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Selection of substances for the 5th Watch List under the Water Framework Directive

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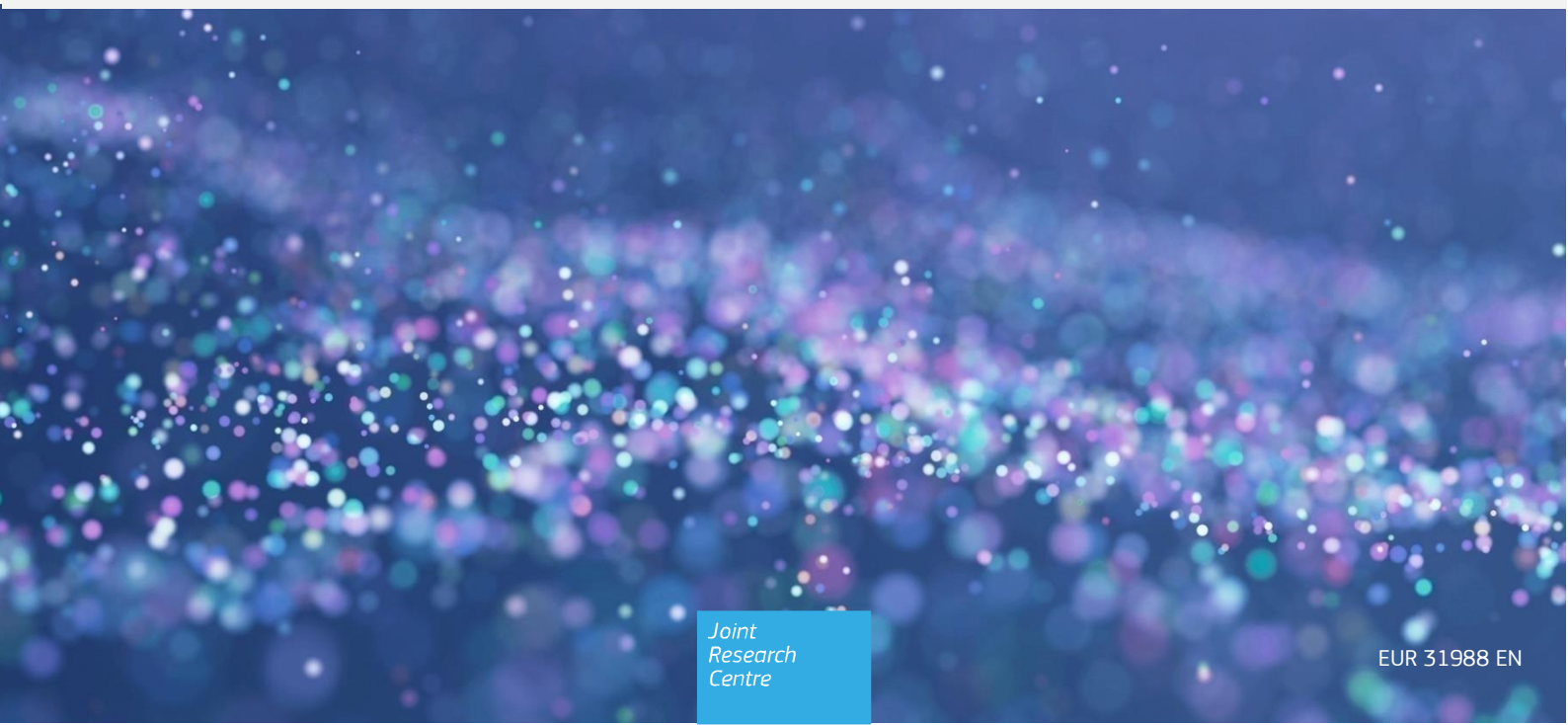

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Contents

Abstract

The surface water Watch List (WL) under the Water Framework Directive (WFD) is a mechanism for collecting high-quality Union-wide monitoring data on emerging pollutants and substances that may pose a significant risk at Union level to or *via* the aquatic environment, but for which available monitoring data are insufficient to draw conclusions on the actual risk posed. According to Article 8b of the Environmental Quality Standards Directive (EQSD Directive 2008/105/EC as amended by Directive 2013/39/EU), the WL should be updated every two years.

The obligation to remove substances from the list that have been on it continuously for four years, combined with analysis of the monitoring data from the 4th WL, leads to the conclusion that up to nine new substances could be added to the 5th WL if it is to contain the maximum allowed number of fourteen substances or groups of substances.

