals from waste water are relatively costly and thus not preferred, but could be helpful for ibuprofen and carbamazepine. Ozonation could help to remove macrolide antibiotics. Diclofenac is more costly to remove. The revision of the UWWTD IA shows that the deployment of enhanced water treatment technology results in considerable additional resource and energy costs (resulting in a significant increase of the associated carbon footprint). Also, the undesired formation of bromide as unwanted breakdown product is relevant for some substances. Annex 10 contains overview tables with pharmaceutical substances, potential alternatives and the costs of each as well as tables with an overview of the most common end-of-pipe measures and their cost per substance.

Increasing interest for surface and groundwater pollution by pharmaceuticals is fuelling interest in developing new pharmaceuticals – or re-designing existing ones – to be more environmentally friendly, or 'benign by design.' This includes drugs that are better absorbed by the human body, or that biodegrade more rapidly in the environment. For example, by structurally modifying propranolol – a commonly used and highly persistent beta blocker –

[45] Currently, three out of four PCP sold in the EU display some kind of environmental claim or label, yet many of these claims are untransparent about assessment criteria used, and/or difficult to understand or confusing for the consumer.

[46] In this IA, it was assumed that 70% of facilities between 10 000 and 100 000 p.e. with a dilution rate of 10 or less would be considered as 'at risk'- see UWWTD SWD Annex 4.

researchers have been able to synthesise a derivative that breaks down much more easily in the environment than its parent compound[47].

Green Pharmacy initiatives are already operating in a large number of MS. New Green Pharmacy initiatives and actions, e.g. consisting of return schemes for unused and disposed medicines, will expectedly strongly benefit SMEs and start-ups. Cost of those initiatives are estimated to range between €1-10 million per MS. Local pharmacies / chemists and research institutes are important players in such initiatives that boost innovation and employment including in SMEs. In the pharmaceutical sector, SMEs drive innovation and play a major role in the development of new medicines. More than 4 out of 10 medicines selected for Environmental Medicine Agency priority medicines scheme were from SMEs[48]. Therefore, the push for substitutes will likely benefit those SMEs in the pharmaceutical sector.

In the cosmetics and personal care products sector, SMEs also play an important role. In 2020 France had 840 small and medium-sized enterprises (SMEs) specialized in the manufacturing of cosmetic products followed by Italy (735), Poland (606), Spain (515), Germany (348)[49].

Also, the EU-funded research projects such as 'Implementation of Research and Innovation on Smart Systems Technologies' (IRISS) have helped innovation and supported EU efforts to extend competitive advantages of European research institutes and industry (e.g. the Institute for Sustainable Chemistry, the Fraunhofer Institute, Starlab Barcelona, Siemens, Hitachi and other partners) related to Smart Systems research e.g. to help reduce hazardous substances in production in the textile and plastics industries (66). Such projects, illustrate that 'Safe by Design' concepts increasingly find their way into politics and the chemical / pharmaceutical and personal care products industry (67).

Pesticides

For pesticides, emissions are best limited by a combination of use restrictions, replacement by less harmful alternatives, pathway disruption (e.g. buffer strips) and end-of-pipe measures.

The most important pathway to the (aquatic) environment is run-off from fields. Consequently, on-farm measures are the most effective. Currently 1472 active substances, safeners and synergists are registered in the EU pesticides database (68). This implies that there are numerous approved authorised active substance that can be used to identify less harmful substitutes to replace more harmful pesticides.

Less toxic chemical alternatives for pyrethroids are limited (often other pyrethroids). For imidacloprid and triclosan (neonicotinoids) the primary uses relate to the use as a biocide and associated losses to the aquatic environment often to sewer. Imidacloprid is used to controls fleas and ticks in domestic pets. Primary chemical alternatives for imidacloprid are likely pyrethroids, which may present some issues for certain animals sensitive to them (69). Triclosan is mainly used in medicated soaps / disinfectants, for which substitution by less harmful alternatives is realistic. Silver is commonly used as a substitute, but also has risks. Annex 10 lists several pesticides, potential alternatives, and estimated costs of alternatives.

[47] https://www.pharmaceutical-technology.com/comment/commentgreen-pharma-the-growing-demand-for-environmentally-friendly-drugs-5937344/

[48] https://www.ema.europa.eu/en/human-regulatory/overview/support-smes

[49] https://www.statista.com/statistics/579043/number-of-smes-in-the-cosmetic-industry-in-europe-by-country/

The use of physical barriers is not at saturation level in the EU yet and could thus be envisaged by MS. Calculations undertaken to help derive indicative (orders of magnitude) of costs attributed to the use of pathway disruption for pesticides is included in Annex 10.

Box 13: Implications of the Urban Wastewater Treatment Directive revision – advanced treatment to be applied over time

The impact assessment for the revision of the Urban Wastewater Treatment Directive looks amongst others at the the increasing quantities and variety of micro pollutants (mainly pharmaceuticals). The impact assessment suggests a phased approach to implementation of more advanced treatment, including:

- 2025: setting up extended producer responsibility schemes.
- 2030: identification of areas at risk (facilities from 10-100k people equivalent) and interim targets for facilities above 100k people equivalent.
- 2035: all facilities greater than 100k people equivalent equipped with advanced treatment and interim targets for areas at risk.
- 2040: all facilities at risk equipped with advanced treatment.

For biocidal uses, particularly within indoor settings, the potential wash-off or rinsing to drains during cleaning and maintenance is an issue. Consequently, end-of-pipe measures for those specific uses can have an added value. Annex 10 provides the results of indicative cost estimates for the removal of several substances in use as biocides. The IA for the revision of the UWWTD indicates that ozonation could be reasonably cost effective to remove imidacloprid. Removing triclosan requires reverse osmosis (RO) which is costly and challenging to implement at local level. Removing Acetamiprid, Thiamethoxam, Permethrin requires Granulated Activated Carbon (GAC) which is also expensive. Reverse osmosis investment costs are estimated around €100,000 to €10,000,000 per plant, with operating costs of €0.4 per dm^3 (71). Also, RO results in an additional 20% water extraction needed to prepare drinking water (due to the requirement for membrane flushing/cleaning), which will add to existing water shortage pressure in many MS.

The main costs in relation to the reduction of pesticides in surface- and groundwater are expected to be covered by the implementation of the revised legislation on the sustainable use of pesticides directive (SUPD). According to the SUPD evaluation there have been no remarkable drops in pesticide sales, or losses since 2009.

Reducing concentrations of pesticides and chemicals overall in GW and SW will reduce costs of the drinking water purification sector, an important share of which are SMEs. SMEs are for example active in monitoring and testing of (drinking) water and data analysis. EU wide treatment costs amount to 510 million EUR per year. If, in line with the targets of the F2F strategy, pesticide use is decreased by 50%, treatment costs decrease accordingly by 205 million/year. Corresponding costs savings for consumers are then around EUR 5-10 per person/year (see Annex 3 for more details).

According to the progress report from the European Commission on the implementation of the EU Pollinators initiative (72) the economic value of pollinating insects to crop production in the EU is at least 3.7 billion EUR per year. New research shows pesticides are contributing to the decline in pollinators. In particular the neonicotinoids are very toxic and persistent and contribute to the loss of honeybees. Quite a number are known to be directly toxic for bees and co-responsible for bee poisoning and bee death, like e.g. Imidacloprid, Clothianidin, Thiacloprid, Thiamethoxam, Dinotefuran, Nitenpyran, Fipronil, and Oleofin. Neonicotinoids are extremely toxic to bees. LD50 rates (the rate at which half of the exposed population dies) for clothianidin are 22-44 nanograms per bee for direct contact and 2.8-3.7 nanograms per bee for oral ingestion. In other words, a single corn kernel with neonicotinoid seed treatment potentially contains enough active ingredient to kill over 80,000 honey bees (73) (74). Some scientific studies show that bumblebees exposed to neonicotinoids have at least 10% smaller colonies than those not exposed to the insecticide, others report a 57% decline in reproduction rates (75), with pesticide exposure having the greatest impact on nesting activity and the number of offspring the bees produced. Assuming that between 10% or 50% of the economic losses from pollinator decline are attributed to pesticide toxicity[50], this results in mean annual benefits of EU and MS action on such pesticides (one of which is the current proposal) from 370 million to 1.85 billion EUR (see Annex 3 for more details).

Pesticides users are almost exclusively SMEs (farmers, landscapers, etc). As regards the production and production and marketing side, while a large number of SMEs are active here as well (fastest growing segment companies with 50-250 employees, the sector is dominated by very large companies, with 88% of the market share for the top 7 crop protection companies in the EU[51]. Impacts will depend heavily on the types of measures taken by MS to ensure compliance with the legislation. If users need to revert to alternative pest management methods or alternative pesticides this may lead to lower yields or higher costs. If the policy measures lead to a drive for innovation, both SMEs and large companies on the development and production side will profit.

Metals

For silver and its compounds, a myriad of sources and pathways to environment exist. For anthropogenic activities like smelting, combustion of coal, manufacturing of silver containing products, source control options consist of increased abatement and monitoring. Silver is used widely as antibacterial agent in medicinal, personal care and other consumer products. The widespread use of silver has already led to the release and accumulation of the AgNPs in water and sediment, in soil and even, wastewater treatment plants (WWTPs) and is thus impacting microbial communities in different environmental settings. Scientific evidence of silver-driven co-selection of antibiotic resistance determinants is also numerous.

The resistance mechanism for nanosilver (NAg) is linked to indicated to increasing environmental antibiotic resistance gene pools indicated by the many antibiotic resistance genes already detected in samples from different environmental settings. These antimicrobial resistance genes could ultimately find their ways to animals and humans. This is worrisome, as the increasingly indiscriminate use of NAg could further promote the development of silver resistance in bacteria. The bacterium *'Acinetobacter baumannii'* (a bacterial pathogen) was recently listed as the "number one" critical level priority pathogen because of the significant rise of antibiotic resistance in this species[52]. Currently, NAg still has proven

[50] In the United Kingdom, 54% honeybee population lost in the last decades. In the US 30–40% disappearance of the honeybee colonies attributed to colony collapse disorder.

[51] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues

[52] 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

bactericidal activity towards this bacterium (*A. Baumannii*) even against strains that display multi-drug resistance. Therefore, it is of utmost importance to avoid silver resistance developing in this bacterium also in the light of scientific reports on heavy metal-driven co-selection of antibiotic resistance. Consequently, the widespread use of NAg in commercially available products promotes a prolonged microorganism exposure to bioavailable silver, which enhances the advance of multi resistant bacteria / micro-organisms.

Finally, NAg and its transformed products are toxic to environmental microbes. Microbial and gene abundance shifts are observed in various environmental settings. Physical and chemical transformations of NAg can shift the diversity and abundance of microbes, including those that are important in nitrogen cycles and decomposition of organic matters. The combined ecological impacts of NAg call for a prudent use of silver and AgNPs and minimising their water related emissions [53].

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[54]. 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. Assuming the benefits of reducing silver related AMR to equal between 50% to 100% of the AMR costs for antibiotics, this results in EU-benefits of between €22 to €63 billion[55] (2014 data, subsequently corrected for inflation between 2014 and 2021).

Pathway disruption measures consist of capturing and treating of mine drainage water before it reaches water bodies. A targeted plan of action to tackle emission might be needed on a MS by MS basis.

As detailed in Annex 9, table A9.1, the social impact of listing additional substances mentioned in this paragraph concerns better protection of health in particular through addressing the health and environmental effects of nanosilver, including the role of silver in antimicrobial resistance, food security and ecosystem services such as avoided impact on pollinators.

[53] The impact of silver nanoparticles on microbial communities and antibiotic resistance determinants in the environment, Kevin Yonathan et.al. Environmental Pollution 15 January 2022, 293: https://pubmed.ncbi.nlm.nih.gov/34793904/

[54] An extrapolation of the RO costs based on the number of EU non-ferrous metals production facilities 847[54] 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 billion[54]) this would equal 0.1%.

[55] Costs are converted using an average of USD 1 = EUR 0.75 for 2014, and then using an average inflation rate of 1.95% per year between 2014 and 2021, producing a cumulative price increase of 14.5%

Box 14: Views on positive impacts of listing new PS expressed during consultation activities

When asked to estimate the significance of economic, health, social and environmental benefits / impacts resulting from the inclusion of new candidate PS, the respondents generally found all impacts to be cumulatively positive (i.e. % selecting minor, moderate or major benefit outweighed the % rating as 'no benefit'). **Benefits from improved surface water quality, lower risk of damage to natural resources and benefits from improved environment and human health protection were valued most** (respectively 34%, 32% and 30% of respondents selecting 'major' benefits). The impacts of new candidate substances on the quality of process water for agriculture and industry received the greatest number of 'no benefit' responses (16%). Impacts regarding employment opportunities were identified as being largely unknown, indicated by the large share of 'I do not know/no opinion' responses (57%).

6.2.2 6.2.2 Policy option 2 – listing candidate PS as a group

Under this policy option substances would be added under family groupings: PFAS[56], estrogenic hormones, macrolide antibiotics, neonicotinoids and pyrethroids. This could limit the burden on MS as well as disincentivise substitution with another similarly hazardous substance in the same group. A group approach also helps better address overall cumulative risks of substances with similar toxicity and modes of action and can help capture degradation products of the substances with the same effects.

There are 9,000+ per- and polyfluoroalkyl substances (PFAS) in existence, which makes regulating PFAS individually infeasible. It is estimated that an EU PFAS ban in firefighting foams may cost society €390 million per year over a 30-year period (26). For surface water the major pathway is fire-fighting foams providing significant losses directly to the wastewater system. The environment of oil-drilling sites and airports (due to drills and exercises) is typically highly contaminated, with potential remediation costs of €0.6-2.5 billion for the 850[57] larger airports in Europe[58] or even €18.3 billion when all EU military and small airports[59] are included. Economic benefits from avoiding PFAS ending up in water include the potential for water reuse, including for irrigation purposes in line with the new Regulation on minimum requirements for water reuse. Benefits (avoided costs) of PFAS removal in waste water are considerable: at least €9.13 billion/year[60]. Moreover, PFAS removal processes create large additional amounts of waste (brine) – approximately 25% of treated water (76) requires separate treatment and subsequent re-mineralisation to create drinking water. Estimates of the avoided cost for reverse osmosis, specifically, to prepare drinking water amount to over €1/m³ equalling circa €200 per household per year (77), equalling avoid water treatment costs of 39.1 billion annually, if applied to all 195 million EU households. Also, not having to use RO to produce drinking water will result in 20% savings of water extraction volumes compared to a situation in which RO would be required. Total annual health-related costs, for three different levels of exposure, were found to be at least EUR 52 to EUR 84 billion in the EEA countries. Non-health-based costs environmental PFAS remediation totalling EUR 821 million to EUR 170 billion (EEA/EU), with plausible best estimate EUR 10–20 billion. In addition, measures at source would avoid costs of at least

[56] Note PFAS substances include around 4,000 to 7,000 substances (depending on definition), so addition always requires grouping approaches. Consequently, in this initiative PFAS are grouped using a grouping metric (PFOA-equivalents) and relative potency factors (RPFs).
[57] Eurostat : https://appsso.eurostat.ec.europa.eu/nui/setupDownloads.do
[58] https://ourairports.com/continents/EU/
[59] If counting all military and recreational airstrips the total number increases to 6106 airports: https://ourairports.com/continents/EU/
[60] Results from the ZeroPM project (EU funded Horizon 2020) identified PFAS in 100% of the wastewater samples across the EU https://zeropm.eu/ and https://www.ngi.no/eng/Projects/ZeroPM

€39.4 million EU-wide related to a complete removal of PFAS from paper mills effluents and sludges.

Health costs of hormone disrupting chemicals, including estrogenic hormones, are estimated at €150 billion a year[61]. Studies also show strong toxicological evidence for male infertility attributable to EDC exposure, with a 40-69% probability of causing 618,000 additional assisted reproductive technology procedures, costing €4.71 billion annually (78) (79) (80). The effects of the exposure such endocrine disrupting substance (EDCs) have been linked to reproductive problems (e.g. with declining sperm counts), some cancers, impaired intelligence, obesity and diabetes, but also with effects on animals, with invertebrates being the most sensitive (81). Studies concluded an EDC causation for IQ loss and associated intellectual disability, attention-deficit hyperactivity disorder, childhood obesity, adult obesity, adult diabetes, cryptorchidism, male infertility, and mortality associated with reduced testosterone, e estimated to cost of €157 billion (corresponding to 1.23% of EU gross domestic product) annually (82). For macrolide antibiotics, measures across the life cycle of medication are required. As an example, many pharmaceuticals but also PFAS, can harm reproduction, reproductive success, and population health not only for aquatic species, but indirectly also for humans. Therefore, benefits are also expected for the aquaculture sector through avoided costs associated with losses of fish and shellfish populations in aquaculture farms. Some of the most affected species are trout (2019 EU production value €677 million), seabass (€491 million), crustaceans (€1.05 billion) and salmon (€1.34 billion) (83). Assuming that 5% -10% of the production value can be related to EDC exposure results in annual EU wide avoided costs ranging from €177 - €355 million.

Social impacts of the policy option assessed in this paragraph are, as mentioned in Annex 9, table A9.3, limited to more effective management of the substances when grouped as opposed to individual listing.

6.2.3 6.2.3 Policy option 3 – revising EQS for certain existing PS

The assessment finds that, for the substances concerned, the additional effort to be made by MS to reach the EQS will be small to relatively large (see Chapter 6.1.1 and Annex 4).

For cypermethrin, a combination of source control, substitution by less harmful alternatives, and end-of-pipe measures are likely needed as the substance is commonly used as pesticide and wood preserving chemical. Costs to remove cypermethrin in UWWTPs are estimated at €26.2 (per population equivalent, per year). PBDEs and Di-2-ethylhexyl phthalate (DEHP) and its compounds are associated with health effects such as cognitive deficits, (testicular) cancer and cryptorchidism as well as adult obesity, adult diabetes, and reproductive effects for females (endometriosis) (84). Mercury and its compounds and organophosphate pesticides are associated with cognitive deficits resulting from exposure (85).

For diuron and chlorpyrifos, market authorisations expired recently, meaning remaining stockpiles will be used up and exemptions (emergency authorisations) will drive emissions. Other topics relate to legacy issues resulting from the persistence of such substances. For

[61] https://www.bbc.com/news/health-31754366 and https://www.theguardian.com/environment/2015/mar/06/health-costs-hormone-disrupting-chemicals-150bn-a-year-europe-says-study and https://www.endocrine.org/news-and-advocacy/news-room/2015/estimated-costs-of-endocrine-disrupting-chemical-exposure-exceed-150-billion-annually-in-eu

diuron a possible remediation measure could be removing and replacing obsolete contaminated wood-based infrastructure. In some instances, the use of dredging may be appropriate for the removal of substances bound to the sediment in waterbodies, which can be relatively cheap or very costly, depending on the level of after treatment required.

The social impacts of this option are principally in greater human health protection from the chronic or bio accumulative nature of the pollutants concerned. Details can be found in Annex 9, table A9.4.

6.2.4 6.2.4 Policy option 4 – deselection of priority substances

These substances were identified to no longer pose an EU-wide risk to the environment and public health. Alachlor, Simazine and Chlorfenvinphos (herbicides) have banned in the EU for many years, and concentrations above the EQS are identified in a very limited number of water bodies (table A11.2). Therefore, the overall risk to the environment is considered to be low.

Use of Trichlorobenzenes (solvents and chemical intermediates) is ongoing, and the substances are acutely toxic to the aquatic environment. The rates of EQS exceedance are not very high, but deselection is more questionable than for the other substances given the degree of risk they post and their relevant for the MSFD.

Carbon tetrachloride is not recognised as a POP and the rates of EQS exceedances are low with declining trends, indicating localised issues and no EU-wide risk. Also, the ongoing use of this substance is directly or indirectly controlled and monitored under other policies like REACH, IED, the Regulation for the Classification and Labelling of Chemicals (CLP), therefore deselection from the PS list would not result in a negative environmental or societal impact.

All substances have in common that, even if they were removed from the PS list, they might still be relevant as RBSPs, and MS could decide to continue monitoring them at national level where needed. Deselection could free up resources that can be reallocated to emerging risks, e.g. due to saved monitoring costs (between €4 and €12 million annually at EU level).

Deselection as assessed in option 4 is not expected to have negative social impacts since the risk of exposure to the substances concerned is very low. A possible negative effect, in relation to trichlorobenzenes and carbon tetrachloride, may be that less monitoring would reduce the information base for deciding on reduction measures. Hence for these substances an approach at River Basin level should be considered.

Box 15: Views on impacts of deselection expressed during consultation activities
Deselection of Alachlor, Chlorfenvinphos and Simazine was considered by most (respectively 47%, 46% and 45%) of the TEC respondents to have no negative impacts for either the environment or human health, whereas only 8% thought so for Carbon tetrachloride. The biggest concern raised for deselection was a loss of monitoring data to track trends. However, one respondent highlighted that if there was a concern a substance could be retained as an RBSP. Many (i.e. 48-64%) respondents 'didn't know/had no opinion' regarding the economic benefits of deselection, however, the remaining responses indicate deselection to have at least some economic benefits for all substances considered (28-45%). *Note: Trichlorobenzenes were not included in the consultation surveys due to their late addition to the candidate list for deselection.*

6.3 6.3 Groundwater – impacts of policy options

A key aspect of understanding the potential impact of the groundwater policy options is defining the "gap" between the baseline situation and meeting the proposed GW QS or likely national TVs set at MS level for pollutants listed in Annex II of the GWD. Subsequently this assessment was 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. Likely environmental, economic and social impacts were assessed, and various impacts of the options described (incl. the administrative burden on responsible authorities).

It needs to be noted however that the quality of the data for groundwater in Europe are, for several reasons[62], of a lower quality compared to surface water. Consequently, the outcomes of the distance to target assessment and the comparison of the impacts of the policy options are subject to a higher level of uncertainty.

Measures to address PFAS, nrMs or pharmaceuticals can be remediation of soil or the groundwater (e.g. in case of polluted fire-fighting sites), source control (bans or restrictions on use, substitutes, guidance on proper use, avoiding production losses) and end-of-pipe/ pathway disruption (wastewater or landfill leachate treatment, incineration or landfilling).

Costs vary strongly depending on the type of measure. Examples can be found in Annex 10.

6.3.1 6.3.1 Policy option 1 – listing LFR substances individually or as group of specific chemicals in GWD Annex I

PFAS

The main additional expense for most MS will be the costs of laboratory analysis, and in particular Option 1 (a group of 24 PFAS in Annex I and assigned a GW QS of 4.4 ng/l PFOA equivalent), where a "sum of" methodology or very low concentrations need to be analysed and are likely to require more effort, and 2 (all PFAS in Annex I with a GW QS for "PFAS total" of 0.5 µg/l). The measures likely to be used by MS are similar for all options (aside from Option 3).

A cheap source measure to reduce future emissions of one of the 24 specific PFAS would be to use other PFAS substitutes not used yet. This would however potentially trigger new legacy issues in the future because of PFAS persistence. For the regulated PFAS (PFOS, PFOA, PFHxS, PFHxA and the C9-C14 carboxylic acids) stringent measures that restrict emissions are already in place; it is likely that, for the remaining group of 10 substances, which overlap with the DWD substances and the EQSD proposed substances, further controls should be instigated at the EU level with cost to industry.

Pathway disruption measures like the capture of contaminated sludge, containing and incineration are very costly due the energy intensiveness, so these measures are suitable only in extreme circumstances. Guidance on the best practise use of waste and wastewater by-products in agriculture would be a cheaper option. However, this will ultimately result in

[62] For the 15,930 GWBs reported by the EU27 in 2016, a large number of water bodies have no monitoring results. This means their status is assessed through grouping of characteristics including pressures and risk, extrapolation of evidence, and expert judgement. Generally, the GW WL data is of much lower quality compared to surface water watch list data for reasons like the voluntary nature of data collection and inconsistent reporting formats used.

PFAS accumulating in agricultural soils. Instead of using pathway disruption measures, it is more likely that for Options 1 and 2 actions to restrict use of PFAS and better management of waste streams are used, as well as groundwater or soil remediation.

Pharmaceuticals

As regards Option 1 (adding Carbamazepine and Sulfamethoxazole to Annex I), this would likely lead to some administrative burden on those MS which do not yet monitor these substances. A worst-case estimate is €2 million per year at EU level.

nrMs

The costs of adding nrMs to the monitoring networks are likely to be limited, since the existing framework for assessing risk to groundwater from ‘parent’ pesticides and their relevant metabolites are already in place. A small increase in costs is likely for Option 1 (adding all nrMs to Annex I as individual substances with a GW QS of 0.1 µg/l), since it requires, at least for those countries which are not already doing this, that “all nrMs” are included in the analysis.

The implementation of the EU Farm to Fork Strategy will likely lead to reductions in the use of any permitted parent pesticides of the nrMs considered. This will be delivered in part through the planned revision of the Directive on the Sustainable Use of Pesticides and national action plans for pesticide use reduction. This will limit what additional measures need to be taken to protect their water bodies. By including all nrMs in Annex I under Options 1 and 2, the administrative burden may be progressively reduced further as the legislation would be “future proofed”.

Environmental benefits are rather similar for all the nrM options but options covering all nrMs and setting a GW QS at EU level (i.e. Option 1 and 2) are expected to generate greater benefits. Benefits include reduction and possibly reversal of impacts on groundwater biota, benefits for ecosystems services provided by the groundwater and linked surface water, increased quality process water from groundwater / surface water for drinking water, agriculture and industry.

6.3.2 6.3.2 Policy option 2 – listing LFR substances as groups of substances in GWD Annex I

By grouping similar pollutants, with a GW QS for the total group, legislation can deal with large substance groups with rapidly changing information on the impacts which would, in a sense, “future proof” legislation.

PFAS

The main additional expense under Option 2 (all PFAS in Annex I with a GW QS for “PFAS total” of 0.5 µg/l) for most MS will be the costs of laboratory analysis.

Pharmaceuticals

The main administrative benefit of Option 2 (adding all pharmaceuticals as a group to Annex I) is that it “future proofs” the listing by including substances which may become problematic in future and stimulates the modernisation of analytical techniques. The latter would result in considerable cost savings as soon as modern techniques have become more commonplace. Under Option 2b direct analytical costs will be around €5.5 million per year, with potential administrative costs taking this up to a total of €11 million per year. For Option 2c (adding all pharmaceuticals as a group to Annex II for MS to consider setting a TV), the analytical costs will vary between MS depending on the TVs adopted and the monitoring strategy used, but the impact on administrative burden to MS would be smaller.

Estimated costs of measures for Option 2 are shown in Annex 10. Many of these are considered cost-effective and acceptable for society. The main environmental costs of adding pharmaceuticals to the GWD would be implementation of measures to deal with wastewater /biosolids containing pharmaceuticals which can be energy intensive and require the use of chemicals. The incineration /landfilling of biosolids is suggested as a last resort measure as there is currently no viable treatment to remove pharmaceuticals from these media.

Environmental benefits of adding substances largely consist of lower risk of (irreversible) damage to natural ecosystems. These benefits are greatest under Option 2, due to the wider range of pharmaceuticals addressed.

Under Option 2 the understanding of the impact of pharmaceuticals on groundwaters is most pronounced. Also, the aim of the Pharmaceuticals Strategy to reduce the level of anti-microbial resistance is best supported by this option.

nrMs

The costs of adding nrMs to the monitoring networks are likely to be limited, since the existing framework for assessing risk to groundwater from 'parent' pesticides and their relevant metabolites are already in place. A small increase in costs is likely for Option 2 (adding all nrMs to Annex I with a group GW QS of 10 µg/l), since it requires, at least for those countries which are not already doing this, that "all nrMs" are included in the analysis.

Environmental benefits are rather similar for all the nrM options but options covering all nrMs and setting a GW QS at EU level (i.e. Option 1 and 2) are expected to generate greater benefits. Benefits include reduction and possibly reversal of impacts on groundwater biota, benefits for ecosystems services provided by the groundwater and linked surface water, increased quality process water from groundwater / surface water for drinking water, agriculture and industry.

6.3.3 6.3.3 Policy option 3 – listing LFR substances in GWD Annex II

PFAS

Option 3 for PFAS would lead to TVs being set by individual MS using drinking water standards and likely focusing on point source pollution rather than on diffuse pollution. The most likely measures to deal with pollution point sources could be to initiate soil remediation measures, e.g. for pollution hotspots like firefighting sites. This option would moreover lead to diverging national TVs and thus be detrimental to the objective under Art. 7 WFD to setting uniform EU quality standards for groundwater. Setting a uniform GW TV at EU level would, on the contrary, lead to savings in treatment costs.

Costs for all PFAS inclusion in Annex II for MS to consider setting a TV (Option 3) will be the lowest, given the DWD requirements and additional data collated. This is especially the case for the MS which are already monitoring PFAS and carrying out risk assessments for groundwater.

Pharmaceuticals

Option 3 will have significantly less environmental benefits compared to Options 1 and 2 and distortion of the 'level playing field'.

nrMs

The costs of adding nrMs to the monitoring networks are likely to be limited, since the existing framework for assessing risk to groundwater from 'parent' pesticides and their relevant metabolites are already in place. The administrative burden of Option 3 (adding all nrMs to Annex II for MS to consider setting a TV) will be smaller at EU level but higher at MS level, because of the need to set TVs at national level.

Additional measures that could be considered by MS would mainly focus on the amenity /legacy pollution including substitution through less harmful substances, remediation of existing / historical sources and use of other weed control methods for amenity use.

If measures taken by MS to reduce nrMs in groundwater would include source control such as restrictions on use this would have an impact on the farming sector and possibly also on crop yields. Estimated costs of using substitution products are shown in Annex 10: it should be in particular stressed that less toxic alternatives do exists for at least the five permitted parent pesticides, with similar cost ranges.

For Option 3 (TV set at MS level) greater variance in environmental benefits is expected between MS. Benefits include reduction and possibly reversal of impacts on groundwater biota, benefits for ecosystems services provided by the groundwater and linked surface water, increased quality process water from groundwater / surface water for drinking water, agriculture and industry.

As specified in tables A9.7 through A9.9 social impacts are mostly related to better protection of health due to lower exposure to substances, in particular from the PFAS group and pesticides. Indirect social benefits are generated through improved ecosystem services (better protected water sources, recreation, less polluted fish etc). Possible negative effects include lower yields increased costs in farming or higher costs, as well, in relation to antibiotics, a limited reduction of choice in available antibiotics options.

Impacts on SMEs under the groundwater options follow the same pattern as under the surface water options.

Box 16: Views on positive impacts of listing groundwater pollutants expressed during consultation activities

Majority of TEC respondents were unsure about the significance of benefits of listing new groundwater pollutants (32-56% indicating 'I don't know / No opinion'). Overall, cumulative positive impacts were perceived for all categories included in the questionnaire, with the following significance levels most widely chosen:

- **Major** benefits from improved water quality, improved environment and human health protection (35%), lower production and maintenance costs through availability of cleaner raw water (32%), improved well-being (2%).
- **Moderate** benefits associated with availability of clean GW for abstraction (24%).
- **Minor** benefits from increased resource efficiency through reuse and recovery of materials (32%), climate change through reduced energy use (29%), lower risk of (irreversible) damage to natural resources (21%).

Views on the significance of benefits from increased potential employment opportunities were inconclusive (major and minor levels each selected by 18%). Respondents were most sceptical about benefits from reduced risk of water-related illnesses and premature deaths (21% selecting 'No benefit'), benefits for agriculture and industry as well as wastewater treatment (15%).

6.4 6.4 Monitoring, reporting and administrative streamlining – impacts of options

The impacts of all policy options related to monitoring, reporting and administrative streamlining are described below. Clear synergies exist between this initiative, 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, and the Directive on Public Access to Environmental Information. In particular, data collected under policy options 3, 4, 6 and 7 would lead to better water quality data in shorter than the current 6-years intervals. This water related data could complement and be cross referenced with publicly available data on emissions from industrial installations covered by the IEPR and help monitor the effects of the implementation of new Best Available Techniques on the aquatic environment surrounding such installations. Vice versa, an improved digital data collection on geographical and seasonal pesticides use under the envisaged revised Sustainable Use of Pesticides Regulation, would be highly valuable input for an improved implementation of legislation like the WFD and the EQSDs, as well as the EU Biodiversity Strategy 2020, the common agricultural policy (CAP), and the Thematic Strategy on Soils. Finally, for practically all of (sub)options, related to digitalisation, improved monitoring etc., existing EU research projects funded through FP7, H2020 and Horizon Europe can support a further practical development, and outcomes of past and ongoing Research & Innovation (R&I) projects could consequently also help reduce costs of an increased digitalisation .

Box 17: Views on monitoring, reporting, and administrative streamlining options expressed during consultation activities

Regarding **monitoring approaches**, varying views were provided on guidelines to alternative monitoring methods, noting that innovative approaches (such as EBM) could improve freshwater quality yet may result in a greater monitoring burden to actors.

Respondents voted **the increase in monitoring frequency of substances in the Surface Water Watch List** as the most effective method for improving the risk response and management (average score of 3.2 on a scale from 1 - not at all – to 5 – very much). However, the responses received displayed significant polarity: 26% (n=12, represented by a mix of business associations, companies and MS competent authorities) rating the measure as non-effective (i.e. 1) and another 28% (n=13, mostly representatives of MS authorities and academic research) as highly effective (i.e. 5).

On **data management**, most benefits were perceived for guidelines to standardise data collection and reporting formats. Overall, the responses indicated that a combination of approaches may be more suitable in achieving the desired harmonization of the RBSP thresholds rather than just one specific measure.

6.4.1 6.4.1 Policy option 1 – Guidance and advice on monitoring

Sub-option (a): Develop guidelines on applying innovative methods in monitoring procedures, including continuous / automated monitoring techniques

The impacts of Sub-option 1a are limited since it would summarise best practise examples and use those to detail how approaches can be implemented. The expected costs are limited, but the potential impacts and associated benefits for MS monitoring programmes can be significant if properly implemented and would lead towards harmonised monitoring and measurement approaches for contaminants of emerging concern. The costs for developing EU guidelines ranges from around €290,000 for simple guidance documents to around €500,000 for more elaborate documents (see Annex 10). Based on the assumption that around 1 or 2 guidance documents on innovative monitoring methods would be required, total EU costs range from €580,000 to €1 million.

Sub-option (b): Improve existing EBM guidelines to improve monitoring of groups/mixtures of pollutants by using EBMs, and define trigger values for assessing the status of a water body.

The impacts of Sub-option 1b involve the further development of guidelines on the types of effect-based methods, and deriving trigger values[63] for mixture pollutants to be applied in practise. Effect-based trigger (EBT) values establish the likelihood of adverse impacts on water quality and are used to differentiate good from poor water quality. EBT values for in vitro bioassays can be used to assess if a water body is in good or poor status based on the effects on the aquatic organisms. Also, by dividing bioanalytical responses by their respective EBT values, effect-based risk quotients can be obtained, which can then be summed per location to assess the cumulative ecotoxicological risks. Consequently, they are important for surface water quality monitoring while considering mixture toxicity, but of course in close alignment with EQSs for individual chemicals. Costs for the further development of EBM guidelines are comparable to those of a simple guidance document and are estimated at €290,000.

Sub-option (c): Develop a harmonised measurement and monitoring method and guidance for microplastics in surface water and groundwater, as a basis for MS reporting on microplastics and a future listing under EQSD and GWD.

Overall cost to society of microplastics is estimated between €10.8 to €19.1 billion (36) (86). One major microplastics category the EU intends to address (others are textiles, pellets, paints, geotextiles, detergents capsules) is tyres. A recent revision of the Tyre Approval Regulation has removed the worst performing tyres from the market (87) while EU labelling of tyres according to their abrasion rates is a strong incentive to push the market to the best performing tyres amongst those left on the market. Physical barriers to avoid microplastics ending up in surface waters would be effective measures as well (so called gully pots to capture particles or microplastic filters in washing machines (88) as foreseen in the EU microplastics initiative. End-of-pipe treatments for microplastics could be effective too, at a cost between €0.08-0.20 per cubic metre of wastewater treated per year (see upcoming

[63] Bioassay responses are compared to effect-based trigger values to identify potential ecotoxicological risks in water bodies (126).

UWWTD revision, whereby the application of tertiary level treatment in WWT plants is being proposed for larger agglomerations at risk). This treatment will trigger knock-on problems with the plastic-contaminated sludge, which are being assessed in the ongoing Evaluation of the SSD

The impacts of Sub-option 1c involve the costs of development of a harmonised measurement standard and guidelines for monitoring. As a relatively unchartered territory, initial costs may be higher than for traditional chemical substances or groups of substances. 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[64], the development of a harmonised measurement and monitoring methodology for microplastics and the accompanying guidance is estimated to cost between €290,000 to €500,000[65]. Once the method is developed, the annual EU costs for measuring and monitoring microplastics are estimated to range from €7.3 to €13.4 million[66].

A harmonised measurement and monitoring method for microplastics is a vital prerequisite for monitoring by MS and future development of policies to reduce emissions to surface water, groundwater and coastal waters. 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 like the Bleu2 study (89), and allows developing and validating future simulation models (no microplastics simulation model was found in the EC Modelling Inventory (MIDAS)). Finally, obtained monitoring results could facilitate the assessment of effectiveness of other EU policies dealing with microplastics (e.g. the upcoming initiatives on controlling unintentional releases).

Sub-option (d): Develop guidelines on sampling frequency for PSs and RBSPs.

Sub-option 1d involves the development of a guidance document for MS on best-practice sampling approaches for PSs and how to integrate such approaches into water-quality assessments and monitoring strategies. This sub-option will require limited administrative effort, particularly at EU level, while benefits relate to increased harmonisation of sampling frequencies across the EU, and therefore greater comparability of data between countries and river basins, allowing for more targeted policy interventions. Costs to develop these guidelines are expected to be between €290,000 to around €500,000 (Annex 10). The Fitness Check of EU environmental reporting and monitoring acquis (10) estimated the approximate annual administrative burden related to reporting to MS for the EQSD to be moderate (i.e. within the range of €30,000 and €100,000 per MS). The estimated additional costs of aligning sampling frequencies to the developed guidance is expected not to exceed more than 5-10% of those costs.

[64] Horizon 2020 EUROqCHARM project works towards validated harmonised methods for monitoring & assessing macro-, micro- and nanoplastics in environment: https://www.euroqcharm.eu/en

[65] Estimate based on development of microplastics methodology for Drinking Water Directive and the qualification of guidance documents from Annex 10 Table A10.5.

[66] Based on the assumption that each MS will designate one of its water analysis laboratories as national laboratory of excellence for measuring microplastics. Between 5% and 10% of the total number of surface water bodies and groundwater bodies would be sampled. Estimates of CAPEX and OPEX costs were taken from literature.

Sub-option (e): Provide a repository for sharing best practices from MS regarding available monitoring techniques, and foster cooperation to implement these.

Option 4 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 to facilitate knowledge transfer. This option will require a limited administrative effort, particularly at EU level. Cost of developing and hosting a simple repository of best practices is similar to those for drafting guidance documents and ranges from €290,000 to €500,000 (Annex 10, Table A10.5).

6.4.2 6.4.2 Policy option 2 – Obligatory monitoring practices

Sub-option (a): Include an obligation in the EQSD to use EBMs to monitor estrogens.

Option 2a involves the mandatory use of EBMs to monitor estrogens in practice (90). Commercially available bioassays (e.g. ER-CALUX, A-YES and others) are important tools for assessing the toxicity of water samples (91). License-free versions of this type of assay are commercially available and are covered by international inter-laboratory trials. ISO 19040-3 defines validity criteria covering further cell-line-based reporter gene assays. Also, sample preparations do not require special treatment, and extraction / concentration methods are based Solid Phase Extraction (also used for analytical methods) which is very cheap. If performed in-house, costs of around €60/sample (incl. costs for personnel and consumables) are possible. If using commercial labs, costs are around €60-200 euros per sample. Standard Operating Procedures (SOPs) for this type of in vitro EBMs are available and three assays are even ISO standardised. Standardisation has already driven down costs, but future further validation and inter-laboratory studies for other bioassays, used to evaluate effects from estrogenic compounds, would provide a wider choice of methods and result in a further decrease of costs in the coming years. EBM related costs can also be reduced by reusing outcomes of FP7 funded research projects like ‘Solutions’. Solutions already developed chemical, effect-based and ecological tools for monitoring and assessing the presence and effects of mixtures including contaminants of emerging concern (92).

Sub-option (b): Establish an obligatory Groundwater Watch List mechanism analogous to that for surface waters and drinking water, and provide guidance as necessary on the monitoring of the listed substances.

Impacts of this sub-option are comparable to those of the existing SW WL and consist of annual sampling and analysing, by MS, of a limited number of substances. The information gathered would be collected and analysed at EU level, at an approximate annual cost below €1 million. The administrative cost at MS level are comparable to those of the EQSD (see option 1 sub-option d), i.e. between €30,000 and €100,000 per MS per year. The benefit, compared to the existing voluntary watch list, is in achieving a much-improved data set, allowing more targeted and effective policy interventions at both EU and national level.

Sub-option (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.

The sub-option would require, for some substances, an increased frequency of sampling/analysis for monitoring, which would however be compensated by an extension of the watch list review cycle from 2 to 3 years. Therefore, it is expected that the cost impact will be neutral. The major benefit is in capturing substances that have strong seasonal fluctuations, rendering the watch list results more accurate.

6.4.3 6.4.3 Policy option 3 – Reporting and classification

Sub-option (a): Establish an automated data delivery mechanism for the EQSD and the WFD.

Currently, the minimum frequency of monitoring of priority substances in surface water is once per month. However, the aggregated data are only reported every six years. The benefits of sub-option 3a are in obtaining more frequent accessibility of monitoring and status data, allowing to show to the public and policy makers at EU and MS level intermediate progress. It is expected that this will require a significant administrative effort both at EU and MS level. On the EEA side, the costs of facilitating an increased "digitalisation" to accommodate this option will require additional staff at EEA plus EUR 50-100K / year for IT consultancy and hardware. Preparedness for an automated data delivery mechanism varies across MS authorities. While MS maintain their own data sources, data is not usually aligned in terms of spatial coverage and temporal trends and thus requires harmonisation. Also, the system of 'pass /fail' does not provide much insight in the magnitude of exceedances and thus hampers focusing policy responses on pollution hotspots. If concentration data would be reported, this would yield valuable information to investigate the nexus between better water quality and improved human health by using data from the water quality monitoring and evaluation. Expected efforts needed to streamline reporting will, in the long-term, be compensated by reduced administrative burdens, with costs also likely to reduce in the medium to long term. In addition, through digitalisation and automated data reporting, MS data and metadata can be more easily and more frequently accessed and compared, and made available via an online, centralised platform, making them more transparent and up to date. This intervention is coherent with the Zero Pollution Monitoring and Outlook as it improves the basis for better Water Pollution Outlooks reports and introduces co-benefits for the '1-substance-1-assessment' work by ECHA.

The harmonised digital automated data delivery will simplify reporting on inventory of emissions and increase links with the revised Industrial Emissions Portal. This is beneficial for the obligation for MS, according to Article 5 of the EQSD, to establish an inventory of emissions, discharges and losses of all PS and pollutants listed in Part A of Annex I the Directive. This is also coherent with the recent Commission proposal establishing an Industrial Emissions Portal (93), as it can improve the exchange of data between the EU European Pollutant Release and Transfer Register (E-PRTR) and the inventories of industrial emissions. This will enhance the implementation and policy making (including at EU level) through more transparent and real time data enabling focussed decision making and effective control. This would also be beneficial for an increased compliance by MS with the provisions of the EU INSPIRE, and Access to Environmental Information Directives. It also increases coherence with the proposed EU Data Act (94). Whilst there may be an initial administrative burden resulting from the instalment of interoperable data sets which can be accessed by the EC and the relevant EU Agencies, considerable gains, including a reduced administrative burden for MS, are expected in the medium and long run.

Sub-option (b): 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.

Creating a repository assists MS in deriving national EQS, in turn allowing EU standards to be developed and included in the repository following adoption by comitology. This aligns to a proposal under the Chemicals Strategy, which envisages the development of a wider repository of all EU standards for chemical substances. EQS data could feed directly into that work. A harmonised repository would lower the overall administrative burden.

A common repository of standards would secure that knowledge stays accessible to MS and stakeholders. According to EEA data, MS have reported around 150 RBSPs under the 2nd RBMPs. This data would be transferred to the EEA / JRC in a one-off migration to the newly created EU repository. This facilitates quality assurance and measures for RBSPs at River Basin Districts (RBDs) level. One-off costs for developing a repository of standards are comparable to those for developing guidance (€290,000 to €500,000). For hosting and maintenance 0.5 FTE plus EUR 10-20K / year for IT consultancy/hardware are required.

The second part of this option aims at ensuring that, when assessing the chemical status, the results of the RBSPs assessment are included in the assessment of the overall chemical status of a SWB (currently the results are assessed as part of the ecological status assessment). This will improve the consistency within the WFD. This is a relatively significant change for MS and stakeholders and would result in a one-off alignment of reporting systems. Benefits would consist of removing the bias in the status of a SWB since it would be based on harmonised EQSD for RBSPs as currently some MS might have implemented too strict or too lax standards for their RBSPs. Another expected side-effect is that the number of WBs in good ecological status would increase, since possible exceedances due to RSBPs have less effects on achieving good chemical status as they are generally in worse status.

6.4.4 6.4.4 Policy option 4 – Legislative and administrative aspects

Sub-option (a): 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.

This option would allow for a significant acceleration of the time required to update the lists of substances under the EQSD and the GWD. The main impact in administrative terms is on EU Institutions, which would be called to act via delegated acts rather than through the ordinary legislative procedure. In environmental and public health terms, it will allow a swifter policy reaction to emerging pollutants, and a faster delisting if pollutants are no longer a threat, in line with the latest scientific progress and knowledge. Administrative costs will be lower at EU level while at Member State level no significant impact is expected.

Sub-option (b): 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.

The eight pollutants concerned (pesticides Aldrin, Dieldrin, Endrin, Isodrin, DDT, and industrial chemicals Tetrachloroethylene, Trichloroethylene, Carbon tetrachloride) are listed in Annex I of the EQSD and have EQSs derived, but it is stated in footnote 7 of the Annex that these substances are not Priority Substances. 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 value 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. Formally assigning them PS status is merely administrative and entails no costs.

Furthermore, it is not clear why some of these substances have not been designated as PHS[67] 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.

Sub-option (c): 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.

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 edocrine 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.

[67] PHS are a subset of PS that are identified as "toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern" (WFD article 2(29)). Substances identified by the following processes and legislations are relevant: Substances of Very High Concern (SVHC) under REACH, Persistent Organic Pollutants (POPs) under the Stockholm Convention and substances identified as Persistent, Bio-accumulative and Toxic (PBTs) under Regulation (EEC) No.793/93.

6.5 6.5 Administrative burden

As indicated in Chapter 6.4 the approximate annual administrative burden related to reporting ranges from €30,000 to €100,000 per MS. The impact assessment estimated the additional monitoring costs as €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 (10). However, the Fitness Check on the EU environmental reporting and monitoring acquis also concluded that the benefits of reporting obligations significantly exceed the costs, as without reporting obligations the Commission cannot verify a correct implementation. This is even more pertinent in light of the revamped impulse provided by the European Green Deal and the co-legislators' agreement to put in place an encompassing Environmental Monitoring Framework under the 8th Environmental Action Programme (95). In particular, the outputs from this policy intervention would feed into the Zero Pollution Monitoring and Outlook Framework announced by the ZPAP.

The costs related to putting in place an obligatory monitoring method for microplastics are calculated to range from €7,298,800 to €13,362,700.

The administrative burden associated to the groundwater options is limited. For nrMs and pharmaceuticals, these range between €2 and 11 million depending on the level of ambition, with no significant additional administrative costs for risk /status assessments of substances. For PFAS the EU costs are higher, and estimated between €15 and 48 million, depending on the level of ambition, with no significant additional administrative costs for risk /status assessments of substances. All options benefit from the focus on PFAS in the recast DWD, triggering more attention for monitoring relevant substances in source water.

In the implementation of the WFD, EQSD and GWD, the Commission intends to concentrate all work related to the identification and prioritisation of pollutants, including their risk assessment, for inclusion in future revisions of the legislation and in the watchlists for surface water and groundwater, at ECHA. This will require reinforcement of the staff table of ECHA, though it should be noted that at the same time there will be some reductions in administrative expenses in the Commission.

6.6 6.6 Note on impacts for individual MS

The differences in impacts across MS will vary depending on national measures already in place and/or newly proposed and the extent of pressure-exerting activities (agriculture, industry). For pharmaceuticals, for example, many MS already have compulsory or voluntary return programmes in place (Belgium, Czech Republic, Denmark, France Greece, Italy, Netherlands, Spain, Sweden), and/or launched environmental classification schemes for pharmaceuticals (Finland) and/or started other Green Pharmacy initiatives (Finland, Netherlands, Portugal, Sweden) and/or participate in EU funded projects in this area (the EU #Medsdisposal campaign[68] and the EU project "Priorisation and Risk Evaluation of Medicines in the Environment"[69]). The best practice paper on Green and Sustainable

[68] EU Medsdisposal: is a pan-European interdisciplinary stakeholder collaboration campaign to raise awareness on the appropriate disposal of expired or unused medicines in Europe and includes associations representing European healthcare, industry and student organisations: http://medsdisposal.eu/

[69] https://cordis.europa.eu/project/id/875508

Pharmacy in Europe[70] lists these as examples. In the abovementioned MS the potential impacts of proposed quality standards for pharmaceuticals will likely be less, than in MS who have not taken these (or other equivalent) measures.

The impacts also vary depending on the distance to target. As explained in section 6.1.1, it was not possible to conduct this assessment for each Member State, hence the distance to target indicates the situation at EU level. However, it can be considered that in MS and river basin districts where the water already (mostly) meets the proposed standards, the impacts will be less than in MS and river basin districts where the distance to target is still (relatively) large. Generally, areas of intensive agriculture and pesticide use (DE, FR, ES and IT account for 2/3 of sales of pesticides in the EU), those where domestic wastewater is not centrally collected and therefore less connected to treatment networks (e.g. areas with low population densities), as well as areas where the legislation on UWWT is not complied with (e.g. BG and RO and parts of IT, ES, PT), and water bodies with a limited flow (i.e. less dissolution of pollutants) would see the highest impact.

In summary, the EU water legislation does not specify exact measures to be taken to reach a given water quality standard, meaning that the respective efforts required by MS are largely dependent on the current status of pollution and individual choices (beyond what is required under EU legislation) of MS to address the situation with country specific measures.

7 7 HOW DO THE OPTIONS COMPARE AND WHAT ARE THE PREFERRED OPTIONS?

The comparison, where relevant, and evaluation of proposed surface and groundwater policy options is structured around the pollutants being assessed, i.e. the following:

- Pollutants considered for addition to the Priority Substance list (surface water options 1 and 2);
- Pollutants considered for existing EQS amendment (surface water option 3);
- Pollutants considered for deselection from the Priority Substance list (surface water option 4);
- Pollutants considered for addition to the GWD Annexes I and II (groundwater options 1, 2 and 3);

The evaluation of proposed monitoring, reporting and administrative streamlining options is structured around the policy elements being assessed, i.e. the following:

- Policy elements addressing monitoring guidelines;
- Policy elements addressing obligatory monitoring practices;
- Policy elements addressing reporting and classification;
- Policy elements addressing legislative and administrative aspects.

The assessment is presented below, with tables summarising the overall magnitude of impacts (considering the economic, environmental, and societal costs and benefits set out in Chapter 6, Annexes 3 and 9).

In addition, the efficiency, effectiveness and coherence of each of the policy options has been assessed and the results are summarised in throughout the tables in this section.

[70] https://www.pgeu.eu/wp-content/uploads/2019/11/PGEU-Best-Practice-Paper-on-Green-and-Sustainable-Pharmacy-in-Europe.pdf

Quantitative and qualitative factors were considered in assigning the rankings for each criterion. The scale outlined below shows how "+" and "-" are attributed to positive and negative impact expectations.

Very large negative impact	Large negative impact	Medium negative impact	Small negative impact	Balanced impact	Small positive impact	Medium positive impact	Large positive impact	Very large positive impact
----	---	--	-	+/-	+	++	+++	++++

The multi-criteria evaluation made of impacts, effectiveness, efficiency and coherence of the policy options provides support for the preferred policy package.

7.1 7.1 Surface water

The substances in the surface water options were grouped into three different categories. A first category in which the benefits of adding candidate substances to the PS list clearly outweigh the costs (with a sub-category for micro and nanoplastics). A second category where the costs and benefits are more balanced (in these cases a clear set of benefits have been identified, meaning that adding them is worthwhile, but there is a closer balance between the costs and benefits). For the third category, the costs outweigh the benefits.

7.1.1 7.1.1 Pollutants considered for addition to the PS list

The individual (SW option 1) and group (SW option 2) additions of candidate priority substances were compared, where possible, and the preferred option selected for relevant substances. More detailed information about the comparison of environmental, economic and social impacts of these options can be found in Annex 9.

Benefits clearly outweigh the costs for: industrial chemicals - PFAS (all 24 named substances plus the total of all PFAS) (96); 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)).

As detailed in Annex 9, benefits largely relate to avoided healthcare costs stemming from an expected reduced exposure to harmful substances – to be noted this is exposure through all environmental media, not only groundwater or surface water. Specifically, for PFAS, the avoided health costs thanks to reduced exposure (via consumer products, background levels) a result of all EU and Member States policies addressing PFAS – therefore not only those linked to this initiative – are estimated at €52-84 billion/year. According to the Centre for Disease Control and Prevention (CDC), antimicrobial resistance adds a 20-billion-dollar surplus in direct healthcare costs in the United States, which is exclusive of about 35 billion dollars in loss of productivity annually. Numbers for the EU are comparable. The threat of antimicrobial resistance is of particular importance in the category of antibiotic resistance in bacteria. The European Union has an annual mortality rate of 27,000 attributable to AMR. This is comparable to the United States where 2 million people are affected every year by AMR and about 23,000 die as a result[71]. Worldwide, 700.000 people die annually from resistant infections and this means that if no action is taken, the estimated annual deaths attributable to AMR will be 10 million by 2050 (a 14-fold increase). Water can be a reservoir of bacteria resistant to pharmaceuticals due to the presence of pharmaceuticals as pressure, and/or bacteria that are co-resistant to both antibiotics and silver (bacteria share the same mechanism of the resistance). OECD analyses from 2018 found that investing just EUR 1.5 per capita per year in a policy package to tackle AMR is effective and cost-saving, avoiding 27 000 deaths and saving around EUR 1.5 billion each year in EU/EEA countries[72]. Without action AMR related costs will likely also increase 14-fold by 2050 which could then result in annual AMR related costs of around 21 billion by 2050. The EU benefits from an enhanced protection against the development of AMR is estimated at around €1.5 billion/year based on healthcare costs and productivity losses (relevant e.g. for the substances Azithromycin; Clarithromycin; Erythromycin). The annual benefits from a reduced exposure to endocrine disruptors are estimated at €163 billion. This is due to the fact that endocrine disruptors in Europe contribute substantially to neurobehavioral deficits and diseases, as well as to childhood obesity, costing costs €1.54 billion annually.

Avoided/reduced impacts on pollinators and agriculture (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam, Bifenthrin, Deltamethrin Esfenvalerate, Permethrin) account for approximately €14.6 billion annually. Costs for packages of measures such as source control, pathway disruption and end-of-pipe are significant, but they tend to be lower after initial investment or one-off costs, while health and environmental benefits are recurring. Examples of costs are pathway disruption for glyphosate (buffer strips), estimated at around €285 million. Additional controls and treatment for farmed animal use of deltamethrin could cost around €185 million.

The following substances have “balanced” impacts: Ibuprofen, Nicosulfuron, Clothianidin, Bisphenol A, and Silver and are suggested for inclusion.

For silver, costs of listing are expected to be high but comparable to the benefits. This is in particular related to its role in avoiding antimicrobial resistance of bacteria (see also pharmaceuticals sections related to AMR). Water can be a reservoir of bacteria resistant to the silver due to the presence of silver as pressure, and/or bacteria that are co-resistant to both antibiotics and silver (bacteria share the same mechanism of the resistance). Since silver has antimicrobial effects comparable to pharmaceuticals similar costs are assumed to occur for silver[73] (around €1.5 billion/year based on healthcare costs and productivity losses). Similar to pharmaceuticals, without action AMR related costs will likely increase also increase 14-fold by 2050, resulting in annual AMR related costs of around 21 billion by 2050. Therefore, this substance is also suggested for inclusion on the PS list.

[71] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6929930/

[72] https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf

[73] State of the art on the contribution of water to antimicrobial resistance: Sanseverino eta al., 2018, https://publications.jrc.ec.europa.eu/repository/handle/JRC114775

These benefits and costs apply do not arise exclusively from this initiative, but would be the result of joint EU and Member State action, based on all policy instruments that address these pesticides and antimicrobials.

Table 7.1.1: Pollutants considered for addition to the Priority Substance list – preferred option

Substances		Policy option	Environmental impacts	Economic impacts	Social impacts	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
		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 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
		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
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

Substances		Policy option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	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 Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam		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. 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.	Yes
		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 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
		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
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 threshold 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
	Nicosulfor	Policy Option	+	+/	+/	+	++	+	Distance to target is small, primary concern	Yes

Substances	Policy option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
on	1 (individual addition)		-	-	+			could be application by boom-sprayers and spray drift. Assume small benefits to environment from listing. Improved monitoring data could help 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
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 small, suggesting small environmental benefits. 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. Questionable about how efficient a	No

Substances	Policy option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
								listing would be in terms of addressing the issues, and no coherence benefits identified with other legislation. As assume efficiency and coherence are neutral, but a listing in the EQSD would at least address some of the issues, and therefore assume medium benefits for effectiveness.	

As indicated in Chapter 6, there are various reasons to use grouping approaches when adding substances to the priority substance list.

The assessment shows that, out of the four possible groups identified under this option (noting that the addition of PFAS as a group has already been included as part of Option 1) only for the macrolide antibiotics benefits outweigh the costs. Adding these substances as a group would ensure greater coherence in the approach to AMR. Also, correlations in use, pathways to environment and measures will result in significant cost savings if managed as a group. If grouped, possible measures by MS would likely be based on the EQS for Azithromycin as is expected to show the biggest distance to target.

A grouping approach is not recommended for estrogenic hormones, the neonicotinoid and pyrethroid pesticides.

For PFAS, the use of a relative potency factor (RPF[74]) 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 (see Annex 7 for more information) seems a more appropriate way forward.

7.1.2 7.1.2 Pollutants considered for existing EQS amendment

The assessment resulted in two categories of substances. A first category of substances for which the re-assessment of the threshold concluded that the benefits of an improved protection outweigh the costs, or where a less stringent threshold value has only limited impacts. For those an amendment of the EQS is preferable. The second category consists of substances for which the review and reappraisal of EQS concluded that additional measures may be warranted. In this case costs are higher but considered proportionate to the risks. For this category amendment is still considered preferable.

[74] PFOA-equivalent relative potency factors are an indication of the relative toxicity of a PFAS substance compared to PFOA.

Table 7.1.2: Pollutants considered for existing EQS amendment – preferred option

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Pesticides	Chlorpyrifos	+++	+/-	+	+++	+++	+++	Evolving science and nomination as POP under the Stockholm Convention suggests the proposed threshold is appropriate. Would confer strong environmental benefits, while further use of EQSD to support other legislation (particularly the POPs Regulation), would suggest strong benefits for effectiveness, efficiency, and coherence.	Yes
	Cypermethrin	+++	--	+	+++	++	+/-	Proposed EQS thresholds are lower than existing ones, leading to strong environmental benefits. No specific new coherence benefits identified.	Yes
	Diuron	+++	-	+	+++	+++	+	Proposed EQS thresholds lower than the existing ones, leading to strong environmental benefits. Approval of diuron as a pesticide ended in September 2020, so small coherence benefits from reducing the EQS threshold.	Yes
	Dicofol	+/-	+	+/-	+/-	+/-	+/-	Proposed threshold for dicofol higher than the existing one. Rates of exceedance are already low so little impact for environment. Possibly small economic benefits for being able to use analytical equipment with higher LOD.	Yes
	Hexachlorobenzene	+/-	+	+/-	-	+/-	+/-	Proposed threshold for higher than the existing one. Rates of exceedance already low so little impact for environment. Possibly small economic benefits for being able to use analytical equipment with higher LOD.	Yes
	Heptachlor / Heptachlor epoxide	+/-	+	+/-	-	+/-	+/-	Proposed threshold is higher than the existing one. Rates of exceedance already low so little impact for environment. Possibly small economic benefits for being able to use analytical equipment with higher LOD.	Yes
Industrial chemicals	Dioxins	+	-	+	+/-	+/-	++	Proposed biota threshold is more strict. Dioxins are already addressed by a range of legislation (particularly POPs Regulation). Stricter controls have coherence benefits with aims of POPs Regulation and provide environmental and societal benefits (food-chain) from a reduced EQS.	Yes
	Fluoranthene	+/-	+	+/-	+/-	+/-	+/-	Proposed threshold is higher than the existing one. Rates of exceedance are already low so expect little impact for environment. Possibly small economic benefits for being able to use analytical equipment with higher LOD.	Yes
	Hexabromocyclododecane	+/-	+/-	+/-	+/-	+/-	+/-	Amendment of EQS justified through latest evidence. In reality it will not have a material impact on environmental protections, economics, or society.	Yes
	Hexachlorobutadiene	++	+/-	+/-	+/-	+/-	+/-	Amendment would lower EQS. 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	+	+	+/-	+/-	+/-	+/-	Amendment would lower EQS. This would provide environmental benefits. Current distance to target small but could be expected to include a wider number of waterbodies with exceedances. Assume benefits will be medium positive.	Yes
	PAHs	++	-	+	+/-	+/-	++	Amendment would lower EQS. Distance to target already medium, therefore medium positive environmental benefits. Given potential for PAHs to bioaccumulate better controls would have societal benefits (food-chain). Also expect small negative economic benefits if more advance analysis is needed to achieve the LOD/LOQ.	Yes
	PBDEs	+	-	+	+	+/-	+	Amendment would lower EQS for biota (via secondary poisoning). Distance to target already large, with other legislation listing proposals to also reduce critical thresholds. In particular the low POP content for waste under the POPs Regulation. Small	Yes

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
								positive benefits for coherence, and societal (food-chain).	
	Tributyltin	+	+/-	+/-	+	+/-	+/-	Proposed EQS more strict than the existing one. Therefore positive benefits for environment, and effectiveness of the EQSD.	Yes
Metals	Mercury	+++	--	++	+	+	+/-	Amendment would add an annual average EQS (currently only MAC). Distance to target large, and greater control to manage the issues needed. Would lead to strong environmental benefits because it provides more granularity. Medium benefits for society through improved protections, small benefits for effectiveness and efficiency, because annual average EQS threshold aligns mercury with other priority substances.	Yes
	Nickel	++	--	+/-	+	+/-	+/-	Amendments for nickel would lower thresholds. Existing distance to target is medium, with potentially more water bodies failing to meet good chemical status. Medium positive benefits for environment expected, and small benefits for improved effectiveness. Negative economic impacts for greater use of controls and POMs.	Yes

For the following substances the benefits of an EQS amendment outweigh the costs: Dicofol; Diuron; Heptachlor/heptachlor epoxide; Hexachlorobenzene; Tributyltin; Dioxins and furans; Fluoranthene; Hexachlorobutadiene; Nonyl Phenol; PBDEs.

For the substances Chlorpyrifos; Cypermethrin; PAHs; Mercury and Nickel the impact assessment showed that the overall balance of costs and benefits will be neutral. This is because the revised EQS is significantly more stringent and thus yields benefits from increased protection (currently risks are underestimated and therefore additional effort is warranted) but could also trigger a need for new measures to help achieve the new EQS.

7.1.3 7.1.3 Pollutants considered for deselection from the Priority Substance list

Under this option two different categories are identified: 1) deselection would have more benefits than costs; 2) the costs and benefits are more balanced.

Table 7.1.3: Pollutants considered for deselection from the PS list – preferred option

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
Pesticides	Alachlor	+/-	+	+	+	+	+/-	Fully meets deselection criteria, which would assume no negative impacts for the environment if deselected. Small positive benefits in cost savings, and for society, effectiveness, and efficiency (redeployment of resources for other substances).	Yes
	Chlorfen	+/-	+	+	+	+	+/	Fully meets deselection criteria, so no negative impacts for the the	Yes

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	vinphos						-	environment if deselected. Small positive benefits in cost savings, as well as for society, effectiveness, and efficiency (redeployment of resources for other substances).	
	Simazine	+/-	+	+	+	+	+/-	Fully meets deselection criteria, so 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).	Yes
Industrial chemicals	Carbon tetrachloride	+/-	+	+	+	+	+/-	Fully meets deselection criteria, so 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).	Yes
	Trichlorobenzenes	+/-	+	+	+	+	+/-	Largely meet deselection criteria but still in use. Based on very low exceedance rates deselection would have neutral impacts for the environment. Also provide benefits in terms of cost savings and redeployment to other substances. Potential issue due to loss in the time series if releases increased in the future.	No

The substances Alachlor, Simazine and Chlorfenvinphos (herbicides) are placed in the first category. They are banned in the EU for many years, and concentrations above the EQS are identified in only a limited number of water bodies. The overall risk to the environment is considered to be low. Deselection could free up resources that can be reallocated to emerging risks. The deselection of substances is likely to bring cost savings estimated at €3.8 m- €11.7 million per year.

Trichlorobenzenes (solvents and chemical intermediates) are placed in the second category. Their use is ongoing, and the substances are acutely toxic to the aquatic environment. The rates of exceedance are not very high, but deselection is more questionable than for the other substances given the risk quotient RQ and its MSFD relevance. To maintain protection, this substance could be monitored as a RBSP where needed. Consequently, trichlorobenzenes are not proposed for deselection.

All substances have in common that, even if they were removed from the PS list, they might still be relevant as RBSPs, and MS could decide to continue monitoring them at national level where needed.

7.2 7.2 Groundwater

Table 7.2.1: Pollutants for addition to GWD Annexes I and II – preferred option

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
PFAS	Policy Option 1 (Annex I addition as group of specific substances)	Soils: +++ Carbon: --	--- (mitigation measures) +++ (avoided costs DW, health care)	++++	++	++++	++++	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
	Policy Option 2 (Annex I addition as group of all)	Soils: ++++ Carbon: ---	---- (mitigation measures) ++++ (avoided costs DW, health care)	+/-	+++	+++	+++	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
	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
Pharmaceuticals	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

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	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
	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
nrMs	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
	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
	Policy Option 3 (Annex II	----	+/-	+/-	--	+/-	+++	Small impact on reducing levels at European scale means environmental impacts are low	No

Substances		Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	addition)							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.	

Of all options, Option 3 (all PFAS in Annex II, TVs to be possibly set at MS level) not only provides the weakest protection of groundwater, but would also result in a fragmented approach per MS. Given the widespread pollution of PFAS in groundwater and the societal and environmental impacts, EU harmonised action is essential.

For Option 1 (group of 24 PFAS in Annex I) the distance to target is large, meaning that the concentrations in a large number of locations will likely exceed the proposed GW QS in a large number of MS. While the distance to target is similar for Option 2, a simple sum of all PFAS approach is suggested in order to future-proof the legislation. As the distance to target is similar, the types of implementing measures (requiring action on both point and diffuse pollution) would be similar for both options and costs and benefits would also be within the same ranges.

Option 2 are considered in line with the current DWD, but Option 2 would not "future proof" the legislation in terms of the remaining PFAS substances and is therefore not considered protective enough of public health. On this basis Option 1 is selected as the preferred option for PFAS. The latest EFSA opinion on the maximum tolerable intake also points in this direction.

The assessment, the SCHEER opinion and the results of the stakeholder consultation give a preference to Option 1 (add carbamazepine and sulfamethoxazole to Annex I, with individual GW QS). This option has generally smaller costs than Option 2 (adding the two substances as a group). Option 1 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'[75] initiatives or other source control and pathway disruption measures.

The assessment also showed that there is enough evidence for Primidone[76] to be added to Annex II[77] (i.e. partly implementing Option 3), which would not have a large impact on costs

[75] Green pharmacy – a narrative review: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6296717/#b1-cm-91-391
[76] During the period of the SCHEER review, the Groundwater Watch List dataset was supplemented with additional data following a SCHEER request.

or benefits. Adding Primidone means that MS have to establish suitable threshold values for this substance at national level.

Most of the parent pesticides of the 16 nrMs identified are already banned. For the remaining parent pesticides, a number of strategies and legislation at EU level will drive down pesticide use, as well as national action plans under the SUPD[78]. Stakeholder feedback suggests that there is a common understanding that nrMs are widely found in groundwater in worrying concentrations and that the emissions of the parent substances need to be limited.

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 likely to maintain the status quo and no additional measures beyond those identified under the dynamic baseline scenario are needed. Option 3e (all nrMs in Annex I with lower GW QS) are coherent with that. Given that the 16 nrMs are already detected in groundwater, there is a risk of further substances detected in future at levels of concern. Option 3e extends the more stringent GW QS to all nrMs of pesticides and thus future proofs legislation, whilst following the precautionary principle: it should therefore be selected.

7.3 7.3 Monitoring, reporting and administrative streamlining options

Error! Reference source not found. summarises the impacts of implementing the monitoring, reporting and administrative streamlining options, compared to the status quo. The options presented are not mutually exclusive.

Table 7.3.1: Monitoring, reporting and administrative streamlining – preferred options

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	+/-	+/-	+	+/-	+/-	++++	As above	Yes

[77] During the March 2022 stakeholder workshop, participants concluded that from the 9 pharmaceutical substances (Clopidol, Cortamiton, Amidozoic Acid, Sulfadiazine, Primidone, Sotalol, Ibuprofen, Erythromycin, Clarithromycin) considered on the Groundwater Watch List only for Primidone there was enough evidence to consider inclusion at this point in time.

[78] COM(2022) 305, proposal for a regulation on the sustainable use of plant protection products.

Policy option	Sub-option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
	microplastics.								
	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
<u>Option 2:</u> 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
<u>Option 3:</u> 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
	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

Policy option	Sub-option	Environmental impacts	Economic impacts	Social impacts	Effectiveness	Efficiency	Coherence	Justification	Preferred option
<u>Option 4:</u> 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

8 8 PREFERRED POLICY PACKAGE

8.1 8.1 Preferred options summary

The preferred policy options are aggregated in Table 8.1.1 below. The package of options all surface and groundwater options and the digitalisation, administrative streamlining and better risk management options marked as preferred in the preceding chapter.

Table 8.1.1: 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
Groundwater		
<u>Option 1:</u> Addition to Annex I with GW QS set for each individually		**2 pharmaceutical substances:** Carbamazepine and Sulfamethoxazole 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"		PFAS (sum of 24 named substances)
<u>Option 3:</u> Addition to Annex II		**1 substance:** Primidone
Digitalisation, administrative streamlining and better risk management		
<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. .
	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.

8.2 8.2 Overall magnitude of impacts

The proposed policy package ensures that legislative changes remain proportionate, i.e. that societal and environmental benefits are larger than economic costs incurred and that the issues are best addressed at EU level. An overview of direct and indirect costs and benefits associated with the options is provided in Annex 3.

As set out in the introduction to section 6 it is not possible, in this impact assessment, to identify the isolated cost and benefit of listing substances since this will depend on measures chosen by MS and on distance to target in the concerned water bodies. Moreover, water legislation works in sync with other legislation (waste water treatment, source control, international requirements, etc). Figures mentioned are therefore often related to estimated costs / benefits from groups of substances with similar characteristics or effect.

For surface water, significant direct adjustment costs are expected for instance from the fact of adding ibuprofen, glyphosate, PFAS, Bisphenol-A and Silver to the PS list, as well as from the amended EQS of PAHs, mercury and nickel. In relation to groundwater, the most significant costs are expected for PFAS, associated with the restriction of use (e.g. in fire-fighting foams - up to €390 million/year per substitute use) and the management of contaminated bio-solids (up to €755 million/year for incineration and €201 million/year for landfilling at EU level). The cumulative costs of the preferred digitalisation, administrative streamlining and better risk management options are of an administrative nature, initially materialising at EU level and generally low (below €1 million), with the possible exception of the automated data delivery mechanism.

It is worth noting that costs cannot be attributed solely to this initiative, due to inevitable interactions and synergies with many other EU policies tackling the same substances. The costs of pollution are mostly internalised through the IED and the UWWTD, the future ban on all PFAS except in essential uses, the implementation of the microplastics initiatives and others. For example, the revision of the UWWTD will boost the upgrade of many UWWTPs, and introduce extended producer responsibility (EPR) to cover the costs, which will significantly reduce the load of micropollutants (like pharmaceuticals and microplastics) entering surface and groundwaters.

The proposed initiative will contribute to the benefits of water policy primarily by reducing concentrations of acutely toxic and/or persistent chemicals in surface and groundwater. It will also improve the value of the aquatic ecosystems and of the services they deliver. However, the valuation of these benefits is challenging. First, this is because it is difficult to attribute benefits to specific measures. Many measures are multifunctional and have multiple benefits that contribute to the objectives of several policies. A second challenge is that the evaluation of benefits requires taking account of various non-quantifiable and location-specific factors, which limits the potential for aggregation and accurate monetisation (this is the case in particular for ecosystem services).

Nevertheless, this impact assessment concludes that overall benefits for society outweigh costs considerably, based on reduced impacts on the environment, human health, pollinators and agriculture, as well as avoided costs of water treatment. For example, annual healthcare costs related to endocrine disruptors' exposure are estimated to be €163 billion, whereas hypertension brought about by background PFAS exposure contributes to an estimated €10.7-35 billion of annual health costs. The annual health benefits from lowering the risks of PFAS exposure are estimated to be at least €52-84 billion in the EEA countries. The annual avoided costs from not using reverse osmosis to remove PFAS from DW are estimated to be at least €9.13 billion. Not having to use reverse osmosis would also lower by 20% the amount of water extraction needed to produce drinking water. In addition, the annual costs associated with treating BPA-containing leachate from landfills are estimated at around €103.7 million (assuming 25-year lifetime), whilst the costs of end-of-pipe removal of microplastics from waste water are estimated to be between €0.76-3.14 billion per year. Regulating background levels of these chemicals in surface and groundwater bodies is important to drive down emissions, hence avoiding or significantly reducing these costs. When assessing the annual health benefits from the health and environmental effects of nanosilver[79] the possible role of silver in antimicrobial resistance is a relevant issue and is therefore included.

These costs and benefits should be understood as the joint result of all policy actions by EU and Member States that address the concerned pollutants, and should therefore not be seen as the result of this initiative alone.

The preferred policy package will result in water quality improvements contributing to the achievement of the main objective of this review, in line with the Zero Pollution and Biodiversity targets. As water quality issues (especially those caused by emerging pollutants) have a clear cross-border dimension, they need to be addressed at EU level to ensure a uniform level of protection for EU citizens and ecosystems. Considerations of proportionality have been embedded into the legislative review so that decisions are guided by the presence (or absence) of an EU-wide risk. Where no such risk was identified, flexibility was left for MS to set their own TVs.

8.3 8.3 One In, One Out

In the context of the '**one in, one out**' approach to which the Commission committed, it is important to pay specific attention to the costs and implications to business, especially small and medium sized enterprises. Costs to business, including the agriculture sector related to this initiative include: (i) administrative costs; (ii) costs related to fertiliser and pesticide management, adjusted feed techniques and sampling, and waste water treatment; (iii) taxes and fees for the cost recovery of water services and activities with a significant impact on the environment; and (iv) in certain cases, costs of substitution. Costs on business and administration will be felt more upstream due to the need to limit emissions during production or find substitutes for certain substances. Benefits may be felt rather by business downstream, such as the waste water treatment sector and the drinking water producers, as well as water users such as farmers and building sector.

Administrative costs cannot be assessed at the level of businesses, since MS will take very different measures to comply, considering the characteristics of the water body and the distance to target of the substances proposed for listing. Administrative expenses at EU level,

[79] Based on scientific opinions of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on 'Nanosilver: safety, health and environmental effects and role in antimicrobial resistance' (https://health.ec.europa.eu/system/files/2016-11/scenihr_o_039_0.pdf) from 2014 and SCCS (2018) opinions

in particular those linked to the monitoring, reporting and administrative simplification options, are specified in section 6. Those costs range from € 1.9 to 2.3 million for the guidances (effect based methods), methodology for microplastics, repository of RBSPs and groundwater watchlist analysis, of which €1 million is annually recurring. Administrative expenses at MS level associated with monitoring pollution are overall expected to increase, due to the increased number and different nature (like microplastics and groundwater) of substances covered by the legislation. Cumulative costs are estimated between €9 and 15.1 million annually across the EU-27 (thus estimated at around 0.33 million to €0.55 million per year per MS). Both the European Environment Agency and the European Chemicals Agency will be tasked to carry out tasks on the water quality data access and the risk assessment of pollutants respectively, leading to annually recurring costs in the form of additional staff.

8.4 8.4 REFIT

In line with the FC of 2019 and with the more holistic Monitoring Framework put in place by the 8th Environmental Action Programme, several elements of the existing Directives will be clarified and simplified in the legislative proposal on the basis this IA. This concerns notably the requirements related to reporting and data sharing. An improved collection of digital information at EU level which allows improved understanding of pollutants in EU waters (and so better targeting of measures), is likely to reduce the administrative burden of MS 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 by publishing them on an online, centralised platform. This would also be beneficial for increased compliance of MS with provisions of the EU INSPIRE Directive, e.g. by using the INSPIRE Geoportal for this purpose. Digitalisation also helps to act independently of reporting timeframes, thus making data available more often and closer to real time. This would be beneficial for MS authorities, to demonstrate progress at national scale, and better empower civil society too.

The revised Directives will introduce monitoring obligations for the newly listed substances while removing the obligations related to deselected substances. The extent to which the monitoring obligations trigger follow-up actions to reduce the emissions of those substances is limited to water bodies that are not in good status already (currently 59% of surface waters (11) (97)). In these cases, MS are obliged to take additional measures to ensure their surface water bodies achieve good chemical status.

The Impact Assessment has differentiated this picture by assessing the expected 'distance to target' according to the type of pollutants (see Chapter 0). This revealed that for 13 of the 24 substances or substance groups included in the preferred policy package as additions and for 10 of the 15 substances or substance groups for which a change in EQS values is proposed, the expected distance to target is small to medium. Consequently, for these substances only limited or no additional measures are expected.

A relatively large distance to target is expected only for 10 of 24 (groups of) substances proposed for addition, namely PFAS, four pyrethroid insecticides (Deltamethrin, Esfenvalerate; Permethrin; Bifenthrin), Glyphosate (herbicide), Bisphenol-A (industrial chemical), Silver, and three pharmaceuticals (Carbamazepine, Diclofenac, Ethinylestradiol (EE2)). The same is also expected for Mercury and the flame-retardants Polybrominated diphenyl ethers (PBDEs) for which a change in EQS values is proposed. For Mercury it needs to be noted that this is a ubiquitous substance which is already causing failure to achieve good status in a large number of water bodies, so a revision of its EQS will likely not deteriorate the compliance situation significantly.

9 9 HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

9.1 9.1 Indicators of success

The following success indicators were identified for the general objectives of this initiative to help compare the merits of the policy options and facilitate monitoring and evaluation.

1. Increase the protection of EU citizens and natural ecosystems
    - Declining concentrations of PS / PHS and ultimately achieving good chemical status for all EU surface waters, groundwaters and coastal waters.
    - An agreed EU measuring and monitoring method for microplastics in place by 2025
    - A more effective surface and groundwater watchlist mechanism (e.g. introduction of an obligatory GW WL mechanism by 2025)
2. Increase effectiveness and reduce administrative burden
    - Introducing automated data delivery mechanisms for reporting water monitoring data
    - Using delegating acts for future revisions of the list of water pollutants

These indicators will support, and feed into the integrated monitoring of pollution that has been created by the Commission's Zero Pollution Action Plan.

9.2 9.2 Monitoring and evaluation under the existing EU water quality legislation

The existing WFD has a 6-yearly reporting cycle. In every cycle, MS report on the state of water in each river basin to the Commission, through the EEA. The EEA utilises this data to produce a State of Water report. The monitoring results for individual PS/ PHS feed into chemical status assessments (pass/fail) per WB. The Commission uses the information to assess the RBMPs and as a basis to assess compliance with the legislation. MS are required to report the specific measures they have taken to reduce pressures on water quality. As such success can be heterogeneous between different WBs. This heterogeneity learns that success factors also relate to measures in other policy areas. Measures to address mercury levels in surface water largely depend on measures to tackle Hg-emissions from the combustion of coal in large combustion plants, and pesticide emissions relate to DSUP measures.

The monitoring and reporting obligations under 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 MS will be introduced as a result of the preferred policy package (e.g. by the mandatory GW WL).

Currently, data reach the public domain with considerable delays. For example, the 2018 EEA State of Water report is based on 2012-2014 data and is, at the time of writing, the most up to date information publicly available at EU level. While acknowledging that an assessment of good status (ecological or chemical) is dependent on many different data put together, better uptake of modern monitoring and digital reporting would allow generating those overviews with a higher frequency than every 6 years, feeding into the 8th EAP Monitoring Framework and the bi-yearly Zero Pollution Monitoring and Outlook Reports. It should also be possible to produce data on individual quality elements. This is in line with digitalisation, administrative streamlining and better risk management options 4 (a repository for sharing best practices regarding available monitoring techniques and their implementation) and 5 (an automated data delivery mechanism to ensure shorter intervals of monitoring, while streamlining reporting).

9.3 9.3 Joint monitoring and evaluation

In addition to the monitoring established under the WFD and the improvements proposed in this initiative, monitoring of water pollutants in EU laws that address pollution is crucial. In particular, the monitoring provisions included in the revised Industrial Emissions Portal (formerly: E-PRTR), UWWTD and other relevant legislation will be used to assess the policy effectiveness. Currently, the E-PRTR does not require reporting of PFAS emissionsHowever, PFAS is one category of substances that is envisaged to be added to the Industrial Emissions Portal Regulation based on the Commission proposal for revision. Automated links with the most recent lists of water polluting substances under this initiative are envisaged.

This initiative is related to many other work strands under the ZPAP which are ongoing or only starting to deliver results. By 2025 the Commission will take stock of the degree of implementation of the ZPAP action plan, building on the second Zero Pollution Monitoring and Outlook Report. The water quality monitoring in the MS will help evaluate the success of the present initiative, which will realistically only start to become visible after 2027. Combining the output and outcome indicators of those pieces of legislation with the impact indicators set by assessing “good chemicals status” will give a measure of whether the health and ecosystem benefits have been achieved or where there are gaps in implementation.

Proper monitoring and reporting is key to ensure compliance with the Directive and to allow EU and MS to adjust policies in case these appear not to deliver the desired effects. In order for the legislative changes to become operational and effective, compliance at MS level must be secured. An important part of compliance assurance will be done through sectoral legislation (IED, UWWTD, Sustainable Use of Pesticides, REACH, Mercury Regulation, etc.) setting requirements for polluters, but also through the Environmental Liability Directive and Environmental Crime Directive which are currently under revision. The existing WFD contains several provisions that, in combination with the above-mentioned legislation, lay down a comprehensive compliance assurance mechanism. The more continuous availability of monitoring and status data (a combined effect of policy options 2a, 2b, 5 and 6) both to the European Commission and the general public will increase the overall enforceability of the legislation. The creation of a mandatory groundwater watch list (Option 7) will lead to a more structured involvement of stakeholders in prioritising action on the most harmful substances, likely enhancing their interest in compliance.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The preparation of this impact assessment was led by Unit C1 Sustainable Freshwater Management within DG Environment, with support from DG Joint Research Centre, Unit D2 Water and Marine Resources. The file concerns the revision of the lists of pollutants and corresponding regulatory standards under the WFD, EQSD and GWD. These Directives were evaluated according to Better Regulation guidelines. The Decide planning number is PLAN/2020/8554 - Revision of lists of pollutants affecting surface and groundwaters.

2. ORGANISATION AND TIMING

2.1. COMMISSION INTERNAL PROCESS - INTER SERVICE STEERING GROUPS

The Inception Impact Assessment Roadmap (98) was published on 23 October 2020 with feedback period closed on 20 November 2020.

The inter-service steering group (ISSG) for the impact assessment is the same one as for the Evaluation. It is a shared group with other water and pollution related files: the revision of the UWWTD, the Evaluation of the SSD and the back-to-back Evaluation and impact assessment of the Bathing Water Directive. The ISSG includes members from the following DGs: AGRI (Agriculture), CLIMA (Climate Action), ENER (Energy), FISMA (Financial Stability, Financial Services and Capital Markets Union), GROW (Internal Market, Industry, Entrepreneurship and SMEs), HOME (Migration and Home Affairs), JRC (Joint Research Centre), JUST (Justice and Consumers), MARE (Maritime Affairs and Fisheries), RTD (Research and Innovation), REGIO (Regional and Urban Policy), SANTE (Health and Food Safety), SG (Secretariat General), SJ (Legal Service), TAXUD (Taxation and Customs Union) as well as the EEA (European Environment Agency).

Seven meetings of the ISSG were organised between October 2020 and September 2022, the final meeting being held on 22 September 2022. The ISSG has been consulted on all major deliverables for this file, including the inception impact assessment, the stakeholder consultation, including stakeholder consultation workshops, open public consultation and targeted experts survey and key deliverables for the support study prior to its submission to the Regulatory Scrutiny Board. The ISSG that was consulted during this process is identical to the one involved in the REFIT Evaluation of the Directives.

3. CONSULTATION OF THE RSB

On 15 July 2021 an upstream meeting with the Regulatory Scrutiny Board (RSB) took place. The RSB provided several comments in relation to this file, centred on the following:

- Need to prevent pollution at the source, enforceability and monitoring of the changes to the Priority Substances list and clarifications on the applicability of the precautionary principle;

- Need to establish a Dynamic Baseline Scenario, allowing to account for implications of existing and planned EU legislative initiatives (e.g. Human Pharmaceuticals legislation, Drinking Water Directive, UWWTD, etc.).

The IA was submitted to the RSB on 25 May 2022 and discussed on 22 June. On 24 June the RSB issued its positive opinion with reservations. The points have been addressed as follows:

RSB 'What to improve'	**How the comment has been addressed**
(1) The design of options should allow the identification of impacts, separately for each option or their combination. The options and their presentation should be simplified, and purely technical elements moved to the Annexes. The report should provide more aggregated and more relevant options and sub-options. Options linked to administrative simplification and burden reduction should be grouped together.	Presentation of the policy options has been simplified in section 5 and onwards. In particular the options aimed at monitoring, reporting and administrative streamlining have been aggregated to four main options with sub-options. The link with the overall objectives has been clarified, in particular in section 5.
(2) The analysis of the impacts on SMEs and citizens should be further developed. The report should elaborate on the impacts on SMEs, including in terms of the compliance costs and administrative burden, and present the results of the application of the proportionate SME test. The impacts on consumers should also be further analysed (indicatively, in relation to pharmaceuticals, personal care products, consumers' health, cost of water services) and the evidence should be clearly presented for the conclusions reached. The report should be more explicit on the implementation deficits in the problem analysis and examine the different possible impacts across MS. It should map out the respective efforts required from different MS to meet the targets set.	The impacts on SMEs has been further developed throughout the text, from the perspective of the different groups of pollutants. The SME test has been used as a guidance but could not be applied in full because of missing data and the context-specific nature of the measures to be taken by MS in response to the legislation. Information on impacts on consumers for several categories of products (including personal care products) has been addressed, in sections 2 and 6. As regards efforts required from MS, Annex 4 provides more information where the distance to target is largest and Annex 11 indicates for each substance which MS have measured exceedances at present.
(3) The report should critically examine the validity of the benefit and cost estimates presented as the examples of the potential impacts, provide more detail on the scope and methods used and indicate how relevant the examples are to this initiative. It should strengthen a summary of the results of the cost benefit analysis, taking into account all qualitative and quantitative evidence and indicating the overall order of magnitude of the expected impacts of the preferred option. Given the link with many existing and ongoing initiatives, the report should discuss the relevance and attribution of costs and benefits to this initiative. Annex 3 should be simplified to integrate in a concise manner the qualitative and quantitative evidence. The analysis should reflect any changes to the options' structure.	It has been clarified in sections 6 and 8 how the examples of benefits and costs need to be interpreted, to avoid the impression that the costs and benefits quoted are solely linked to measures following from this initiative. Annex 5 shows the approximate effect of existing and future policies on the substances proposed as part of this initiative.
(4) The report should clarify the costs and cost savings in scope of the One In, One Out approach. The dedicated section and Annex 3 seem incomplete. All costs and benefits related to the One In, One Out approach should be identified and clearly presented.	The paragraph on One In, One Out in section 8 has been supplemented with information on the costs of the monitoring, reporting and administrative streamlining options. Relevant information has also been included in Annex 3.
(5) The report should systematically integrate the	Section 7 now includes a summary assessment of

criteria of effectiveness, efficiency and coherence in the comparison of options.	effectiveness, efficiency and coherence for the options and sub-options, including a justification for a particular score on these criteria.