The JRC defined three criteria for identifying substances for the 5th WL, and based on these criteria, seven substances or groups of substances were selected as most suitable candidates for the 5th WL. They include the industrial product N-1,3-Dimethylbutyl-N'-phenyl-p-phenylenediamine (6PPD) and its transformation product 6PPD-quinone; a group of ten azole fungicides, among them three pharmaceuticals (climbazole, itraconazole and ketoconazole), one biocidal product (propiconazole), five Plant Protection Products (PPP) (bromuconazole, cyazofamid, difenoconazole, mefentrifluconazole, and triticonazole), and epoxiconazole, although it is no longer approved as PPP; two other PPPs used as insecticides (abamectin and etoxazole); a group of tetracycline-class antibiotics (tetracycline and oxytetracycline) and two other pharmaceuticals (fluoxetine and propranolol). An additional substance (ethylhexyl salicylate or octisalate) is proposed to be included in the group of sunscreen agents already included in the 4th WL update (EU/2022/1307).

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We would like to thank Helen Clayton of Unit C1, DG ENV for her helpful comments and discussions as well as all Member State experts and stakeholders for information, comments and suggestions. We are particularly grateful to the experts who provided information on Environmental Quality Standards or analytical methods, in some cases complete substance dossiers. Finally, we acknowledge Ana Carolina de Almeida Kumlien for the literature and information search and support preparing the substances' factsheets and Robert Loos for his useful comments and suggestions.

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Executive summary

The surface water Watch List (WL) under the Water Framework Directive (WFD) is a mechanism for collecting high-quality Union-wide monitoring data on emerging pollutants and substances that may pose a significant risk at Union level to or *via* the aquatic environment, but for which available monitoring data are insufficient to draw conclusions on the actual risk posed. According to Article 8b of the Environmental Quality Standards Directive (EQSD - Directive 2008/105/EC as amended by Directive 2013/39/EU), the WL should be updated every two years.

Up to nine new substances could be added to the 5th WL if it is to contain the maximum allowed number of fourteen substances or groups of substances, assuming that those added in 2020 are removed (as required after four years) as well as two of the substances (azoxystrobin and diflufenican) added to the 4th WL in 2022. For those two, analysis shows that sufficient high-quality monitoring data have been collected for the risk assessment.

The purpose of this report is to propose candidate substances for the 5th WL.

Three criteria were used to identify and select the candidate substances:

1. Substances shortlisted, but not included in the 4th WL because of limitations of the monitoring methods available at the time or unreliable Predicted No-Effect Concentration (PNEC) information, and for those that an adequately sensitive analytical method and a reliable PNEC have become available.

2. Recommendations from Member States (MS) and stakeholders as established in Article 8b of Directive 2008/105/EC, again where adequate methods and reliable PNEC are available.

3. Substances of emerging concern (e.g. industrial products, pharmaceuticals, plant protection products –PPP- and biocides identified based on research projects and articles, in line with Article 8b of Directive 2008/105/EC), where adequate methods and reliable PNEC are available.

To prioritise substances for inclusion in the WL it is important to take into account the existence of reliable information on the toxicity of the substances pointing to a possible risk.

Particularly important is, then, the availability of a reliable PNEC to define the safety threshold, and relevant analytical methods for monitoring in the appropriate environmental matrix. Although the PNEC is based on ecotoxicity data, hazard properties were also taken into account to support the selection, i.e. the persistence, bioaccumulation, carcinogenicity, mutagenicity, toxicity to reproduction, endocrine disruption and contribution to Antimicrobial Resistance (AMR).

Using these criteria, the JRC classified the selected substances as most suitable candidates for the 5th WL.

In the first outline of the report, the JRC proposed candidates for inclusion in the next WL based mainly on selection criteria 1 and 3. In this report, Table 1 has been modified as explained in Chapter 2 and shown here as Table S1 to amend the list of the most suitable substances for the 5th WL taking into account the suggestions, recommendations and comments of MS and stakeholders. The eight substances/groups of substances in bold are proposed for the 5th WL, while the others are listed as alternatives. Seven out of the eight substances in bold are proposed as new substances/groups, while one substance is proposed to be added to the existing group of sunscreen agents introduced in the 4th WL (EU/2022/1307).

Among the substances suggested by the WG Chemicals, Per- and Polyfluoroalkyl Substances (PFAS) and pyrethroids have not been included, because four pyrethroids and twenty-four PFAS are already included in the Commission's proposal to revise the Priority Substances (PS) list (EC 2022). Due to their hazard properties and high concern, additional PFAS and/or pyrethroids could be proposed for addition to the PS list at the next review, without prior WL monitoring.