A large number of other improvements have been made as well, in reaction to more detailed RSB comments as well as other corrections deemed necessary.

4. EVIDENCE, SOURCES AND QUALITY

To support the impact assessment, the European Commission awarded a contract to external experts. The revision of the lists of pollutants under EQSD, GWD and WFD was prepared by the Commission's Joint Research Centre (JRC) which elaborated dossiers for each individual substance. To draft the scientific dossiers JRC collected data from available EU official reports (ECHA, RIVM, INERIS, UBA, OEKOTOXZENTRUM, etc.) and collections of data send by experts and stakeholders. In most cases such dossiers were prepared in consultation with working groups consisting of experts from MS and stakeholders, allowing each to bring their expertise to bear on the content of the dossier. In a next step, the Commission consulted stakeholders through the relevant CIS-working groups. Finally, the Scientific Committee on Health and Environmental and Emerging Risks (SCHEER) expressed an independent scientific opinion on the proposed EQSs for each of the dossiers. Preliminary SCHEER opinions for substances of the "Draft Environmental Quality Standards (EQS) for priority substances under the WFD and GWD" are published for a 4-week commenting period. During this period comments were collected and considered, if relevant they were addressed directly by SCHEER in the final opinion. All substance dossiers both for new candidate PS and EQS revision substances were submitted to SCHEER for scientific opinion. Below is an overview of the progress of the work by the SCHEER.

1. Preliminary SCHEER opinions are available for the following substances:
   - *Nonylphenol, Glyphosate, Nickel, Fluoranthene.*
2. Opinions being finalized (comments from public consultation period being processed):
   - *Ibuprofen*
3. Final SCHEER opinions are completed for the following substances:
   - *Pesticides (Nicosulfuron), Pesticides-Pyrethroids (Bifenthrin, Esfenvalerate, Permethrin, Deltamethrin); Pesticides-Neonicotoids (Acetamiprid, Clothidianidin, Thiamethoxam, Thiacloprid, Imidacloprid); Macrolide antibiotics (Azithromycin, Clarithromycin, Erythromycin); Estrogenic hormones (17-Alpha-Ethinyl-Estradiol (EE2), 17-Beta-Estradiol (EE2), Estrone (E1)), Metals (Silver), Diclofenac, PFAS, Cypermethrin, Groundwater (PFAS, Pharmaceuticals & nrMs), Carbamazepine, Chlorpyrifos, Bisphenol-A, Hexachlorobenzene, Diuron.*
4. Pending SCHEER Opinions:
   - For the following dossiers for **new candidate** substances the SCHEER has not yet published a preliminary option: *Triclosan.*

- For the following dossiers for **existing candidate** substances for a revised EQS the SCHEER has not yet published a preliminary option: *Mercury, PAHs, Hexachlorobutadiene, Heptachlor, PBDEs, Dioxins, Tributyltin, Tetrachloromethane*.

For substances proposed for deselection: Alachlor, Simazine, Carbon tetrachloride there was no need for a SCHEER opinion.

A summary of the stakeholder consultations that were carried out (Open Public Consultation and Expert Survey) is included in Annex 2 Stakeholder Consultation (Synopsis report).

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. INTRODUCTION

The Impact Assessment accompanying the revision of the lists of pollutants affecting surface and groundwaters and the corresponding regulatory standards in the Environmental Quality Standards, Groundwater and WFD was subject to a thorough consultation process that included a variety of different consultation activities. During the process, the Priority substances proposed for revision were consulted with stakeholder through the sub-groups of experts relevant to each substance and overall in the WG Chemicals, WG Groundwater and Strategic Consultation Groups. Furthermore, an Open Public Consultation has been conducted, as well as a Targeted Experts Survey and two Stakeholder workshops.

2. CONSULTATION STRATEGY & ACTIVITIES

2.1. Purpose of the online public consultation and targeted consultation

Consultations for the impact assessment of the possible revision of the lists of pollutants affecting surface and groundwaters and the corresponding regulatory standards in the Environmental Quality Standards, Groundwater and WFD were conducted with the aim of gathering the opinion of the general public and experts.

The scope of the consultations primarily concerned three key water policy domains in the EU: the WFD, the EQSD and the GWD. The WFD aims to ensure that all surface and groundwater bodies (including transitional and coastal zones) achieve “good status”. For a water body to be classified in overall good status, both the chemical status and the ecological or (for a groundwater body) quantitative status must be at least good. Regarding chemical status (the focus of this consultation)- a process to analyze substances which pose a significant EU-wide risk to the environment and require further action (Priority Substances) is enshrined in the WFD. The EQSD establishes standards for these Priority Substances- ensuring that MS do not surpass thresholds which pose a threat to the environment and human health. The GWD expands WFD requirements for groundwater quality and protection through providing a list of relevant pollutants and groundwater quality standards. Furthermore, the GWD establishes a list of substances which MS should consider when setting national threshold values for pollutants.

The key objectives of the consultation process were (i) to confirm the scope of the impact assessment and (ii) to collect information on potential impacts of proposed options and measures- particularly on potential costs and benefits.

2.2. Consultation strategy

The consultation strategy was developed at the start of the study, in collaboration with the European Commission. The consultation methods and tools outlined in the strategy have been followed, as described in more detail in the following sections. Table A2.1 presents the stakeholder groups mapped to each consultation activity.

Table A2.1: Stakeholder groups consulted by each consultation approach

Stakeholder type	Consultation approach		
	Open Public Consultation	Targeted consultation survey	Targeted consultation meetings
EU institutions		X	X
General Public	X		
EU MS' Authorities	X	X	X
Third-country stakeholders	X	X	X
Businesses and trade associations	X	X	X
Non-governmental organisations	X	X	X
International organisations	X	X	X

2.3. Methods of stakeholder engagement

The main consultation activities for the study were the following:

- Feedback received on the Impact Assessment roadmap;
- Open public consultation (OPC);
- Targeted stakeholder engagement through a and expert survey;
- Targeted stakeholder meetings (2 workshops and dedicated interviews).

2.3.1. Impact Assessment Roadmap

The European Commission published the roadmap on 'Integrated water management – revised lists of surface and groundwater pollutants' (98) 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 are synthesised in section 3.1 of this annex.

2.3.2. Open Public Consultation

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

- 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;
- Ensure a high and equal level of protection of groundwater resources including their connected or dependent ecosystems and their uses;
- 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. The consultation period started on 26th July 2021 and ended on 1st November 2021. The OPC received a total of 151 responses. An analysis of the feedback received is presented in section 3.2 of this report. A factual summary was published on the Commission's Have Your Say pages (98).

2.3.3. 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 targeted 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 and 19th October 2021.

The survey addressed the three topic areas: surface waters, groundwaters and the digitalisation, administrative streamlining and better risk management options. The policy options were based on:

- Addition of substances and/or groups of substances to the list of Priority Substances (PS) in surface waters (Annex X to the WFD) and the setting of corresponding Environmental Quality Standards (EQS) in the EQSD;
- Possible amendment of EQS / deselection of existing PS from Annex X to the WFD and Annex I to the EQSD;
- Designation of some PS as Priority Hazardous Substances (PHS) in Annex X to the WFD; re-designation of the eight "other pollutants" in Annex I of the EQSD: conversion to PS, deselection, or retention 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;
- A set of complementary options aiming to encourage the use of new monitoring methods and improve current monitoring approaches, improve risk assessment and the translation into risk management, and enhance data management transparency and utilization.

The targeted survey received a total of 124 responses.

3. METHODOLOGY AND TOOLS USED TO PROCESS THE DATA

3.1. Open Public Consultation (OPC)

The approach taken included:

- Respondents were asked to respond to stand-alone open-ended questions in combination with elaborating their answers in open text fields. .
- Based on the responses to questionnaire data graphics were created to summarise and present the outcomes.
- Finally, any attachments, links, or other materials submitted by stakeholders were analysed and incorporated.

3.2. Targeted stakeholder consultation - survey

The analysis steps were:

- Questionnaire raw data was imported and cleaned in an Excel template.
- Graphics were created to summarise and present the outcomes.
- Respondents were asked to respond to stand-alone open-ended questions in combination with elaborating their answers in open text fields.

- Finally, any attachments, links, or other materials submitted by stakeholders were analysed and incorporated.

Due to the low number of responses and a general lack in EU wide representation it was not possible to interpret Member State specific response patterns in the obtained answers. As such, the analysis focuses on a general overview of respondents' opinions regarding the matter, without concluding broadscale national or sector specific positions/opinions.

3.3. Targeted stakeholder consultation - workshop and interviews

Throughout the course of the project, two thematic workshops were held. The workshops focused on specific core subjects of interest, as highlighted in Table A2.2 below.

Table A2.2: Workshops summary

Workshop	Topic	Number of participants
1: 21st May, 2021	Primary objective: gather feedback from stakeholders on the policy options presented. The workshop was split into three distinct components to align with the types of options considered in the Impact Assessment, namely: surface waters, groundwaters and digitalisation, administrative streamlining and better risk management options	247 participants registered.
2: 18th March, 2022	Primary objective was to gather feedback on the elaborated set of policy options and the cost-benefit assessment. The workshop was split into a groundwater and a surface water session, and a session to discuss the digitalisation, administrative streamlining and better risk management options.	250 participants registered

3.3.1. Workshop 1

The workshop was split into three distinct components to align with the types of options considered for the impact assessment, namely: surface waters, groundwaters and digitalisation, administrative streamlining and better risk management options.

For surface water, four topic areas of options formed the basis of the discussion: addition of candidate substances to the PS list; amendment of EQS for existing PS; designation of the eight "other pollutants" (included in Annex I of the EQSD) as PS; and deselection of existing PS which no longer present an EU-wide risk.

For groundwater, three topic areas of options would form the basis of the discussion within the group: adding PFAS substances to Annex I or II of the GWD; adding pharmaceuticals to Annex I or II of the GWD; and, adding (potentially) harmful degradation products from pesticides (nrMs) to Annex I or II of the GWD.

Finally, the digitalisation, administrative streamlining and better risk management option segment of the workshop focussed on measures identified in the FC of the WFD and Daughter Directives (10). The digitalisation, administrative streamlining and better risk management measures session of the workshop focussed on three topics that aimed to maximize the (cost) effectiveness of procedures, namely: monitoring approaches; risk assessment and the translation into risk management; and data management.

3.3.2. Workshop 2

The second workshop took place on 18 March 2022, when the work both on the substance dossiers and the impact assessment background study had advance considerably. The meeting was used to present the results of the stakeholder consultation activities so far, in particular the expert survey and open public consultation. The lionshare of the meeting was however devoted to the review of the first results of the assessment of environment / social / economic costs and benefits of the options developed. To this end, a separate session was organized on surface water options, groundwater options and the range of digitalisation, administrative streamlining and better risk management options. Participants received a background document containing the core results of the assessment and an extensive powerpoint presentation.

4. SUMMARY OF RESULTS OF THE STAKEHOLDER CONSULTATION

The key findings overarching all consultation activities can be summarized as follows:

- Stakeholders noted concerns about contaminants of emerging concern, their impacts and how these are being addressed. PFAS, microplastics and pharmaceuticals stood out as concerning substances that require attention in both surface waters and groundwaters.
- In surface waters, stakeholders did not provide a clear preference across consultation activities as to whether specific substances should be added as groups (rather than separate entries), except for PFAS. Overall, stakeholders were uncertain, or had no opinion on this, given the varying potencies of specific substances within broad groups, the threat of losing the granularity over specific substance risks, or the required modes of action on substances.
- For groundwater, results across consultation activities were coherent and indicated that PFAS should be added to GWD Annex I with a standard 0.10 ug/l. Also, pharmaceuticals (Carbamaxepine and Sulfamethocazole) should be added as individual substances Annex I. Consultation activities indicated that stakeholders agree that metabolites from pesticides should be added, however there were conflicting observations regarding whether the addition should be to Annex I or Annex II.
- There was a strong recognition from stakeholders that upstream measures in the form of the precautionary principle and the application of polluter pays principles are needed to be considered when addressing risks of contaminants of emerging concern.
- Finally, stakeholders indicated that the revision of pollutants and their EQS's need to be coherent with other directives (e.g. DWD, UWWTD and agricultural policies), and there must be improvements of data collection and transparency of monitored data.

4.1. Impact Assessment Roadmap

Feedback on the Impact Assessment Roadmap was provided by 19 stakeholders, with one document not included in the analysis due to duplication. 10 responses were from business associations, whereas 2 were from EU citizens, NGOs, company/business organization and 'other'. One response was received from a public authority. The key themes in the feedback included:

- Stakeholders noted that stronger coherence between the WFD and other EU legislation is required- in particular with EQSD (n=2, other, public authority), GWD (n=2, other, public authority), DWD (n=3, Public authority, other, business association), agricultural policy (n=4, other, business association, company/business organization, public authority), and REACH (n=1, other);
- Stakeholders also noted the need for stronger upstream prevention and control to force prevention at source (n=4, NGO, 3 Business associations);
- More focus on substances of emerging concern is needed, in addition regarding pollutant mixtures (n=3, NGO, Company/business organization, Business association), in addition to pharmaceuticals, (micro) plastics and PFAS (per and polyfluoroalkyls) (n=1, other);
- Local conditions should be considered when establishing EQS values- particularly, Priority Substances should be carefully assessed to see if there is a risk to the EU as a whole, or only of local relevance (n=5, 4 Business associations, 1 company/business organisation);
- A number of stakeholders reiterated the need to identifying new Priority Substances and setting their EQS based on sound science (n=2, Business associations);
- Transparency- 2 stakeholders noted the need for greater transparency relating to monitoring data (NGO) and dossier outputs (Business association).

5. OPEN PUBLIC CONSULTATION

Here we present the most relevant results from the OPC, identifying the percentage of responses in relation to each answer.

5.1. Respondents' profiles

Although in total 151 respondents filled in the questionnaire during the consultation period, it should be noted that the number of responses to each specific question has varied throughout the survey. Due to the non-mandatory nature of most questions, it is typical that fewer than 151 responses have been provided to certain questions. From the 151 respondents, Germany (n=40; 26%), Belgium (n=25; 17%) and France (n=19; 13%) were the primary countries of origin. In total, from the 151 respondents 144 (95%) were from EU-27 countries. The remaining 7 were from Morocco (n=1), Norway (n=2), Switzerland (n=1), and the United Kingdom (n=3). The most common stakeholders to reply (Figure A2.1) were business associations (n=34; 23%), EU citizens (n=33; 22%) and companies/business organisations (n=29; 19%). Stakeholders who selected the 'other' option (n=16; 11%) and provided a response included: civil society organization (n=1), MS competent authority (n=3), water services and utility company (n=1), international organization (n=2).

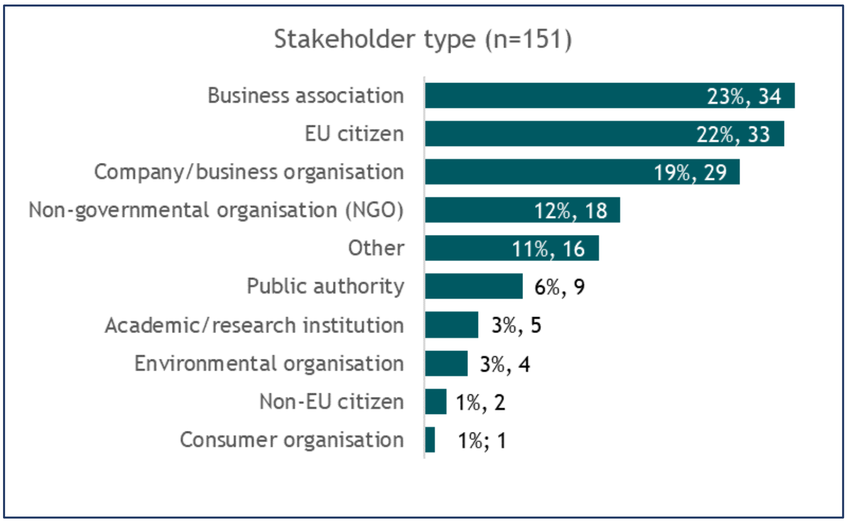


Figure A2.1: Stakeholder types

Figure A2.2 provides an overview of the scope of each stakeholder type. As shown, the majority of business associations, EU citizens, NGOs, Public Authorities, Academics/research institutions and consumer organisations had a national scope. The majority of company/business organisations had an international scope.

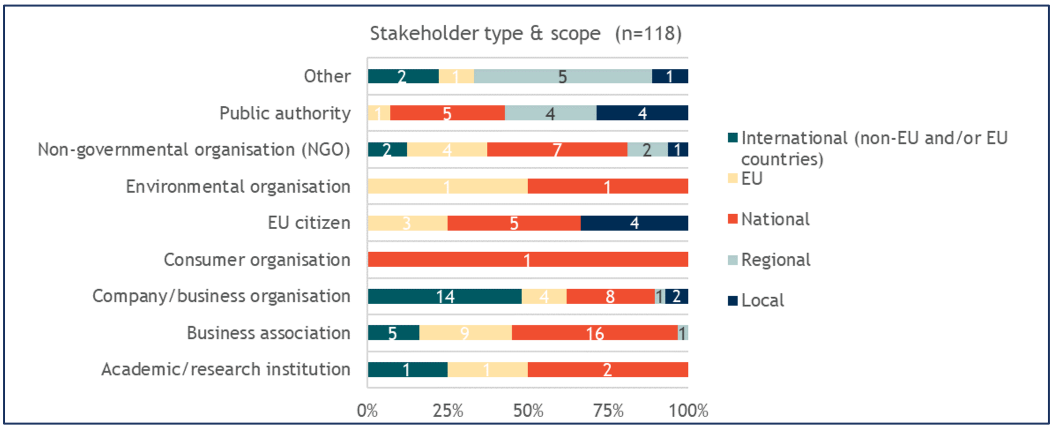


Figure A2.2: Stakeholder scope

In relation to organisation size, the majority of respondents stated they were from large (i.e. >250 employees) (n=46; 40%), followed by those from micro (n=30; 26%), small (n=25, 22%) and medium (n=15; 13%) organisations.

Finally, stakeholders indicated their sector of activity (Figure A2.3). The highest number of responses indicated activity in the water industry and/or management (n=30; 21%), and biodiversity and/or environment (n=26; 18%). Stakeholders who responded ‘other’ included mining and extractive industries (n=4), education (n=1), paper industries (n=1).

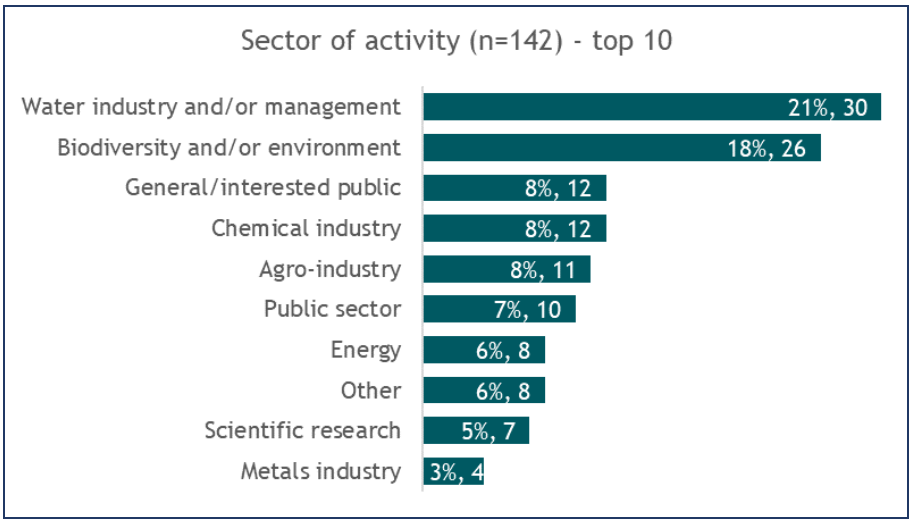


Figure A2.3: Stakeholder sector of activity

5.2. Presence of substances

Stakeholders were asked how concerned they were with the presence of pharmaceuticals, microplastics, substances from household items, pesticides, industrial chemicals and metals in both surface and groundwaters. Stakeholders were asked to rate their concerns on a scale of 1 (not at all) to 5 (very much). For both surface waters and groundwaters, stakeholders designated a minimum average score of 3.5 (for groundwater microplastics) for the substances listed, indicating that stakeholders are concerned about the presence of all substances listed. Figure A2.4 below outlines the average scores for each substance.

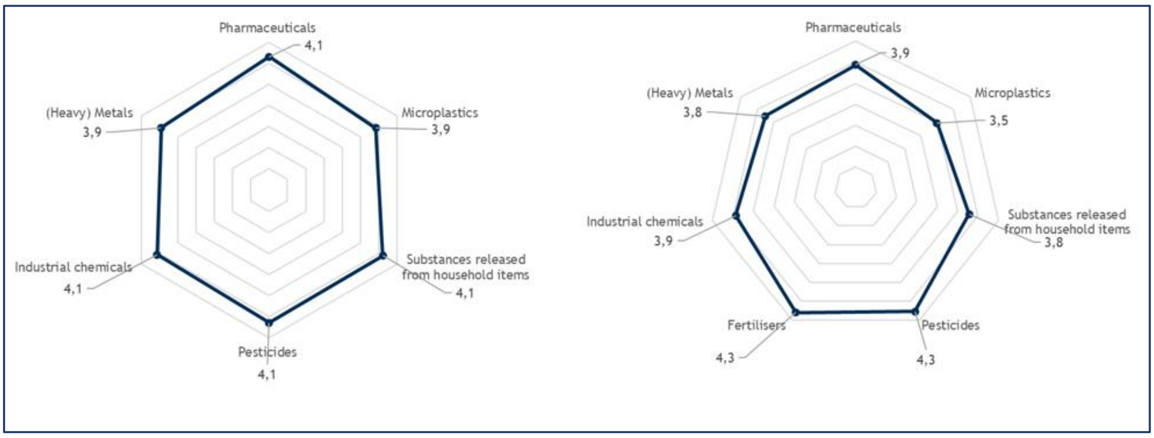


Figure A2.4: Responses to the question: "How concerned are you about the presence of these substances in European surface water (L) and groundwater (R) bodies? Please rate your concerns on a scale of 1 (not at all) to 5 (very much)"

5.3. Regulatory measures to combat water body pollution

Stakeholders were asked which regulatory measures contributed to WB pollution, and to rate their contribution on a scale of 1 (not at all) to 5 (very much). The average rating for each of the measures listed was above 3.0, indicating that stakeholders harbored at least some concern of their contribution to water pollution. As shown in Figure A2.5 below, "lack of the use of ‘precautionary’ and ‘polluter pays’ principles…”, “lack of investment/incentives for emission reduction” and “lack of incentives to take control measures at the source of pollution” all received an average score of 3.8, whilst the last measure listed received the greatest number of ‘5’ responses (n=61, 41%).

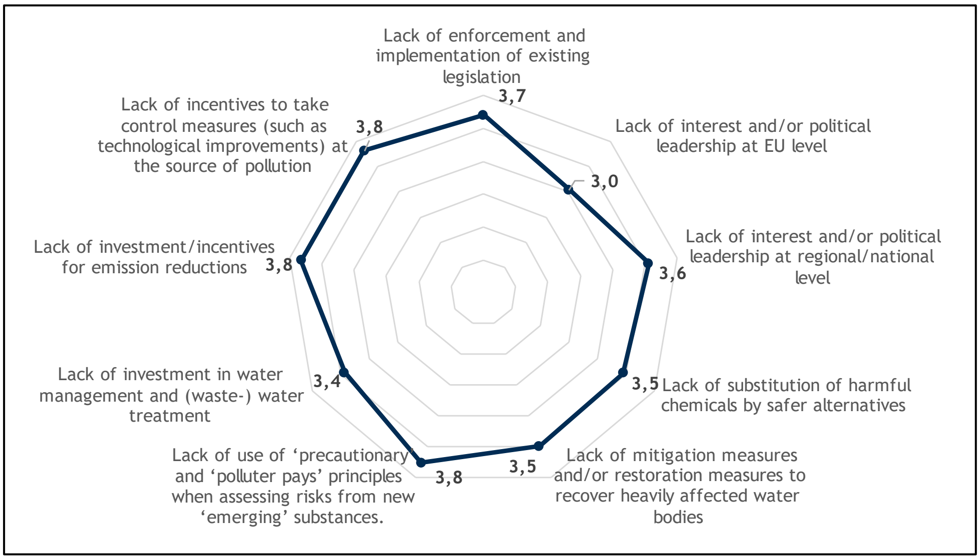


Figure A2.5: Responses to the question: “Regarding regulatory measures and their implementation, in your opinion, to what extent do the following issues contribute to surface water and groundwater pollution? Please rate each option below on a scale of 1 (not at all) to 5 (very much)”

5.4. EU actions/strategies to address pollution

Stakeholders were asked to outline which policy actions/ strategies could more effectively address surface and ground- water pollution. Three options were presented, where stakeholders could indicate on a scale of 1 (not at all) to 5 (very much) which options should be improved. As shown in Figure A2.6 below, option c ‘improve collection of data on new pollutants…’ received the highest average score of 4.2. Stakeholders elaborated in open text, stating that there is a need for more transparent, publicly accessible data (n=6) to assist in making science-based decision making.

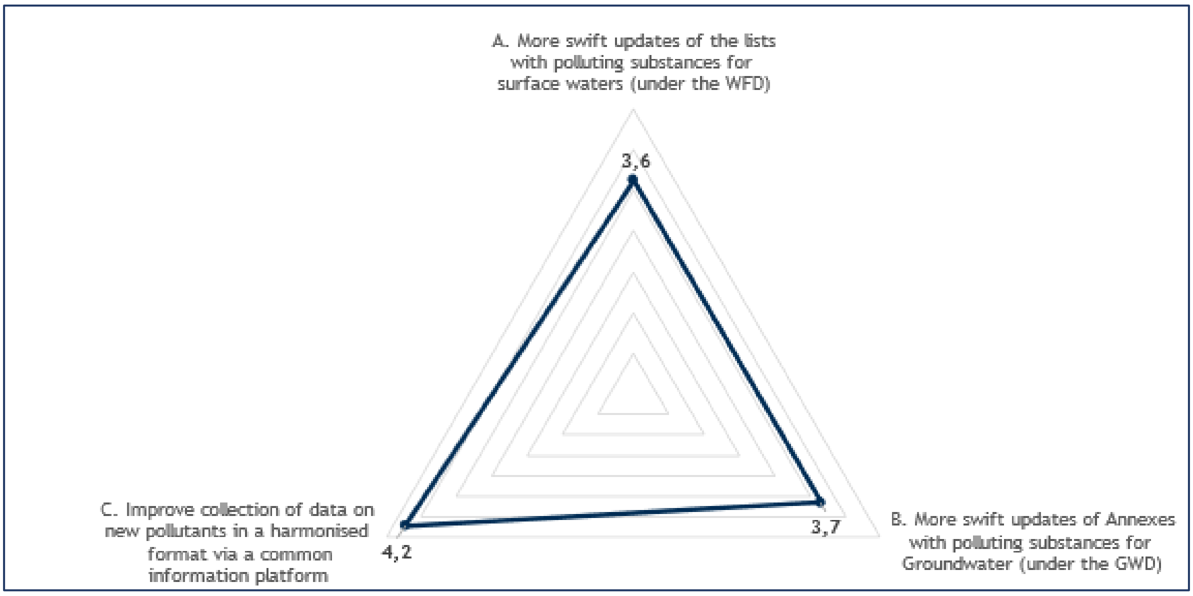


Figure A2.6: Responses to the question: What in your opinion should the European Commission improve to ensure its policy actions / strategies address more effectively surface and groundwater pollution? Please rate each option below on a scale of 1 (not at all) to 5 (very much)

Finally, according to the OPC respondents, the following issues were not included in the OPC-questionnaire, but should be addressed by the European Commission:

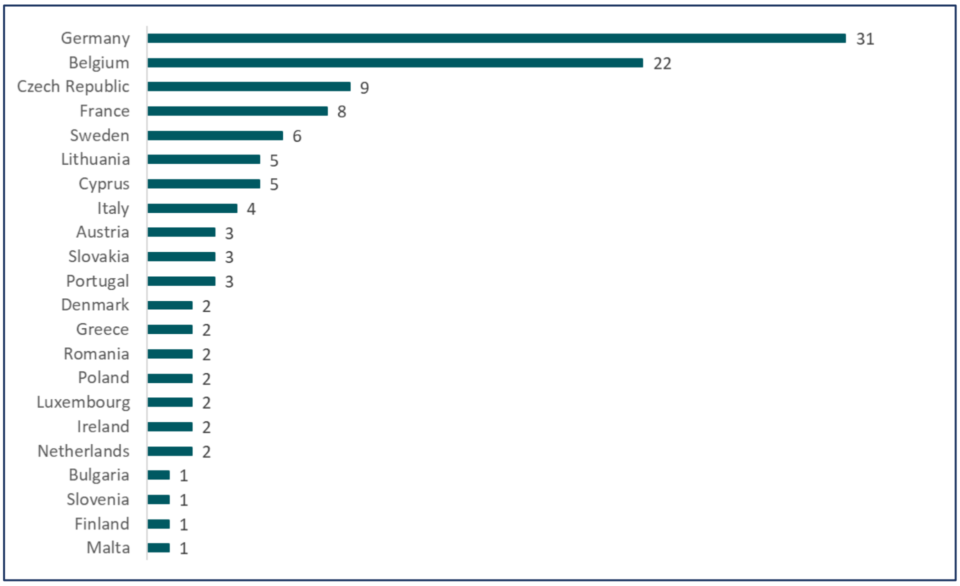
- Need to develop a shared list of priority and watch list substances across policies: water policy (groundwater, surface water, marine MFSD), CAP, sewage sludge, Fertilising Products (FPR), REACH, IED.
- Overall, a more strict and integrated system to reduce emissions of harmful substances should be implemented, by connecting REACH, IED, UWWTD and WFD, via restrictions of emissions & substances of very high concern (SVHC's).
- Water protection must be pursued according to the precautionary and polluter pays principles. End-of-pipe solutions are neither a holistic nor a sustainable solution; extended producer responsibility (EPR) must be applied to cover costs.
- Addition of so-called 'non-relevant' metabolites (nrMs) of pesticides to Annex I of the GWD, together with relevant metabolites. The pesticides total value should include nrMs.
- Data collection for additional pollutants should be driven at the EU level.
- Need to enhance the protection of groundwater as an ecosystem (including better protection of organisms responsible for self-purification of groundwater) in line with recital 20 of GWD, and inclusion of non-material indicators like biology and temperature.

6. TARGETED STAKEHOLDER CONSULTATION - SURVEY

6.1. Respondents profiles

All 124 respondents provided replies to the 'About you' section of the survey. As seen in the figure below, the highest number of respondents came from Germany (n=31). This was followed by Belgium (n=22), Czech Republic (n=9), and France (n=8). Thereafter, Member State representation was generally lower. Figure A2.7 shows all EU-27 represented countries. There were also several non-EU respondents, including from the United States (n=1), Norway (n=1), Switzerland (n=4) and Turkey (n=1).

As a follow-up, respondents indicated the country where their organisation is located. The trends seen in Figure A2.8 do not significantly deviate from Figure A2.8: the most significant number of respondents identified their organisations based in Germany (n=33), followed again by Belgium (n=25), Czech Republic (n=8), and France (n=8). Respondents could only choose EU27 countries as their organisation base or were given the opportunity to write the answer in. Three respondents noted that their organisation was based in Switzerland, and one in Turkey.



FigureA2.7: Responses to: Country of Origin

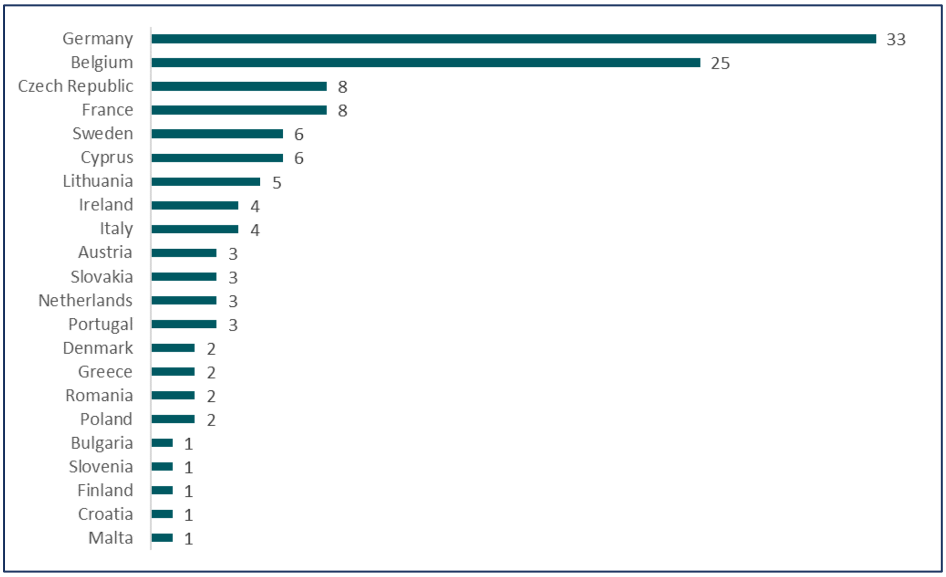


Figure A2.8: Responses to: Which country are you or your organisation based?

When asked about the scope which the respondents organizations covered, the majority indicated working at a national scale (n=64). A similar number of respondents indicated working at regional (n=26) or EU wide level (n=20), and a significant number (n=10) also indicated working for organisations with an international scope. Five respondents indicated 'Other' scope, of which three expressed that they worked at regional scales (naming the region of their Member State).

Responses did not indicate a wide distribution of stakeholder groups. Most of the participants represented MS competent authorities (n=46), followed by business associations (n=31) and academic/research institutions (n=13) (Figure A2.9). A number of respondents identified themselves as 'Other' (n=11). Those that provided details, identified themselves as 'Candidate country competent authority' (n=1), 'Non-profit association of expert organisations' (n=1), 'Competent authority for water' (n=1) and 'Groundwater Expert Consultant' (n=1).

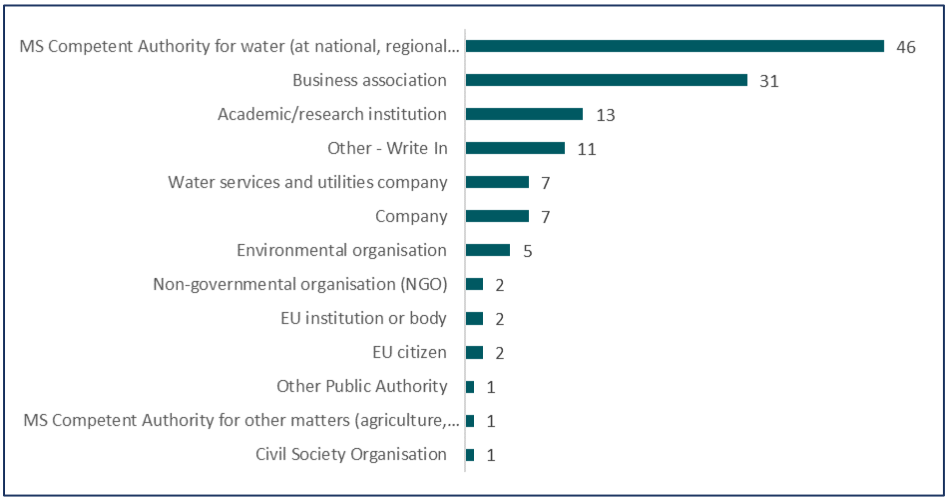


Figure A2.9: Responses to: I am giving my contribution as…

Finally, respondents were asked to indicate the sector they represent (Figure A2.10). Here the distribution of representation was wider, with biodiversity and/or environment and the water industry sectors having the highest representation (n=34 and n=33 respectively). Interestingly, a number of respondents (n=20) indicated 'Other' sectors. Two respondents indicated to be working for national water authorities, three indicated working in groundwater monitoring and protection, three indicated working in water and environmental monitoring of pollutants and hazardous substances, and one indicated working in petroleum refineries. The sectors of energy, investment and finance, pharmaceuticals, plastics, textiles and urban planning had no respondents.

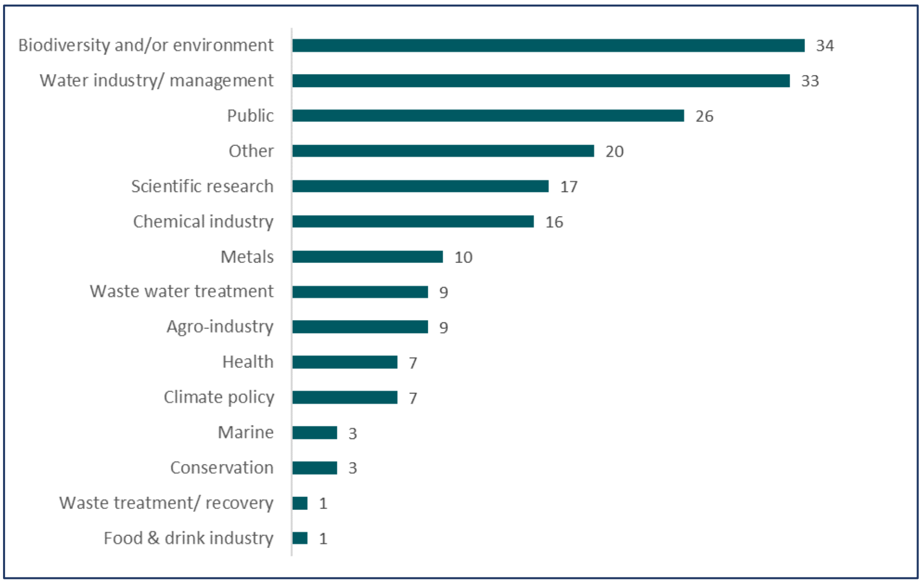


Figure A2.10: Responses to: Please indicate the sector(s) you are active in:

Respondents had the opportunity to respond to surface water, groundwater and complementary questionnaires. They could choose to answer as many as they felt familiar with. A total of 101 indicated an interest in answering surface water questions, with 65 and 78 participants selecting groundwater and complementary questionnaires, respectively. Note that this does not represent the total number of responses received per question, as respondents were not obliged to answer any questions.

6.2. Surface water

6.2.1. Addition of candidate Priority Substances

For all of the candidate substances listed, stakeholders indicated a preference to including them as Priority Substances (Figure A2.11). Regarding whether specific substances should be added as groups (rather than separate entries), the responses did not present such a clear preference (Figure A2.12). Macrolide antibiotics (n=19; 31%) and PFAS (n=34; 52%) received a greater number of 'yes' responses than 'no'- indicating a preference to add substances as a group with a set of joint EQS values. Conversely, Neonicotinoids (n=24; 38%) and Pyrethroids (n=23; 36%) received a greater proportion of 'no', indicating a preference not to group such substances.

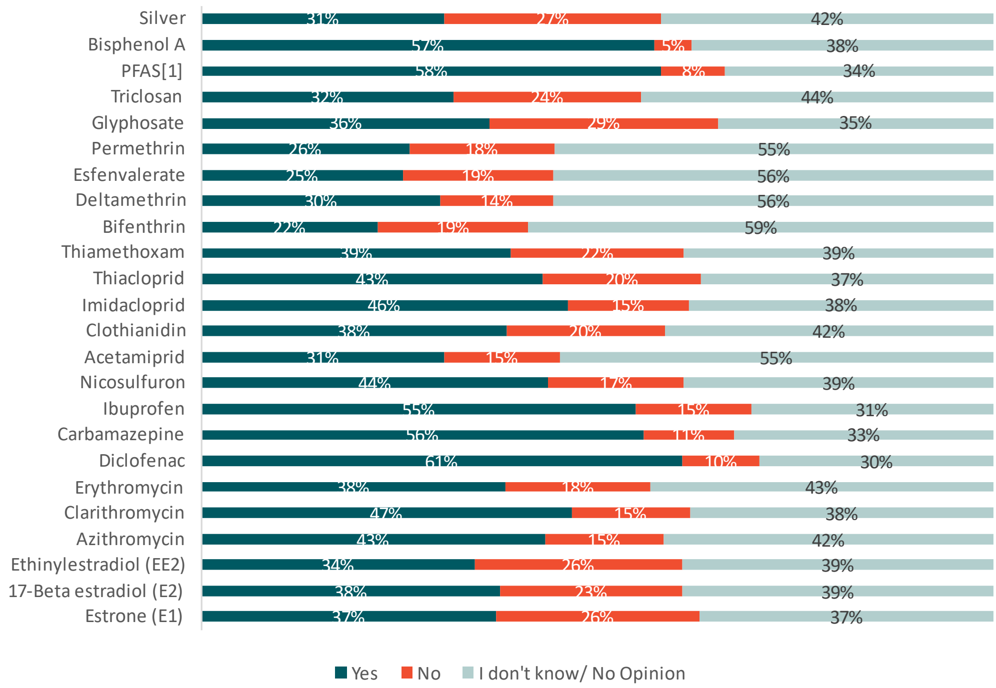


Figure A2.11: Responses to: Should the substances in the table below be added as Priority Substance?

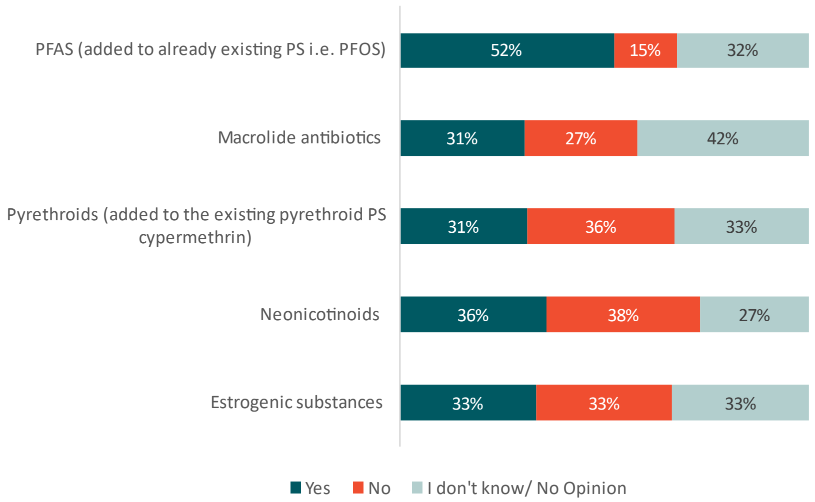


Figure A2.12: Responses to: Please indicate whether you think the substances should be added as groups.

When asked to estimate the significance of economic, health, social and environmental benefits / impacts resulting from the inclusion of new candidate PS, the respondents generally found all impacts to be positive (i.e. rated at minor, moderate or major benefit). Benefits from improved surface water quality, lower risk of damage to natural resources and benefits from improved environment and human health protection were valued most (Figure A2.13). The impacts of new candidate substances on the quality of process water for agriculture and industry received the greatest number of 'no benefit' responses (n=8; 16%). Impacts regarding employment opportunities were identified as being largely unknown, indicated by the large share of 'I do not know/no opinion' responses (n=31; 57%).

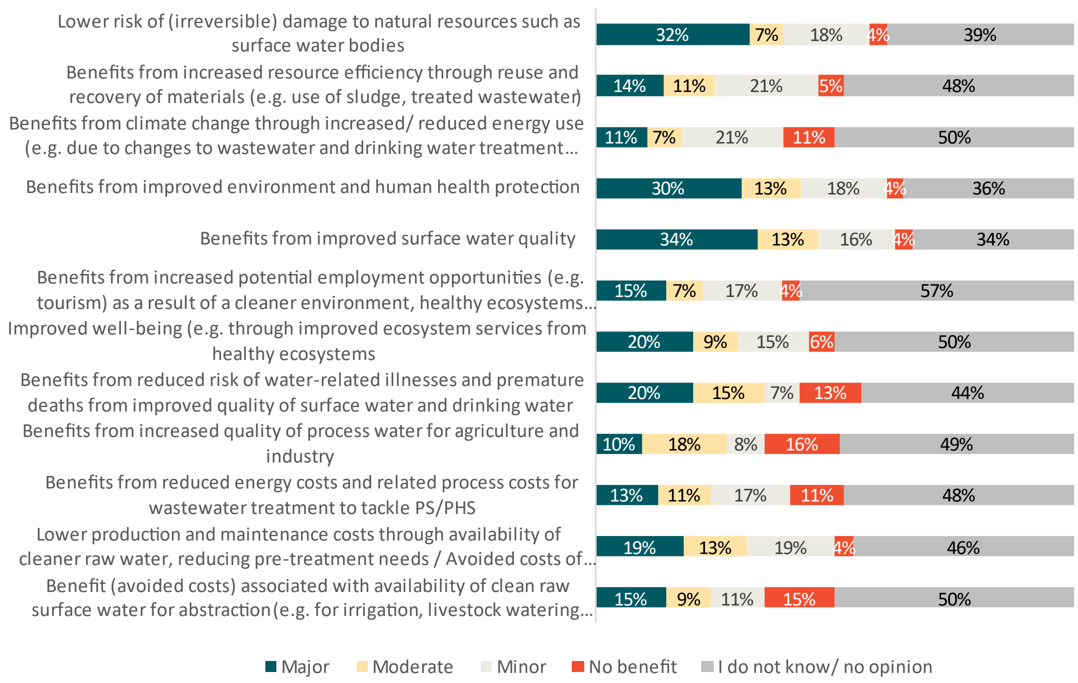


Figure A2.13: Responses to: Can you please provide your estimate of significance of economic, (human) health and social, as well as environmental benefits/ impacts resulting from the inclusion of new candidate priority substances?

For the majority of benefits listed, respondents were unable to provide cumulative estimates of their potential economic, health, social or environmental impacts. Lower production and maintenance costs through the availability of cleaner raw water received the fewest number of ‘I do not know/no opinion’ responses, where 7% (n=3) estimated costs above €10,000,000 and 2% (n=1) at €501,000-€1,000,000.

6.2.2. *Change of status of the “eight other pollutants”*

DDT received the greatest number of ‘fully added as a PS’ responses (n=15; 23%), followed by Trichloroethylene (n=6; 10%) and Tetrachloroethylene (n=5; 8%). Isodrin, Endrin, Dieldrin and Carbon tetrachloride all received 38% of responses for them to be removed from EQSD entirely, whilst DDT received the greatest number of responses to retain it as a ‘other pollutant’ (n=18; 28%).

6.2.3. *Revision of existing EQS*

Stakeholders were asked whether they believed the Annual Average (AA), Maximum Allowable Concentration (MAC), and/or biota EQS values are too high, too low, or assigned correctly to a selection of Priority Substances. Here, a summary of the responses (excluding ‘I do not know/ no opinion’ answers) is presented.

Regarding AA concentrations, Chlorpyrifos (n=11; 20%) and Diuron (n= 6; 11%) received the greatest number of ‘too high’ responses, whilst Nickel (n=14, 25%) received the greatest number of ‘correct’ responses. PAHs (based on Benzo[a]pyrene) (n=14; 30%) and Fluoranthene (n=12; 27%) received the greatest number of ‘too low’ responses.

Regarding MAC, the majority of responses indicated that Chlorpyrifos (n=15; 27%) and Diuron (n=14; 25%) values were ‘too high’, EQS values for MAC are ‘correct’ for Nickel (n=13; 25%) and ‘too low’ for Heptachlor and Heptachlor epoxide (n=6; 12%).

Finally, biota concentrations were regarded as ‘too high’ for PAHs (n=6; 12%), ‘correct’ for Hexachlorobenzene (n=5; 10%), Hexachlorobutadiene (n=4; 9%), Mercury and its compounds (n=5; 10%), and ‘too low’ Brominated diphenyl ethers (n=10; 20%) by the majority of respondents.

6.2.4. *Deselection of existing Priority Substances*

Stakeholders were asked to comment on which existing PS no longer pose an EU-wide risk. Except for Hexachlorobenzene, all the substances identified for deselection during the technical work[80] received a greater number of ‘yes’ (deselect) than ‘no’ (keep as PS) responses. Alachlor received the greatest number of ‘yes’ responses (n=34; 54%), followed by Chlorfenvinphos (n=32; 53%).

[80] Substances targeted for deselection at the time: Alachlor, Chlorfenvinphos, Simazine, Benzene, Hexachlorobenzene and Hexachlorobutadiene

For all substances listed, the majority of responses indicated that respondents 'don't know/have no opinion' regarding the economic benefits of deselection. All substances received a greater proportion of 'yes' responses than 'no', with Alachlor (n=25; 45%), Chlorfenvinphos (n=24; 44%) and Simazine (n=22; 41%) receiving the greatest number of responses indicating economic benefits of deselection.

6.3. Groundwater

6.3.1. Additions to GWD Annexes

Stakeholders were asked to select which option for adding PFAS to the GWD annexes would be preferred. Option A (Add 10 PFAS with a 'group of 10' (i.e. 'Sum of PFAS') standard of 0.10 µg/l to Annex I of the GWD (based on DWD recast)) received the greatest proportion of responses (n=17; 46%), followed by Option F (None of the above / Business as usual (BAU)) (n=9; 24%). Option B (Add 10 PFAS with a 'group of 10' standard (i.e. 'Sum of PFAS') to Annex I of the GWD but with a different GW QS to Option A) garnered the lowest preference by stakeholders (n=1; 3%).

In relation to adding Carbamazepine and Sulfamethoxazole to the GWD annexes, Option A (Add the two named pharmaceuticals to Annex I with the following indicative GWQS: Carbamazepine 0.5 µg/l; Sulfamethoxazole 0.1 µg/l) received the greatest number of responses (n=10; 30%), followed by Option E (n=9; 27%). Option D (Add pharmaceuticals as a group to Annex I, but with a different value for the GWQS to Option C) received the lowest number of responses (n=0).

Finally, responses for adding harmful breakdown products (metabolites) from pesticides (nrMs) to the GWD Annexes indicated that Option A (Add the 16 harmful breakdown products (metabolites) from pesticides (nrMs) to Annex I with individual GWQS of 1 µg/l for each substance) (n=13; 37%) was the preferred option.

6.3.2. Benefits/impacts

Stakeholders were asked to identify which economic, (human) health and social, and environmental impacts related to groundwaters provided the most significant benefits. The results are shown in Figure A2.14. Stakeholders identified 'benefits from improved water quality' and 'benefits from improved environment and human health protection' as providing the greatest positive impacts (n=12; 35%), followed by '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' (n=11; 32%). Very few monetised estimates could be provided by respondents. Those which were provided, estimated high costs above €10,000,000 related to *lower risk of damage to natural resources* and *lower production and maintenance costs through availability of cleaner raw water*, receiving 4% (n=1) and 12% (n=3) of total responses respectively.

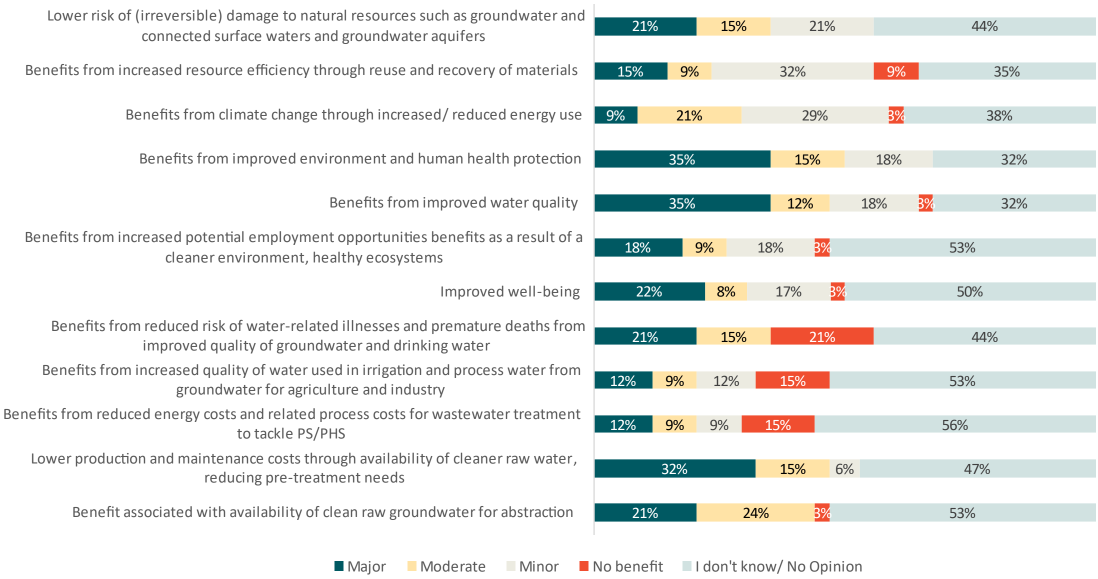


Figure A2.14: Responses to: Can you please provide your estimate of significance of economic, (human) health and social, as well as environmental benefits/ impacts?

6.4. Monitoring, reporting and administrative streamlining options

6.4.1. Guidance documents

Respondents were asked to rank on a scale of 1 - not at all - to 5 - extensively used to inform decisions - which past guidance documents (of relevance to the legislation under the scope of the Impact Assessment) have been used in their MS. Guidance related to ‘risk assessment’ were deemed the most extensively used (average score of 4.6), closely followed by ‘guidance on reporting’, ‘guidelines on water quality analytical methods’ (4.3) and ‘Guidelines on Environmental Quality Standards’ (4.2). ‘Guidelines for public participation and transparency’ received the lowest average score of 3.2, indicating that they are not extensively used to inform decisions.

Stakeholders were also asked which additional guidance documents would be deemed useful (Figure A2.15). ‘Guidelines on the characterization on groups/mixtures of pollutants and their possible toxicity’ and ‘Guidelines on applying innovative methods in monitoring procedures’ received the highest average scores and highest number of ‘very useful’ responses (n=25; 53% and n=26; 55% respectively).

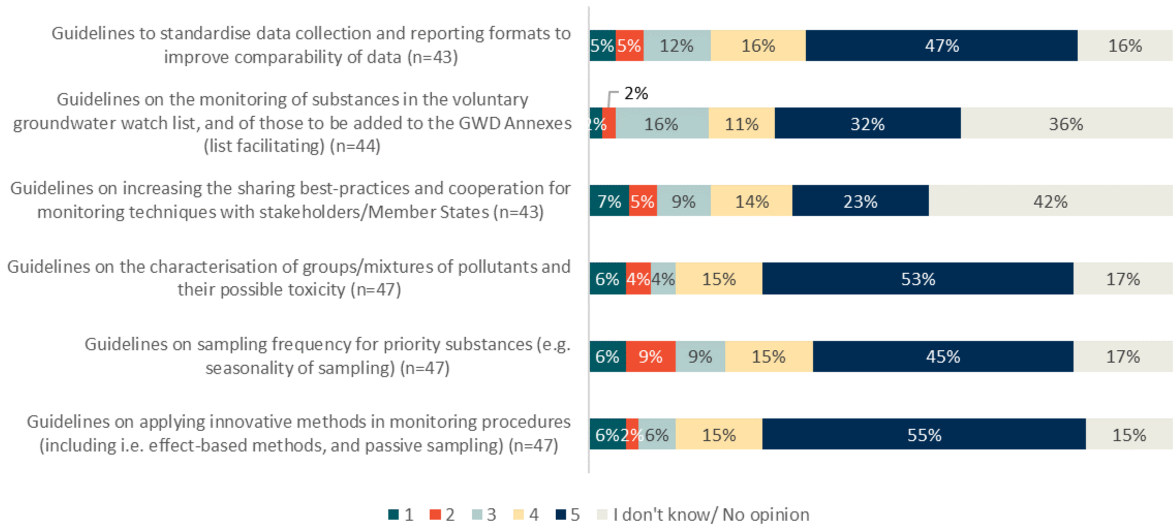


Figure A2.15: Responses to: In your opinion, how useful would the following additional guidance documents be?

6.4.2. Surface Water Watch List

Respondents voted the increase in monitoring frequency of substances in the Surface Water Watch List as the most effective method for improving the risk response and management (average score of 3.2). However, the polarity of the responses received for this measure was also significant. In total, 26% (n=12) voted the measure as non-effective (rating 1) and another 28% (n=13) rated it as highly effective (rating 5). Respondents that voted the measures as highly effective represented mostly MS authorities (n=8) and academic research (n=2), while those that related the measures as non-effective represented a mix of business associations (n=3), companies (n=2) and MS competent authorities (n=3). A similar polarity exists for the measure of increasing the frequency in which WL substances are incorporated as Priority Substances (30% rated 1, 30% rated 5). The main consensus is evident for the possible increase in reporting frequency obligations, for which half the respondents very clearly indicated that they did not see such a measure improving the risk response.

6.4.3. Harmonisation of RBSP thresholds

All measures presented to assist in the harmonization of the RBSP thresholds had very similar rating scores around 3.2. The highest rated (average 3.3) was to provide a recommended range for thresholds for reference RBSPs under the EQSD, while the lowest rated (3.0) was the guidance on monitoring needs for RBSPs. Generally, all measures had very similar distributions in response ratings, indicating that there may be a combination of approaches that may assist in achieving the desired harmonization rather than just one specific measure.

6.4.4. Data management

Stakeholders were asked to rate (on a scale of 1 (not at all) to 5 (very much)) measures aimed at achieving data management, transparency and utilization were important from their perspective. ‘Standardise data collection and reporting methods to improve comparability of data’ was noted as the measure with the highest average rating of 4.1, closely followed by ‘Optimise the coordination of data-sharing practices with other policy sectors’ (average rating of 4.0).

6.5. Targeted stakeholder consultation - workshops

Here we present the most relevant results from the two targeted workshops. The primary objective of the workshops was to inform stakeholders of a set of proposed policy options and gather their inputs relating to these options. The first sessions of both workshops split participants based on their expertise relating to surface waters and groundwaters. The second session of the day reconvened all participants to discuss measures relating to digitalisation, administrative streamlining and better risk management options. The key outcomes of these distinctive sessions are presented in turn below.

6.5.1. Surface water session

The first topic area theme ascertained which candidate substances stakeholders would like to see added to the PS list as separate entries, or added as groups of substances. Estrogenic hormones (n=56; 62%), PFAS (n=61; 73%) and neonicotinoids (n=40; 52%) all received a majority of votes by stakeholders indicating a preference to add as groups. The majority of participants noted that antibiotics should be added as individual substances (n=38; 46%). The second topic area sought stakeholder views on amendments to EQS for existing PS and other pollutants. Stakeholders noted that EQS for PBDEs (n=27; 41%), mercury (n=22; 33%) and heptachlor (n=19; 29%) in particular, should be reviewed. The final topic area looked at the potential of deselecting existing PS. Stakeholders here showed a preference to deselecting all the listed substances (Alachlor, Chlorfenvinphos, Simazine, Benzene, Hexachlorobenzene and Hexachlorobutadiene) (n=28; 55%).

6.5.2. Groundwater session

Topic area one of the session discussed adding PFAS substances to Annex I or II of the GWD. Stakeholders showed preference to adding PFAS to Annex II (to allow MS to deal with local conditions) (n=22; 42%). Participants notes that if PFAS quality standards were listed under Annex I, standards should be established at 0.10 µg/l (n=30; 52%). The second topic area asked stakeholders for their views on adding pharmaceuticals to Annex I or II of the GWD- with 67% (n=39) of participants showing preference to add these as individual substances. Finally, topic area three focused on the addition of pollutants consisting of degradation products from pesticides (nrMs) to Annex I or II of the GWD. The majority of participants stated a preference to add nRMs to Annex II (n=29; 56%).

In targeted stakeholder feedback industry stakeholders indicated that a GWQS for the 16 nrMs of 9 µg/l could be calculated using a Threshold of Toxicological Concern approach (99), whereas other stakeholders noted that the EFSA methodology explicitly states 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. The position from the non-industry stakeholder was that Europe wide legislation is needed to ensure that the levels of nrMs reduced in groundwater and that more sensitive biota in groundwater ecosystems were protected. MS and representatives from the drinking water industry states that there is widespread detection of nrMs in groundwater and that this situation needs to be addressed, while noting that the GWD requires that inputs of hazardous substances need to be limited in their entry into groundwater, and nrMs fall within this group. Consequently, further regulation of the entry of nrMs to groundwater is needed to deliver on this requirement.

6.5.3. Session on monitoring, reporting and administrative streamlining options

This session centred on three topics that aimed to maximize the (cost) effectiveness of procedures, namely: monitoring approaches; risk assessment and the translation into risk management; and data management. Regarding monitoring approaches, stakeholders provided contrasting views on guidelines to alternative monitoring methods - noting that innovative approaches (such as effect-based monitoring) could improve freshwater quality yet may result in a greater monitoring burden to actors. In the topic area two discussions, stakeholders noted that deriving harmonized EQS values for RBSPs were challenging due to changes in values from knowledge development and a lack of current harmonised approaches between MS. Finally, on data management stakeholders noted that guidelines to standardise data collection and reporting formats could be beneficial.

ANNEX 3: WHO IS AFFECTED AND HOW? PRACTICAL IMPLICATIONS OF THE INITIATIVE

1. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	*Amount*	*Comments*
Direct benefits		
Improved surface water quality	**Additions:** total benefits not quantified for EU27, but: - Avoided/reduced environmental impacts and potential toxic effects on aquatic species. E.g. Carbamazepine (impacts on fertility and reproduction);ibuprofen potential toxic effects for some aquatic species including fertility effects ; Nicosulfuron has aquatic toxicity and concerns over carcinogenicity as a secondary poisoning. Diclofenac potential toxic effects on avian populations via surface water species. Estrone E1, 17- Beta estradiol (E2), Ethinyl estradiol (EE2) are associated with chronic ecosystem level impacts from exposure to hormones and EDC. PFAS has a widespread and very long-lasting environmental effects while Bisphenol A as an endocrine causes disrupting chemical for aquatic organisms. Triclosan is toxic for aquatic organisms particularly larvae and fish eggs. Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate and Permethrin are associated with toxic aquatic effects against invertebrates, arthropods, and crustaceans with wider environmental concerns for terrestrial pollinators. Glyphosate is associated with harm to aquatic environments given the very high usage rates and risks for loss to water. - Avoided/reduced human health impacts via reduced exposure through drinking water, from specific exposure to Neonicotinoids, EDC and (potential) carcinogenic effects. E.g. 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) (84).. Protection against AMR has clear societal benefits and avoided costs to healthcare from protection against the development of AMR : estimated AMR costs in EU €1.5 billion per year in healthcare costs and productivity losses[81] (64) (101) (102). - The long term benefit of adding antimicrobials and silver onto the lists is limiting antimicrobial resistance, allowing current and future antimicrobials to retain their positive effect on patients. - 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. - Benefits /avoided costs of reducing AMR from antibiotics in relation to infections from multi-drug resistant bacteria are estimated to add up to a total of €41 billion (2014 data). - The EU benefits / avoided costs of removing silver to reduce the risk for AMR and other risks are estimated to range between €20 to €41 billion (2014 data). - Avoided/reduced impacts on pollinators and agriculture. E.g. across Europe, crop pollination by insects accounted for approximately €14.6 billion annually (103). - Avoided costs of water treatment for drinking water, agriculture and industry E.g. in 2015, approximately €0.5 billion was spent annually to remove pesticides in wastewater treatment plants (WWTP) in Europe (104). - Economic benefits for aquaculture from improved food quality - Innovation for development of alternative chemicals and technologies (e.g. Bisphenol A)	
	Amendments: total benefits not quantified for EU27, but: - Updated EQS based on new science and re-appraisal of risk would provide more appropriate protections (all substances) - Improved protections for human health particularly in relation of POP substances, issues around bioaccumulation (dioxins and furans, chlorpyrifos, hexachlorobutadiene, HBCDD), EDC (diuron, chlorpyrifos), exposure to chronic pollutants (mercury, nickel). E.g. 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 (100). It was also estimated that the cognitive deficits caused by chlorpyrifos and methylmercury would cost the EU €177 billion and €9.89 billion, respectively - Reduced environmental concentrations, improved environmental protections for ecosystem services (cypermethrin, nonylphenols, PAHs) - Avoided health costs for aquaculture (cypermethrin, tributyltin, mercury, nickel) - Cost savings and efficiencies: the proposed EQS is less stringent for heptachlor/heptachlor oxide, hexachlorobenzene, PBDEs and fluoranthene, meaning resources can be reallocated and costs saved from measures no longer needed.	

[81] Based on an exchange rate of 1 EUR = 1.09 USD

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	*Amount*	*Comments*
	Other eight pollutants: total benefits not quantified for EU27, but: - Three of the four cyclodiene pesticides (aldrin, dieldrin, endrin;,isodrin is an isomer of aldrin) are listed as POPs under the Stockholm Convention and have been banned in the EU for many years. The rate of EQS exceedance suggests environmental risk is low, and benefits of continued monitoring may be limited. However, monitoring data are needed anyway under the POPs Regulation and could inform decontamination measures. - DDT is also a recognised POP. Use in EU has long since ceased and rate of EQS exceedance is extremely low. Maintaining the monitoring time-series would support the tracking of DDT in the environment, and link with monitoring of, e.g. imported foods. While tetrachloroethylene and trichloroethylene are still in use, and health concerns well founded, the monitoring data shows exceedances in only 6 and 3 surface water bodies out of 97,000 suggesting a very low environmental risk at present. However, these substances are still of concern in groundwater and drinking water, and in marine waters.	
	Deselection: total benefits not quantified for EU27, but • Deselection of substances that no longer represent an EU-wide risk could free up resources for reallocation by Competent Authorities to the monitoring and/or management of emerging pollutants, including watch-list substances and the new priority substances. • The pesticides alachlor, simazine and chlorfenvinphos are clearly hazardous but no longer approved for use; the risk of exposure is very low and would be expected to remain so.	
Improved groundwater quality	**PFAS:** total benefits not quantified for EU27, but • 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); • Avoided illness / death through low level exposure through drinking water / food to PFAS: estimated the annual health expenditure due to kidney cancer €12.7 to €41.4 million in the EEA countries; hypertension in the EEA countries estimated at €10.7 to 35 billion per year (based on 207.8 million population); • Improved availability of clean raw groundwater for abstraction and lower production and maintenance costs (for drinking water, irrigation, livestock watering) • Benefits to sectors requiring a high quality of groundwater such as bottled water and other water uses (angling, swimming, etc). • Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for drinking water supply, agriculture and industry (GAC treatment costs € millions per site) in the case of source control and pathway disruption measures • Reduced energy costs and related process costs for wastewater treatment to tackle PFAS (in the case of source control and pathway disruption measures) • Increased knowledge and understanding of the risks of PFAS posed to the water environment. • Consistent approach to data collection at EU level and improved knowledge (more data collected) on the impact of PFAS. **Pharmaceuticals:** total benefits not quantified for EU27, but • Reduced pollution of groundwater and connected aquatic ecosystems with reduced impact on sensitive habitats. • Increased reuse and recovery of pharmaceutical-free materials (e.g. use of sludge, treated wastewater). • Reduction in AMR likely to be small (mainly covered by baseline measures) - Reduction in AMR through control of anti-biotic use (costs avoided of €1.5 billion to the EU) • The long term benefit of adding antimicrobials onto the lists is limiting antimicrobial resistance, allowing current and future antimicrobilal to retain their positive effect on patients. • 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 • Reduced energy, carbon emissions and chemicals use associated with reduced treatment of drinking water (in the case of source control and pathway disruption measures) • Improved efficiency - 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 • Consistent approach to data collection at EU level and improved knowledge (more data collected) on the impact of these two pharmaceuticals. **nrMs:** total benefits not quantified for EU27, but • Reduced risk of damage to natural resources such as groundwater and connected ecosystems • Benefits to sectors requiring a high quality of groundwater such as bottled water or aquaculture and other water uses (angling, swimming, etc.). • Increased availability of clean raw groundwater for abstraction (for drinking water, irrigation,	

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	livestock watering) • Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for agriculture and industry • 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). • Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment. • 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. • Improved knowledge and better data for use during pesticide parent authorisation process. • The main costs in relation to the reduction of concentration levels of pesticides in surface- and groundwater are expected to be covered by the implementation of the revised legislation on the sustainable use of pesticides directive (SUPD). According to that evaluation, costs related to training, inspections, Integrated Pest Management (IPM) will mainly fall on the professional users of pesticides, in particular farmers, who on the other hand have little or no direct economic benefit from implementing SUPD provisions, except for the reduced expenses on (expensive pesticides). The SUPD evaluation also showed that since 2009 there have been no remarkable drops in pesticide sales, or losses in terms of forgone sales. • In the Netherlands, the costs associated with the treatment of water from pesticides and their transformation products corresponds to approximately 18 million EUR per year, which corresponds to around 1 million per million inhabitants. Extrapolated to the EU this corresponds to 510 million EUR per year in treatment costs. If, in line with the targets of the F2F strategy, pesticide use is decreased by 50%, treatment costs would be expected to decrease correspondingly and by 205 million/year. In Wallonia, Belgium, the additional costs to consumers passed on by water treatment utilities due to pesticide pollution are currently around EUR 0.2 to 0.4 per m³, primarily caused by the costs for activated carbon filters. These costs to consumers would likely also decrease by 50% : On average, 144 litres of water per person per day is supplied to households in Europe , corresponding to 52m3 per year. Costs savings for consumers would thus be around EUR 5-10 per person/year. • Economic value of pollinating insects to crop production in the EU is at least €3.7 billion per year. It is clear that pesticides (and in particular the neonicotinoids) are very toxic and persistent and contribute to the loss of honeybees. • Bumblebees that were fed the neonicotinoids at the same level found in treated rape plants and found that these colonies were about 10% smaller than those not exposed to the insecticide • Assuming that between 10% or 50% of the economic losses from pollinator decline are attributed to the toxicity of pesticides, this results in mean annual benefits from €370 million to 1.85 billion.	
Indirect benefits		
Monitoring, reporting and administrative streamlining options	Option 1 (**Guidelines on the monitoring of groups/mixtures of pollutants**): not quantified for EU27, but the guidance document itself has limited impact, however a provision for monitoring estrogens with EBM could have substantial positive impacts. Option 2b (**An obligatory Groundwater Watch List**): not quantified for EU27, but positive impacts due to better decision-making processes regarding substances posing risks and better comparability of data. Option 3d (**Repository of standards of EQSs for the RBSPs**): not quantified for EU27, but positive impact through harmonization of EU-wide standards allowing more effective measures. Positive impacts for social well-being and health, providing equal standard of water resource across EU. Option 4a (**Flexible adaptation to scientific progress and knowledge by updating the lists of pollutants and their EQS (under both EQSD and GWD) by delegated acts**): not quantified for EU27, but positive impact due to quicker actions to address new substances. Positive impacts as innovation and research will lead to possible employment opportunities.	
Administrative cost savings related to the 'one in, one out' approach*		
(direct/indirect)	<u>Deselection of existing PS:</u> €3.8 million - €11.7 million per year (monitoring of 5 substances).	

II. Overview of costs – Preferred option							
Cost type		Citizens / Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Surface water	Direct adjustment costs	Not applicable - €0	Not applicable - €0	**Additions:** Not quantified for EU27, but: **Significant costs** to ensure compliance with proposed EQS for Ethinyl estradiol (EE2), Ibuprofen, Clothianidin, Imidacloprid, Thiamethoxam, Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin, Glyphosate, Triclosan, PFAS and Bisphenol A implementing a range of source control, pathway disruption, targeted end of pipe treatment measures. E.g. the cost of a take-back scheme for unused pharmaceuticals in France is €10 million. The 2022 Annex XV restriction report for the proposed restriction of PFASs in firefighting foams estimates that the ban is estimated to cost society €6.8 billion over a 30-year period or €390 million per year (26). Costs of pathway disruption measures (e.g. buffer strips) is €472 million per year for pharmaceuticals; for pesticides these range from €162 million for clothianidin and imidacloprid to €285 million for glyphosate. Wastewater treatment range is €10- €32 per population equivalent, per annum (technology dependent). **Moderate/Small costs** to ensure compliance for Estrone E1, 17-Beta estradiol (E2), Diclofenac, Carbamazepine, Azithromycin, Clarithromycin, Erythromycin, Acetamiprid, Thiacloprid, Nicosulfuron due to small distance to target, availability of source control and pathway disruption measures and/or positive impact of forthcoming revision of the UWWTD on quaternary end of pipe treatment. E.g. costs of pathway disruption measures (e.g. buffer strips) for pesticides range from €1.6 million for acetamiprid to €12.8 million for nicosulfuron. Wastewater treatment cost range is €10- €20 per population equivalent, per annum (technology dependent). **Amendments:** Not quantified for EU27, but: **Significant costs** to ensure compliance for Cypermethrin, Chlorpyrifos, Diuron, PAHs, Mercury, Nickel implementing a range of source control, pathway disruption, targeted end of pipe treatment measures. E.g. 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 would cost €45m (105) over a 10-year period. Costs of additional controls and treatment for farmed animal use of cypermethrin are €27.6 m[82]. Wastewater treatment (Mercury, Nickel, PAH, Cypermethrin) - €1.17- €26.2 per population equivalent, per annum (technology dependent). Mine drainage (Mercury) - €100,000 -€10,000,000 per plant and €0.4 per dm^3 operating costs. **Moderate/Small costs** to ensure compliance for Dioxins and furans, Hexachlorobutadiene, Nonyl Phenol, Tributyltin due to small distance to target and/or limited scope for additional measures (likely to be natural attenuation and baseline end of pipe treatment (under the revised UWWTD)). E.g. the costs of restricting nonylphenol (NP) and its ethoxylates (NPE) in		Not quantified	Not quantified

[82] 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.

II. Overview of costs – Preferred option							
Cost type		Citizens / Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
				textiles was estimated to cost the EU €3.2m per annum for a reduction of 15 tonnes of NP/NPE released to surface water (105). **No additional costs** for Dicofol, Heptachlor/ Heptachlor oxide, Hexachlorobenzene, Fluoranthene, PBDEs. Other 8 pollutants: Not quantified, but minor additional compliance costs (extremely low current exceedances).			
Surface water	Direct administrative costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Not quantified
Surface water	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not applicable - €0	Not applicable - €0
Surface water	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Additions: Not quantified for EU27 but additional analytical costs range from €11-100 per sample for all substances except for PFAS (€250). Amendments: Not quantified, but amendments for Chlorpyrifos and Dioxins and furans could lead to additional analytical costs Other 8 pollutants: Not quantified, but cyclodiene pesticides, DDT, tetrachloroethylene and trichloroethylene have an EQS that warrants monitoring and analysis by MS.

II. Overview of costs – Preferred option							
Cost type		Citizens / Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Surface water	Indirect costs	<u>Additions</u>: Not quantified but additions of new substances could lead to societal impacts from less use (contraceptive pill, HRT, hormone treatments) Similar /restricted use of Diclofenac, Carbamazepine, Ibuprofen and increased costs for other types of medicine (including prescription only medications) Possible food security issues if loss of use without chemical/non-chemical alternatives in place (Bifenthrin, Deltamethrin Esfenvalerate, Permethrin) Societal impacts for domestic pet owners if use of Imidalcoprid is restricted		Not quantified	Not quantified	Not applicable - €0	Not applicable - €0
Groundwater	Direct adjustment costs	Not applicable - €0	Not applicable - €0	**PFAS:** Not quantified for EU27, but: Restriction of use: €6.8 billion over a 30-year period or €390 million per year (26) per substitute use. Management of contaminated biosolids (water industry): €201 million/yr (landfilling) to €503-€755 million/yr high temperature incineration of 10% of all biosolids Paper manufacturing: €77 million/yr (landfilling) to €192 -€288 million/yr high temperature incineration of paper mill wastes **Pharmaceuticals:** Not quantified for EU27, but: Returns program / Green Pharmacy initiatives in a small number of MS (<€1-10 million per MS) **nrMs:** Not quantified for EU27, but: Costs to pesticide sector through loss of approved substances, costs of product development and product substitution to the farming sector.		**PFAS:** Not quantified for EU27, but: Contaminated soil remediation €5 million - €760 million Legacy pollution landfill sites – €690,000 up to €77 million per site	Not quantified
Groundwater	Direct administrative costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Not quantified but no significant additional costs for risk / status assessments

II. Overview of costs – Preferred option							
Cost type		Citizens / Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not applicable - €0	Not applicable - €0
	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Additional analytical costs for EU27: PFAS: €45-48 million Pharma: €2 million nrMs: €4-5 million
	Indirect costs	Not quantified but proposals could lead to: - Possible societal impacts from loss of use of pharmaceuticals - Restricting use could impact on health and well-being of people and animals where alternatives have side effects / different efficacy.		Not quantified but proposals could lead to: <u>Pharmaceuticals</u>: - additional costs associated with substitution of pharmaceuticals and availability of alternatives (product substitution viable for Sulfathemoxazole but unlikely for Carbamazepine) <u>nrMs</u>: - 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 - 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 - Increased data requirements could make gaining authorisation of new products more challenging.		Not applicable - €0	Not applicable - €0
Digitalisation, administrative streamlining and better risk management options	Direct adjustment costs	Not applicable - €0	Not applicable - €0	Not quantified for EU27, but: Option 2 (Guidelines on the monitoring of groups/ mixtures of pollutants): Costs due to monitoring of estrogen are low, but possible measure to be taken due to monitoring results may be substantial. Policy option 3 – Reporting and classification - sub-option (a): Establish an automated data delivery mechanism for the EQSD and the WFD. This option makes best use of the European Environment Agency's (EEA) and IPBES's DPSIR frameworks. Contributes to a more streamlined, simplified, modern, digital monitoring and reporting as well as uptake of new digital and earth observation technologies resulting in real-near time data flows Consequently, it will also contribute to a streamlined and effective (bi)annual presentation of monitoring results. Option 8 (Repository of standards of EQSs for the RBSPs): agreeing on RBSPs EQSs would likely lead to substantial costs for MS for implementation of substantive measures where necessary. Option 9 (Allowing flexible adaptation to scientific progress and knowledge by updating the lists of pollutants and their EQS (under both SWD and GWD) by way of delegated acts		Not quantified for EU27, but: Option 2 (Guidelines on the monitoring of groups/mixtures of pollutants): Limited cost to develop the guidance document.	Not quantified for EU27, but: Option 6 (An obligatory groundwater watchlist): Additional cost for monitoring and reporting
Monitoring, reporting and	Direct administrative costs	Not applicable - €0	Not applicable - €0			Not quantified	Not quantified

II. Overview of costs – Preferred option							
Cost type		**Citizens / Consumers**		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
administrative streamlining options	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	NA	NA
	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Mon	Not quantified for EU27, but: Option 1 (Guidelines on the monitoring of groups/ mixtures of pollutants): Minor monitoring costs of estrogens. Option 2b (An obligatory groundwater watchlist): Additional cost for monitoring and reporting. Option 3d (Repository of standards of EQSs for the RBSPs): substantial costs for MS for implementation of monitoring (following the agreement on RBSPs EQSs).
	Indirect costs	Substitution Prices				NA	NA
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	NA	NA	NA	NA	NA	NA
	Indirect adjustment costs	NA	NA	NA	NA	NA	NA
	Administrative costs (for offsetting)	NA	NA	NA	NA	NA	NA

1. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals (SDG) – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
Goal 6: Ensure access to water and sanitation for all		
SDG target 6.1: By 2030, achieve universal and equitable access to safe and affordable drinking water for all	Decreased levels of pollution of the main sources of drinking water. By applying the most cost efficient solution (usually prevention / action at source) costs of drinking water should remain affordable.	This initiative will increase the quality both in terms of human health and environmental aspects of surface and groundwater, and will thus also increase the safety of the two by far largest sources for producing drinking water.
SDG target 6.3: By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally	The legislation will lead to an expanded and updated list of pollutants, where MS need to ensure compliance with for their groundwater and surface water. Limit values are set so as to minimise risk on health and environment. Water and sludge recycling rates are dependent on the degree of pollution. By focusing on upstream / preventive action recycling will be facilitated.	This initiative will improve water quality by setting stricter environmental quality standards and bring more hazardous substances under control and thus contributes to minimising the release of hazardous substances into surface and groundwater.
Indicator 6.3.2: Proportion of bodies of water with good ambient water quality	More categories of pollutants, at stricter limit values will be set. By introducing more adequate methodologies, it will allow for more focused policy intervention, in the longer run leading to a larger number of water bodies in good quality.	This legislation will further incentivise action against a larger range of pollutants, at stricter norms. In the longer run
Goal 12: Ensure sustainable consumption and production patterns		
SDG Target 12.4: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment	More pollutants and groups of pollutants will be covered, at stricter limit values. This will require more integrated chemicals management, in particular leading to more action upstream / at source. In particular to facilitate circularity and avoid undue energy use e.g. for sludge management, preference will often go to upstream solutions.	This initiative will allow a more adequate, future proofed management of chemicals in the aquatic environment. It will allow more effective and targeted interventions when risk to the environment and health is identified.
Goal 14: Conserve and sustainably use the oceans, seas and marine resources		
SDG target 14.1 By 2025, prevent and significantly reduce marine pollution of all kinds, in particular from land-based activities, including marine debris and nutrient pollution	Reductions can be expected for pharmaceuticals, industrial chemicals, pesticides and – in the longer run – microplastics, combining both source and end of pipe measures. Ultimately less pollutants will be transported to the marine environment.	

ANNEX 4: ANALYTICAL METHODS USED IN PREPARING THE IMPACT ASSESSMENT

1. Dynamic baseline

A dynamic baseline reflects the likely changes to emissions and by-proxy environmental concentrations in a business-as-usual / do nothing scenario covering the short-to-medium term picture until 2030. External drivers that may affect emissions and environmental concentrations can be policy or non-policy related, as described below.

1.1. Policy drivers

The timing of changes in emissions to the environment depends on timing or focus of legislation or strategies. Therefore, for PFAS which are banned and no longer used for a 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 if use is phased-out. For nrMs with a banned parent compound, their formation and release to the environment will depend on the rate of degradation 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 compound. The decrease in emissions will be faster than for those whose parent compounds are not banned.

Innovation and digitalisation

The implementation of the INSPIRE Directive 2007/2/EC may also have 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. As such, the INSPIRE Directive not only requires MS 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 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.

One caveat is that, as the policy landscape continues to evolve, there are likely to be further changes in decision making and implementation, making it hard to quantitatively predict the impacts of the dynamic baseline.

1.2. Non-policy drivers

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. More frequent and heavier rainfalls can increase urban run-off and storm water overflows from sewer systems, thus placing additional pollutant-load pressure on water bodies, whereas an increase in the duration and frequency of dry seasons and droughts can result in reduced dilution of pollutants in surface waters. Both phenomena 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 chemical status at risk. Furthermore, droughts can 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 groundwater 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. The urban environment is largely impervious to water, resulting in the water transport having to occur through artificial means (e.g. sewer networks). 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 discharged. 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 (106).

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.

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 can reduce operating costs, improve plant lifetimes and facilitate the switching of plant operations depending on different conditions. The increased use of multi-parameter (fluid) sensor technologies is another example. Furthermore, technologies are evolving rapidly that could facilitate data processing and information sharing in the water sector.

1.3. Results of the dynamic baseline exercise for surface and groundwater pollutants

A qualitative analysis of the dynamic baseline for surface water is presented in Table A4.1, whereas substances proposed for listing in Annex I and Annex II of the GWD are covered in Table A4.2. The tables provide an overview of the relevant legislation and the best understanding of how it is evolving, an overview of how this evolution may impact the emissions of candidate and existing priority substances as well as substances on the List Facilitating Review of the GWD Annexes. Note that the dynamic baseline situation, in terms of production, use and emissions, is in most cases subject to significant uncertainty.

Table A4.1: Dynamic baseline for surface water pollutants

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
Possible addition of priority (hazardous) substances					
Estrogenic substances (E1, E2, EE2)	Used as medication, e.g. in hormonal birth control, menopausal hormone therapy, treatment of hormone-sensitive cancers.	Aging population with potential increase in use of HRT. Aging population decrease use of contraceptive pill.	Industrial Emissions Directive (IED); Strategic Approach to Pharmaceuticals in the Environment (PiE); Classification and Labelling of EU Pharmaceutical Strategy; Urban Wastewater Treatment Directive (UWWTD), but possibly not before 2030, Directive on the Sustainable Use of Pesticides (DSUP), Classification, Labelling and Packaging (CLP) of chemical substances and mixtures Regulation	Changes under UWWTD could have an impact, but unlikely to be widely implemented before 2030.	Some emissions minimisation s (10-30%)
Macrolide antibiotics (azithromycin; clarithromycin; erythromycin)	Used in animal farming and as medication to treat various infections.	Changes to way antibiotics are used in farmed animals. Rate of human use difficult to predict in future years. EU Population is largely static albeit aging.	IED; Pharma legislation (veterinary); PiE; EU Pharmaceutical Strategy; UWWTD; Farm to fork strategy (F2F).	Pre-emptive use of antibiotics for farmed animals ceased end of 2019. Pharmaceutical strategy specifically includes initiatives to address anti-microbial resistance	Significant emissions reductions (30-50%)
Carbamazepine	Used as medication to treat trigeminal neuralgia, diabetic neuropathy and bipolar disorder.	No specific underlying drivers identified.	IED; PiE; EU Pharmaceutical Strategy; UWWTD	EU pharmaceutical Strategy could assess alternative medicines.	Some emissions reductions (10-30%)
Diclofenac	Used as medication to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis.	Aging population, potential increase in use, depending on national approaches.	PiE; EU Pharmaceutical Strategy; UWWTD	No specific initiatives identified.	Some emissions reductions (10-30%)
Ibuprofen	Used as medication to reduce fever and treat pain or inflammation caused by many conditions such	Aging population, potential increase in use, depending on national approaches.	PiE ; EU Pharmaceutical Strategy; UWWTD	No specific initiatives identified.	No change. (+/- 10% current emissions)

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
	as headache, toothache, back pain, arthritis, menstrual cramps, or minor injury.				
Neonicotinoids (Acetamiprid; Clothianidin; Imidacloprid; Thiacloprid; Thiamethoxam)	Used to control insect pests in agriculture (crops, vegetables, fruits), animal farming (e.g. for invertebrate pest control in fish farming).	Use as plant protection products (PPPs) now largely banned; however very few chemical alternatives, so emergency authorisations have been used. Uses as biocides still approved for four out of five neonics. Usage rates not expected to increase significantly up to 2030.	EQSD; GWD; DWD; Biocidal Products Regulation (BPR); Plant Protection Products Regulation (PPPR); Sustainable Use of Pesticides Directive (SUPD)[83]	F2F could be important, but the point was made that the approvals for use as a pesticide have been removed for four neonicotinoids, and strict controls for acetamiprid. Therefore, difficult to further control use. Primary driver for emission reduction will be PoMs under WFD with synergistic benefits to other pesticides. Acetamiprid, clothianidin, and imidacloprid are all candidates for substitution under BPR which should aid phase-out.	Some emissions reductions (10-30%)
Pyrethroids (Bifenthrin; Deltamethrin; Esfenvalerate; Permethrin)	Used to control insect pests in agriculture, public health and animal farming.	Approvals in place under both PPPR and BPR, but consistency would need to be ensured in the best possible way. Very limited choice of chemical alternatives. Use could increase in the future for a variety of reasons.	EQSD, GWD, DWD; BPR; F2F; PPPR; SUPD	F2F sets targets to reduce the use of pesticides which could aid emissions. Under BPR Bifenthrin is a candidate for substitution which aid its phase-out.	Some emissions reductions (10-30%)
Nicosulfuron	Used as an herbicide to control weeds.	Difficult to predict; a range of chemical alternatives exist. Assume usage rates remain broadly stable.	EQSD, GWD, DWD; PPPR; SUPD	No specific initiatives identified.	Some emissions reductions (10-30%)
Glyphosate	Used as an herbicide to control weeds and grasses.	Current approval expires December 2022. Based on communication with Commission approval is likely to be extended at least 12 months while review continues. Further extension possible. Usage rates are already high, could assume continued	EQSD, GWD, DWD; PPPR; SUPD	The assessment of glyphosate is ongoing, at present continued authorisation is expected. It is not directly mentioned in the F2F strategy, and based on current usage rates and EU policy, emissions are assigned to the category 'no change'.	No change. (+/- 10% of current emissions)

[83] Revision of SUPD is ongoing.