Table S1. List of the most suitable WL candidate substances, fulfilling the selection criteria and updated following comments from Member States (MS) and stakeholder groups (after circulating the first outline of the 5th WL report and after the WG Chemicals meeting held in October 2023). In bold, substances selected for the 5th WL, and listed in alphabetical order. The others are potential alternatives, also listed in alphabetical order. Matrix: environmental compartment for monitoring. PNEC: Predicted No-Effect Concentration; PPP: Plant Protection Product. Further abbreviations are included in the list on pages 78-79.

Substance/group Name	CAS Number	Use	PNEC	Matrix
6PPD and its transformation product 6PPD-quinone	793-24-8 **6PPD**	Industrial (tyre rubber antioxidant)	0.37 µg/L PNEC freshwater ECHA (2023)	Water
	2754428-18-5 **6PPD-quinone**	Transformation product of 6PPD		Water
Abamectin	Abamectin (CAS N. 71751-41-2) is a mixture of ≥ 80% avermectin B1a (CAS N. 65195-55-3) and < 20% avermectin B1b (CAS N. 65195-56-4).	PPP (insecticide and anthelmintic) Pharmaceutical (anthelmintic, veterinary only) Avermectin family	0.001 µg/L RIVM (2008) and SYKE (2011)	Water
Group of azole fungicides	116255-48-2 **Bromuconazole**	PPP (azole fungicide)	0.015 µg/L RIVM indicative value (MTR)	Water
	38083-17-9 **Climbazole**	Pharmaceutical (azole fungicide)	0.11 µg/L CQC ad hoc - Switzerland	Water
	120116-88-3 **Cyazofamid**	PPP (azole fungicide)	0.13 µg/L RIVM (2006)	Water
	119446-68-3 **Difenoconazole**	PPP (azole fungicide)	0.36 µg/L UBA (2020)	Water
	133855-98-8 **Epoxiconazole**	PPP currently not approved in EU (azole fungicide)	0.18 µg/L INERIS, 2011	Water

	84625-61-6 **Itraconazole**	Pharmaceutical (azole fungicide)	0.008 µg/L PNEC-(resistance selection) Bengtsson-Palme and Larsson, 2016	Water
	65277-42-1 **Ketoconazole**	Pharmaceutical (azole fungicide)	0.05 µg/L Vestel et al., 2016	Water
	1417782-03-6 **Mefentrifluconazole**	PPP (azole fungicide)	1.6 µg/L Registration report, 2018	Water
	60207-90-1 **Propiconazole**	Biocide (azole fungicide)	1 µg/L (UBA, 2023)	Water
	131983-72-7 **Triticonazole**	PPP (azole fungicide)	1 µg/L CQC ad hoc - Swiss Ecotoxcentre (from NORMAN)	Water
Etoxazole	153233-91-1	PPP (acaricide and insecticide)	0.0004 µg/L RIVM, 2014	Water
Fluoxetine	54910-89-3	Pharmaceutical (Prozac)	0.012 µg/L Oakes et al., 2010	Water
Propranolol	525-66-6	Pharmaceutical - antihypertensive	0.02 µg/L Vestel et al. (2016); RIVM (2020)	Water
Group of tetracycline class antibiotics	79-57-2 **Oxytetracycline**	Antibiotic – Tetracycline class	0.5 µg/L PNEC-(resistance selection) AMR Industry Alliance Antibiotic, 2023	Water

	60-54-8 **Tetracycline**	Antibiotic – Tetracycline class	0.09 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)	Water
Sunscreen Agents: Octisalate[1]	118-60-5	Cosmetic products UV filter	0.168 µg/L ECHA	Water
Amisulbrom	348635-87-0	Fungicide	0.229 µg/L UBA (2020)	Water
Group of antiarrhythmic – medicines	1951-25-3 Amiodarone	Pharmaceutical - antiarrhythmic medicine	0.24 µg/L RIVM (2020)	Water
	141625-93-6 Dronedarone	Pharmaceutical - antiarrhythmic medicine	0.4 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN and FASS)	Water
Citalopram	59729-33-8	Pharmaceutical (serotonin-selective reuptake inhibitor) for treating depression and anxiety	6.4 µg/L LANUV (2016)	Water
Cyprodinil	121552-61-2	PPP (anilinopyrimidine fungicide)	0.026 µg/L INERIS, 2011	Water
Disulfiram	97-77-8	Pharmaceutical - chronic alcoholism	0.02 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)	Water
Gemfibrozil	25812-30-0	Pharmaceutical Treatment of abnormal blood lipid levels	0.5 µg/L Ecotox Knowledgebase (from NORMAN)	Water

[1] To be added to the group of sunscreen agents already included in the 4th WL (EU/2022/1307).