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
		rates at a similar level. Question of whether high usage rates lead to tolerance, and greater use of alternatives or co-mixtures with glyphosate?			
Triclosan	Used as an antibacterial and antifungal agent in some consumer products, e.g. toothpaste, soaps, detergents, toys, surgical cleaning treatments. Also added to other materials, such as textiles, to make them resistant to bacteria.	Remaining use as a biocide in limited range of applications. Candidate for substitution. Expect future use to decline.	EQSD, GWD, DWD, BPR; Cosmetics	Candidate for substitution under BPR.	Some emissions reductions (10-30%)
PFAS	Used in stain- and water-resistant fabrics and carpeting, cleaning products, paints, and fire-fighting foams.	The PFAS market has been through successive step changes as EU and global policy has intervened. Expect further diversification, and role of fluoropolymer as a replacement for at least some non-polymeric applications. Legacy issues will from continued pollution from substitution and from already polluted hot spots will remain. Those will still creating future problems for surface and groundwater concentrations levels if unaddressed. Therefore, policy actions under the WFD, EQSD and GWD will remain necessary.	IED, EQSD; GWD; DWD; REACH, Food contact materials (FCM); REACH; Waste legislation; Chemicals Strategy for Sustainability (CSS); expect revised UWWTD to have further impacts, but possibly not before 2030.	Restriction on the use of PFAS. Development of analytical standards under DWD.	Significant emissions reductions (30-50%)
Bisphenol A	Used in the manufacture of various plastics, including for	Some restrictions on Bisphenol A already in place, and substitution from the	IED; DWD; REACH; FCM	New standard adopted under DWD, which could aid emission reduction earlier in the life-cycle.	No change. (+/- 10% of current emissions)

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
	shatterproof windows, eyewear, water bottles, and epoxy resins that coat some metal food cans, bottle tops, and water supply pipes.	same family in use. Many of the issues for emissions may now relate to legacy aspects (polycarbonate and epoxy resins). Assume usage rates broadly stable.		However, given the complex issues at play, expect limited impact. Assume emissions are largely unchanged.	
Micro-plastics	Intentionally added to a range of products including fertilisers, plant protection products, cosmetics, household and industrial detergents, cleaning products, paints and products used in the oil and gas industry. Also used as the soft infill material on artificial turf sports pitches.	Two issues – intentional use of micro-plastics and secondary micro-plastics from use of plastic more widely. Controls likely for intentional use, expect usage rates to decline by 2030. Legacy issues[84] will from continued pollution from continued pollution and from loads of plastics already present in the environment will remain. Those will still creating future problems for surface and groundwater concentrations levels if unaddressed. Therefore, policy actions under the WFD, EQSD and GWD will remain necessary	UWWTD; REACH; Waste legislation; Marine Strategy Framework Directive (MSFD), EU Plastics Strategy (incl. upcoming EU initiatives on micro-plastics), product design requirements under the Ecodesign Directive, Sustainable Textiles Strategy and other Sustainable Products Initiative (SPI) actions.	REACH restriction on the intentional use of micro-plastics. EU initiatives on micro-plastics will tackle unintentional releases.	Some emissions reductions (10-30%)
Silver	Used in coins, silverware, jewellery, mirrors and windows as well as in various industrial and electrical applications, medicine (in surgical equipment, wound dressings, ointments) and even film photography.	Complex issue as this is a naturally occurring substance but also used in silver containing biocides and PCP. There will also be legacy issues (e.g., mine drainage, landfill, etc.). Some usage rates can be assumed to be broadly stable while others like the use of silver as anti-bacterial agent and in a wide range of products is	IED; DWD; BPR; Waste legislation	ECHA Biocides committee rejected approval of four silver containing active substances[85] due to unacceptable risks for human health when used as part of activated carbon water filters. Possibility for silver to be selected as key performance indicator under IED BREF process.	Some emissions reductions (10-30%)

[84] Plastics degrade slowly (often over hundreds to thousands of years) and absorb persistent organic pollutants. Consequently, microplastics are classified as PHS. Specific surface degradation rates (SSDR) are sued to extrapolate half-lives. Mean SSDRs for high density polyethylene (HDPE) in the marine and aquatic environments lead to estimated half-lives ranging from 58 years (bottles) to 1200 years (pipes) (125).
[85] https://echa.europa.eu/-/biocides-committee-proposes-not-to-approve-four-silver-containing-active-substances

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
		increasing. Finally, it must also be considered that silver is the basis for important nanomaterials.			
Possible amendment of existing priority (hazardous) substances					
Chlorpyrifos	Past use as an insecticide to control foliage and soil-borne insect pests on a variety of food and feed crops.	Use is banned in the EU, and recently nominated as a POP under the Stockholm Convention.	EQSD; GWD; DWD Persistent Organic Pollutants (POPs) Regulation	Already banned in the EU. Nominated as a POP to the Stockholm Convention in 2021.	Some emissions reductions (10-30%)
Cypermethrin	Used as an insecticide to control a range of pests in arable and livestock farming, homes and gardens, and in public and commercial buildings. Also used as a medication to treat parasitic skin diseases.	Approved as both a PPP and biocide, with approvals to 2029 and 2030 respectively. Expect usage rates to increase as pressure on other pyrethroids drives substitution.	EQSD; GWD; DWD; F2F; SUPD	F2F may provide some positive impacts for emission reduction of pesticidal use. Biocidal use unaffected.	Some emissions reductions (10-30%)
Dioxins	Mainly by-products of industrial practices, e.g. production of some chlorinated organic compounds, chlorine bleaching of pulp and paper. Also formed during combustion processes (including smoking).	No commercial use. Major emission sources are now largely under control (metals, incineration, power generation). Emissions in the EU now largely static, and further reduction challenging.	IED; POPs Regulation	No specific initiatives identified.	No change. (+/- 10% of current emissions)
Diuron	Past use as a pre-emergence herbicide for general weed control on noncroplands and also to control weeds and algae in and around water bodies and as a component of marine anti-fouling paints.	Approval ended September 2020. Expect all remaining stocks to be exhausted in near term.	EQSD; GWD; DWD	Use ceased recently, but the very high persistence in soil, could create legacy issues that limit the emission reduction up to 2030.	Some emissions reductions (10-30%)

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
Fluoranthene	Used as a fluorescent agent for non-magnetic metal surface inspection, synthesizing yellow and blue vat dyes, and manufacturing medicine.	PAH family member found in crude oil and distillates. Used in some manufacturing processes relating to oils, dyes, and speciality chemicals. No specific underlying drivers identified; assume use is stable.	EQSD; GWD; DWD; REACH	No specific initiatives identified.	No change. (+/- 10% of current emissions
PAHs	Occur naturally in coal, crude oil, and gasoline. Released during combustion processes (including smoking).	No commercial use. Formed as mixtures within fossil fuels and crude oil.	IED; EQSD	Further emission reduction under IED and EQSD.	Some emissions reductions (10-30%)
Heptachlor / Heptachlor epoxide	Past use as an insecticide to control various insect pests, and for soil and seed treatment, wood protection.	Banned in the EU 40 years ago, but highly persistent.	EQSD, POPs Regulation	No specific initiatives identified.	No change. (+/- 10% of current emissions)
Hexachloro-benzene	Past use as a fungicide for seed treatment, especially on wheat to control the fungal disease bunt.	Banned in the EU 45 years ago, but highly persistent.	EQSD, POPs Regulation	No specific initiatives identified.	No change. (+/- 10% of current emissions)
Hexachloro-butadiene	Used in the manufacture of rubber compounds, in the production of lubricants, as a fluid for gyroscopes, as a heat transfer liquid, and in hydraulic fluids.	Not intentionally used in the EU since end of the 1980s. Possible contamination of imported products. But addition to Stockholm Convention will drive down use.	EQSD, POPs Regulation	Added to Stockholm Convention in 2017. However, EU use ceased in 1980s, emissions should already be very low.	No change. (+/- 10% of current emissions
Mercury	Wide range of uses e.g. in thermometers, barometers, manometers, blood pressure meters, float valves, mercury switches, mercury relays, fluorescent lamps and other devices.	Natural occurring substance. Wide range of uses but significant steps over the last decade to control emissions. No specific non-policy drivers identified.	EQSD, GWD, DWD; IED; SSD; Restriction of Hazardous Substances (RoHS) Directive, Mercury Regulation, Minamata Convention	Priority for emission reduction to support EQSD. Including Key Performance Indicator under IED, controls under Mercury Regulation, and waste legislation. Reductions from new provisions for Large Combustion Plans and decarbonising industry.	Significant emissions reductions (30-50%)
Nickel	Used to make stainless steel and other	Similar issues as for other metals, naturally occurring	EQSD; GWD; DWD; IED; REACH	Possible work under IED BREF process.	Some emissions reductions

Substance	Main Uses	Non-policy underlying drivers	Policy (potentially) driving emission reduction	Examples of specific initiatives / actions for emission reduction	Overall outcome
	alloys, for plating, foundry and batteries.	substance. No specific underlying drivers identified.			(10-30%)
Nonylphenol	Used for industrial processes (e.g. for washing and dying of yarns and fabrics) and in consumer laundry detergents, personal hygiene, automotive, latex paints, and lawn care products.	Intentional use has ceased. Imported textiles still an issue and likely to continue to be the case in future.	EQSD; GWD; DWD; REACH; UWWTD, but unlikely before 2030	UWWTD revision could tackle this issue; otherwise EQSD will be the main driver.	Some emissions reductions (10-30%)
PBDEs	Used as flame retardants in plastics, furniture, upholstery, electrical equipment, electronic devices, textiles and other household products.	Use has largely ceased. Primarily a legacy issue for in-use stock and landfill.	IED; POPs Regulation; Waste legislation	Low POP content threshold for PBDEs planned to be reduced.	Some emissions reductions (10-30%)
Tributyltin	Past use as a biocide in anti-fouling paint applied to commercial vessels, pleasure craft and mariculture equipment.	No longer used, but diffuse sources exist from past use.	EQSD, GWD, DWD, International Convention on the Control of Harmful Anti-fouling Systems on Ships (AFS) (the HAFS Convention)	EQSD would be the main driver for emission reduction.	Some emissions reductions (10-30%)
Dicofol	Past and some current use for ornamental plants and fruits	Dicofol containing DDT under severe restriction in Europe	Stockholm Convention, EQSD		No change. (+/- 10% of current emissions
Hexabromo-cyclododecane	Used as flame-retardant within insulation boarding, plastics, and textiles	Not produced or imported into Europe	Stockholm Convention Annex A EQSD		No change. (+/- 10% of current emissions

Table A4.2: Dynamic baseline for groundwater pollutants

Substance	Legislation or strategy driving change	Overall outcome
Pharma-ceuticals	Pharmaceutical legislation & strategy The Veterinary Medicinal Products Directive 2001/82/EC; Directive 2001/83/EC — Community code relating to medicinal products for human use	+ from drive to reduce anti-microbial resistance in the environment which reduces use as veterinary medicines
	EC pharmaceutical strategic approach Various guidelines on Environmental Risk Assessment for pharmaceuticals	0 Environmental risk assessment process may be too weak to have an impact on wider groundwater pollution meaning a limited change from EU pharmaceuticals strategy
	Industrial emissions Directive (IED)	+ at manufacturing sites for pharmaceuticals and future expansion of scope to include intensive cattle farming
	EQSD	+ Carbamazepine, Erythromycin and Clarithromycin under consideration as PS
PFAS	GWD	++ for PFAS based on prevent and limit requirements and TVs.
	REACH Regulation	+ relevant PFAS (HFPO-DA (better known as GenX[86]) has replaced PFOA as processing aid for producing fluoropolymers and PFBS) for future manufacturing
	Persistent Organic Pollutants (POPs) Regulations	+ for relevant PFAS (PFOS has already been restricted in the EU for more than 10 years)
	Food Contact Materials Regulation (EC) No 1935/2004; and Commission Regulation (EU) No 10/2011	+ for PFAS (PFOA, PFECA and ADONA) not permitted for use in food contact materials. EFSA threshold for PFAS TWI of 4.4 ng/kg)
	Industrial Emissions Directive (IED)	+ at manufacturing sites for PFAS
	Drinking Water Directive (DWD) recast	++ in the long term
	EQSD	+ in long term for GWBs connected to SWBs. PFOS is already a Priority Substance with an EQS of 0.00065 µg/l.
nrMs of pesticides	GWD	++ based on measures to address pesticides through Annex I and Annex II listing and TVs
	Regulation No 1107/2009 concerning the placing of plant protection products on the market	++ for nrMs with banned parent compounds.
		++ where permitted parent compound is reviewed in light nrMs in groundwater
	Directive 2009/128/EC, establishing a framework for community action to achieve the sustainable use of pesticides (SUPD)	+ for nrMs with reduction in use of parent product. SUPD supports the Farm to Fork initiative, which aims to reduce hazardous pesticide use by 50% by 2030.
	Biocidal Products Regulation	+ for Tolylfluanid and Dichlofluanid
	Stockholm Convention	+ for nrMs derived from POPs parent compounds
	Drinking Water Directive (DWD) recast	+ for nrMs
	MS drinking water standards	+ for nrMs
	EQSD	+ in long term for GWBs connected to SWBs. Glyphosate (nrM parent) is under consideration as PS

[86] In 2019, GenX was identified as a Substance of Very High Concern (SVHC): https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e1832708a2

2. Distance to target

As explained in the main text of the SWD (in particular section 6.1.1), the distance to target cannot be determined for each Member State vis-à-vis each substance or group of substances under consideration because the monitoring data underpinning such measurement are either anonymised, incomplete or both. For the candidate priority substances, data from the surface water watch list is obtained from the JRC in an anonymised format, in which data reported by individual MS are separate but the counties are not named (e.g. it is clear which data belong to Country 1, but no indication of which MS it is). In the case of existing PS, data to inform the distance to target assessment is largely obtained from the WFD reporting, where reporting measured concentrations is voluntary, leading to a fragmented dataset. In the case of emerging groundwater pollutants, the voluntary nature of monitoring under the Groundwater Watch List limits the amount of data available. In addition, the measurements are reported in concentration ranges (e.g. <LOQ, ≥LOQ-0.05 µg/L, 0.05-0.1 µg/L etc.), therefore it is not possible to know exact concentrations (22).

Considering the above, it was necessary to adapt the distance to target methodology keeping in mind the specific data availability for new PS, existing PS and LFR substances. The sections below explain the approaches taken to assess the scale and magnitude of the gap between the current concentrations in surface and groundwater and the new quality standards considered for each pollutant.

2.1. Substances for addition to PS list

Criteria shown in Table A4.3 were developed to assess the 'distance to target' for candidate priority substances (PS). They allow for a pathway 1 (data -rich) or a pathway 2 (data -poor) assessment, depending on the number of MS (MS) reporting data. The criteria evaluate two metrics: the scale of the problem (i.e. how wide-spread geographically are exceedances of the proposed EQS, and, in the case of pathway 2, the temporal spread (i.e. how frequently do we see exceedances occur consistently year on year?), and the magnitude of the problem (i.e. how large are the exceedances above the EQS?). Substances within each pathway are listed in Table A4.4 below. It is worth to note that the uncertainty in the results for substances assessed under pathway 2 will be bigger than for those under pathway 1. For the available monitoring data see Table A11.1 in Annex 11.

Table A4.3: 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.	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).
	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.	
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
	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.	years. (i.e. maximum AA/MAC is 1.5 x EQS for all years).

Table A4.4: Data-rich and data-poor candidate priority substances

Pathway 1 (data rich)	No. of MS providing monitoring data (last 10 years)	Pathway 2 (data poor)	No. of MS providing monitoring data (last 10 years)
Estrone (E1)	26	Ibuprofen	8
17-Beta estradiol (E2)	24	Nicosulfuron	7
Ethinyl estradiol (EE2)	18	Bifenthrin	2
Diclofenac	26	Deltamethrin	4
Azithromycin	24	Permethrin	5
Clarithromycin	25	Esfenvalerate	4
Erythromycin	25	Glyphosate	13
Carbamazepine	15	Triclosan	10
Acetamiprid	22	PFAS	6
Clothianidin	22	Silver	9
Imidacloprid	25		
Thiacloprid	24		
Thiamethoxam	21		
Bisphenol A	15		

The methodology followed a 2-stage process. For each substance, the screening criteria were used to rank the substance in a category defining the distance to target (i.e. compliance with the new EQS). This defines the distance to target as ‘large’, ‘medium’, or ‘small’. Then, the dynamic baseline was applied to assess whether the scale and magnitude of the exceedances would be altered by expected changes or effects in other policy areas 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 size of the gap 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 size of the gap increasing.

Table A4.5: Summary of the distance to target assessment for candidate priority substances

Substance category	Substance	Current Distance to Target[87]		Expected emission change (Dynamic Baseline)	Overall expected Distance to Target
		Scale % of MS with exceedances against total no. of MS providing monitoring data	**Magnitude** % of MS with mean monitored concentration >30% of recommended EQS		
Estrogenic hormones (pharmaceuticals)	17 alpha-ethinylestradiol (EE2)	Large (83%)	Large (94%)	Some reduction (10% - ≤30%)	Relatively large
	17 beta-estradiol (E2)	Medium (54%)	Medium (58%)		Medium
	Estrone (E1)	Medium (65%)	Large (69%)		Medium
Macrolide	Azithromycin	Medium (54%)	Medium (54%)	Significant reduction	Medium

[87] Based on data from JRC substance dossiers submitted to the SCHEER, supplemented by data from JRC

Substance category	Substance	Current Distance to Target[87]		Expected emission change (Dynamic Baseline)	Overall expected Distance to Target
		Scale % of MS with exceedances against total no. of MS providing monitoring data	**Magnitude** % of MS with mean monitored concentration >30% of recommended EQS		
antibiotics (pharmaceuticals)	Clarithromycin	Small (16%)	Small (32%)	(30% - ≤50%)	Small
	Erythromycin	Small (4%)	Small (4%)		Small
Other pharmaceuticals	Diclofenac	Large (80%)	Large (84%)	Some reduction (10% - ≤30%)	Relatively large
	Carbamazepine	Large (100%)	Large (100%)		Relatively large
	Ibuprofen	Small (26%)	Medium (40%)	No change (≤10%)	Medium
	Triclosan	Large (100%) (very small data-set)	Medium (40%)		Medium
Neonicotinoid pesticides	Acetamiprid	Medium (36%)	Medium (36%)	Some reduction (10% - ≤30%)	Small
	Clothianidin	Medium[88] (41%) to small (12%)	Small (18%)		Small
	Imidacloprid	Medium (64%)	Large (72%)		Medium
	Thiacloprid	Medium (58%)[89] to Small (29%)	Small (29%)		Small
	Thiamethoxam	Small (14%)	Small (19%)		Small
Pyrethroid pesticides	Bifenthrin	Large (100%) (very small data-set)		Some reduction (10% - ≤30%)	Relatively large
	Deltamethrin	Large (100%) (very small data-set)			Relatively large
	Esfenvalerate	Large (100%) (very small data-set)			Relatively large
	Permethrin	Large (100%) (very small data-set)			Relatively large
Other pesticides	Glyphosate	Large (92%)	Large (92%)	No change (≤10%)	Relatively large
	Nicosulfuron	Large (71%)[90] to Medium (40%)	Medium (40%)	Some reduction (10% - ≤30%)	Medium
Industrial chemicals	PFAS	Large (100%) (very small data-set)		Significant reduction (30% - ≤50%)	Relatively large
	Bisphenol A	Large (100%) (very small data-set)		Some reduction (10% - ≤30%)	Relatively large
Metals	Silver	Large (89%[91]) to medium (40%) (very small data-set)		Some reduction (10% - ≤30%)	Medium

2.2. Substances considered for EQS amendment

[88] Data used for the scientific dossier on Clothianidin, jointly prepared by the JRC and the WG Chemicals, based on a data set of more than 12000 samples from 22 Member States, showed exceedances corresponding to 41% of the samples

[89] Data used for the scientific dossier on Thiacloprid, jointly prepared by the JRC and the WG Chemicals, based on a data set of more than 15000 samples from 24 Member States, showed exceedances corresponding to 58% of the samples

[90] Data used for the scientific dossier on Nicosulfuron, jointly prepared by the JRC and the WG Chemicals, based on a data set from Member States, showed exceedances corresponding to 71% of the samples

[91] Data used for the scientific dossier on Silver, jointly prepared by the JRC and the WG Chemicals, based on a data set of more than 11000 samples from 24 Member States, showed exceedances corresponding to 89% of the samples.

The assessment for the amended EQS has largely been completed using a combined quantitative and qualitative approach. Quantitative monitoring data were used where available and supplemented by data from the EEA dashboards providing details around the current rate of exceedances for named substances, based on number of water bodies and MS (noting that a total of 137,000 surface water bodies are identified in the EEA data). Data from the EQS dossiers (where available) include data from monitoring samples from a large number of Member States allowing the calculations of exceedance rates. In 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 A11.2 in Annex 11).

Then as a second step based on the proposed EQS (where available) and guidance from the JRC, 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. Combined with the expected changes due to dynamic baseline, an overall distance to target has been determined, as shown in Table A4.6.

Table A4.6: Summary of the distance to target assessment for existing PS substances considered for EQS amendment

Substance category	Substance	Current Distance to Target [92]		Change in distance to target due to new EQS	Expected emission change (Dynamic Baseline)	Overall expected Distance to Target
		Scale	Magnitude			
Pesticides	Chlorpyrifos	Medium	Small	Increase	Some reduction (10% - ≤30%)	Medium
	Cypermethrin	Medium (assumed)	Medium (assumed)	Increase		Medium
	Diuron	Medium	Small	Increase		Medium
	Heptachlor and Heptachlor epoxide	Small (assumed)	Small (assumed)	Decrease	No change (≤10%)	Small
	Hexachlorobenzene	Medium	Small	Decrease		Small
	Tributyltin	Large	Medium	Increase	Some reduction (10% - ≤30%)	Medium
Industrial chemicals	Dioxins and furans	Medium (assumed)	Medium (assumed)	Increase	No change (≤10%)	Medium
	Fluoranthene	Medium	Medium	Decrease		Small
	Hexachlorobutadiene	Medium	Small	Increase		Small
	Nonylphenol	Medium	Small	Increase	Some reduction (10% - ≤30%)	Small
	PAHs	Large	Medium	Increase		Medium
	PBDEs	Medium	Large	Increase		Relatively large
Metals	Mercury	Large	Large	Increase	Significant reduction (30% - ≤50%)	Relatively large
	Nickel	Large	Medium	Increase	Some reduction (10% - ≤30%)	Relatively large

2.3. Role of the 'One-Out-All-Out' approach

[92] Based on data from JRC substance dossiers submitted to the SCHEER

Despite the observation that the estimated 'gap size' for an individual pollutant can vary from relatively large, medium or small, this is only a rough and indicative approach with a wide range of limitations. The 'one-out-all-out' (OOAO) principle that is embedded in the WFD, means that a WB can only achieve good status if this status is achieved for all pollutants. In other words, if the water does not achieve good status for one or more of the existing pollutants included in the assessment of the chemical status, the addition of a new PS does not make a difference. The current list of PS under the EQSD contains 53 priority (hazardous) substances. So only if a WB achieves good status for all those 53 pollutants, which is the case only for 38% of all WBs, the addition of a single new PS/PHS could make a difference between pass / fail. Thus, in the theoretical situation where 100% of the WBs in all MS would fail to achieve good status based on this single pollutant, the maximum contribution to the chance for a WB to fail to achieve good status could be 1.9% (1/53 * 100%), based on a significant exceedance of the EQS for this new PS/PHS. To estimate the likely indicative contribution of adding a single substance to the PS list, the maximum 1.9% must first be multiplied by 38% (the no. of WBs currently achieving good status) and subsequently also with the average of the size of the predicted exceedances (16.5% for the 'small' category; 49.5% for the 'medium' category; and 83% for the 'large' category). This would result in the following maximum contribution to the chance to fail for a single substance added:

- Small: 1.9% *16.5% *38%= 0.14% indicative contribution per substance
- Medium: 1.9% *49.5% *38% = 0.36% indicative contribution per substance
- Large: 1.9% *83% *38% = 0.59% indicative contribution per substance

Multiplying the obtained values with the number of polluting substances under each distance to target category mentioned in Tables A4.5 and A4.7 results in the overall cumulative contribution of the new and revised EQSs to the chance to fail to achieve good status of 14.44%:

- Small: 13 (no. of new and existing substances in small category) *0.14% = 1.82% indicative estimation of the additional contribution to failure to reach good status
- Medium: 12 (no. of new and existing substances in medium category) *0.36% = 4.32% indicative estimation of the additional contribution to the gap size
- Large: 13 (no. of new and existing substances in large category) *0.59% = 7.67% indicative estimation of the additional contribution to the gap size

Although this estimate cannot be directly translated into the efforts required by each individual Member State, it provides a good indication of the 'worst-case' additional good chemical status failures. In more concrete terms, this means that there is a 14.44% chance exceedances of the new and amended EQSs cause failure to achieve good chemical status in any surface water body.

Microplastics are excluded from these calculations at this stage since they can only be added to the PS list after monitoring results, obtained following the development and implementation of the proposed harmonised EU methodology, have become available.

2.4. Groundwater

The lack a Europe-wide risk assessment based on monitoring data for the LFR pollutants means that an estimation of the likely current day status of GWBs in relation to PFAS, pharmaceuticals and nrMs is needed to understand how the problem would evolve. To estimate the proportion of the circa 13,746 GWBs reported on by the EU27 which are potentially at risk of being at poor status due to these pollutants, the following assumptions were made:

- The majority of MS will set a TVs based on the current day Drinking Water Standard (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)[93] test (the remaining tests are not relevant or would need more detailed datasets).

Criteria shown in Table A4.7 were developed to assess the 'distance to target' for groundwater options. The emissions, pathways and detection in groundwater were used to estimate the scale of pollution and whether this would trigger a failure of the General Chemical Assessment (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.

Table A4.7: Criteria for the distance to target assessment for groundwater options

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 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 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)

Note that the likely time for changes in observed pollutant levels in groundwater is strongly controlled by the lag (residence) time in aquifers. Most shallow, rapid recharge aquifers have a residence time of between 10-30 years (e.g. gravel aquifers linked to river systems), whilst deeper, thicker, more consolidated aquifers can have residence times of 10 to 100 years. For some of the LFR substances which are already banned or whose use is restricted (PFOA, PFOS and the parent products of some nrMs), concentrations may already start decreasing in groundwater, whilst for others like pharmaceuticals they are increasing. To avoid further deterioration of the quality and to reduce the level of purification treatment required in the production of drinking water, setting quality standards remains essential.

[93] 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).

Table A4.8: Summary of the distance to target assessment for groundwater options

Substance group	Policy Option	Current Distance to Target		Impact of change in emissions & aquifer lag time	Overall expected Distance to Target
		Scale % of reporting MS with predicted exceedances	**Magnitude** % of monitoring points with predicted exceedances		
Options included in the main report					
PFAS	Option 1 (Annex I - list of 24 with PFOA-equivalent 4.4 ng/l GW QS)	Large (90%)	Large (68%)	30% - ≤50% reduction due to dynamic baseline, but long aquifer lag times limit short- & medium-term impact.	Large
	Option 2 (Annex I - sum of all at 0.5 µg/l GW QS)	Large (70%)	Large (75%)		Large
	Option 3 (Annex II - assuming TVs set using DWS)	Medium (35%)	Large (2.5%)*		Large
Pharma-ceuticals	Option 1 (Annex I - Carbamazepine at 0.1 µg/l, Sulfamethoxazole at 0.5 µg/l GW QS)	Small (37% and 12.5%, respectively)	Small (8% and 0.43%, respectively)	10% - ≤30% reduction due to dynamic baseline	Small
	Option 2 (Annex I - group at 0.5 µg/l)	Medium (47%)	Medium (50%)		Medium
	Option 3 (Annex II - group, considering Primidone; assuming TVs set using DWS)	Small (17%)	Small (1%)		Small
Non-relevant metabolites of pesticides (nrMs)	Option 1 (Annex I - all individually at 0.1 µg/l GW QS)	Large (93%)	Medium (59%)	10% - ≤30% reduction due to dynamic baseline	Large
	Option 2 (Annex I - group of all at 10 µg/l GW QS)	Large (87%)	Small (6%)		Medium
	Option 3 (Annex II - assuming TVs set using DWS)	Medium (40%)	Small (2%)*		Medium
Other options considered					
PFAS	List of 10 PFAS identified by the GW WL in Annex I at 0.1 µg/l GW QS	Large (70%)	Large (75%)	30% - ≤50% reduction due to dynamic baseline, but long aquifer lag times limit short- & medium-term impact.	Large
nrMs	List of 16 nrMs identified by the GW WL individually at 1 µg/l GW QS	Large (80%)	Small (29%)	10% - ≤30% reduction due to dynamic baseline	Medium
	List of 16 nrMs identified by the GW WL individually at 0.1 µg/l GW QS	Large (93%)	Medium (59%)		Large

*Magnitude is represented by % of groundwater bodies failing based on proxy substance.

2.4.1. PFAS

European emissions

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.

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.

Predicted current day risk and GWB 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 (i.e. sum of 20 PFAS with a limit of 0.1 µg/l).

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 A4.9: 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 – human health based (relatively high compared to man-made chemicals)	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 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.	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	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.

2.4.2. Pharmaceuticals

European emissions

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[94]. The number of people with epilepsy in the EU (6 million[95]) is likely to far outweigh the number of horses with

[94] Carbamazepine | VCA Animal Hospitals (vcahospitals.com)
[95] euro_report.pdf (who.int)

headshaking (circa 5 million tame horses in the EU of which 1% (107) 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 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 (108). 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).

Pathways to groundwater

The European Union Strategic Approach to Pharmaceuticals in the Environment 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[96], 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."

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.

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 (109)). The pathway from land spreading of biosolids and manures is likely to provide a

[96] 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.

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 A4.10). 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.

Table A4.10 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.	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 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.

2.4.3. Non-relevant metabolites of pesticides (nrMs)

European emissions

Non-relevant metabolites from pesticides (nrMs) are not manufactured products, forming in the water environment through degradation of a parent pesticide compound. 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. 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 (45) 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[97] (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

[97] 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.

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.

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.

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 GW QS (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 A4.11), 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 A4.11: Benchmarking for GWB status due to nrMs of pesticides

Substance leading to RBC2 GWB failure	No. GWBs failing	No. MS reporting failures	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 persistent, permitted substances typically have low persistence in soils but once in groundwater can persist.	Includes the parent products so could provide worst case.
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)		

3. Cost-benefit analysis

Since the options do not specify the exact measures to be taken to attain the set quality standard, the assessment of the potential costs and benefits of measures themselves (as compared with the costs and 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 in addition to exposure and intrinsic hazard of the substances themsleves.

3.1. Identification of possible measures and impacted stakeholders

Completion of this part of the impact assessment has utilised in part the steps outlined within the Better Regulation Toolbox #16. 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 undertaken.

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 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.

Table A4.12 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. Very broadly the measures identified can be 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.

Table A4.12: Possible policy measures to identify and subsequently limit emissions of PS and PHS respectively to identify costs and benefits (the possible burden).

Type	Pharmaceuticals	Pesticides	Industrial Chemicals	Metals
Industry	Manufacture	Manufacture		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)		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	

Type	Pharmaceuticals	Pesticides	Industrial Chemicals	Metals
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
	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	

3.2. General cost considerations

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, 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, Annex I and Annex II substances will fall upon water companies to an extent (monitoring and analysis, reporting, treatment, etc.)
- To users, this would include 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.).

3.3. Environmental benefits

The most significant environmental benefit from addition of candidate substances to the EQSD list (under Option 1 (add individually), 2 (add as groups), 3 (amend existing PS/PHS), 4 (change in status), 5 (deselect)) or GWD Annex I or Annex II is that it promotes action across the EU, in particular bilateral co-operation for MS with shared rivers and water bodies (60% of EU waters are transboundary). The use of standardised EQS, GW QS or an approach to derivation of quality standards at EU-level provides a foundation for MS to work collectively towards protection of the aquatic environment. Which would mean the efforts deployed would be more effective and efficient at managing chemical risks than MS working in isolation.

Building upon the point above, regular monitoring of additional PS substances (under Option 1, 2, 3 and 4 in surface water and Annex I and II substances in groundwater) has the added benefit of increased knowledge of the extent of water pollution across the EU. This allows the 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 insuffiicent; 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 5 (deselection), data and knowledge would be lost on these substances if removed from the PS list.

Measures employed to deal with new or amended PS and related EQS and with GWD Annex I and Annex II substances and to further limit chemical emissions should help to improve biodiversity (even beyond the immediate aquatic ecosystem) and thus result in a more resilient aquatic ecosystem, enhancing its capacity to deliver ecosystem services such as the processing of excess nutrients (Cardinale 2011). Indirectly, this will also translate into better human health protection through a cleaner aquatic environment and cleaner drinking water.

Cleaner sediments should result in less potential for re-dissolution of pollutants in the water column and reduced uptake of harmful substances by plants and animals.

3.4. 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.

Cleaner sediment negating the need for 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.

3.5. Social and public health benefits

The following social and public health benefits have been identified:

- 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). These improvements will also benefit the push for a significantly increase organic aquaculture sector, and the use of less antimicrobials in the sector[98], which is again supportive to public health and building a sustainable food system[99].
- 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 in meat and milk, hence reduced human exposure to hazardous substances, likewise, less accumulation in meat, surface waters, groundwaters and and drinking water;
- Reduced potential for accumulation of hazardous substances in crops when untreated water is used for irrigation.

[98] Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030" (COM(2021) 236 final

[99] Farmed seafood has a comparatively low-carbon footprint in comparison to (intensive) livestock farms.

ANNEX 5: RELATIONS BETWEEN ONGOING INITIATIVES AND THE PRESENT INITIATIVE

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
Evaluation of the Sewage Sludge Directive	This Directive regulates the use of sludge in agriculture and includes limit values (mainly for heavy metals) when sewage sludge is used in agriculture. The Directive is under evaluation before deciding on its possible revision.	Measures aiming at better controlling pollution at source notably for non-domestic pollution will contribute to improve the quality of the sludge, making it more suitable for agriculture. Actions to better capture and treat storm water overflows and urban runoff are expected to allow capturing more micro-plastics and increase their presence in sludge. Moving towards energy neutrality will only happen if more sludge is digested (production of biogas).	Evaluation of the SSD has been excluded from the impact (dynamic baseline) assessment as at the time of analysis it was still at early stages of the better regulation process.
Revised Industrial Emission Directive	The Industrial Emission Directive (IED) regulates water and air emissions from large industrial facilities. Commission proposal adopted on 6 April 2022.	The revised IED will contribute to better control emissions to air and water from large industrial facilities notably for what relates to non-domestic pollution. The inclusion of cattle farming under the scope of the Directive will result in limited to weakly positive impacts on water quality. Besides nutrients, this concerns also veterinary pharmaceuticals. Monitoring of substances on the PS list will help evaluate the effectiveness of measures introduced under the IED. Also the revision of the lists of polluting substances and the reporting thresholds under the Industrial Emissions Portal Regulation (IEPR, former E-PRTR), will include new emerging pollutants like PFAS, which will help to better assess the actual emissions in the future (provided the legislator does not change these elements)	Pharmaceuticals used in animal farming: 10-30% emission reduction Pesticides: no impact nrMs: n/a Silver: no impact PFAS: 10-30% emission reduction BPA: 10-30% emission reduction
Revised Drinking Water Directive	The Drinking Water Directive (DWD) concerns the quality of water intended for human consumption. Its objective is to protect human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. The revised DWD was formally adopted on 16 December 2020 and entered in force on 12 January 2021.	The recast DWD is particularly relevant to the GW WL 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. Measures aiming at better controlling pollution at source will improve quality of surface and groundwater, which in turn contributes to lower costs of (pre)treatment as a result of improved quality for potable water and process water for drinking water supply.	Pharmaceuticals: no impact Pesticides: no impact nrMs: 10-30% emission reduction Silver: no impact PFAS: 10-30% emission reduction BPA: 10-30% emission reduction
Marine Strategy Framework Directive	The Marine Strategy Framework Directive (MFSD) obliges MS to achieve Good Ecological Status in all marine waters by 2020. It will be revised (Commission Proposal planned for 2023).	The MFSD GES includes (through the 'descriptors') reducing the presence of contaminants in the aquatic environment, including in seafood. Given the strong links between the marine and the freshwater environment, a reduction of contaminants in either is mutually beneficial (e.g. for migrating fish and generally in waterbodies connecting river and sea like estuaries). Moreover, the WFD and the MSFD overlap geographically as the regards the first nautical mile off the coast.	N/A

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
		Listing of substances, especially for surface water, will lead to reduction of these substances in the linked marine waters.	
Revised Urban Waste Water Treatment Directive	The UWWTD obliges collection and treatment of waste water from agglomerations. It is currently under revision (adoption planned for July 2022)	The revised UWWTD is likely to bring a range of important improvements in the period up to 2020. The better management of storm water overflow should reduce plastic pollution. The increased connection of UWWTPs below 2000pe in combination with lowering the threshold for reporting to a wastewater treatment to 1000 inhabitant equivalent and a stricter inspection of 'individually appropriate systems' should reduce diffuse pollution of all types and their monitoring. Specifically, to reduce pollutants ending up in effluents producer responsibility schemes will be set up and advanced treatment will become mandatory for areas at risks and in bigger agglomerations. The resulting waste water sludge will, as result, contain more pollutants.	Revised Directive assessed to lead to 44% reduction of toxic load (which includes the substances considered in this initiative) of which 64% are in areas of risk. Revision of the UWWTD has been excluded from the impact (dynamic baseline) assessment as at the time of analysis it was still at early stages of the better regulation process.
Proposal for Nature Restoration Regulation (NRR)	The proposal for a Nature Restoration Regulation, scheduled for 20 June 2022, aims at restoring ecosystems in the EU, including aquatic ecosystems.	The NRR will directly contribute to increase the green areas in the cities and therefore the capacities of urban soils to absorb rainwater. In case heavy rains, less 'clean' rainwater will be mixed to polluted waters in the urban collecting systems and less untreated water will be sent to the environment. Outside cities, the NRR will lead to more natural river and lake systems, allowing water to be retained longer and restoring the capacity of ecosystems to purify water. The precise effects on water absorption of the NRR will depend on the very local circumstances, but both legislations will act in a synergetic way.	In the long term (2050) the gradual increased restoration of ecosystems will increase the purification capacity of nature, leading to lower emissions to water for all substances.
Mercury Regulation	The 2017 Mercury Regulation prohibits the export and import of mercury containing products and phases out its uses	The Mercury Regulation will reduce significantly any new emission of mercury to water. However, mercury deposition (eg as a result of burning coal) will continue and mercury currently in the aquatic environment is extremely persistent.	Significant impact on new emissions except those deposited through the air; limited impact on mercury concentrations given large legacy concentrations.
Ban on all but the essential uses of PFAS	The Chemicals Strategy for Sustainability announced a ban on all but the essential uses of PFAS. Commission proposal for a ban on placing on the market of PFAS expected end of 2024.	Depending on the final definition of 'essential use', this should over time significantly impact on new emissions to water. Existing products containing PFAS will however continue to emit PFAS over the years to come.	Significant legacy PFAS pollution remains, new emissions will gradually decrease, depending on the scope of the PFAS ban.
Regulation on the Sustainable Use of Plant Protection Products (SUR)	A proposal for a Regulation on the Sustainable Use of Plant Protection Products (SUR) is scheduled for adoption by the Commission on 20 June 2022.	The SUR will introduce a binding target at EU level of 50% pesticide use and risk reduction, and require MS to set nationally appropriate binding targets. It will also prohibit the use of any pesticide in urban areas and vulnerable zones under nature legislation (eg Natura 2000 sites) and water legislation (for WFD the	Achieving the 50% reduction will only be partially the result of the SUR – other factors are change of crops, nature protection, substitution. The SUR

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
		drinking water protection zones). Once implemented this should significantly reduce especially pesticide pollution from diffuse sources, while in urban areas it will complement the results of the modified UWWTD. An improved digital data collection on use, quantities, geographical application and seasonal pesticides use, under the envisaged revised Sustainable Use of Pesticides Regulation, would provide hugely valuable input for an improved implementation of legislation like the WFD and the EQSD, as well as the EU Biodiversity Strategy 2020, the common agricultural policy (CAP), and the Thematic Strategy on Soils.	alone will likely have a limited negative impact on the concentrations of pesticides in water. An improved data collection on pesticide use at farm level will improve the data quality on pesticides which will not only reduce costs related to data assessment related to setting future EQSs, but also speed up the identification of emerging health and environmental risks and the revision of standards to scientific progress.
Veterinary pharmaceuticals legislation	The [Veterinary Pharmaceutical legislation] regulates the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.	The Veterinary Pharmaceutical legislation requires an environmental risk assessment to be performed to assess the potential harmful effects, which the use of the veterinary medicinal product may cause to the environment and to identify the risk of such effects. The assessment shall also identify any precautionary measures which may be necessary to reduce such risk. Relevant to water, a guidance on the environmental risk assessment of medicinal products for use in aquaculture including, where appropriate, recommendations for risk management measures is being develop. Once ready, this would promote a more prudent and responsible use of veterinary medicines.	ERA and guidelines are expected to lead to a limited effect on emissions of relevant veterinary pharmaceuticals, particularly in rural areas.
Revision of Human Pharmaceuticals Legislation	The Human Pharmaceuticals Legislation regulates the placing on the market as well as authorisation, supervision and phar-macovigilance of medicinal products for human consumption. A Proposal for revision is scheduled for 2022.	The Human Pharmaceuticals Legislation requires Environmental Risks Assessment (ERA) of pharmaceuticals to be placed on the EU market. However such ERA are not required for many of the pharmaceuticals currently on the market. Requiring ERA may not prevent active pharmaceutical ingredients reaching the aquatic environment; they would however provide national authorities with information useful to manage emissions and impacts.	Very limited impact; if any, it will be from increased pharmacovigilance following stricter application of ERA for relevant human pharmaceuticals, particularly in urban areas.
Initiative on micro-plastics	The Micro-plastics initiative is expected to reduce non-intentional micro-plastics emissions from some sources such as textiles and geotextiles, tyres, plastic pellets, paints, and detergent capsules.	With the planned initiative and in the mid-term, lower emissions of micro-plastics from these sectors could be expected in urban waste waters. However even if all possible measures are taken to reduce emissions at source, there will always be residual emissions. Micro-plastics are well captured in wastewater treatment plants (between 80% up to 99% when tertiary treatment is in place). The	Overall EU target of 30% reduction by 2030 (cf ZP Action Plan). Mix of measures as yet not established (impact assessment ongoing).

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
		proposed measures under the UWWTD will improve the abilities of capturing more micro-plastics in the collecting and treatment system. The proposed monitoring of microplastics in surface water will be complementary to this initiative.	
EU Strategy for Plastics in a Circular Economy	The EU Strategy for Plastics in a Circular Economy proposes action along four strands: 1) restrictions to intentional addition of microplastics to products via REACH, 2) actions on unintentional release of microplastics, 3) measures to reduce plastic pellet spillage and 4) use of UWWTD to capture and remove microplastics	The planned initiative support the efforts to reduce plastics in water by developing a methodology and a mechanism to monitor presence of microplastics in the aquatic environment. On the other way around, the EU plastics strategy and its related actions will drive down the presence of such plastics. Thus, the two initiatives are working complementarily.	Strategy will support action to achieve the 30% reduction target for microplastics by 2030 cf ZP Action Plan
Ecodesign for Sustainable Products Regulation	The proposal aims to reduce the negative life cycle environmental impacts of products and improve the functioning of the internal market via significantly improving product circularity, energy performance and other environmental sustainability aspects.	The push for product circularity under the Ecodesign Regulation will promote reduction and/or phase-out of some hazardous chemicals which currently may hinder the circularity potential of the product. This will reduce the manufacturing and end-of-life releases of such substances into the environment, including water bodies.	Longer term effect on emissions (in use and end-of-life) of industrial chemicals, including PFAS.
EU Ecolabel	The updated EU Ecolabel criteria now applies to all cosmetic products, as defined under the EU Cosmetic Regulation. Previous EU Ecolabel requirements only covered a limited range of so-called 'rinse-off' products such as body wash, shampoo and conditioner. The updated rules include 'leave-on' cosmetics such as creams, oils, skin-care lotions, deodorants and anti-perspirants, sunscreens, as well as hairstyling and make-up products. In the animal-care sector, the EU Ecolabel can be awarded to rinse-off products, such as soaps and shower preparations.	The new EU Ecolabel criteria for cosmetics and animal-care products (adopted in October 2021), offers consumers across the EU the benefit of trusted proof for genuine green brands. The EU Ecolabel is a reliable third party verified label of environmental excellence, which takes into account the environmental impact of a product throughout its entire life-cycle, from the extraction of raw materials to final disposal. Consequently the uptake of the EU ecolabel for this category of products can drive down emissions. Today, three out of four care products sold in Europe display an environmental claim or label, and yet many of these claims are difficult to understand or confusing for the consumer.	Limited positive impact; if any, but an increased uptake could reduced emissions from pharmaceuticals (e.g. conservation agents, substances with endocrine disrupting effects, microplastics and PFAS) contained in personal care products.
EU Strategy for Data, the INSPIRE Directive, and the Directive on Public Access to Environmental	The strategy for data aims at creating a single market for data that will boost the Europe's global competitiveness and data sovereignty. Common European data spaces will ensure that more data becomes available for use in the economy and society, while keeping the companies and	Water related data could complement and be cross referenced with publicly available environmental data on emissions from industrial installations covered by the IEPR and e.g. help monitor the effects of the implementation of new Best Available Techniques on the aquatic environment surrounding such installations. This also benefits data made available under the EU	Limited positive impact; as data is collected once and reused many times, thus generating clear synergies and reducing costs, while boosting innovation in the data economy, like e.g.