Norfloxacin	70458-96-7	Antibiotic – Quinolone class	0.16 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)	Water
Tylosin	1401-69-0	Antibiotic – Macrolide class	1 µg/L PNEC-ENV AMR Industry Alliance (2023)	Water

Source: EC-JRC

1. Introduction

The surface water Watch List (WL) under the Water Framework Directive (WFD) is a mechanism for collecting high-quality Union-wide monitoring data on emerging pollutants and substances that may pose a significant risk at Union level to or *via* the aquatic environment, but for which available monitoring data are insufficient to draw conclusions on the actual risk posed. According to Article 8b of the Environmental Quality Standards Directive (EQSD - Directive 2008/105/EC as amended by Directive 2013/39/EU), the WL should be updated every two years. When updating the WL, the Commission should remove any substance for which a risk-based assessment can be concluded without additional monitoring data. New substances or groups of substances may be added to the WL during each update. The maximum number of substances or groups of substances that the Commission is allowed to include in the list increases by one at each update to a maximum of 14 substances or groups of substances. The duration of a continuous WL monitoring period for any individual substance may not exceed four years.

The 1st WL for substances in surface water under the Environmental Quality Standards Directive (EQSD - Directive 2013/39/EU) was established by the Commission Implementing Decision (EU) 2015/495 in March 2015. The list was first updated in June 2018 by the Commission Implementing Decision (EU) 2018/840, and a second time in August 2020 by the Commission Implementing Decision (EU) 2020/1161.

The period of continuous monitoring for any WL substance should not exceed four years (Article 8b of the EQSD). Thus, in 2022 the three substances added in 2018, i.e. the insecticide metaflumizone and the antibiotics amoxicillin and ciprofloxacin, were removed.

Six substances/groups of substances were added to the 3rd WL (EU/2020/1161) and kept also in the 4th WL (EU/2022/1307), including the antibiotics sulfamethoxazole and trimethoprim, the antidepressant venlafaxine and its metabolite o-desmethylvenlafaxine, a group of ten azole compounds used as antifungal pharmaceuticals or pesticides and the fungicides dimoxystrobin and famoxadone.

The above six substances/groups of substances need to be removed at the next update. A risk assessment will be carried out for these substances (if possible) after processing the latest monitoring data reported by the MS to the European Environmental Agency (EEA) in 2023 (a dedicated report is being prepared by the JRC).

For two substances added in 2022 to the 4th WL, i.e. the fungicide azoxystrobin and the herbicide diflufenican, the analysis shows that sufficient high-quality monitoring data are available for a risk assessment to be conducted. Thus, they too could be removed from the list. However, the remaining five substances or groups of substances added during the 2022 WL update (EU/2022/1307), i.e. the insecticide and veterinary pharmaceutical fipronil, the antibiotics clindamycin and ofloxacin, the human pharmaceutical metformin and its metabolite guanylurea, and the group of three sunscreen agents (butyl methoxydibenzoylmethane, also known as avobenzone; octocrylene; and benzophenone-3, also known as oxybenzone), should be carried over to the 5th WL to ensure that enough high-quality monitoring data are collected for their risk assessment. Thus, at least seven (and up to nine) new substances could be added to the 5th WL such that it would contain 12 or up to 14 substances or groups of substances.

The purpose of the present report is to propose candidate substances to be included in the 5th WL.

The report is structured as follows:

Chapter 2: Selection of substances for the WL. This chapter describes the overall process for selecting candidate substances for the WL. Section 2.1. describes the criteria for selecting the substances, Section 2.2 lists the substances fulfilling the criteria and Section 2.3 explains the rationale for the selection.

Chapter 3: Recommendations and Conclusions. This chapter describes the recommendations and gives the conclusions for the 5th WL.

The report also includes four annexes: **Annex I**: Sources of information; **Annex II**: Tables containing additional information regarding antibiotics, fungicides and azole related substances; **Annex III**: Factsheets for the candidate substances (a separate document). **Annex IV**: Summary of additional monitoring data for folpet and metazachlor. Supporting information in a separate Excel file for additional substances proposed by Members of the WG Chemicals.

2. Selection of substances for the WL

To select the substances, the following sources of information were considered: the outcome of the selection of substances for the 4th Watch List (WL) under the Water Framework Directive (WFD) (Gomez Cortes et al., 2022); recommendations from Member States (MS) and stakeholders as established in Article 8b of the Environmental Quality Standards Directive (EQSD), and literature search and other information (COM/2019/128 final). Moreover, a search for information on exposure to each substance in the aquatic environment was carried out in order to avoid proposing substances for which enough monitoring data are already available. For the freshwater compartment, Environmental Quality Standards (EQS) or Predicted No-Effect Concentration (PNEC) values were collected or derived considering toxicity effects to aquatic freshwater organisms ($PNEC_{fw,eco}$). For highly hydrophobic substances, the EQS or PNEC values were also considered for sediment-dwelling organisms ($PNEC_{eco,sed}$). EQS or PNEC values should protect freshwater and marine ecosystems from possible adverse effects of chemicals.

Hazard properties of the substances, such as Persistence (P), Bioaccumulation (B), Toxicity (T), Carcinogenicity (C), Mutagenicity (M), Reproductive Toxicity (R) and Endocrine Disruption (ED), were also investigated, as were the substances' usage and authorisation or approval status.

Annex I includes all information on the sources used by the JRC for the selection of candidate substances for the 5th WL.

2.1. Criteria for identification of candidate substances for WL update

The JRC proposes three **criteria** for the identification of new Watch List (WL) substances, in addition to the criterion that more (reliable) monitoring data are needed to determine the risk posed by them.

Respecting the requirements of the Environmental Quality Standards (EQS) Directive (Directive 2008/105/EC as amended by Directive 2013/39/EU), the JRC proposes the following **criteria** for identifying potential candidates for inclusion in the 5th WL:

1. Substances shortlisted, but not included in the 4th WL because of limitations in the monitoring methods available at the time or unreliable Predicted No-Effect Concentration (PNEC) information, and for those that an adequately sensitive analytical method and a reliable PNEC have become available.
2. Recommendations from MS and stakeholders as established in Article 8b of Directive 2008/105/EC, again where adequate methods and reliable PNECs are available.
3. Substances of emerging concern (e.g. industrial products, pharmaceuticals, plant protection products and biocides) identified based on research projects and articles, in line with the article 8b of Directive 2008/105/EC, again where adequate methods and reliable PNECs are available.

Please note that banned substances are not taken into consideration as potential candidates for the WL following the final recommendation cited in the document on the development of the 1st WL (Carvalho et al., 2015). An exception is made in this report for the substance epoxiconazole, which is currently not approved in the EU as PPP, but it is included in the group of azole fungicides due to its persistence and toxicity.

When considering the inclusion of a substance in the WL, consideration should be given to the

persistence of the substance and to the relevant monitoring matrix (and thus for the availability of reliable PNEC and relevant analytical methods).

The selection of candidate substances should take into consideration also other hazard properties, including the contribution to antimicrobial resistance (AMR) for antibiotics and potentially for fungicides.

The preferred monitoring matrix for hydrophobic substances with high octanol/water partition coefficient values (log K_{OW}) is sediment or biota as recommended in the WFD CIS Guidance document No. 25 (Guidance document No. 25 on chemical monitoring of sediment and biota under the WFD 2010). Compounds with log K_{OW} > 5 should preferably be measured in sediments, or suspended particulate matter (SPM), while compounds with a log K_{OW} < 3 should preferably be measured in water. Then, for compounds with a log K_{OW} between 3 and 5, either the liquid, sediment or SPM matrix may be used depending on the degree of contamination (a more precise investigation of the partitioning behaviour is needed) (Loos et al., 2024).

Moreover, for substances with a potential to accumulate through food chains and thus to expose top predators via their diet (log K_{OW} > 3, biomagnification factor (BMF) > 1 or bioconcentration factor (BCF) ≥ 100 and not readily biodegradable), biota monitoring is also recommended (WFD CIS Guidance document No. 27. on Deriving Environmental Quality Standards. Updated version 2018).

2.2. List of substances fulfilling the criteria

In the first outline of the report, the JRC proposed candidates for inclusion in the next Watch List (WL) based only on the selection criteria 1 and 3. Taking account of the suggestions, recommendations and comments from MS and stakeholders, the selection of the substances has been revised and all the analysed substances have been grouped in three tables.

Table 1 lists sixteen substances or groups of substances as the most suitable candidates, and among them seven have been identified as the most suitable substances for the 5th WL (in bold). One additional substance has been selected to be included in the group of sunscreen agents, added to the WL in 2022 (4th WL, EU/2022/1307). Their prioritisation, as explained in Section 2.3 (Rationale for selection), has been based on hazard properties, contribution to Antimicrobial Resistance (AMR), widespread use, information on authorisation, the existence of a reliable Predicted No-Effect Concentration (PNEC) and analytical method(s), and the availability or lack of exposure data (sufficient amount with a good quality) to develop a screening of potential EU-wide risk.