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
Information	individuals who generate the data in control. Data driven applications will among others be aimed at improving health care, create safer and cleaner transport systems, generate new products and services, reduce the costs of public services (by reusing data multiple times) and improve sustainability and energy efficiency. As part of its data strategy the Commission has proposed a Regulation on European data governance.	INSPIRE Directive Clear synergies exist between this initiative, the Zero Pollution Outlook, and the Commission proposal for a Regulation of the Industrial Emissions Portal (IEPR, former E-PRTR), the. Especially, data collected under policy options 3, 4, 6 and 7 would lead to better water quality data in shorter than the current 6-years intervals	close to real time environmental monitoring data for authorities and citizens.
Textile Strategy	The EU strategy for sustainable and circular textiles addresses the production and consumption of textiles and aims that all textile products placed on the EU market are durable, repairable and recyclable, to a great extent made of recycled fibres, free of hazardous substances, produced in respect of social rights and the environment.	The Textile Strategy will harmonise EU Extended Producer Responsibility rules for textiles and economic incentives to make products more sustainable. It will also address the unintentional release of micro-plastics from synthetic textiles.	Effect on microplastics and industrial chemicals including PFAS used in textiles production
Liability Directive	The Environmental Liability Directive, currently under revision, sets the EU framework for environmental liability, including compensation.	The Environmental Liability Directive could lead to compensation for water damage caused by pollution (including the pollutants to be added under this initiative) from IED installations or discharges to water in breach of WFD	If implemented as proposed, small negative effect on emissions / abstractions.
Environmental Crime Directive	The Environmental Crime Directive, currently under revision, sets the framework for environmental crime.	The Environmental Crime Directive would, in situations where the damage is the result of a breach and intentional, give rise to criminal sanctions.	If implemented as proposed, small negative effect on emissions / abstractions.
Commission Communication 'Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030'	The annex to this Communication also proposes specific actions by the Commission, the EU Member States and the Aquaculture Advisory Council to make progress in various areas to the make the aquaculture sector more sustainable while ensuring its competitiveness. The guidelines reinforce the specific aquaculture targets from the Farm to Fork Strategy, in particular the reduction of sales of antimicrobials and a significant increase in organic aquaculture.	In the process of implementation of the "Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030", the Commission plans to develop a guidance document on environmental performance in the aquaculture sector. This will include, among other issues, the mapping of good practices for the "use of chemicals and medicines" at governmental and industry level. In the guidelines, the Commission highlighted the necessity to develop solutions to reduce the use of veterinary products and other substances (e.g. anti-fouling agents), through, for example, appropriate husbandry practices.	If implemented as foreseen a small positive effect on emissions.

Initiative	Brief description of the initiative	Potential interactions and added value of the preferred option	Expected impact on this policy initiative (specified per group of substances)
Stockholm Convention (POPs)	The Stockholm Convention on Persistent Organic Pollutants regulates POPs by either prohibiting their presence on the market or reducing / regulating their use.	The EU and MS are a party to the Convention and have to implement its decisions in the EU / MS	Implementation of the Convention will drive down emissions of POPs. If further POPs are added in the future, corresponding measures will have to be taken by EU and MS.
Minamata Convention	The Minamata Convention regulates Mercury mining, storage and use.	The EU and MS are a party to the Convention and have to implement its decisions in the EU / MS	Implementation of the Convention will drive down emissions of mercury. If further uses are regulated / prohibited through the Convention, EU / MS will have to implement this as well.
Global Plastics Agreement	The UN Environment Assembly agreed, in 2022, to launch negotiations towards a globally binding agreement on plastics	While still many years before such an agreement will enter into force, it is likely to have significant impacts on what plastics stay on the market and in what quantities these will reach the environment	Monitoring methods and regulation of plastics in water is relatively new area and this initiative may inspire what rules are agreed in the global instrument.

ANNEX 6: TECHNICAL PROCESS FOR THE REVISION OF THE LIST OF PRIORITY SUBSTANCES AND THEIR EQS IN SURFACE WATER

1. Introduction

The review of the list of priority substances (PS) in surface waters under the Water WFD considered which substances should be added to the list of PS, the environmental quality standards (EQS) that should be set for them in the EQS Directive (EQSD), the deselection of existing PS, the revision of EQS for some others, and the designation of priority hazardous substances (PHS). PHS are a subset of PS that are identified as being "toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern" (WFD article 2(29)). In this context, the substances identified by the following processes and legislations are relevant: Substances of Very High Concern (SVHC) under REACH, Persistent Organic Pollutants (POPs) under the Stockholm Convention and substances identified as Persistent, Bio-accumulative and Toxic (PBTs) under Regulation (EEC) No.793/93.

The prioritisation exercise (to identify new PS) was based on the criteria set out in the WFD Article 16(2), and the derivation of EQS followed the 2018 Technical Guidance Document for deriving EQS (53). Thresholds are usually set one substance at the time, except for cases where adding substances in groups (of substances with similar effects) has a clear added value. The multi-dimensionality of water pollutants and their effects is addressed by the fact that for each substance, where possible, EQSs are derived for different types of media (inland surface waters, other surface waters, and biota) and different concentrations/ multivariate thresholds (Annual Average (AA) and Maximum Allowable Concentration (MAC)).

2. Technical process underpinning the selection of substances

The technical work for the review was led by the Joint Research Centre (JRC) and DG ENV, in close cooperation with subgroups of experts and members of the Working Group (WG) Chemicals under the Common Implementation Strategy (CIS) for the WFD. The membership of WG Chemicals consists of Commission DGs, MS and stakeholder organisations including a range of European industry associations, NGOs and intergovernmental organisations. The steps of the review process are described below.

2.1. Preparatory phase

During this phase data were collected (including monitoring and hazard data) and a prioritisation process for identifying candidate PS was carried out. Figure A6.1 illustrates the prioritisation process.

Whether a compound is "discharged in significant quantities" is commonly decided based on the substance's exposure level, referred to as Predicted Environmental Concentration (PEC). This in turn is compared to an ecological safety threshold expressed as PNEC. PEC/PNEC risk ratios above 1 would trigger the substance's inclusion in the routine monitoring and the derivation of a legally-binding EQS.

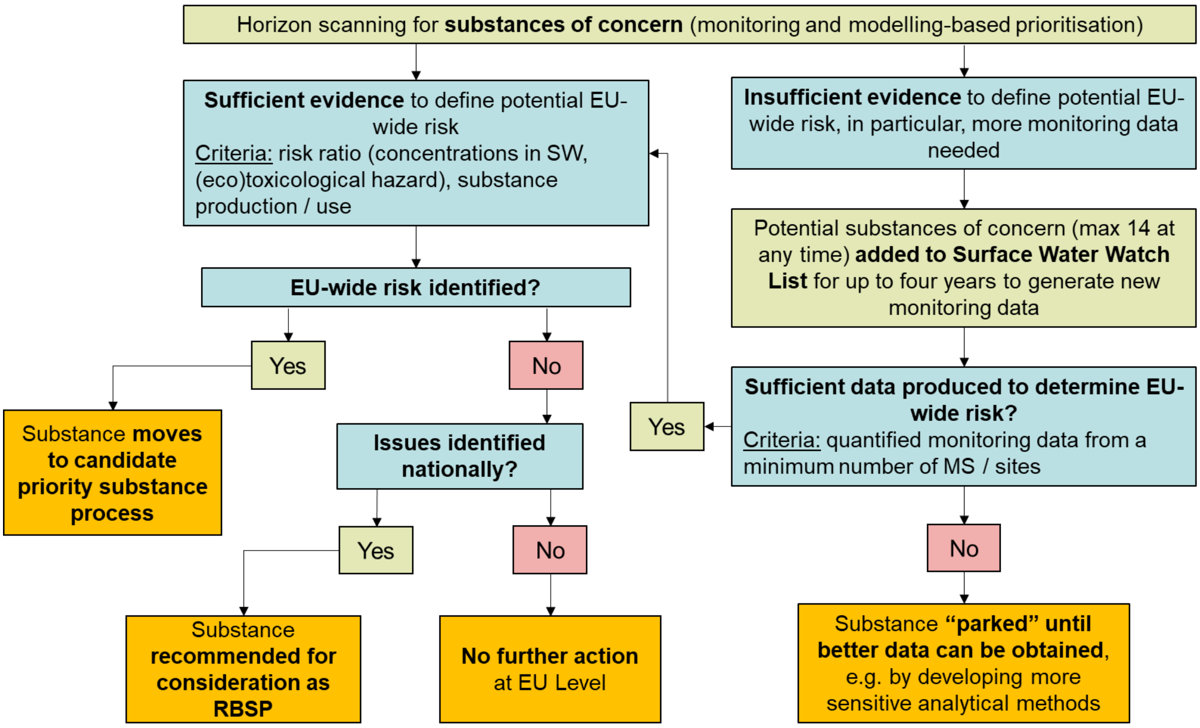


Figure A6.1: Substance selection process for surface water

Subsequently, individual draft substance dossiers for prioritised surface water contaminants were prepared by subgroups of experts, with rapporteurs, under WG Chemicals, and consultants contracted by the Commission. The subgroups included experts from MS, industry actors and NGOs alike. For the prioritised substances, EQSs were derived for individual substances or groups of substances based on the aforementioned 2018 Technical Guidance for deriving EQS. The document provides detailed information on criteria and issues to be considered. Those relevant to setting EQSs are mentioned below:

- Data acquiring, evaluation, selection and quality assessment of data;
- Risk assessments to be performed, and relations with (pesticide) risk assessments under other pieces of legislation;
- Calculations, extrapolation and expression of QSs;
- Deriving quality standards for water abstracted for drinking water;
- Standards to protect water quality;
- Derivation of standards protecting aquatic species and wildlife from (secondary) poisoning;
- Protection of humans against adverse health effects from consuming contaminated fisheries;
- Limitations in experimental data – use of non-testing approaches;
- Calculation of QS for substances occurring in mixtures;
- Implementation of EQSs.

2.2. Validation stage

During this stage the draft dossiers for the candidate PS, in particular their draft EQSs, were reviewed/commented and validated by the MS (MS) and other members of the WG Chemicals, and were publicly available in CIRCABC.

2.3. Independent review stage

During this stage independent scientists of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed the EQS in the substance dossiers and provided an independent scientific opinion on their appropriateness.

2.4. Commenting period on the SCHEER preliminary scientific opinions

During this phase, the preliminary SCHEER opinions on the EQS derived for each candidate PS were published for commenting during 4 weeks, allowing all stakeholders to make additional/final comments, and in particular the submitter. These comments were collected, discussed and addressed when relevant by the SCHEER to inform its final scientific opinions. The final opinions are published on its website[100]. For some substance dossiers, the SCHEER is still in the process of formulating preliminary or final opinions, and commenting periods on a few others are still ongoing. This means that the review is still in process and that some EQSs might need to be modified to take the final SCHEER opinions into account.

2.5. Outcome of the Prioritisation exercise

The prioritisation exercise resulted in 24 possible new PS for surface water, including PFAS as a group. The candidate substances included in this revision process are shown below.

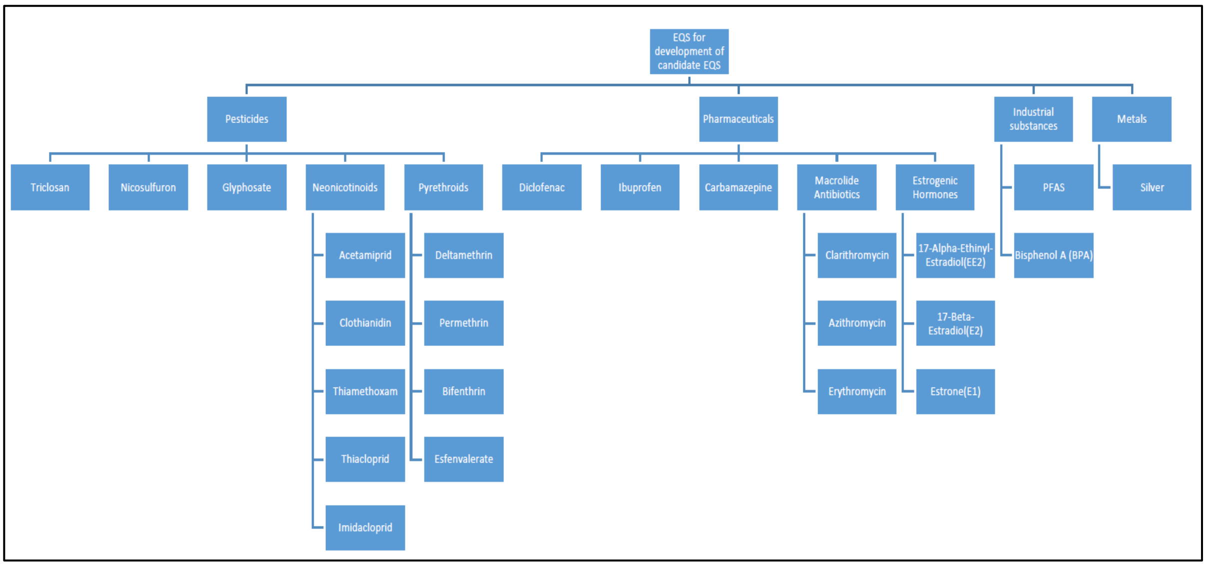


Figure A6.2: Candidate substances for setting new EQSs for surface water.

2.6. Input from Surface Water Watch List monitoring

100 https://ec.europa.eu/health/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer/scheer-opinions_en

The obligation introduced into the EQSD in 2013 to establish a surface water watch list has so far resulted in the adoption of the following three Commission implementing decisions establishing a watch list of substances for Union-wide monitoring in the field of water policy (in chronological order): 2015/495/EU, 2018/840/EU and 2020/1161/EU. Monitoring results from the 3rd WL are not yet available, but the data collected for substances listed in the first two Commission implementing decisions have resulted in the following substances now being proposed for inclusion in the PS list: 17-Alpha-ethinylestradiol (EE2); 17-Beta-estradiol (E2); Estrone (E1); Diclofenac; Macrolide antibiotics; and Neonicotinoids (Imidacloprid, Thiacloprid, Thiamethoxam, Clothianidin, and Acetamiprid).

3. Designation of priority hazardous substances

The review considered whether the candidate substances are SVHCs and/or POPs, and thus whether they should be designated as PHS. For PHS, the aim is to completely phase out emissions to the aquatic environment. Also, if a substance/ RBSP is classified a PHS the risk is expected to be an EU-wide risk, whereas for PS the risk can be a non EU-wide risk.

4. Amendment of EQS for existing PS, and review of status

The updated (2018) version of the Technical Guidance Document for Deriving EQS was applied to check and revise the EQS for all existing PS, also taking into account any new scientific findings. Based on this process, 15 substances were identified as candidates for EQS amendment, as summarised below.

Consideration was also given to changing the status of some existing PS, with Octylphenols being a possible candidate for designation as a PHS.

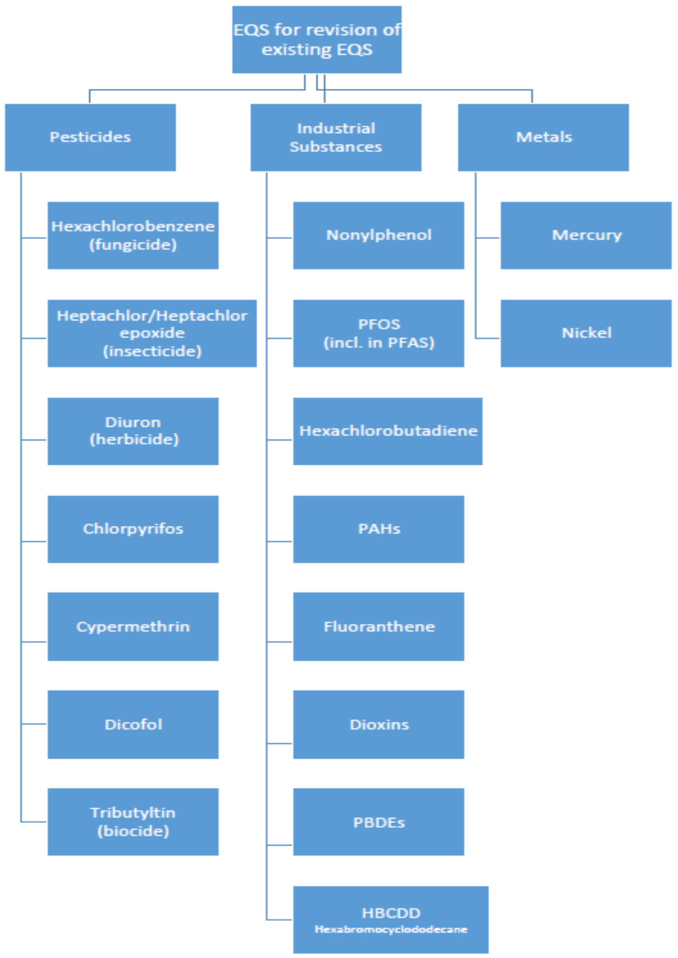


Figure A6.3: PS for possible revision of existing EQS for surface water.

5. Deselection of existing PS

The JRC drafted a document on criteria for the deselection of existing PS, and proposed a list of candidates for deselection. The final version took into account comments from members of the WG Chemicals and comments submitted by stakeholders through the Impact Assessment consultation process. It is published in CIRCABC[101].

5.1. Criteria for deselection

As mentioned before, the potential deselection of existing PS (excluding those recently added) was done by following the 'deselection' criteria listed in the document. The agreed criteria for the deselection were extensively discussed with the experts. The JRC started drafting the first version of deselection criteria in 2016. Briefly the main criteria were: i) the inclusion of only banned substances, and ii) no exceedance in more than three MS based on monitoring data available at that time, covering the period 2006-2014.

5.2. Substances proposed for deselection

Application of the criteria resulted in the proposed deselection of the following PS: Alachlor, Chlorfenvinphos, Simazine, and Carbon-tetrachloride.

[101] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a953a59a-b899-4b8e-9815-0fee9006239f/details

Annex 7: Technical process for the revision of the Lists of Pollutants in Groundwater

1. Introduction

Article 10 of Directive 2006/118/EC (review clause) requires the Commission to review Annexes I and II of the GWD every six years. The last review led to amendment of Annex II via Directive 2014/80/EU. Following this, the Commission introduced the first list facilitating the review of Annexes I and II (LFR) in 2014 and published its results (22). This LFR summarised the main output of the Voluntary Groundwater Watch List process described in the Groundwater Watch List Concept & Methodology. In 2021, under the umbrella of the Working Group Groundwater (WG GW), the sub-group on the Voluntary GW Watch List was reactivated[102]. The membership of both the WG GW and GW WL sub-groups consists of Commission DGs, MS and stakeholder organisations including a range of European industry associations, NGOs and intergovernmental organisations.

Furthermore, Article 3(5) of the GWD requires MS to publish information on the TVs they have established in their RBMPs. The 2014 GWD amendment updated these detailed reporting specifications. CIS Guidance Document No. 35 (110) further specifies how the reporting of TVs is to be operationalised (111).

CIS Guidance Document No. 18 (112) provides recommendations and considerations for Member State administrations on how to set and use TVs. It explains the links between TVs and the ‘prevent or limit’ objective of GWD Article 6. The document also defines some important terminology, the scale and location of TV application, and the general methodology for establishing them, including the different aspects of groundwater chemical status to consider. Finally, the Guidance Document elaborates how TVs fit into the groundwater chemical status assessment process using the five pertinent tests for chemical groundwater status.

2. Technical process underpinning the selection of substances

The technical work for the review was led by the subgroups of experts and members of the Working Group (WG) Groundwater under the Common Implementation Strategy (CIS) for the WFD. The steps of the substance prioritisation process are described in Figure A7.1 below.

[102] https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a53f1d54-0cd9-4de6-b370-2cbb14004986?p=1&n=10&sort=name_ASC

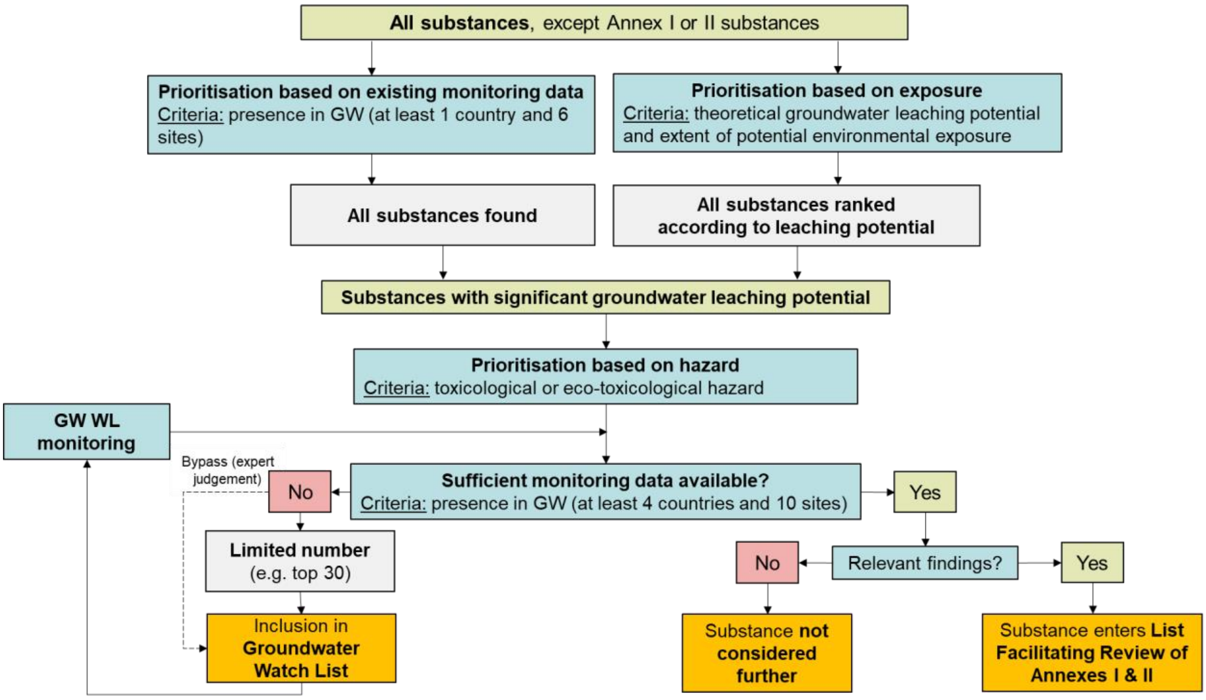


Figure A7.1: Substance selection process for groundwater

The data collection was primarily focused on substances causing risk and/or failure of good chemical status. Data were collected on MS level only; no differentiation into RBDs or GWBs was made. Depending on availability, MS provided GQA-TVs for 2nd RBMP (most values) or 3rd RBMP (some values). In total 20 MS submitted data for 100 pollutants. Of these, 21 substances reported by at least 4 MS were selected for further assessment. Although only GQA-TVs are considered, there is still a wide range in TVs. Data provided for TVs, CVs (for drinking water and "other uses") and NBLs as well as complementary remarks allowed in most cases for explaining the wide range. It turned out that wide ranges are not only caused by particularly high NBLs, but also by particularly low NBLs. Apart from NBLs also CVs for DW substantially account for the GQA-TVs reported. As provision of CVs was incomplete, not all TVs could be explained.

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 (often referred to as non-relevant Metabolites (nrMs)), as outlined below.

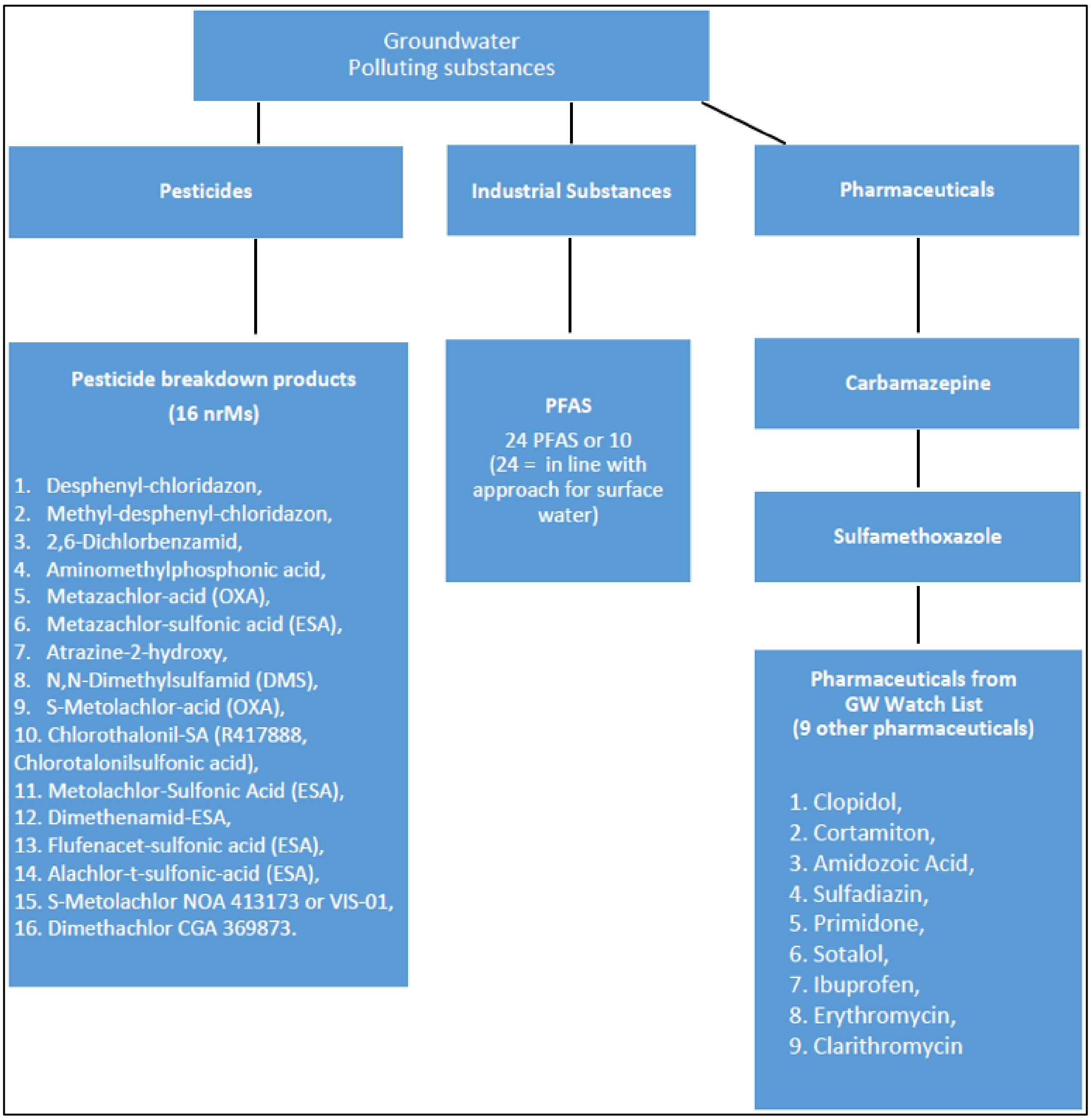


Figure A7.2: Substances proposed for inclusion in the Annexes to the GWD.

2.1. Input from Groundwater Watch List monitoring

2.1.1. PFAS

PFAS have been detected in groundwater in many MS [103]. 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 A7.1 and indicate the widespread nature of the PFAS detections.

Table A7.1: PFAS detected in groundwater in more than 4 PC and at more than 10 sites

Substance Name	Acronym	CAS #	No of PC	No. of sites monitored	No. of sites >LOQ	% of sites >LOQ	PC with detections	Status

[103] Voluntary Groundwater Watch List Process Study on Per- and Poly-fluoroalkyl substances (PFAS) – Monitoring Data Collection and Initial Analysis – Draft V.2.3 / 23 February 2020

Substance Name	Acronym	CAS #	No of PC	No. of sites monitored	No. of sites >LOQ	% of sites >LOQ	PC with detections	Status
Perfluorooctane Sulfonamide	PFOSA	754-91-6	6	1,715	22	1.3	4	GW WL
Perfluoroundecanoic Acid	PFUnA	307-55-1	7	2,598	39	1.5	6	GW WL
Perfluorododecanoic Acid	PFDoA	2058-94-8	7	2,830	62	2.2	6	GW WL
Perfluorodecanoic Acid	PFDA	335-76-2	8	2,945	173	5.9	7	LFR
Perfluorononanoic Acid	PFNA	375-95-1	8	3,752	195	5.2	7	LFR
Perfluorobutanoic Acid	PFBA	375-22-4	5	1,189	552	46.4	5	LFR
Perfluorobutane Sulfonate	PFBS	375-73-5	7	2,209	577	26.1	5	LFR
Perfluoropentanoic Acid	PFPeA	2706-90-3	7	2,452	701	28.6	7	LFR
Perfluoroheptanoic Acid	PFHpA	375-85-9	9	4,224	817	19.3	8	LFR
Perfluorohexane Sulfonate	PFHxS	432-50-8	8	2,328	873	37.5	7	LFR
Perfluorohexanoic Acid	PFHxA	307-24-4	9	4,662	1,175	25.2	8	LFR
Perfluorooctane Sulfonate	PFOS	1763-23-1	11	6,971	1,435	20.6	11	LFR
Perfluorooctanoic Acid	PFOA	335-67-1	11	6,429	1,553	24.2	11	LFR

2.1.2. Pharmaceuticals

The two pharmaceuticals on the LFR are Carbamazepine and Sulfamethoxazole. 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)[104] 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.

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 4 or more PC and at 10 or more sites in each of these countries and were put forward on the LFR.

[104] Primidone is a beta blocker / barbiturate medication used as an anticonvulsant or to treat partial and generalized seizures as well as essential tremors. It is available as a generic medication. In 2017, it was the 238th most commonly prescribed medication in the United States, with more than two million prescriptions.

2.1.3. Non-Relevant Metabolites (nrMs) of Pesticides[105]

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 (see Table A7.2). These substances fulfilled the criteria for addition to the LFR. From the assessment, WG GW 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 GW WL.

Table A7.2: The 16 non-relevant metabolites on the List Facilitating Review of the GWD Annexes

	nRM substance	CAS	Parent Compound	Use	Status (EU pesticides database)
1	Desphenylchloridazon (metabolite B)	6339-19-1	Chloridazon	Herbicide	Not approved (EC1107/2009)
2	Methyl-desphenyl-chloridazon (Metabolite B1)	17254-80-7	Chloridazon	Herbicide	Not approved (EC1107/2009)
3	2,6-Dichlorbenzamid (2,6-D, BAM, M01, AE C653711)	2008-58-4	Dichlobenil Fluopicolide	Herbicide Fungicide	Not approved (EC1107/2009) Approved
4	Aminomethylphosphonic acid	1066-51-9	Glyphosate	Herbicide	Approved
5	Metazachlor-acid (OXA) (BH 479-4)	1231244-60-2	Metazachlor	Herbicide	Approved
6	Metazachlor ESA Metazachlor-SA (BH 479- 8) (Metazachlorsulfone acid, Metazachlorsulfonic acid (ESA)	172960-62-2	Metazachlor	Herbicide	Approved
7	Atrazine-2-hydroxy	2163-68-0	Atrazine	Herbicide	Not approved since 2004
8	N,N-Dimethylsulfamid (DMS)	3984-14-3	Tolylfluanid, Dichlofluanid	Fungicide	Not approved (EC 1107/2009)
9	s-Metolachlor-acid, (OXA, CGA 51202, CGA 351916)	152019-73-3	S-metolachlor	Herbicide	Not Approved (EC 1107/2009)
10	Chlorthalonil-SA (R417888 or VIS-01 / M12) (Chlortalonilsulfone acid)	1418095-02-9	Chlorothalonil	Fungicide	Not registered
11	Metolachlor-Ethanesulfonic acid (ESA, CGA 380168, CGA 354743)	171118-09-5	S-metolachlor	Herbicide	Not Approved (EC 1107/2009)
12	Dimethenamid-ESA	205939-58-8	Dimethenamid	Herbicide	Not approved
13	Flufenacet-sulfonic acid (ESA) 201668-32-8		Flufenacet	Herbicide	Approved
14	Alachlor-t-sulfonic-acid (ESA)	142363-53-9	Alachlor	Herbicide	Not approved
15	S-Metolachlor NOA 413173 or VIS-01 (Chlortalonilsulfone acid) Metabolite	1418095-19-8	Chlorothalonil S-metolachlor	Herbicide	Not registered Not Approved (EC 1107/2009)

[105] 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.

	nRM substance	CAS	Parent Compound	Use	Status (EU pesticides database)
16	Dimethachlor CGA 369873 1418095-08-5		Dimethachlor	Herbicide	Approved

3. Derivation of groundwater quality standards

3.1. Annex I or Annex II?

Under the GWD substances can be added to Annex I or Annex II. Inclusion of a substance in Annex I needs to be accompanied by an EU-wide groundwater quality standard (GW QS). Substances added to Annex II must be considered by MS during the risk assessment phase of river basin management planning, and appropriate threshold values (TVs) must be set at national level, also considering the background concentrations of naturally occurring substances. The choice of Annex is likely to reflect the extent of the problem and could influence the effort needed to meet the environmental objectives for groundwater.

3.2. Links with the Drinking Water Directive

Although the PFAS listed for surface water and in the recast of the Drinking Water Directive were selected using criteria related to human health and ecotoxicity, new scientific evidence became available towards the end of the adoption process. One example of this is the 2020 scientific opinion from the European Food Safety Authority (EFSA), outlining risks to human health arising from PFAS in human food are higher than previously assumed. This information arrived too late in the process to be reflected in the revised DW standards. In light of the ever-increasing evidence of the harmful effects of PFAS to human health, this new information is included in the scientific process to derive the EQS.

3.3. Links with the derivation of EQS for PS

Regarding PFAS, the situation of standard setting based on groundwater monitoring data is slightly diverging from the situation for surface waters. This is primarily caused by the fact that different PFAS substances are identified in surface waters compared to those found in groundwater due to the long lag times associated with adsorption processes in soil layers. Once the adsorption capacity is exhausted however, the same substances will start to appear in GW as well, which is potentially highly problematic since groundwater is the primary source for producing drinking water in the EU.

Group of 10 PFAS[106] was originally proposed for groundwater, differing from the 24 PFAS substances proposed for surface water.

3.4. Opinions of the SCHEER[107]

The SCHEER was asked to evaluate groundwater quality standards for proposed additional pollutants, including pollutant groups, in the annexes to the GWD. To do so,

[106] Perfluorobutanoic Acid, Perfluorobutane Sulfonate, Perfluorodecanoic Acid, Perfluoroheptanoic Acid, Perfluorohexanoic Acid, Perfluorohexane Sulfonate, Perfluorononanoic Acid, Perfluorooctanoic Acid, Perfluorooctane Sulfonate, Perfluoropentanoic Acid.
[107] https://ec.europa.eu/health/publications/groundwater-quality-standards-proposed-additional-pollutants-annexes-groundwater-directive-2006118ec_en

the SCHEER discussed the specificity of groundwater ecosystems, the relationship between quality standards for surface waters (freshwaters) and groundwater, the risk assessment of mixtures, and the harmonisation of quality standards in MS.

General conclusions:

- uniform EU-wide quality standards should be set for the groundwater body for chemicals with no natural background concentrations,
- it is appropriate to apply freshwater EQSs to groundwater given that these would have included an AF to account for the considerable surface freshwater biodiversity,
- groundwater quality standards should not exceed the concentrations put forward as quality standards for surface waters (AA-EQS),
- quality standards set for groundwater should be less strict than those for drinking water,
- for harmonising principles, drinking water QS may be used as GW standards, unless lower specific EQS exist, such as, for pharmaceuticals.

For PFAS:

- similar quality standards should be used for freshwater and groundwater,
- the relative potency factor (RPF) approach could be used for QSs of PFAS, and that the value of 4.4 ng/L for PFOA equivalents can be adopted as a quality standard for GW. The SCHEER did not agree with an EU group quality standard of "PFAS-30 total" of 0.50 µg/L.

For Pharmaceuticals:

- the value of 0.5 µg/L proposed as a groundwater quality standard for carbamazepine may not be sufficiently protective.
- the proposal for a sulfamethoxazole groundwater quality standard of 0.1 µg/L may not be sufficiently protective for human health, ecosystems and for antibiotic resistance,
- a general standard of 0.5 µg/L for all pharmaceuticals would not be sufficiently protective,
- there is no scientific reason to consider moving pharmaceuticals as a group to Annex II.

For non-relevant metabolites of plant protection products:

- a uniform approach should be followed in the evaluation of nrMs,
- not all sixteen metabolites were correctly identified as "non-relevant",
- the proposal to use a uniform quality standard(s) for individual nrMs and for total nrMs does provide adequate protection for human health and dependent ecosystems,
- a group total quality standard for nrMs of 10 µg/L is not supported,
- a value of 0.75 µg/L for all non-relevant metabolites should protect human health if no additional relevant toxicological information is made available, e.g., ED effects. However, the SCHEER recommends to use a value of 0.1 µg/L as an interim quality standard for nrMs in the groundwater body, protecting exposed groundwater biota,
- the approach should not be limited to the 16 nrMs currently identified but also applied to other nrMs identified in the future.

3.5. Groundwater option selection

Following the comments of the Regulatory Scrutiny Board stating that the groundwater option design was complex and too technical, an attempt to re-arrange and simplify the available policy choices and their presentation in the main report was made. Instead of aggregating options per each substance group (i.e. PFAS, pharmaceuticals and nrMs), the design was changed to better reflect the legislative choices (i.e. Annex I or Annex II?; listing individually or as groups?). This presentation also aligns with surface water option design and increases the coherence within the IA report.

Table A7.3 shows all the options for the LFR substances, presented in the arrangement of Annex I/Annex II policy choices as in the main report, but including the original numbering as in the support study. The opinions of the SCHEER are also indicated as they were the main driver for selection of one option over another concerning the same substance within the same policy option. The differences among these choices relate to the scope of addition (i.e. substances included as group of some listed compounds or all) and the proposed quality standard. The rationale of selection among the original options for PFAS and nrMs concerning their Annex I listing individually is explained below.

Table A7.3: Transposition of groundwater options from the IA support study to the SWD main text

Policy option	Description	Option No. in support study & SCHEER opinion	Included in main text of IA SWD?
Option 1	**Add LFR substances to GWD Annex I individually or as group of specific chemicals**		
PFAS	PFAS (Group of 10) included in Annex I and assigned a GW QS of 0.10 µg/l as "sum of" the 10 PFAS.	1a	No
	PFAS (Group of 24 as for SW) included in Annex I and assigned a GW QS of 4.4 ng/l sum of PFOA-equivalents.	1d (SCHEER recommended)	Yes
Pharma-ceuticals	Carbamazepine and Sulfamethoxazole added to Annex I and assigned GW QS of 0.5 and 0.1 µg/l respectively (protective of human health).	2a (SCHEER endorsed)	Yes
nrMs	nrMs (Group of 16) added to Annex I as individual substances with a GW QS of 1 µg/l.	3a	No
	nrMs (Group of 16) added to Annex I as individual substances with a GW QS of 0.1 µg/l (protective of human health and groundwater biota).	3d (SCHEER recommended)	No
	All nrMs added to Annex I as individual substances with a GW QS of 0.1 µg/l (protective of human health and groundwater biota).	3e (SCHEER recommended + future proofing)	Yes
Option 2	**Add LFR substances to GWD Annex I as groups of all substances**		
PFAS	All PFAS added as group to Annex I with a GW QS for "PFAS total" of 0.5 µg/l (again following the drinking water standard for PFAS total).	1b	Yes
Pharma-ceuticals	Pharmaceuticals added as a group to Annex I and assigned a GW QS of 0.5 µg/l.	2b	Yes
nrMs	All nrMs added to Annex I as a group and assigned a group GW QS of 10 µg/l (analogous with the existing group value for "pesticides").	3b	Yes
Option 3	**Add LFR substances to GWD Annex II**		
PFAS	All PFAS added as a group to Annex II for MS to consider setting a TV for specific substances posing a risk to groundwater bodies (GWBs).	1c	Yes
Pharma-ceuticals	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.	2c	Yes
nrMs	All nrMs added to Annex II for MS to consider a TV for substances	3c	Yes

Policy option	Description	Option No. in support study & SCHEER opinion	Included in main text of IA SWD?
	that pose a risk to their GWBs.		

For PFAS:

Option 1a is based on the findings from the GW WL which indicates 10 PFAS for addition to the LFR (see Table A7.1). The proposed QS is based on the drinking water standard for 20 identified PFAS[108] – the 10 PFAS would be a subset of the 20. This option was not endorsed by the SCHEER.

Option 1d was proposed by the SCHEER in their Preliminary Opinion on groundwater quality standards REF. This option entails an individual standard of 4.4 ng/l PFOA-equivalent for the 24 listed PFAS in line with surface water EQS. The concentration of each listed PFAS would be calculated using the relative potency factor (RPF) compared to PFOA. For PFAS not included on the PS list, the PFOA RPF would be used to calculate the GW QS. If no RPF exists, then the RPF of PFOA should be assumed and a GW QS of 4.4 ng/l applied. For some reservations regarding this approach, see section 3.6 below.

For nrMs:

Option 3a is based on reported TVs used by MS which range from 0.1 µg/l to 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. Commission 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. This option was not endorsed by the SCHEER.

The SCHEER recommendations for nrMs were translated into Options 3d and 3e. The difference between these two options is the number of nrMs covered: the 16 individual compounds as identified by the GW WL (see Table A7.2) or all nrMs. The wider scope of Option 3e contributes to future-proofing the legislation as it sets a limit for any nrM compound found in groundwater even if not explicitly mentioned in the legislation. Therefore, out of the two SCHEER proposals, Option 3e was selected to represent the Annex I individual listing policy choice in the main text of this document.

3.6. Considerations around the possible use of Relative Potency Factors for PFAS

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

[108] This refers to the following compounds: Perfluorooctanoic acid (PFOA) (CAS 335-67-1), Perfluorooctane sulfonic acid (PFOS) (CAS 1763-23-1), Perfluorohexane sulfonic acid (PFHxS) (CAS 355-46-4), Perfluorononanoic acid (PFNA) (CAS 375-95-1), Perfluorobutane sulfonic acid (PFBS) (CAS 375-73-5), Perfluorohexanoic acid (PFHxA) (CAS 307-24-4), Perfluorobutanoic acid (PFBA) (CAS 375-22-4), Perfluoropentanoic acid (PFPeA) (CAS 2706-90-3), Perfluoropentane sulfonic acid (PFPeS) (CAS 2706-91-4), Perfluorodecanoic acid (PFDA) (CAS 335-76-2), Perfluorododecanoic acid (PFDoDA or PFDoA) (CAS 307-55-1), Perfluoroundecanoic acid (PFUnDA or PFUnA) (CAS 2058-94-8), Perfluoroheptanoic acid (PFHpA) (CAS 375-85-9), Perfluorotridecanoic acid (PFTrDA) (CAS 72629-94-8), Perfluoroheptane sulfonic acid (PFHpS) (CAS 375-92-8), Perfluorodecane sulfonic acid (PFDS) (CAS 335-77-3), Perfluorononane sulfonic acid (PFNS) (CAS 68259-12-1), Perfluoroundecane sulfonic acid (PFUnDS) (CAS 749786-16-1), Perfluorododecane sulfonic acid / 10:2 Fluorotelomer sulfonic acid (PFDoS or PFDoDS) (CAS 120226-60-0) and Perfluorotridecane sulfonic acid (PFTrDS or PFTriS) (CAS 791563-89-8).

one or more relatively better-studied PFAS such as PFOA or PFOS (EFSA bases its limit on epidemiologic results for the sum of four PFAS) (113) (114). To this is compared the sum of concentrations of a small number of PFAS including some that are less well studied but are thought likely to have similar pharmacokinetics and toxicity. This summing approach is concentration additive. A refinement of this approach using relative potency factors (RPFs) has also been proposed (115), but this additional step is not yet warranted for legislative purposes.

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 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.

The best known RPF system is for dioxin-like compounds where the RPFs are called TEFs and 2,3,7,8-TCDD is the reference compound (117). The TEF system has been widely tested. Its validity depends in part on the fact that dioxin-like compounds are believed to act via the AhR, a cellular receptor. Here the AhR acts as the molecular initiating event (MIE). Assuming that downstream biological effects are a function of the signal arising from the MIE, the RPF model (indeed other mixtures effects) should still apply at downstream biological effects even if the concentration-response curve has changed (116).