Furthermore, as shown in Table 1, for each substance, recent data on Measured Environmental Concentrations (MEC), if available, were retrieved from the European Environment Agency (EEA) water quality database (the latest version from 2023 was used) or obtained from other sources and used to develop an initial tentative screening of risk. Further details on MECs (i.e. data quality check and statistical analysis), Predicted Environmental Concentrations (PEC) (if any) and results of risk evaluation are presented for each substance in a dedicated factsheet (see Annex III).

Table 2 includes substances which could be good candidates but for which some information is lacking, e.g. a reliable PNEC or adequately sensitive analytical method, or whose expiry date is close. For the latter, it is important to verify whether the renewal process is launched and the expiry date extended; if so, these substances could be selected as suitable candidates for the next WL.

Table 3 shows substances for which good-quality monitoring data are available from more than four

MS and for which a risk assessment could therefore be performed, as shown in the penultimate column of the table. The collected monitoring data were either retrieved from the WISE database of the EEA or sent by the MS to the JRC.

In this report, the calculated tentative Risk Quotients (RQ) are based usually on raw data for MECs (Sc2 data scenario) and should be considered as preliminary. Nevertheless, the performed tentative analysis includes an evaluation of the EU representativeness of the available exposure data and a check of the sensitivity of the analytical method in relation to the PNEC. Since this is an initial assessment, the derived statistical parameters for MECs and RQs were estimated using the common approach of substituting non-quantified values (censored data) by half the Limit of Quantification (LOQ). However, for completeness, the analysis of substances, particularly those listed in Table 1, was elaborated by applying an additional data-quality check, i.e. by calculating the MEC when excluding the non-quantified samples (i.e. Sc3 data scenario; for details see Carvalho et al., 2016).

Finally, to keep a record of the chronological process for the selection of substances, the identification of substances in the first outline is explained in the next paragraph and updated following the comments of the WG Chemicals. Subchapter 2.2.2 provides the overall analysis of the additional substances suggested by the members of the WG Chemicals.

Table 1. List of most suitable substances for the next WL. In bold the substances selected for the 5th WL. The substances are grouped according to their use or chemical structure (antibiotics, azole fungicides, industrial products, pharmaceuticals, PPP, and sunscreen agents). The groups are listed alphabetically. PPP: Plant Protection Products, LOQ: Limit of Quantification, PNEC: Predicted No-Effect Concentration.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
Antibiotics	Norfloxacin	70458-96-7	Pharmaceutical Antibiotic Quinolones class Human medicine	Suspected of impairing fertility or the unborn child (ECHA, 2023)	Authorised for use in the European Union	PNEC-ENV = 120 µg/L PNEC- (resistance selection) =0.5 µg/L AMR Industry Alliance **0.16 µg/L** ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)	LC–MS/MS LOQ = 62.5 ng/L (Chitescu et al., 2015)	No available data (WISE 2023, EEA). Additional information or data from SE, DE and NORMAN. Details provided in the factsheet.
	Group of Tetracycline antibiotics: Oxytetracycline Tetracycline	79-57-2 **Oxytetracycline**	Pharmaceutical Antibiotic Tetracycline class Human and veterinary	Suspected of impairing fertility or the unborn child, may cause harm to breast-fed children (ECHA,2023)	Authorised for use in the European Union	PNEC-ENV = 47 µg/L PNEC- (resistance selection) **0.5 µg/L** Source: AMR Industry Alliance Antibiotic (2023)	SPE-LC-MS/MS method quantification limits (MQL)=3.8 ng/L (Jia et al., 2009); LC–MS/MS LOQ = 24.3 ng/L (Chitescu et al., 2015)	WISE 2023 (EEA): 86 samples (all non-quantified) taken at 29 sites in 2 MS (BE and NL) during 2016-2019. The available data are insufficient and are not EU-representative. The quality of available data is not acceptable, and a reliable risk screening is not possible.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
								Additional information or data from AT, SE, DE and NORMAN. Details provided in the factsheet.
		60-54-8 **Tetracycline**	Pharmaceutical Antibiotic Tetracycline class Human and veterinary	Stockholm's list of environmentally harmful APIs Potentially persistent Very high acute toxicity. (Janusinfo, 2023)	Authorised for use in the European Union	PNEC-ENV = 3.2 µg/L PNEC- (resistance selection) =1 µg/L Source: AMR Industry Alliance (2023); **0.09 µg/L** ad hoc EQS List Swiss Ecotoxcentre	SPE-LC-MS/MS method quantification limits (MQL)=2.3 ng/L (Jia et al., 2009); UPLC-MS/MS LOQ = 3.9 ng/L (Sanseverino et al., 2022)	No available data (WISE 2023, EEA). Additional information or data from SE, DE and NORMAN. Details provided in the factsheet
	Tylosin	1401-69-0	Pharmaceutical Antibiotic class of Macrolides Veterinary use	Very toxic to aquatic life with long lasting effects. Suspected of causing cancer. Suspected of damaging the unborn child (ECHA,	Authorised for use in the European Union	PNEC-ENV = **1 µg/L** PNEC- (resistance selection) =4 µg/L AMR Industry Alliance (2023)	LC–MS/MS; LOQ = 29.4 ng/L (Chitescu et al., 2015)	No available data (WISE 2023, EEA). Additional information or data from SE, DE and NORMAN. Details provided in the factsheet

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
				2023)				
Azole Fungicides	**Group of ten azole fungicides Bromuconazole Climbazole Cyazofamid Difenoconazole Epoxiconazole Itraconazole Ketoconazole Mefentrifluconazole Propiconazole Triticonazole**	116255-48-2 **Bromuconazole**	Azole fungicide	Very toxic to aquatic life with long lasting effects) (ECHA, 2023c).	Approved as PPP (EU Pesticides database, expiry 30/04/2027)	1.5 µg/L CQC ad hoc - Switzerland **0.015 µg/L** RIVM indicative value (MTR)	LC-ESI-Q-Orbitrap-MS LOQ = 0.01 µg/L Casado et al. (2019) LC–MS/MS LOQ = 0.0115 µg/L Chitescu et al., (2015) Single method AR 74-89 (E): GC-ECD, conf. by GC-MSD (Bromuconazole) LOQ = 0.1 µg/L EFSA Scientific Report (2008)	No available data (WISE 2023, EEA). Additional information or data from AT and IT. PECs available. Details provided in the factsheet.
Azole Fungicides		38083-17-9 **Climbazole**	Pharmaceutical Topical antifungal agent commonly used in the treatment of human fungal skin infections	Under assessment as Endocrine Disrupting (https://echa.europa.eu/substance-	Authorised for use in the European Union	**0.11 µg/L** CQC ad hoc – Switzerland (from NORMAN); 0.79 µg/L (ECHA, 2023c)	UHPLC-MS/MS LOQ = 0.08 ng/L (Z.-F. Chen et al., 2012) Online solid phase extraction LC coupled to LC-Q-Exactive-HRMS system (LOQ = 0.1 ng/L Creusot et al.,	No available data (WISE 2023, EEA). Additional information or data from AT, SE, DE and NORMAN. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
				information/-/substanceinfo/100.048.870)			2020) SPE-LC-MS/MS (LOQ = 8.4 ng/L Iancu et al., 2023)	
		120116-88-3 **Cyazofamid**	Fungicide used as PPP	Very toxic to aquatic life and is very toxic to aquatic life with long lasting effects (ECHA)	Approved as PPP (EU Pesticides database, expiry 31/07/2036)	1.1 µg/L CQC ad hoc – Switzerland (from NORMAN); 0.77 µg/L (UBA, 2020) **0.13 µg/L** (RIVM, 2006)	LC–MS/MS UFZ LOQ = 0.0066 µg/L KGM 2019, Halbach et al., (2021)	No available data (WISE 2023, EEA). Additional information or data from AT, IT, SE, FI and NORMAN. Details provided in the factsheet.
		119446-68-3 **Difenoconazole**	Azole fungicide used as PPP	Very toxic to aquatic life with long-lasting effects Suspected of causing cancer (Carc. 2; H351) (RAC, 2021). Not classified (conclusive but not	Approved as PPP (EU Pesticides database, expiry 15/03/2026) National authorisation AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	**0.36 µg/L** UBA(2020); 0.56 µg/L (INERIS, 2013; EFSA, 2011); 0.76 µg/L RIVM (2008)	LC–MS/MS LOQ=0.032 µg/L Chitescu et al., (2015); LC-ESI-Q-Orbitrap-MS, LOQ=0.005 µg/L Casado et al., (2019); Solid phase extraction liquid chromatography coupled to LC-Q-Exactive-HRMS system, LOQ=0.8 ng/L Creusot et al., (2020)	No available data (WISE 2023, EEA). Additional information or data from AT, IT, SE, DE, FI and NORMAN. PECs available. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
				sufficient for classification). (CHL, 2020)				
Azole Fungicides		133855-98-8 **Epoxiconazole**		Suspected to be Carcinogenic Toxic to Reproduction. A majority of data submitters agree this substance is PBT (ECHA)	Not approved as PPP at EU level	0.2 µg/L Switzerland Swiss Ecotox Centre (2016); **0.18 µg/L** INERIS (2011); 0.46 µg/L (UBA (2020); 0.19 µg/L, RIVM (2013) 0.7 µg/L ECHA (2023)	LC–MS/MS, LOQ=0.0083 µg/L (Chitescu et al., 2015); LC-ESI-Q-Orbitrap-MS, LOQ=0.0025 µg/L (Casado et al., 2019)	WISE 2023 (EEA): 69894 samples (8.2% quantified) taken at 2225 sites in 9 MS (DE, EE, FI, FR, HR, IE, IT, NL, SE) during the period 2010-2020. Range of LOQs 0.002 – 0.05 µg/L. Good sensitivity of monitoring regarding PNEC=0.18 µg/L. However, these data are not EU-representative since 3 MS (FR, IT, NL) hold together about 97.7 % of all samples. In addition, the available data do not include recent exposure (after 2020). The WISE data showed exceedances in