There are two main problems with applying a RPF system to PFAS:

1) There may be more than one MIE. PFAS can bind to a number of receptors, e.g. (118). Although it is possible that key sensitive biological outcomes might depend on a single MIE, the biology is not well enough understood to know this yet or which one. When there is more than one MIE it is more difficult to predict the downstream mixture effects. Converging AOPs may or may not lead to CA downstream, although CA might be the more protective default position.

2) PPARα is one of the better studied MIEs for PFAS and may be involved with effects in the liver and elsewhere. A recent paper (118) studied concentration-response curves for a number of PFAS using a reporter-cell line and compared mixture results with several different models. They found that PFAS can differ in both potency and efficacy (i.e., maximal effect), violating an assumption of the RPF model. Consequently, the RPF model did worse at predicting mixture effects than other more general models that do not make this assumption.

While research into RPF models for PFAS is worthwhile, it is premature to use them as a basis for regulation as it would place more confidence in the values of the RPFs than is warranted at this time. Consequently, one or both of the following options are preferred:

1) The current system of summing a small number of PFAS for which there are some data appears to be a reasonable first step. While one can think of this procedure as assuming the same RPF (one) for all compounds, it makes the uncertainty behind this assumption explicit. One problem with this approach is that it can ignore other PFAS. To limit the risks of that an additional uncertainty factor to take this into account is considered.

2) Another approach could examine extractable organic fluorine (EOF). Typically there is a gap between the total EOF in a sample of water, serum, and other media and that which can be explained by measured PFAS, e.g. (119). The identity of the

uncharacterized EOF is not known and is a current area of research. Although it is unlikely that all of the compounds in a sample that contribute to EOF have the same kind of toxicity, such an approach might serve as a warning sign.

ANNEX 8: RESULTS OF THE QUALITY STANDARD DERIVATION PROCESS FOR REVISION OF THE ANNEXES TO THE EQSD AND GWD

ANNEX I to Directive 2008/105/EC

ENVIRONMENTAL QUALITY STANDARDS (EQS) FOR PRIORITY SUBSTANCES IN SURFACE WATERS

Note: Where an EQS is listed between [] this value is subject to confirmation in the light of the opinion requested from the Scientific Committee on Health, Environmental and Emerging Risks.

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
N°	Name of substance	Category of substances	CAS number (1)	EU number (2)	AA-EQS (3) Inland surface waters (4) [µg/l]	AA-EQS (3) Other surface waters [µg/l]	MAC-EQS (5) Inland surface waters (4Error! Bookmark not defined.) [µg/l]	MAC-EQS (5) Other surface waters [µg/l]	EQS Biota (6) [µg/kg wet weight] or EQS Sediment [µg /kg dry weight] where so indicated	Identified as priority hazardous substance	Identified as Ubiquitous Persistent, Bioaccumulative and Toxic (uPBT) substance	Identified as substance that tends to accumulate in sediment and/or biota
(2)	Anthracene	Industrial substances	120-12-7	204-371-1	0,1	0,1	0,1	0,1		X		X
(3)	Atrazine	Herbicides	1912-24-9	217-617-8	0,6	0,6	2,0	2,0				
(4)	Benzene	Industrial substances	71-43-2	200-753-7	10	8	50	50				
(5)	Brominated diphenylethers	Industrial substances	not applicable	not applicable			0,14 (7)	0,014 (7)	[0,00028] (7)	X (8)	X	X

(6)	Cadmium and its compounds (depending on water hardness classes) ([9])	Metals	7440-43-9	231-152-8	≤ 0,08 (Class 1) 0,08 (Class 2) 0,09 (Class 3) 0,15 (Class 4) 0,25 (Class 5)	0,2	≤ 0,45 (Class 1) 0,45 (Class 2) 0,6 (Class 3) 0,9 (Class 4) 1,5 (Class 5)	≤ 0,45 (Class 1) 0,45 (Class 2) 0,6 (Class 3) 0,9 (Class 4) 1,5 (Class 5)		X		X
(7)	C_{10-13} Chloroalkanes ([10])	Industrial substances	85535-84-8	287-476-5	0,4	0,4	1,4	1,4		X		X
(9)	Chlorpyrifos (Chlorpyrifos-ethyl)	Organophosphate pesticides	2921-88-2	220-864-4	0, 00046	$4,6\ 10^{-5}$	0,0026	0,00052		X	X	X
(9a)	Cyclodiene pesticides: Aldrin Dieldrin Endrin Isodrin	Organochlorine pesticides	 309-00-2 60-57-1 72-20-8 465-73-6	 206-215-8 200-484-5 200-775-7 207-366-2	Σ = 0,01	Σ = 0,005	not applicable	not applicable		X		
(9b)	DDT total ([11])	Organochlorine pesticides	not applicable	not applicable	0,025	0,025	not applicable	not applicable		X		
	para-para-DDT		50-29-3	200-024-3	0,01	0.01	not applicable	not applicable		X		
(10)	1,2-Dichloroethane	Industrial substances	107-06-2	203-458-1	10	10	not applicable	not applicable		X		
(11)	Dichloromethane	Industrial substances	75-09-2	200-838-9	20	20	not applicable	not applicable				
(12)	Di(2-ethylhexyl)-phthalate (DEHP)	Industrial substances	117-81-7	204-211-0	1,3	1,3	not applicable	not applicable		X		X
(13)	Diuron	Herbicides	330-54-1	206-354-4	0,049	0,0049	0,268	0,054				

(14)	Endosulfan	Organochlorine pesticides	115-29-7	204-079-4	0,005	0,0005	0,01	0,004		X		
(15)	Fluoranthene	Industrial substances	206-44-0	205-912-4	7,62 10^{-4}	7,62 10^{-4}	0,012]	0,012	6,1	X	X	X
(16)	Hexachlorobenzene	Organochlorine pesticides	118-74-1	204-273-9			0,5	0,05	19,63	X		X
(17)	Hexachlorobutadiene	Industrial substances (solvents)	87-68-3	201-765-5	0,44	0,044	0,6	0,6	24,5	X		X
(18)	Hexachlorocyclohexane	Insecticides	608-73-1	210-168-9	0,02	0,002	0,04	0,02		X		X
(19)	Isoproturon	Herbicides	34123-59-6	251-835-4	0,3	0,3	1,0	1,0				
(20)	Lead and its compounds	Metals	7439-92-1	231-100-4	1,2 (12)	1,3	14	14		X		X
(21)	Mercury and its compounds	Metals	7439-97-6	231-106-7			0,07	0,07	[0,255]	X	X	X
(22)	Naphthalene	Industrial substances	91-20-3	202-049-5	2	2	130	130				
(23)	Nickel and its compounds	Metals	7440-02-0	231-111-4	2 (12)	3,1	8,2	8,2				
(24)	Nonylphenols (13) (4-Nonylphenol)	Industrial substances	84852-15-3	284-325-5	0,037	0,00182	2,0	0,17		X		
(25)	Octylphenols (14) ((4-(1,1',3,3'-tetramethylbutyl)-phenol))	Industrial substances	140-66-9	205-426-2	0,1	0,01	not applicable	not applicable		X		
(26)	Pentachlorobenzene	Industrial substances	608-93-5	210-172-0	0,007	0,0007	not applicable	not applicable		X		X
(27)	Pentachlorophenol	Organochlorine pesticides	87-86-5	201-778-6	0,4	0,4	1	1		X		

(28)	Polyaromatic hydrocarbons (PAHs) ([15])	Combustion products	not applicable	not applicable	not applicable	not applicable	not applicable	not applicable	Sum of Benzo(a)pyrene equivalents [0.6] ([16])	X	X	X
	Benzo(a)pyrene		50-32-8	200-028-5			0,27	0,027	[0,6]			
	Benzo(b)fluoranthene		205-99-2	205-911-9			0,017	0,017	see footnote 16			
	Benzo(k)fluoranthene		207-08-9	205-916-6			0,017	0,017	see footnote 16			
	Benzo(g,h,i)perylene		191-24-2	205-883-8			$8{,}2\ 10^{-3}$	$8{,}2\ 10^{-4}$	see footnote 16			
	Indeno(1,2,3-cd)pyrene		193-39-5	205-893-2			not applicable	not applicable	see footnote 16			
	Chrysene		218-01-9	205-923-4			0,07	0,007	see footnote 16			
	Benzo(a)anthracene		56-55-3	200-280-6			0,1	0,01	see footnote 16			
	Dibenz(a,h)anthracene		53-70-3	200-181-8			0,014	0,0014	see footnote 16			
(29a)	Tetrachloroethylene	Industrial substances	127-18-4	204-825-9	10	10	not applicable	not applicable				
(29b)	Trichloroethylene	Industrial substances	79-01-6	201-167-4	10	10	not applicable	not applicable		X		
(30)	Tributyltin compounds ([17]) (Tributyltin-cation)	Biocides	36643-28-4	not applicable	0,0002	0,0002	0,0015	0,0015	[1,3] ([18])	X	X	X
(31)	Trichlorobenzenes	Industrial substances (solvents)	12002-48-1	234-413-4	0,4	0,4	not applicable	not applicable				
(32)	Trichloromethane	Industrial substances	67-66-3	200-663-8	2,5	2,5	not applicable	not applicable				

(33)	Trifluralin	Herbicides	1582-09-8	216-428-8	0,03	0,03	not applicable	not applicable		X		
(34)	Dicofol	Organochlorine pesticides	115-32-2	204-082-0	[4,45 10^{-3}]	[0,185 10^{-3}]	not applicable (19)	not applicable (19)	[5.45]	X		X
(35)	Perfluorooctane sulfonic acid and its derivatives (PFOS)	Industrial substances	1763-23-1	217-179-8	See substance 65 (Per- and poly-fluorinated alkyl substances (PFAS) – sum of 24)							
(36)	Quinoxyfen	Plant protection products	124495-18-7	not applicable	0,15	0,015	2,7	0,54		X		X
(37)	Dioxins and dioxin-like compounds (20)	Industrial byproducts	not applicable	not applicable			not applicable	not applicable	Sum of PCDDs+ PCDFs+ PCB-DLs equivalents [3,5 10^{-5}] (21)	X	X	X
(38)	Aclonifen	Herbicides	74070-46-5	277-704-1	0,12	0,012	0,12	0,012				
(39)	Bifenox	Herbicides	42576-02-3	255-894-7	0,012	0,0012	0,04	0,004				
(40)	Cybutryne	Biocides	28159-98-0	248-872-3	0,0025	0,0025	0,016	0,016				
(41)	Cypermethrin (22)	Pyrethroid pesticides	52315-07-8	257-842-9	[3 10^{-5}]	[3 10^{-6}]	6 10^{-4}	6 10^{-5}				X
(42)	Dichlorvos	Organophosphate pesticides	62-73-7	200-547-7	6 10^{-4}	6 10^{-5}	7 10^{-4}	7 10^{-5}				

(43)	Hexabromocyclododecane (HBCDD) ([23])	Industrial substances	See footnote **Error! Bookmark not defined.**3	See footnote 23	[4.6 10^{-4}]	[2 10^{-5}]	0,5	0,05	[3.5]	X	X	X
(44)	Heptachlor and heptachlor epoxide	Organochlorine pesticides	76-44-8 / 1024-57-3	200-962-3/ 213-831-0	[1,7 10^{-7}]	[1,7 10^{-7}]	3 10^{-4}	3 10^{-5}	[0,013]	X	X	X
(45)	Terbutryn	Herbicides	886-50-0	212-950-5	0,065	0,0065	0,34	0,034				
(46)	17 alpha-ethinylestradiol (EE2)	Pharmaceuticals (Estrogenic hormones)	57-63-6	200-342-2	1,7 10^{-5}	1,6 10^{-6}	not derived	not derived				
(47)	17 beta-estradiol (E2)	Pharmaceuticals (Estrogenic hormones)	50-28-2	200-023-8	0,00018	9 10^{-6}	not derived	not derived				
(48)	Acetamiprid	Neonicotinoid pesticides	135410-20-7 / 160430-64-8	603-921-1	0,037	0,0037	0,16	0,016				
(49)	Azithromycin	Pharmaceuticals (Macrolide antibiotics)	83905-01-5	617-500-5	0,019	0,0019	0,18	0,018				X
(50)	Bifenthrin	Pyrethroid pesticides	82657-04-3	617-373-6	9,5 10^{-5}	9,5 10^{-6}	0,011	0,001				X
(51)	Bisphenol-A (BPA)	Industrial substances	80-05-7	201-245-8	[0.46]	[0.46]	[129]	[31]		X		
(52)	Carbamazepine	Pharmaceuticals	298-46-4	206-062-7	2,5	0,25	1,6 10^{3}	160				

(53)	Clarithromycin	Pharmaceuticals (Macrolide antibiotics)	81103-11-9	658-034-2	0,13	0,013	0,13	0,013				X
(54)	Clothianidin	Neonicotinoid pesticides	210880-92-5	433-460-1	0,01	0,001	0,34	0,034				
(55)	Deltamethrin	Pyrethroid pesticides	52918-63-5	258-256-6	$1{,}7\ 10^{-6}$	$1{,}7\ 10^{-7}$	$1{,}7\ 10^{-5}$	$3{,}4\ 10^{-6}$				X
(56)	Diclofenac	Pharmaceuticals	15307-86-5 / 15307-79-6	239-348-5 / 239-346-4	0,04	0,004	290	29				X
(57)	Erythromycin	Pharmaceuticals (Macrolide antibiotics)	114-07-8	204-040-1	0,5	0,05	1	0,1				X
(58)	Esfenvalerate	Pyrethroid pesticides	66230-04-4	613-911-9	$1{,}7\ 10^{-5}$	$1{,}7\ 10^{-6}$	0.0085	0.00085				X
(59)	Estrone (E1)	Pharmaceuticals (Estrogenic hormones)	53-16-7	200-164-5	0,00036	0,000018	not derived	not derived				
(60)	Glyphosate	Herbicides	1071-83-6	213-997-4	0,1[109] 90[110]	9	398,6	39,86				
(61)	Ibuprofen	Pharmaceuticals	15687-27-1	239-784-6	0,22	0,022]						X
(62)	Imidacloprid	Neonicotinoid pesticides	138261-41-3 / 105827-78-9	428-040-8	0,0068	0,00068	0,057	0,0057				

[109] For freshwater used for the abstraction and preparation of drinking water

[110] For freshwater not used for the abstraction and preparation of drinking water

(63)	Nicosulfuron	Herbicides	111991-09-4	601-148-4	0,0087	0,00087	0,23	0,023				
(64)	Permethrin	Pyrethroid pesticides	52645-53-1	258-067-9	0,00027	2.7 10-^{5}	0,0025	0,00025				X
(65)	Per- and poly-fluorinated alkyl substances (PFAS) – sum of 24 ([24])	Industrial substances	not applicable	not applicable	Sum of PFOA equivalents 0,0044 ([25])	Sum of PFOA equivalents 0,0044 ([25])	not applicable	not applicable	Sum of PFOA equivalents 0,077 ([25])	X	X	X
(66)	Silver	Metals	7440-22-4	231-131-3	0,01	0,006 (10% salinity) 0,17 (30% salinity)	0,022	not derived				
(67)	Thiacloprid	Neonicotinoid pesticides	111988-49-9	601-147-9	0,01	0,001	0,05	0,005				
(68)	Thiamethoxam	Neonicotinoid pesticides	153719-23-4	428-650-4	0,04	0,004	0,77	0,077				
(69)	Triclosan	Biocides	3380-34-5	222-182-2	0,02	0,0156	0,02	0,0156				
(70)	Total of active substances in pesticides, including their relevant metabolites, degradation and reaction products ([26])	Plant protection products and biocides			0.5 ([27])	0.5 ([27])						

([1]) CAS: Chemical Abstracts Service.

([2]) EU number: European Inventory of Existing Commercial Substances (EINECS) or European List of Notified Chemical Substances (ELINCS).

([3]) This parameter is the EQS expressed as an annual average value (AA-EQS). Unless otherwise specified, it applies to the total concentration of all substances and isomers.

([4]) Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies.

([5]) This parameter is the EQS expressed as a maximum allowable concentration (MAC EQS). Where the MAC EQS are marked as "not applicable", the AA EQS values are considered protective against short-term pollution peaks in continuous discharges since they are significantly lower than the values derived on the basis of acute toxicity.

([6]) If an EQS biota is given, it, rather than the water EQS, shall be applied, without prejudice to the provision in Article 3(3) of this Directive allowing an alternative biota taxon, or another matrix, to be monitored instead, as long as the EQS applied provides an equivalent level of protection. Unless otherwise indicated, the biota EQS relate to fish. For substances numbered 15 (Fluoranthene) and 28 (PAHs), the biota EQS refers to crustaceans and molluscs. For the purpose of assessing chemical status, monitoring of

Fluoranthene and PAHs in fish is not appropriate. For substance number 37 (Dioxins and dioxin-like compounds), the biota EQS relates to fish, crustaceans and molluscs, in line with Commission Regulation (EU) No 1259/2011* Annex Section 5.3.

([7]) For the group of priority substances covered by brominated diphenylethers (No 5), the EQS refer to the sum of the concentrations of congener numbers 28, 47, 99, 100, 153 and 154.

([8]) Tetra, Penta, Hexa, Hepta, Octa and Decabromodiphenylether (CAS numbers 40088-47-9, 32534-81-9, 36483-60-0, 68928-80-3, 32536-52-0, 1163-19-5, respectively).

([9]) For Cadmium and its compounds (No 6) the EQS values vary depending on the hardness of the water as specified in five class categories (Class 1: <40 mg CaCO3/l, Class 2: 40 to <50 mg CaCO3/l, Class 3: 50 to <100 mg CaCO3/l, Class 4: 100 to <200 mg CaCO3/l and Class 5: ≥200 mg CaCO3/l).

([10]) No indicative parameter is provided for this group of substances. The indicative parameter(s) must be defined through the analytical method.

([11]) DDT total comprises the sum of the isomers 1,1,1 trichloro 2,2 bis (p chlorophenyl) ethane (CAS 50 29 3, EU 200 024 3); 1,1,1 trichloro 2 (o chlorophenyl) 2 (p chlorophenyl) ethane (CAS 789 02 6, EU 212 332 5); 1,1-dichloro 2,2 bis (p chlorophenyl) ethylene (CAS 72 55 9, EU 200 784 6); and 1,1 dichloro 2,2 bis (p chlorophenyl) ethane (CAS 72 54 8, EU 200 783 0).

([12]) These EQS refer to bioavailable concentrations of the substances.

([13]) Nonylphenol (CAS 25154-52-3, EU 246-672-0) including isomers 4-nonylphenol (CAS 104-40-5, EU 203-199-4) and 4-nonylphenol (branched) (CAS 84852-15-3, EU 284-325-5).

([14]) Octylphenol (CAS 1806-26-4, EU 217-302-5) including isomer 4-(1,1',3,3'-tetramethylbutyl)-phenol (CAS 140-66-9, EU 205-426-2).

([15]) Benzo(a)pyrene (CAS 50-32-8) (RPF 1), benzo(b)fluoranthene (CAS 205-99-2) (RPF 0,1), benzo(k)fluoranthene (CAS 207-08-9) (RPF 0,1), benzo(g,h,i)perylene (CAS 191-24-2) (RPF 0), indeno(1,2,3-cd)pyrene (CAS 193-39-5) (RPF 0,1), chrysene (CAS 218-01-9) (RPF 0,01), benzo(a)anthracene (CAS 56-55-3) (RPF 0,1), and dibenz(a,h)anthracene (CAS 53-70-3) (RPF 1). The PAHs anthracene[, fluoranthene] and naphthalene are listed separately.

([16]) For the group of polyaromatic hydrocarbons (PAHs) (No 28), the biota EQS refers to the sum of the concentrations of seven of the eight PAHs listed in footnote 17 expressed as.benzo(a)pyrene equivalents based on the carcinogenic potencies of the substances relative to that of benzo(a)pyrene, i.e. the RPFs in footnote 15. Benzo(g,h,i)perylene does not need to be measured in biota for the purposes of determining compliance with the overall EQS biota.

([17]) Tributyltin compounds including tributyltin-cation (CAS 36643-28-4).

([18]) Sediment EQS

([19]) There is insufficient information available to set a MAC-EQS for these substances.

([20]) This refers to the following compounds:

7 polychlorinated dibenzo-p-dioxins (PCDDs): 2,3,7,8-T4CDD (CAS 1746-01-6, EU 217-122-7), 1,2,3,7,8-P5CDD (CAS 40321-76-4), 1,2,3,4,7,8-H6CDD (CAS 39227-28-6), 1,2,3,6,7,8-H6CDD (CAS 57653-85-7), 1,2,3,7,8,9-H6CDD (CAS 19408-74-3), 1,2,3,4,6,7,8-H7CDD (CAS 35822-46-9), 1,2,3,4,6,7,8,9-O8CDD (CAS 3268-87-9)

10 polychlorinated dibenzofurans (PCDFs): 2,3,7,8-T4CDF (CAS 51207-31-9), 1,2,3,7,8-P5CDF (CAS 57117-41-6), 2,3,4,7,8-P5CDF (CAS 57117-31-4), 1,2,3,4,7,8-H6CDF (CAS 70648-26-9), 1,2,3,6,7,8-H6CDF (CAS 57117-44-9), 1,2,3,7,8,9-H6CDF (CAS 72918-21-9), 2,3,4,6,7,8-H6CDF (CAS 60851-34-5), 1,2,3,4,6,7,8-H7CDF (CAS 67562-39-4), 1,2,3,4,7,8,9-H7CDF (CAS 55673-89-7), 1,2,3,4,6,7,8,9-O8CDF (CAS 39001-02-0)

12 dioxin-like polychlorinated biphenyls (PCB-DLs): 3,3’,4,4’-T4CB (PCB 77, CAS 32598-13-3), 3,3’,4’,5-T4CB (PCB 81, CAS 70362-50-4), 2,3,3',4,4'-P5CB (PCB 105, CAS 32598-14-4), 2,3,4,4',5-P5CB (PCB 114, CAS 74472-37-0), 2,3',4,4',5-P5CB (PCB 118, CAS 31508-00-6), 2,3',4,4',5'-P5CB (PCB 123, CAS 65510-44-3), 3,3’,4,4’,5-P5CB (PCB 126, CAS 57465-28-8), 2,3,3',4,4',5-H6CB (PCB 156, CAS 38380-08-4), 2,3,3',4,4',5'-H6CB (PCB 157, CAS 69782-90-7), 2,3',4,4',5,5'-H6CB (PCB 167, CAS 52663-72-6), 3,3’,4,4’,5,5’-H6CB (PCB 169, CAS 32774-16-6), 2,3,3',4,4',5,5'-H7CB (PCB 189, CAS 39635-31-9).

([21]) For the group of Dioxins and dioxin-like compounds (No 37), the biota EQS refers to the sum of the concentrations of the substances listed in footnote 20 expressed as toxic equivalents based on the World Health Organisation 2005 Toxic Equivalence Factors.

([22]) CAS 52315-07-8 refers to an isomer mixture of cypermethrin, alpha-cypermethrin (CAS 67375-30-8, EU 257-842-9), beta-cypermethrin (CAS 65731-84-2, EU 265-898-0), theta-cypermethrin (CAS 71691-59-1) and zeta-cypermethrin (CAS 52315-07-8, EU 257-842-9).

([23]) This refers to 1,3,5,7,9,11-Hexabromocyclododecane (CAS 25637-99-4, EU 247-148-4), 1,2,5,6,9,10- Hexabromocyclododecane (CAS 3194-55-6, EU 221-695-9), α-Hexabromocyclododecane (CAS 134237-50-6), β-Hexabromocyclododecane (CAS 134237-51-7) and γ- Hexabromocyclododecane (CAS 134237-52-8).

([24]) This refers to the following compounds, listed with their CAS number, EU number and Relative Potency Factor (RPF)::

Perfluorooctanoic acid (PFOA) (CAS 335-67-1, EU 206-397-9) (RPF 1), Perfluorooctane sulfonic acid (PFOS) (CAS 1763-23-1, EU 217-179-8) (RPF 2), Perfluorohexane sulfonic acid (PFHxS) (CAS 355-46-4, EU 206-587-1) (RPF 0,6), Perfluorononanoic acid (PFNA) (CAS 375-95-1, EU 206-801-3) (RPF 10), Perfluorobutane sulfonic acid (PFBS) (CAS 375-73-5, EU 206-793-1) (RPF 0,001), Perfluorohexanoic acid (PFHxA) (CAS 307-24-4, EU 206-196-6) (RPF 0,01), Perfluorobutanoic acid (PFBA) (CAS 375-22-4, EU 206-786-3) (RPF 0,05), Perfluoropentanoic acid (PFPeA) (CAS 2706-90-3, EU 220-300-7) (RPF 0,03), Perfluoropentane sulfonic acid (PFPeS) (CAS 2706-91-4, EU 220-301-2) (RPF 0,3005), Perfluorodecanoic acid (PFDA) (CAS 335-76-2, EU 206-400-3) (RPF 7), Perfluorododecanoic acid (PFDoDA or PFDoA) (CAS 307-55-1, EU 206-203-2) (RPF 3), Perfluoroundecanoic acid (PFUnDA or PFUnA) (CAS 2058-94-8, EU 218-165-4) (RPF 4), Perfluoroheptanoic acid (PFHpA) (CAS 375-85-9, EU 206-798-9) (RPF 0,505), Perfluorotridecanoic acid (PFTrDA) (CAS 72629-94-8, EU 276-745-2) (1,65), Perfluoroheptane sulfonic acid (PFHpS) (CAS 375-92-8, EU 206-800-8) (RPF 1,3), Perfluorodecane sulfonic acid (PFDS) (CAS 335-77-3, EU 206-401-9) (RPF 2), Perfluorotetradecanoic acid (PFTeDA) (CAS 376-06-7, EU 206-803-4) (RPF 0,3), Perfluorohexadecanoic acid (PFHxDA) (CAS 67905-19-5, EU 267-638-1) (RPF0,02), Perfluorooctadecanoic acid (PFODA) (CAS 16517-11-6, EU 240-582-5) (RPF 0,02), and Ammonium perfluoro (2-methyl-3-oxahexanoate) (HFPO-DA or Gen X) (CAS 62037-80-3) (RPF 0,06), Propanoic Acid / Ammonium 2,2,3-trifluoro-3-(1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy)propanoate (ADONA) (CAS 958445-44-8) (RPF 0,03), 2- (Perfluorohexyl)ethyl alcohol (6:2 FTOH) (CAS 647-42-7, EU 211-477-1) (RPF 0,02), 2-(Perfluorooctyl)ethanol (8:2 FTOH) (CAS 678-39-7, EU 211-648-0) (RPF 0,04) and Acetic acid / 2,2-difluoro-2-((2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl)oxy)- (c604) (CAS 1190931-41-9) (RPF 0,06)

([25]) For the group of PFAS (No 65), the EQS refer to the sum of the concentrations of the 24 PFAS listed in footnote 24 expressed as PFOA-equivalents based on the potencies of the substances relative to that of PFOA, i.e. the RPFs in footnote 24.

([26]) 'Pesticides' means plant protection products and biocidal products as defined in Article 2 of 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 in Article 3 of 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, respectively.

([27]) 'Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure, including their relevant metabolites, degradation and reaction products.

ANNEX I to Directive 2006/118/EC

GROUNDWATER QUALITY STANDARDS

(1)	(2)	(3)	(4)	(5)	(6)
Nº	Name of substance	Category of substances	CAS number ([1])	EU number ([2])	Quality Standard ([3]) [µg/l unless otherwise indicated]
1	Nitrates	Nutrients	not applicable	not applicable	50 mg/l
2	Active substances in	Pesticides	not applicable	not applicable	0,1

(1)	(2)	(3)	(4)	(5)	(6)
	pesticides, including their relevant metabolites, degradation and reaction products ([4])				0,5 (total) ([5])
3	Per- and poly-fluorinated alkyl substances (PFAS) - sum of 24 ([6])	Industrial substances	See footnote 6	See footnote 6	0.0044 ([7])
4	Carbamazepine	Pharmaceuticals	298-46-4	not applicable	0.25
5	Sulfamethoxazo le	Pharmaceuticals	723-46-6	not applicable	0.01
6	Pharmaceutical active substances – total ([8])	Pharmaceuticals	not applicable	not applicable	0.25
7	Non-relevant metabolites of pesticides (nrMs)	Pesticides	not applicable	not applicable	0,1 ([9]) or 1 ([10]) 0,5 ([9]) or 5 ([10]) (total) ([11])

([1]) CAS: Chemical Abstracts Service.

([2]) EU number: European Inventory of Existing Commercial Substances (EINECS) or European List of Notified Chemical Substances (ELINCS).

([3]) This parameter is the QS expressed as an annual average value. Unless otherwise specified, it applies to the total concentration of all substances and isomers.

([4]) ‘Pesticides’ means plant protection products and biocidal products as defined in Article 2 of 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 in Article 3 of 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, respectively.

([5]) ‘Total’ means the sum of all individual pesticides detected and quantified in the monitoring procedure, including their relevant metabolites, degradation and reaction products.

([6]) This refers to the following compounds, listed with their CAS number, EU number and Relative Potency Factor (RPF): Perfluorooctanoic acid (PFOA) (CAS 335-67-1, EU 206-397-9) (RPF 1), Perfluorooctane sulfonic acid (PFOS) (CAS 1763-23-1, EU 217-179-8) (RPF 2), Perfluorohexane sulfonic acid (PFHxS) (CAS 355-46-4, EU 206-587-1) (RPF 0,6)), Perfluorononanoic acid (PFNA) (CAS 375-95-1, EU 206-801-3) (RPF 10), Perfluorobutane sulfonic acid (PFBS) (CAS 375-73-5, EU 206-793-1) (RPF 0,001), Perfluorohexanoic acid (PFHxA) (CAS 307-24-4, EU 206-196-6) (RPF 0,01), Perfluorobutanoic acid (PFBA) (CAS 375-22-4, EU 206-786-3) (RPF 0,05), Perfluoropentanoic acid (PFPeA) (CAS 2706-90-3, EU 220-300-7) (RPF 0,03), Perfluoropentane sulfonic acid (PFPeS) (CAS 2706-91-4, EU 220-301-2) (RPF 0,3005), Perfluorodecanoic acid (PFDA) (CAS 335-76-2, EU 206-400-3) (RPF 7), Perfluorododecanoic acid (PFDoDA or PFDoA) (CAS 307-55-1, EU 206-203-2) (RPF 3), Perfluoroundecanoic acid (PFUnDA or PFUnA) (CAS 2058-94-8, EU 218-165-4) (RPF 4), Perfluoroheptanoic acid (PFHpA) (CAS 375-85-9, EU 206-798-9) (RPF 0,505), Perfluorotridecanoic acid (PFTrDA) (CAS 72629-94-8, EU 276-745-2) (1,65), Perfluoroheptane sulfonic acid (PFHpS) (CAS 375-92-8, EU 206-800-8) (RPF 1,3), Perfluorodecane sulfonic acid (PFDS) (CAS 335-77-3, EU 206-401-9) (RPF 2), Perfluorotetradecanoic acid (PFTeDA) (CAS 376-06-7, EU 206-803-4) (RPF 0,3), Perfluorohexadecanoic acid (PFHxDA) (CAS 67905-19-5, EU 267-638-1) (RPF 0,02), Perfluorooctadecanoic acid (PFODA) (CAS 16517-11-6, EU 240-582-5) (RPF 0,02), Ammonium perfluoro (2-methyl-3-oxahexanoate) (HFPO-DA or Gen X) (CAS 62037-80-3) (RPF 0,06), Propanoic Acid / Ammonium 2,2,3-trifluoro-3-(1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy)propanoate (ADONA) (CAS 958445-44-8) (RPF 0,03), 2- (Perfluorohexyl)ethyl alcohol (6:2 FTOH) (CAS 647-42-7, EU 211-477-1) (RPF 0,02), 2-(Perfluorooctyl)ethanol (8:2 FTOH) (CAS 678-39-7, EU 211-648-0) (RPF 0,04) and Acetic acid / 2,2-difluoro-2-((2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl)oxy)- (c604) (CAS 1190931-41-9) (RPF 0,06).

([7]) The QS refers to the sum of the 24 PFAS listed in footnote 6 expressed as PFOA-equivalents based on the potencies of the substances relative to that of PFOA, i.e. the RPFs in footnote 6.

([8]) 'Total' means the sum of all individual pharmaceuticals detected and quantified in the monitoring procedure, including relevant metabolites and degradation products.

([9]) Applicable to 'data-poor substances', i.e. 'substances which are not data rich'

([10]) Applicable to 'data-rich' substances, i.e. substances where the QS can be derived from a species sensitivity distribution with an assessment factor of one, on the basis of chronic and acute toxicity studies covering at least one species of algae, of invertebrates and of fish in fresh and saltwaters.

([11]) 'Total' means the sum of all data-poor or data-rich individual nrMs detected and quantified in the monitoring procedure.

Minimum list of pollutants and their indicators for which MS have to consider establishing threshold values in accordance with Article 3 (ANNEX II to GWD)

1. Substances or ions or indicators which may occur both naturally and/or as a result of human activities

Arsenic

Cadmium

Lead

Mercury

Ammonium

Chloride

Sulphate

Nitrites

Phosphorus (total)/Phosphates [111]

2. Synthetic substances

Primidone

Trichloroethylene

Tetrachloroethylene

3. Parameters indicative of saline or other intrusions [112]

Conductivity

[111] MS may decide to establish threshold values either for phosphorus (total) or for phosphates.
[112] With regard to saline concentrations resulting from human activities, MS may decide to establish threshold values either for sulphate and chloride or for conductivity.

ANNEX 9: DETAILED ASSESSMENT OF IMPACTS PER POLICY OPTION

1. Surface water options

1.1. Option 1: Include each candidate priority substance individually and set corresponding individual EQS

Option 1 provides the impact assessment for the addition of candidate substances to the priority substance list individually with individual EQSs, 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. Where these are in balance with the costs, an 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, where bisphenol A has been identified to have endocrine disrupting effects 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 managing bisphenol A is 'high cost, high benefit', and therefore it belongs in the neutral category.

As silver is used in many products. Its antibacterial properties are driving many medical applications, including e.g. silver-coated medical devices including urinary and vascular catheters and for the treatment of burn wounds by silver containing creams and ointments and by the application of silver sheets. Silver nanoparticles (nanosilver (NAg); are widely produced and used nanoparticles thanks to their unique characteristics and diverse antimicrobial mechanisms[113]. Often, silver is one of few remaining available treatments to protect the body for heavy bacterial infections. Numerous studies have demonstrated the antimicrobial efficacy of NAg against many viral, fungal, parasitic, and bacterial organisms[114] [115]. As a result, the healthcare sector is probably the largest market for NAg,

[113] Silva, G. A. (2004). Introduction to nanotechnology and its applications to medicine. *Surg. Neurol.* 61, 216–220. doi: 10.1016/j.surneu.2003.09.036: https://pubmed.ncbi.nlm.nih.gov/14984987/

[114] Rai, M., Deshmukh, S., Ingle, A., and Gade, A. (2012). Silver nanoparticles: the powerful nanoweapon against multidrug-resistant bacteria. J. Appl. Microbiol. 112, 841–852. doi: 10.1111/j.1365-2672.2012.05253.x: https://pubmed.ncbi.nlm.nih.gov/22324439/

with nanoparticles being widely used as a coating agent in medical devices, such as intravenous catheters, wound dressings, and organ/dental implants to inhibit bacterial colonisation[116 117]. Worryingly, NAg is also used into many ordinary consumer products, like in household appliances, textiles /clothing, cosmetics, childcare products, food packaging and containers[118].

The widespread use of NAg has raises concerns related to the rise of silver-resistant bacteria [119]. Over several years, a multitude of studies describe the increasing resistance in bacteria exposed to different forms of silver, including NAg. Silver resistance has been reported in *A. baumannii* and many other important pathogenic bacteria [120 121 122 123 124 125]. Evidence also shows that NAg also promotes the co-emergence of antibiotic resistance in bacteria[126 127 128]. In combination with the fact that, in Europe, 6.5% of patients in acute care hospitals develop at least one healthcare-associated infection[129] thus affecting millions of patients every year, is a worrying and challenging concern.

In this case the distance to target was identified as 'medium'. While acknowledging that the specific form of silver plays a key role in its bioavailability and impacts, it is also undisputed that (surface) water is a pool/ reservoir of bacteria with various forms of

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[117] Rai, M., Yadav, A., and Gade, A. (2009). Silver nanoparticles as a new generation of antimicrobials. Biotechnol. Adv. 27, 76–83. doi: 10.1016/j.biotechadv.2008.09.002: https://pubmed.ncbi.nlm.nih.gov/18854209/

[118] State of the art in human risk assessment of silver compounds in consumer products: a conference report on silver and nanosilver held at the BfR in 2012: https://pubmed.ncbi.nlm.nih.gov/23779146/

[119] Gunawan, C., Teoh, W. Y., Marquis, C. P., and Amal, R. (2013). Induced adaptation of *Bacillus* sp. to antimicrobial nanosilver. *Small* 9, 3554–3560. doi: 10.1002/smll.201300761: https://pubmed.ncbi.nlm.nih.gov/23625828/

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[129] Widmer, A.F. et.al. Long-term antimicrobial effectiveness of Ag-impregnated foil on high-touch hospital surfaces... Antimicrobial Resistance & Infection Control 2021, Vol. 10: https://aricjournal.biomedcentral.com/articles/10.1186/s13756-021-00956-1

antimicrobial resistance (AMR)[130]. As a result, bacterial genes encoding for AMR can easily maintain and spread through such reservoirs also to pathogenic bacteria. The widespread over-use of silver also leads to the selection of silver resistant bacteria and may be genotoxic to mammalian cells. Other reports indicate adverse effects of silver nanoparticles on reproduction of experimental animals, as well as neurotoxic effects on cognitive functions[131].

The cost for the removing silver from effluents via UWWTPs is considerable (source control could include pre-treatment or onsite wastewater 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[132]. Alternatively, urban wastewater 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. The benefits of removing silver to reduce the risk for AMR and other risks, similar to the benefits of reducing AMR from antibiotics, are also 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[133][134], adding up to a total of $55 billion, which corrected for inflation would result in 63 billion in 2021[135]. In 2021 this would translate to costs of $0,19 billion per million inhabitants[136]. 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)[137]. 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.

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 per Member State challenging, 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.

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[131] Anna Maria Świdwińska-Gajewska, Sławomir CzerczakNanosilver - harmful effects of biological activity: https://pubmed.ncbi.nlm.nih.gov/25902699/

[132] An extrapolation of the RO costs based on the number of EU non-ferrous metals production facilities 847[132] 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 billion[132]) this would equal 0.1%.

[133] 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/

[134] 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/

[135] https://www.in2013dollars.com/us/inflation/2014?endYear=2021&amount=55

[136] In 2021 the number of US inhabitant was 332 million: https://www.worldometers.info/world-population/us-population/

[137] No. of EU inhabitants in 2021: 447 million (https://european-union.europa.eu/principles-countries-history/key-facts-and-figures/life-eu_en)

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 A9.1: Surface water option 1 – summary of impacts

Substance	Distance to target	Environmental impact	nomic 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.
Ethinyl 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 benefits of addition to the PS list outweigh the costs.
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.	Avoid 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	Source control options look viable (range of alternatives); end-of-pipe measures could also be considered to address risks. Note possible economic costs on pharmaceutical industry if	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	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	nomic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
		species.	restricted/banned but expect production to switch to alternatives.		willingness to pay and advanced WWTWs.	
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 could also be considered to address 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.
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 as neutral. (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 are balanced with the 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 as neutral. (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, wastewater companies, and general public.	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.
Clothianidin	Small	Toxic aquatic effects against invertebrates, arthropods, and crustaceans. Wider	Use as pesticide has ceased. Use as biocide ongoing. Pathway disruption costs may be significant. End-of-pipe	Avoided drinking water treatment costs. Economic benefits for aquaculture from improved food quality.	Avoided human health impacts from exposure to Neonicotinoids	Benefits and costs assessed as neutral. (Small cost / small benefit)

Substance	Distance to target	Environmental impact	nomic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
		environmental concerns for terrestrial pollinators.	technologies based on Ozonation. Costs could be considerable to manage run-off from biocidal use in field.	Avoided economic impacts for agriculture (pollinators).	.	
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.	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.
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	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	The benefits of addition to the PS list outweigh the costs.

Substance	Distance to target	Environmental impact	nomic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
			source control, pathway disruption and end-of-pipe. Costs likely to be significant.		security issues if loss of use without 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.
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.	The benefits 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	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.

Substance	Distance to target	Environmental impact	nomic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
		evidence of anti-microbial resistance issues.				
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.	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 source control, pathway disruption and end-of-pipe. Diffuse sources problematic and costs of achieving compliance likely very significant.	Avoided costs of drinking water treatment. Avoided environmental impacts for aquaculture. Innovation for development of alternative chemicals and technologies.	Avoided health impacts from exposure. Benefits from protection of aquatic environment as ecosystem services.	Benefits and costs assessed as neutral. (High cost / high benefit)
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, and end-of-pipe needed to help achieve compliance. Given the 'small' 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 as neutral. (High cost / high benefit) Costs outweigh the benefits of addition

Table A9.2: Examples of monetized impacts for surface water Option 1

Environmental impact	Economic Impact	Social impact
Avoided/reduced environmental impacts and potential toxic effects on aquatic species. E.g. Carbamazepine has population effects for aquatic species through impacts on fertility and reproduction (particularly crustaceans). Silver also has chronic aquatic toxicity effects, primarily for crustaceans. Ibuprofen exhibits potential toxic effects for some aquatic species including fertility effects (hormone levels) in fish while nicosulfuron has aquatic toxicity (particularly to flora) and concerns over carcinogenicity as a secondary poisoning issue. Diclofenac is one of the highest concern pharmaceuticals for environmental impacts with potential toxic effects on avian populations via surface water species. Estrone E1, 17- Beta estradiol (E2), Ethinyl estradiol (EE2) are associated with chronic ecosystem level impacts from exposure to hormones and EDC. PFAS has a widespread and very long-lasting environmental effects while Bisphenol A causes population level effects as an endocrine disrupting chemical for aquatic organisms. Triclosan is toxic for aquatic organisms particularly larvae and fish eggs with effects identified on a range of aquatic species including amphibians. Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate and Permethrin are associated with toxic aquatic effects against invertebrates, arthropods, and crustaceans with wider environmental concerns for terrestrial pollinators (with Bifenthrin, Deltamethrin Esfenvalerate, Permethrin being highly toxic to the aquatic environment even at low concentrations). Glyphosate is associated with potential harm to aquatic environments given the very high usage rates and risks for loss to water, including non-target aquatic flora. Microplastics: chronic ecosystem level effects from physical and pathological impacts of micro-plastics for aquatic species and accumulation at higher trophic tiers. Primary source for secondary microplastics are brake and tyre wear, emissions to sewer from laundry activities, land spreading for sludges.	**Significant costs** to ensure compliance with proposed EQS for Ethinyl estradiol (EE2), Ibuprofen, Clothianidin, Imidacloprid, Thiamethoxam, Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin, Glyphosate, Triclosan, PFAS and Bisphenol A implementing a range of source control, pathway disruption, targeted end of pipe treatment measures. E.g. the cost of a take-back scheme for unused pharmaceuticals in France is €10 million. The 2022 Annex XV restriction report for the proposed restriction of PFASs in firefighting foams estimates that the ban is estimated to cost society €6.8 billion over a 30-year period or €390 million per year. Costs of pathway disruption measures (e.g. buffer strips) is €472 million per year for pharmaceuticals; for pesticides these range from €162 million for clothianidin and imidacloprid to €285 million for glyphosate. Wastewater treatment range is €10- €32 per population equivalent, per annum (technology dependent). For instance, use of GAC at 20% of UWWTPs at or above 50,000 P.E. would equate to annualised costs of €2 billion per year (25 year lifetime) and would close distance to target for Thiamethoxam. Silver: Multiple pathways and sources to environment with a package of measures spanning source control (abatement upgrades, restricted use, capture and treat for mine drainage), pathway disruption (estimated as €103 million per annum), and end-of-pipe (estimated as €2.5 billion per annum for reverse osmosis in 33% of all UWWTPs serving ≥50K P.E.) needed to help achieve compliance. **Moderate/Small costs** to ensure compliance for Estrone E1, 17-Beta estradiol (E2), Diclofenac, Carbamazepine, Azithromycin, Clarithromycin, Erythromycin, Acetamiprid, Thiacloprid, Nicosulfuron due to small distance to target, availability of source control and pathway disruption measures and/or positive impact of forthcoming revision of the UWWTD on quaternary end of pipe treatment. E.g. costs of pathway disruption measures (e.g. buffer strips) for pesticides range from €1.6 million for acetamiprid to €12.8 million for nicosulfuron. Wastewater treatment cost range is €10- €20 per population equivalent, per annum (technology dependent). For instance, use of ozonation on all UWWTPs at or above 50,000 P.E. would equate to annualised costs of €318 million per year (25 year lifetime) and would close distance to target for Estrone E1, 17- Beta estradiol (E2), Azithromycin, Clarithromycin, Erythromycin, Diclofenac, Carbamazepine. **Monitoring costs:** range from €11-100 per sample for all substances except for PFAS. For PFAS analytical costs are up to €250 per sample. Avoided/reduced impacts on pollinators and agriculture (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam, Bifenthrin, Deltamethrin Esfenvalerate, Permethrin). E.g. across Europe, crop pollination by insects accounted for approximately €14.6 billion annually. Economic benefits for aquaculture from improved food quality (Estrone E1, 17- Beta estradiol (E2), Ethinyl estradiol (EE2), Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, Diclofenac, Carbamazepine, ibuprofen, Nicosulfuron, triclosan, PFAS, bisphenol A). Avoided costs of water treatment for drinking water, agriculture and industry (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, glyphosate, triclosan, bisphenol A, PFAS, microplastics) (in the case of source control and pathway disruption measures). E.g. in 2015, approximately €0.5 billion was spent annually to remove pesticides in wastewater treatment plants (WWTP) in Europe. Innovation for development of alternative chemicals and technologies (e.g. Bisphenol A).	Avoided/reduced human health impacts from Glyphosate, Triclosan, PFAS, Bisphenol A via reduced exposure through drinking water (Bisphenol A is associated with childhood obesity which could cost the EU around €1.8 billion); from Neonicotinoids (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam), EDC (Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, EE2) and (potential) carcinogenic effects (Ethinyl estradiol (EE2), Nicosulfuron). E.g. Annual costs related to endocrine disruptors exposure were estimated to be €163 billion. 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 as well as childhood obesity which costs €1.54 billion annually. Protection against AMR has clear societal benefits and avoided costs to healthcare from protections against the development of AMR within health settings (Azithromycin, Clarithromycin, Erythromycin). E.g. It is estimated that AMR costs the EU €1.5 billion per year in healthcare costs and productivity losses. Specific to PFAS the annual health expenditure due to kidney cancer caused by PFAS exposure estimated 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 products, background levels). Possible societal impacts from loss of use (contraceptive pill, HRT, hormone treatments if Ethinyl estradiol (EE2) is restricted/banned. Societal impacts from loss of use /restricted use of Diclofenac, Carbamazepine, Ibuprofen if controls implemented and increased costs for other types of medicine (including prescription only medications). Possible food security issues if loss of use without chemical/non-chemical alternatives in place (Bifenthrin, Deltamethrin, Esfenvalerate, Permethrin). Societal impacts for domestic pet owners if use of Imidalcoprid is restricted. Increased prices of goods and services as a result of source control measures.

1.2. Option 2: Include candidate PS as groups of substances where appropriate. Set corresponding EQS using markers or the sum of substance concentrations in the case of groups.

The second option also focusses on the candidate substances to add to the PS list, but as groups. 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 A9.3 provides the outcome of the impact assessment and balance of costs and benefits. 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 values vary significantly (Azithromycin AA and MAC 0.019 µg/L; Clarithromycin AA and MAC 0.13 µg/L; Erythromycin AA and MAC 0.5 µg/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.

Table A9.3: Surface water option 2 – summary of impacts

Substance group	Environmental impacts	Economic impacts		Social impacts	Overall balance of costs and benefits
		Cost	Benefit		
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.
Neonicoti-noids	Greater coherence in the approach to protection of pollinators if grouped.	Variations in use, pathways, and measures. Grouping could create incoherence in measures and	No economic benefits identified.	Greater coherence in the approach to protection of pollinators if grouped.	The potential costs outweigh the benefits. Grouping not recommended.

		unnecessary costs.			
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.

1.3. Option 3: Revise EQS where necessary based on new scientific data for existing PS.

Option 3 is based on the fact that the scientific data available has evolved since the original analysis and risk assessment for pre-existing EQS values. Where the proposed EQS amendments reflect a robust and thorough investigation of the new and emerging science to re-appraise the EQS values 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 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 A6.5 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 outweigh the benefits. However, the margins in this case are very tight and overall, the impact assessment assesses that the balance of costs and benefits will be neutral.

Table A9.4: Surface water option 3 – summary of impacts

Substance	Distance to target *	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			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 are considered proportionate to the addressed 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 are considered proportionate to the addressed risks. **Option assessed as neutral** **(Medium cost / medium benefit)**
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.**
Hexachloro-benzen	Small	Updated EQS based on new science and re-	The proposed EQS is less stringent. No additional costs expected.	The proposed EQS is less stringent,	No specific social impacts	On the basis that new scientific evidence has been used to re-assess

Substance	Distance to target *	Environmental impact	Economic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
e		appraisal of risk, would provide more appropriate protections.		meaning resources can be reallocated and costs saved from measures no longer needed.	identified.	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.**
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.**
Fluoran-thene	**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.**
Hexachloro-butadiene	Small	Updated EQS based on new science and re-appraisal of risk, would provide more appropriate protections.	Proposed EQS is more stringent, likely to trigger some additional exceedances, but grouping will still be 'small'. Limited number of sources, which would target manufacturing and end-of-pipe. Costs are considered proportionate to the addressed risks.	No specific cost benefits identified.	Improved protections for human health. Particularly given HBCDD is a POP and issues around bioaccumulation.	On the basis that new scientific evidence has been used to re-assess the 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 preferable.**
PAHs	**Mediu**	Updated EQS based on new	The proposed EQS could be expected to trigger a	No specific cost benefits	Improved health	Based on the review and reappraisal of

Substance	Distance to target *	Environmental impact	nomic Impact		Social impact	Overall balance of costs and benefits
			Cost	Benefits		
	m	science and re-appraisal of risk, would provide more appropriate protections.	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 and field. Costs could be significant.	identified.	protection from avoiding exposure to PAHs. Improved ecosystem services.	EQS additional measures may be warranted. Costs are considered proportionate to the addressed risks. **Option assessed as neutral** **(High cost / high benefit)**
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. Costs are likely to be significant.	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. **Option assessed as neutral** **(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.	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. **Option assessed as neutral** **(High cost / high benefit)**

* Bold and red denotes a change in group based on amended EQS.

Table A9.5: Examples of monetized impacts for surface water Option 3

Environmental impact	Economic Impact	Social impact
Updated EQS based on new science and re-appraisal of risk would provide more appropriate protections (all substances). Reduced environmental concentrations, improved environmental protections for ecosystem services (cypermethrin, nonylphenols, PAHs). Avoided health costs for aquaculture (cypermethrin, tributyltin, mercury, nickel) Potential innovation opportunity to remove use as an intermediate in manufacture of rubber products (diuron).	**Significant costs** to ensure compliance for Cypermethrin, Chlorpyrifos, Diuron, PAHs, Mercury, Nickel implementing a range of source control, pathway disruption, targeted end of pipe treatment measures. Wastewater treatment (end of pipe) related measures for heavy metal removal, generally relates to primary treatments (usually primary settling followed by an activated sludge process). 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) [138] [139]. Also, scientific results show that Apatite can be suitable material to remove cadmium, copper, nickel, cobalt and mercury from water[140]. For PAHs, e.g. 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 would cost €45m over a 10-year period. 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. Costs of additional controls and treatment for farmed animal use of cypermethrin are €27.6 m. Wastewater treatment (Mercury, Nickel, PAH, Cypermethrin) - €1.17- €26.2 per population equivalent, per annum (technology dependent). Mine drainage (Mercury / Nickel) - €100,000 -€10,000,000 per plant and €0.4 per dm^3 operating costs. **Moderate/Small costs** to ensure compliance for Dioxins and furans, Hexachlorobutadiene, Nonyl Phenol, Tributyltin due to small distance to target and/or limited scope for additional measures (likely to be natural attenuation and baseline end of pipe treatment (under the revised UWWTD)). E.g. 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. **No additional costs** for Dicofol. Monitoring: Amendments for Chlorpyrifos and Dioxins and furans could lead to additional analytical costs (due to the proposed EQS being considerably lower). Cost savings and efficiencies: the proposed EQS is less stringent for heptachlor/ heptachlor oxide, hexachlorobenzene, PBDEs and fluoranthene- resources can be reallocated and costs saved from measures no longer needed. For PBDEs it needs to be noted that the avoided costs for human health will also decrease if a less stringent EQS would be implemented.	Improved protections for human health particularly in relation of POP substances, issues around bioaccumulation (dioxins and furans, chlorpyrifos, hexachlorobutadiene), EDC (diuron, chlorpyrifos), exposure to chronic pollutants (mercury, nickel). E.g. 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. It was also estimated that the cognitive deficits caused by chlorpyrifos and methylmercury would cost the EU €177 billion and €9.89 billion, respectively.

[138] 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

[139] https://www.researchgate.net/publication/350998245_Removal_of_Heavy_Metals_during_Primary_Treatment_of_Municipal_Wastewater_and_Possibilities_of_Enhanced_Removal_A_Review

[140] Removal of cadmium, copper, nickel, cobalt and mercury from water by Apatite: https://pubmed.ncbi.nlm.nih.gov/21871722/

1.4. Option 4: Review possible deselection of substances shortlisted following agreed deselection criteria.

The final option within the surface water category relates to the potential deselection of PS that no longer present an EU-wide risk to the environment. A set of deselection criteria were used to identify candidates for deselection. Deselected substances could and should still be addressed as RBSPs at national level where a risk still exists.

The outcome of the impact assessment, which concluded that the identified substances could be deselected from the PS list with the economic and environmental benefits outweighing any potential costs. This includes consideration of the risk that use might recommence/increase.

Table A9.6: Surface water option 4 – summary of impacts

<table>
<tr><th rowspan="2">Substance</th><th rowspan="2">Environmental impacts</th><th colspan="2">Economic impacts</th><th rowspan="2">Social impacts</th><th rowspan="2">Overall balance of costs and benefits</th></tr>
<tr><th>Cost</th><th>Benefit</th></tr>
<tr><td>Alachlor</td><td>Banned in the EU for many years, only 5 water bodies out of 97,000 exceed the EQS. Risk to environment is low.</td><td rowspan="5">Continued monitoring could be expected to utilise finite economic resources with more limited benefit.</td><td rowspan="5">Deselection could free up resources that could be reallocated to monitoring and controlling emerging risks.
Cost savings €3.8 - €11.7 million Euro per year (monitoring of 5 substances).</td><td>While the health hazards of alachlor are clearly documented, risk of exposure is very low and would not be expected to increase.</td><td>Deselection would have more benefits than costs.</td></tr>
<tr><td>Simazine</td><td>Banned in the EU for many years, only 4 water bodies out of 97,000 exceed the EQS. Risk to environment is low.</td><td>While the health hazards of simazine are clearly documented, risk of exposure is very low and would not be expected to increase.</td><td>Deselection would have more benefits than costs.</td></tr>
<tr><td>Chlorfenvinphos</td><td>Banned in the EU for many years, only 6 water bodies out of 97,000 exceed the EQS. Risk to environment is low.</td><td>While the health hazards of chlorfenvinphos are clearly documented, risk of exposure is very low and would not be expected to increase.</td><td>Deselection would have more benefits than costs.</td></tr>
<tr><td>Trichlorobenzenes</td><td>Still in use, and these substances are acutely toxic to the aquatic environment. However, the rate of exceedance is very low. Possible to maintain protection by designating as a RBSP where needed.</td><td rowspan="2">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.</td><td>Deselection would have more costs than benefits.</td></tr>
<tr><td>Carbon tetrachloride</td><td>Still in use but, is not a POP, and as noted under option 4, the rate of exceedance is extremely low and the risk to the environment is equally low. Possible to maintain protection by designating as a RBSP where needed.</td><td>Deselection would have more benefits than costs.</td></tr>
</table>

2. Groundwater options

Tables A9.7 to A9.9 below summarise the impacts of implementing the groundwater policy options, compared to the status quo. The options presented are mutually exclusive for each substance group under consideration. More detailed economic costs of potential measures are included in Annex 10. A note on the impacts of options not analysed in the main report is included below.

Note on impacts of groundwater options not analysed in the main report

As shown in Annex 7 Table A7.3, three groundwater options were not discussed in the main report in order to simplify the presentation and better reflect the key policy choices available. These options were:

- a group of 10 PFAS included in Annex I and assigned a GW QS of 0.1 µg/l;
- group of 16 nrMs added to Annex I as individual substances with a GW QS of 1 µg/l;
- group of 16 nrMs added to Annex I as individual substances with a GW QS of 0.1 µg/l.

For transparency, and to report all analysis done, the impacts of these options are included in the tables below and some explanatory text is also provided here.

PFAS

Costs for a group of 10 PFAS included in Annex I and assigned a GW QS of 0.1 µg/l will be lowest, given the DWD requirements and additional data collated. This is especially the case for the MS which are already monitoring PFAS and carrying out risk assessments for groundwater.

Pathway disruption measures like the capture of contaminated sludge, containing and incineration are very costly due the energy intensiveness, so these measures are suitable only in extreme circumstances. Guidance on the best practise use of waste and wastewater by-products in agriculture would be a cheaper option. However, this will ultimately result in PFAS accumulating in agricultural soils. Instead of using pathway disruption measures, it is more likely that for a group of 10 PFAS included in Annex I and assigned a GW QS of 0.1 µg/l actions to restrict use of PFAS and better management of waste streams are used, as well as groundwater or soil remediation.

nrMs

The costs of adding nrMs to the monitoring networks are likely to be limited, since the existing framework for assessing risk to groundwater from 'parent' pesticides and their relevant metabolites are already in place. This is particularly the case for adding a group of 16 nrMs to Annex I with a GW QS of 1 µg/l and adding a group of 16 nrMs to Annex I with a GW QS of 0.1 µg/l.

The implementation of the EU Farm to Fork Strategy will likely lead to reductions in the use of any permitted parent pesticides of the nrMs considered. This will be delivered in part through the planned revision of the Directive on the Sustainable Use of Pesticides and national action plans for pesticide use reduction. This will limit what additional measures need to be taken to protect their water bodies. By including all nrMs in Annex I under, the administrative burden may be progressively reduced further as the legislation would be "future proofed".

Environmental benefits are rather similar for the 5 assessed options for nrMs but options covering all nrMs and setting a GW QS at EU level are expected to generate greater benefits.

2.1. Option 1: Add LFR substances to GWD Annex I individually, and assign an individual EU-wide GW QS

Table A9.7: Groundwater Option 1 – summary of impacts and preferred option

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
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)	Costs - €15-16 million (Europe) Benefits from the DWD implementation	Cost of remediation of legacy pollution (to taxpayer where polluter pays principle cannot be enforced). From landfill sites this could amount to €0.7 million on average, and up to €77 million per site. Environmental PFAS remediation totalling €821 million to €170 billion (EEA/EU), with plausible best estimate of €10–20 billion. Cost of high temperature incineration of biosolids - €5000-7500 million/yr (EU level). Cost of landfill - €2000 million/yr (EU level). Restriction of use: €390 million per year per substitute use.	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 treatme	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. Increased knowledge and understanding of the risks of PFAS posed to the water environment. Consistent approach to data collection at EU level and improved knowledge (more data collected) on the impact of PFAS. Reduced pollution of groundwater. 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).	Loss of organic materials to spread to land by farming community.	Avoided illness / death through lower exposure to PFAS via drinking water / food. In the EEA countries, health-related costs could reduce by up to €52-84 billion per year (based on population of 207.8 million). 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 PFAS posed to the water environment.	No – protects against current known PFAS but not future pollution.

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
PFAS (Group of 24 proposed as additions to the surface water Priority Substance list) included in Annex I and assigned a GW QS of 4.4 ng/l PFOA-equivalent. If no RPF exists, then the RPF of PFOA should be assumed and a GW QS of 4.4 ng/l applied.	€45-48 million Highest burden due to need to use RPFs Benefits from the DWD implementation		nt costs millions of € per site).				As above but improved targeting on more potent PFAS.	Yes – future proofed / human health focus
Carbamazepine and Sulfamethoxazole added to Annex I and assigned GW QS of 0.5 and 0.1 µg/l respectively.	Costs of monitoring - €2 million (no significant additional administrative costs for risk / status assessments)	Generally smaller than under Option 2 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 (disproportionately expensive).	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 pharmaceuticals under Option 2, 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

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
nrMs (Group of 16) added to Annex I as individual substances with a GW QS of 1 µg/l.	€4-5 million Costs of monitoring (no significant additional administrative costs for risk / status assessments)	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. Cost of legacy pollution from landfill sites – average of €0.7 up to €77 million per site. Increased data requirements could make gaining authorisation of new products more challenging.	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. Better data for use during pesticide parent authorisation process.	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. 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. Climate change benefits 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).	Potential for marginal cost increases in food production due to more limited choice in pesticides.	A healthy ecosystem (fishing, swimming, etc.) Benefits to 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
nrMs (Group of 16) added to Annex I as individual substances		As above but more stringent.		As above but more stringent.	As above plus reduced impacts on groundwater biota.	As above but more stringe		No

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
with a GW QS of 0.1 µg/l.						nt.		
All nrMs added to Annex I as individual substances with a GW QS of 0.1 µg/l.		As above but with future proofing.						Yes

2.2. Option 2: Add LFR substances to GWD Annex I as groups, and assign an EU-wide GW QS for the group "total" or "sum of".

Table A9.8: Groundwater Option 2 – summary of impacts and preferred option

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
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).	€45-48 million Benefits from the DWD implementation.	Cost of remediation of legacy pollution (to taxpayer where polluter pays principle cannot be enforced). Cost of high temperature incineration of biosolids €5000-7500 million/yr (EU level). Cost of landfill €2000 million/yr (EU level).	Reduced energy costs and related process costs for wastewater treatment to tackle PFAS. Avoided cost of drinking water treatment. More data collected to understand the impact of these two PFAS. Consistent approach to data collection at EU level. Reduced pollution of 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.	Avoided costs of availability of clean raw groundwater for abstraction. Lower production and maintenance costs through availability of cleaner raw potable groundwater. 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).	Loss of organic materials to spread to land by farming community.	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 PFAS posed to the water environment.	No – GW QS not sufficiently precautionary / protective, although future proofs legislation.

Description	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
All pharmaceuticals added as a group to Annex I and assigned a GW QS of 0.5 µg/l.	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 (less than €1-€10 million per MS) 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).	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 to reduction in pharmaceuticals in groundwater and informs industry / permitting of new substances.	Energy use to capture, store and destroy biosolids and animal manures to prevent leaching to ground water.	Reduced pollution of groundwater and connected aquatic ecosystems with reduced impact on sensitive habitats. Reduced energy, carbon emissions and chemicals use associated with reduced treatment of drinking water (in the case of source control and 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 anti-biotic use (costs avoided of €1.5 billion to the EU).	Restricting use could impact on the health and well-being of animals where alternatives have side effects / different efficacy. Capture of biosolids / incineration of manures has impact on farming sector with loss of low cost soil improver / fertiliser.	Reduction in AMR through control of Sulfamethoxazole is small in comparison to baseline measure of restricting prophylactic use in animals. Increased knowledge and understanding of environmental behaviours of pharmaceuticals Small increase in well-being from reduced risk of chronic ingestion in drinking water / improved ecosystem health. Benefits from impact on shellfish and fisheries where groundwater inputs to rivers and coastal estuaries is significant.	No
All nrMs added to Annex I as a group and assigned a group GW QS of 10 µg/l.	€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.	Potential for cost increases due to lower crop yields.	As for nrMs under Option 1 but in restricted areas only.	No

2.3. Option 3: Add LFR substances to GWD Annex II for MS to consider setting a TV for specific substances posing a risk to groundwater bodies.

Table A9.9: Groundwater Option 3 – summary of impacts and preferred option

Option	Administrative burden	Economic Impacts		Environmental Impacts		Societal Impacts		Preferred option?
		Costs	Benefits	Costs	Benefits	Costs	Benefits	
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.	Less than all other options for PFAS. Benefits from the DWD implementation.	As for PFAS under Option 1 but fewer sites to remediate.	As for PFAS under Option 1, but reduced consistency / less data collection.	As for PFAS under Option 1, but reduced extent.	As for PFAS under Option 1.	As for PFAS under Option 1, but reduced extent.	As for PFAS under Option 1.	No - too variable and will not address pollution of groundwater at the EU-wide level.
All pharmaceuticals added as a group to Annex II - guideline to include carbamazepine, sulfamethoxazole and primidone.	Costs negligible and absorbed into baseline. If all MS added Primidone via Annex II, the additional costs would be half of Option 1 for pharmaceuticals.	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 for pharmaceuticals under Options 1 and 2.	As for pharmaceuticals under Option 2 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 pharmaceuticals under Option 2 but scale depends on how far MS implement monitoring and measures.	As for pharmaceuticals under Option 2 but scale depends on how far MS implement monitoring and measures.	Yes, only for Primidone
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.	Costs negligible and absorbed into baseline. Dependant on risks identified from nrMs by each MS.	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.	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 schemes which may be too high level to be effective.	Few additional costs (uncertain).	Limited programme of measures required.	No

3. Monitoring, reporting and administrative streamlining policy options

Table A9.11 below depicts the additional impacts of implementing the monitoring, reporting and administrative streamlining options, compared to the status quo. The options presented are not mutually exclusive, and can co-exist. As illustrated in the main text, 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.

Sub-options under Policy Option 1 include the drafting of (additional) guidance documents. For the economic impacts of these sub-options, the primary cost will be the development of the guidance document itself. 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. Extensive guidance documents that involve a lot of technical input (e.g. Best Available Technique Reference Documents under the Industrial Emissions Directive) are an example of costly guidance documents that take years to develop. Within a process like the WFD Common Implementation Strategy guidance, such documents are not envisaged. The primary difference between the two cost estimates stems from the effort required in establishing the guidance document. One-off estimates of costs for the development of several types of guidance documents are presented in Table A9.10 below. Under the WFD CIS, only simple to more elaborate technical guidance documents are drafted, thus not exceeding €500,000 per document.

Table A9.10: Categories for estimating cost of guidance documents

Type of guidance	Range of cost per guidance (€)
Simple	Up to €290,000
Elaborate	€290,000 – €500,000
Extensive	€5 million – €10 million

Table A9.11: Monitoring, reporting and administrative streamlining policy options – summary of impacts

Option description	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
Option 1 – Provide / improve guidance and advice on monitoring				
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 measures.	Depending on uptake of measures.
Option 1b: Follow -up to improve existing guidelines on EBMS in view of setting application 'trigger values' in practice to improve monitoring of groups/mixtures of pollutants by using EBMs, and trigger values.	Guideline impacts would be neutral, and dependent on uptake of measures.	Limited cost (≤€500,000) to develop the guidance document.	Likely to have positive social impacts 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 PS and 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 impacts depending on uptake of measures.	Depending on uptake of measures.
Option 1e: Provide a repository for sharing best-practices from MS 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 outweigh initial costs due to knowledge sharing and development.
Option 2 – Establish / amend obligatory monitoring practices				
Option 2a: Include an obligation in the EQSD to use EBMs to monitor estrogens.	Provision on monitoring estrogens will have positive impacts.	Costs due to monitoring of estrogen are low, but possible measures to be taken due to monitoring results may be substantial.	Monitoring of estrogen will have positive impacts by allowing better targeting of policy measures.	Costs of monitoring estrogens are outweighed by significant benefits.
Option 2b: Establish an obligatory groundwater watch list mechanism 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 description	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
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 3 – Harmonise reporting and classification				
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.	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 long-term benefits outweighing initial costs.
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.	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 4 – Legislative and administrative aspects				
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.	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*	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	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	Benefits outweigh the costs.

Option description	Impacts			Overall balance of costs and benefits
	Environmental impact	Economic impact	Social impact	
PHS) ***Industrial chemicals****: Tetrachloroethylene, Trichloroethylene (to PHS)* *Note: Carbon tetrachloride is deselected under surface water option 4, hence is not considered here.*	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. 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.		exposure via the environment.	
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

ANNEX 10: POTENTIAL COSTS OF SELECTED SURFACE WATER AND GROUNDWATER POLLUTION REDUCTION MEASURES

Surface water measures

Within the pharmaceuticals category, possible measures MS could take is trying to reduce the demand and or the production of the most harmful substances by encouraging producers to switch to manufacturing alternatives. This could 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 the table below with a range of costs. 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 A10.1.

Table A10.1: Pharmaceutical substances, potential alternatives, and the costs of each

Original substance	Cost per prescription of substance (EUR)*	Alternative substance	Cost range for the prescription of alternatives (EUR)*
17-Beta estradiol (E2)	9.87	Tibolone, Clonidine, Sertraline	10.42 to 23.29
Azithromycin	13.75	Clarithromycin, Erythromycin	3.99 to 33.02
Clarithromycin	3.99	Azithromycin	13.75
Erythromycin	33.02	Clarithromycin, Azithromycin	3.99 to 13.75
Carbamazepine	7.45	Pregabalin, Gabapentin, Phenytoin	4.36 to 23.40
Diclofenac	11.93	Aspirin, Celecoxib, Indometacin, Naproxen, Etoricoxib, Ibuprofen	4.00 to 8.93
Ibuprofen	8.93	Aspirin, Celecoxib, Etoricoxib, Diclofenac	4.00 to 11.93

* Only possible substitute substances within a price range of max 3.5x the costs of the original substance are included in the table. 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.

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 requires looking into possible alternatives that might be available instead. The table below provides an overview of possible alternatives to the candidate priority/priority hazardous substances" (non-exhaustive analysis of alternatives to pesticides). Where many alternatives exist, it is 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. An online marketplace was used 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 in Table A10.2 below. 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.

Table A10.2: Pesticides, their possible alternatives, and the estimated costs

Pesticide substance (type in brackets: H:Herbicide; F:Fungicide: I:Insecticide)	**Candidate priority substance** Cost (EUR) per hectare*	**Possible alternative**	**Cost range for possible alternative substances** Cost (EUR) per hectare*
Acetamiprid (I)	3.43	Fludioxonil, Spirotetramat, Tebufenozide, Flonicamid, Avermectin	0.03 to 4.58
Clothianidin (I)	0.82	Pyriproxyfen	0.55
Thiacloprid (I)	0.61	See alternatives to acetamiprid	
Thiamethoxam (I)	0.92	No likely alternatives identified yet	
Bifenthrin (I)	0.24	Cypermethrin	0.07
Esfenvalerate (I)		Lambda-cyhalothrin	0.03
Deltamethrin (I)	0.06	Lambda-cyhalothrin, Pirimicarb	0.03 to 0.33
Nicosulfuron (H)	0.27	Mesotrione, Tembotrione, Glyphosate	0.62 to 1.53
Glyphosate (H)	1.53	Penoxsulam, Florasulam, Oxyfluorfen, Propaquizafop, Clethodim, Metribuzin, Dicamba, Diflufenican, Bentazone, Propyzamide, Bifenox, Chlorotoluron	0.02 to 4.12

* Only possible substitute substances within a price range of max 3.5x the costs of the original substance are included in the table. Costs are converted using an average of USD 1 = EUR 0.8619 for the period between 6 April 2021 to 6 April 2022.

For pesticides in particular a major pathway to environment is run-off from fields, with spray-drift as secondary pathway. This assumes 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 stakeholder workshops indicated that the use of physical barriers is not at saturation level and more can be done. Consequently, calculations have been undertaken to derive indicative (orders of magnitude) costs attributed to the application of pathway disruption[141] for pesticides using physical barriers (see Table A10.3 below). 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 uncertainty in the estimates, and the values in table should only 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.

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

Table A10.3: Pesticides for which the use of physical barriers could possibly be further increased, and associated costs of such measures

Substance	Measure	Total cost* (€), million
Acetamiprid	Physical barriers to surface water buffer strips (see notes to right)	1.6
Clothianidin	Potential to create physical barriers to surface water seems particularly high in the intensive rearing of poultry sector due to use as biocide. Additional emission controls for farm waste.	162
Imidacloprid	Potential to create physical barriers to surface water seems particularly high in the intensive rearing of poultry sector due to use as biocide. Additional emission controls for farm waste.	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	No data
Glyphosate	Physical barriers to surface water buffer strips	284.7

*Cost calculations for 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.

Cost calculations for 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.

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 be important. Conversely, the use of biocides, can be carried out both in outdoor settings (e.g., sheep-dips), and indoor settings (stables, coops, domestic homes, work-places, etc.). Therefore, for biocidal uses, particularly within indoor settings, the potential was wash-off or rinsing to drains during cleaning and maintenance is an issue. Based on work already completed by the JRC to support the revision of the urban wastewater directive and further implementation of quaternary treatment technologies, an analysis of technologies, unit prices, and efficacies for the possible removal of specific substances was made. The same methodology as outlined in the previous sub-section for pharmaceuticals has been used to help identify options and costs for end-of-pipe measures for those substances with biocidal uses. Table A10.4 below provides these results.

Table A10.4: Estimated costs of end-of-pipe measures for biocides

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

* Costs for EU27 in € / year - costs are amortised (assuming 25 year asset lifetime)

Groundwater measures

Table A10.6: Costs of selected measures to address groundwater pollution by PFAS

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 an assumed total of 10-20 airfields / fire training stations sites at EU level identified for remediation.
Groundwater remediation	Receptor remediation	EU level	€1.7-€35 million / yr at EU level (annualised over 30 years)	Soil remediation costs per site are given for low (2,700 m^3) and high (28,125 m^3) volumes of contaminated soils: • Soil incineration - €0.5-18 million per site • Landfill – €2.5-38 million per site Groundwater pump and treat costs per site is €2.9-30.3 million over a 30-year period of construction, operation and maintenance (120). Annual equivalent costs are €0.17 million-€1.75 million per site respectively.
Capture of biosolids for treatment	End of pipe 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 (121)) - €201 million per year.
Capture of industrial waste, e.g. in 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 (122). 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 m^3/yr leachate (123).
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 may contain PFAS	Source control (Behavioural)	per MS	Millions	See see Section 6.2.1 and table A9.7 for derivation

Measure	Type of measure	Unit	Unit cost	Comment on calculation
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 6.2.1 and table A9.7 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.

Table A10.7: Costs of selected measures to address groundwater pollution by pharmaceuticals

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Unit	Unit cost	Comments
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. Product substitution deemed not feasible for carbamazepine in animals (costs of €140,000).
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	
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	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.

Measure	Type of measure	Sulfamethoxazole	Carbamazpine	Primidone	Unit	Unit cost	Comments
						temperature incineration	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 (121)) - €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.

Table A10.8: Costs of selected measures to address groundwater pollution by nrMs

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	No EU estimate / extrapolations available only, limited indicative data from 1 Member State	Irish EPA expenditure on landfill remediation in 2019 at 122 sites €158.4 million ranging from €690,000 to €77 million to per site.

ANNEX 11: SURFACE WATER MONITORING DATA

Table A11.1: Monitoring data for candidate PS

Substance			Main uses / sources of pollution	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing surface water concentration data
Pharmaceuticals	Estrogenic hormones	**Estrone (E1)**	Used as medication, e.g. in hormonal birth control, menopausal hormone therapy, treatment of hormone-sensitive cancers.	1.59 (0.0003-24.49)	CZ, ES
		17-eta-estradiol (E2)		0.00095 (0.0003-0.0033)	CZ, RO
		Ethylestradiol (EE2)		0.000882 (0.00005-0.005)	CZ, RO
	Macrolide antibiotics	**Azithromycin**	Used in animal farming and as medication to treat various infections	41.5 (0.01-3,145.38)	CZ, ES
		Clarithromycin		15.4 (0.01-391)	CZ, ES, DE
		Erythromycin		17.2 (0.01-200)	CZ, ES, DE
	Other	**Carbamazepine**	Used as medication to treat trigeminal neuralgia, diabetic neuropathy and bipolar disorder.	0.053 (0.005-1.85)	CZ, DE, ES, LU, NL
		Diclofenac	Used as medication to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis.	15.1 (0.005-3,998)	CZ, DE, ES, LU, RO
		Ibuprofen	Used as medication to reduce fever and treat pain or inflammation caused by many conditions.	0.0740 (0.005-10)	CZ, DE
Pesticides	Neonicotinoids	**Acetamiprid**	Used to control insect pests in agriculture (crops, vegetables, fruits), animal farming (e.g. for invertebrate pest control in fish farming).	0.0055 (0.000195 – 0.0644)	Data anonymised
		Clothianidin		1.45 (0.005-25)	CZ, ES, SE
		Imidacloprid		2.83 (0.00005-400)	CZ, DE, ES, IT, NL, SE
		Thiacloprid		1.02 (0.0005-88)	CZ, ES, FI, IT, SE
		Thiamethoxam		0.0437 (0.0005 – 2.7135)	Data anonymised
	Pyrethroids	**Bifenthrin**	Used to control insect pests in agriculture, public health and animal farming.	0.1125 (0.0338 – 0.436)	Data anonymised
		Deltamethrin		0.0535 (0.001 – 0.19)	Data anonymised
		Esfenvalerate		0.0430 (0.004 - 0.1495)	Data anonymised
		Permethrin		0.162 (0.0005-20)	CZ, FI, FR, IT, SE
	Other	**Glyphosate**	Used as an herbicide to control weeds and grasses. Current approval expires December 2022, but likely to be extended.	0.525 (0.001-790)	CZ, DE, ES, FI, FR, IE, IT, NL, SE, SK
		Nicosulfuron	Used as an herbicide to control weeds.	0.0160 (0.00206-3)	DE
		Triclosan	Used as an antibacterial and antifungal agent in some consumer products, including toothpaste, soaps, detergents, toys, and surgical cleaning treatments. Also added to other materials, such as textiles, to make them resistant to bacteria.	0.0142 (0.0001-0.458)	CZ, DE

Substance		Main uses / sources of pollution	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing surface water concentration data
Industrial chemicals	**Bisphenol A**	Used in the manufacture of various plastics, including for shatterproof windows, eyewear, water bottles, and epoxy resins that coat some metal food cans, bottle tops, and water supply pipes.	0.623 (0.0005-1,300)	CZ, DE, ES, FI, IT, LT, SK
	PFOA and PFOS and its derivatives (PFAS)	Used in stain- and water-resistant fabrics and carpeting, cleaning products, paints, and fire-fighting foams.	0.288 (0.00003-120)	CZ, DE, ES, FR, IT
Metals	**Silver**	Nanosilver and other forms of (ionic) silver are widely used nowadays for their antibacterial activity, e.g. in silver containing personal care products (PCP), medical products and a wide range of other consumer products. It is noted that currently, products that contain forms of (nano)silver are difficult to track since they are marketed under numerous brand names, and, with a few exceptions, current labelling regulations do not specifically require listing nanomaterials as a constituent. In some areas silver is also a naturally occurring substance e.g. around metal mines.	0.524 (0.003-25)	CZ, DE, FR, IE, IT, LU, NL, PL, RO

Table A11.2: Monitoring data for existing PS

Substance		Main uses / sources of pollution	Current EQS for inland surface waters µg/L	No. of WBs with EQS exceedance	No. of MS with at least 1 WB in exceedance[142] (pass /fail)	MS reporting exceedances (as pass/fail status)	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing concentration data
Substances considered for EQS amendment								
Pesticides	**Chlorpyrifos**	Past use as an insecticide to control foliage and soil-borne insect pests on a variety of food and feed crops. Not approved since 2019. No ongoing commercial use.	AA: 0.03 MAC: 0.1	523	9	BE, CY, CZ, DE, ES, FR, IT, NL, SK	0.187 (0-500)	AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SK
Pesticides	**Cypermethrin**	Used in the protection of wood against wood-destroying insects, applied as an insecticide in agriculture and topically in veterinary applications. Ongoing commercial use.	AA: 8 10^{-5} MAC: 6 10^{-4}	9	1	CZ	(<LOQ (0.01) – 0.0864)	ES, CZ, DE, FR
Pesticides	**Dicofol**	Not approved since 2008. No ongoing commercial use.	AA: 1.3 10^{-3} MAC: n/a	0	0	-	All below LOQ (0.0004)	CY, CZ, DE, ES, FR, IT
Pesticides	**Diuron**	Past use as a pre-emergence herbicide for general weed control on non-croplands, in and around water bodies and as a component of marine anti-fouling paints. Not approved for pesticide use since 2020. Still used within industrial chemicals.	AA: 0.2 MAC: 1.8	1,509	11	BE, CZ, DE, EL, ES, FR, HU,IT, NL, NO, SK	0.390 (0-2,295)	AT, BE, CY, CZ, DE, DL, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK
Pesticides	**Heptachlor / Heptachlor epoxide**	Past use as an insecticide to control various insect pests, and for soil and seed treatment, wood protection. Banned in the EU since 1984. No ongoing commercial use.	AA: 2 10^{-7} MAC: 0.0003	39	6	CY, DE, ES, FR, HR, IT	0.546 (0-20)	BE, CY, CZ, DE, EL, ES, FI, FR, HR, IT, LT, NL, PT, SK
Pesticides	**Hexachloro-benzene**	Past use as a fungicide for seed treatment, especially on wheat to control the fungal disease bunt. Banned in the EU since the early 1980s. No ongoing commercial use.	AA: n/a MAC: 0.05	868	14	AT, CZ, DE, EL,ES, FR, IT, LT, NL, NO, PL, RO, SE, SK	0.123 (0-1,000)	AT, BE, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LV, LU, MT, NL, PL, PT, RO, SK
Pesticides	**Tributyltin**	Past use as a biocide in anti-fouling paints on ships and boats. Banned. No ongoing commercial use.	AA: 0.0002 MAC: 0.0015	1,988	18	AT, BE, CZ, DE, EL, ES, FI, FR, IT, LT, LV, NL, NO, PL, PT, SE, SI, SK	0.261 (0-100)	BE, CZ, DE, ES, FR, LU, MT, NL, PL, SK

[142] Based on pass/fail data reported by MS under the 2nd RBMPs

Substance		Main uses / sources of pollution	Current EQS for inland surface waters µg/L	No. of WBs with EQS exceedance	No. of MS with at least 1 WB in exceedance[142] (pass/fail)	MS reporting exceedances (as pass/fail status)	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing concentration data
Industrial chemicals	**Dioxins**	Mainly by-products of industrial practices, e.g. chlorine bleaching of pulp and paper. Also formed during combustion processes (including smoking). No commercial use.	AA: n/a MAC: n/a	Unknown	Unknown	Unknown	0.843 (0-580)	BE, BG, CY, DE, EL, ES, FR, HR, IT, IU, NL, RO, SK
Industrial chemicals	**Fluoranthene**	PAH family member found in crude oil and distillates. Use as a binding agent in industrial processes, in consumer products such as clay pigeons, and activated carbon, and in professional uses such as road construction. Ongoing commercial use.	AA: 0.0063 MAC: 0.12	2,367	17	BE, CZ, DE, EL, ES, FR, HU, IT, LT, LU, MT, NL, NO, PL, RO, SE, SK	0.552 (0-5,350)	AT, BE, BG, CY, CZ, DE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK
Industrial chemicals	**Hexabromo-cyclododecane**	Used as flame-retardant within insulation boarding, plastics, and textiles.	AA: 0.0016 MAC: 0.5	8	2	CZ, DE	(<LOQ (0.0001) – 0.056)	CZ, DE
Industrial chemicals	**Hexachloro-butadiene**	Unintentional by-product of the chemicals industry, e.g. the manufacture of chlorinated solvents, magnesium production and incineration.	AA: n/a MAC: 0.6	811	11	BG, CZ, DE, EL, ES, FR, IE, IT, NL, NO, SK	0.530 (0-100)	AT, BE, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, RO, SK
Industrial chemicals	**Nonyl phenol**	Past use in industrial processes (e.g. for washing and dying of yarns and fabrics) and in consumer laundry detergents, personal hygiene, automotive, latex paints, and lawn care products. Production and majority of uses have been restricted since 2003. No ongoing intentional use but imported textiles still an issue.	AA: 0.3 MAC: 2	986	11	CZ, DE, EL, ES, FR, HU, IT, NO, PT, SE, SK	0.0863 (0.005-0.15) (based on only 4 data entries by 1 MS)	DE
Industrial chemicals	**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.	AA: 0.0017 MAC: 0.27	3,926	19	AT, BE, CZ, DE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, NO, PL, RO, SE, SK	0.221 (0-2,180)	AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK

Substance		Main uses / sources of pollution	Current EQS for inland surface waters µg/L	No. of WBs with EQS exceedance	No. of MS with at least 1 WB in exceedance[142](pass/fail)	MS reporting exceedances (as pass/fail status)	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing concentration data
	PBDEs	Used as flame-retardants in plastics, furniture, upholstery, electrical equipment, electronic devices, textiles and other household products. Use of lower order homologues was banned internationally in 2004 and use of DecaBDE should have ceased by 2021. Primarily a legacy issue for in-use stock and landfill.	AA: n/a MAC: 0.14	23,800	9	BE, CZ, DE, EL, FR, IT, LV, SE, SK	0.0465 (0-5)	DE, ES, FR, LU, MT, PL, SK
Metals	**Mercury**	Naturally occurring substance. Wide range of uses, e.g. in thermometers, barometers, manometers, blood pressure meters, float valves, mercury switches, mercury relays, fluorescent lamps and other devices. Also forms during combustion of fossil fuels. Ongoing commercial use and unintentional formation.	AA: n/a MAC: 0.07	46,780	25	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, RO, SE, SI, SK	3.54 (0-5,800)	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
Metals	**Nickel**	Naturally occurring substance. Used to make stainless steel and other alloys, for plating, foundry and batteries. Ongoing commercial use.	AA: 4 MAC: 34	1,840	22	BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HU, IE, IT, LV, MT, NL, NO, PL, PT, RO, SE, SK	627 (0-2 10^6)	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SK
Substances considered for deselection[143]								
Pesticides	**Alachlor**	Past use as an herbicide to control grasses and weeds. No longer approved for use in the EU.	AA: 0.3 MAC: 0.7	488	10	BE, CY, CZ, DE, EL, ES, FR, IT, RO, SK	0.0674 (0.0003 100)	AT, BE, CY, CZ, DE,ES, FI, FR, HR, IT, LU, MT, NL, PL, PT, RO, RS, SK
Pesticides	**Chlorfen -vinphos**	Insecticide to control ticks and biting insects for protection of livestock. It has also been used as an insecticide to protect ground crops, such as potatoes and vegetables. No longer approved for use in the EU.	AA: 0.1 MAC: 0.3	809	7	EL, ES, FR, IT, PL, SE, SK	0.122 (0.0005 500)	BE, CY, CZ, DE, ES, FI, FR, HR, IT, LU, MT, NL, PL, RO, RS, SK

[143] Information in columns on the 'No. of WBs with EQS exceedances' and 'No. of MS with at least 1 WB in exceedance' is based on information from the corresponding EEA dashboard(s)

Substance		Main uses / sources of pollution	Current EQS for inland surface waters µg/L	No. of WBs with EQS exceedance	No. of MS with at least 1 WB in exceedance[142] (pass/fail)	MS reporting exceedances (as pass/fail status)	Indication of current concentrations in surface water mean (min and max) µg/L	MS providing concentration data
	Simazine	Past use as an herbicide to control grasses and weeds. No longer approved for use in the EU.	AA: 1 MAC: 4	1,292	5	DE, ES, FR, IT, SK	0.106 (0.00001 - 100)	AT, BE, BG, CY, CZ, DE, EL, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, PL, RO, RS, SK
Industrial chemicals	**Carbon tetrachloride**	Primarily used as a solvent for oils, waxes, resins, and runner. Also used as an intermediate in the manufacture of refrigerants and propellants for aerosol cans. Ongoing commercial use.	AA: 12 MAC: n/a	1,206	4	DE, FR, IT, SK	1.206 (0.0002 - 87.58)	IT, PL, ES, DE, BE, CY, CZ, FR, HR, IE, LU, NL, MT, SK,
	Trichloro-benzenes	Family of chemicals primarily used as solvents and chemical intermediates for other compounds. Sectors of use include as solvent degreaser (primarily for oils and waxes), and to produce dyes and textiles. Ongoing commercial use.	AA: 0.4 MAC: n/a	785	6	CZ, DE, ES, FR, IT, SK	0.510 (0.0001 - 100)	AT, BE, CY, CZ, DE,EL, ES, FR, HR, IE, IT, LU, MT, NL, PL, RO, SK

ANNEX 12: LITERATURE REFERENCES

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