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
								one MS. Information or additional data received from AT, DE, FI, IT, SE and NORMAN. The additional data showed exceedances in one MS. According to NORMAN, the available data showed a high frequency of quantification and some exceedances.
		84625-61-6 **Itraconazole**	Pharmaceutical Antifungal medicine (human and veterinary) for (aspergillosis and candidiasis)		Authorised for use in the European Union	**0.008 µg/L** PNEC- (resistance selection) (Bengtsson-Palme and Larsson, 2016) 0.013 µg/L ToxTrAMs (2017) (Predicted PNEC from NORMAN)	UHPLC-MS/MS (0.31 ng/L; Chen et al., 2012) SPE-LC-MS/MS (LOQ = 10 ng/L, Van De Steene et al., 2010)	No available data (WISE 2023, EEA) Additional info for exposure data from DE, FI and NORMAN. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
Azole Fungicides		65277-42-1 **Ketoconazole**	Pharmaceutical Antifungal medicine (human and veterinary)	Toxic to Reproduction (ECHA)	Authorised for use in the European Union	0.1 µg/L JanusInfo (2023) **0.05 µg/l;** Vestel et al. (2016); 0.0081 µg/L (Predicted-PNEC, NORMAN)	LC–MS/MS, LOQ=0.001 µg/L Chitescu et al. (2015); Online solid phase extraction LC coupled to LC-Q-Exactive-HRMS system, LOQ=0.7 ng/L, Creusot et al. (2020)	No available data (WISE 2023, EEA). Additional information or data from SE, DE, FI and NORMAN. Details provided in the factsheet.
		1417782-03-6 **Mefentrifluconazole**	Azole fungicide used as PPP	According to the harmonised classification and labelling (ATP15) approved by the EU, this substance is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction (ECHA)	Approved as PPP (EU Pesticides database, expiry 20/03/2029)	**1.6 µg/L** (Registration report, 2018)	LC–MS/MS LOQ = 30 ng/L (EFSA, 2018)	No available data (WISE 2023, EEA). Additional data or information from SE and FI. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
Azole Fungicides		60207-90-1 **Propiconazole**	Azole fungicide used as biocide	Toxic to Reproduction and Under assessment as ED (ECHA)	Not approved in EU as PPP This substance is approved for use as a biocide in the EEA and/or Switzerland, for: preservation films, wood preservation, preservation of fibres, leather, rubber, or polymers 30/11/2026	6.8 µg/l (FI Assessment report, 2015); 1.6 µg/l (INERIS (2016); 1.4 µg/l ad hoc EQS List Swiss Ecotoxcentre (From NORMAN); 18.8 µg/l ECHA (2023); 2 µg/l UBA (2020); **1 µg/l** AA-QS DE, UBA (2023); 10 µg/l RIVM (2023)	LC–MS/MS, LOQ=0.0136 µg/l, Chitescu et al., (2015); Online solid phase extraction liquid chromatography coupled to LC-Q-Exactive-HRMS system, LOQ=0.3 ng/L, Creusot et al., (2020)	WISE 2023 (EEA): after the regulation undertaken in 2018, there are available 26975 samples (16.2% quantified) taken at 2506 sites in 7 MS (DE, EE, FI, FR, IT, NL, SE) during the period 2019-2020. Range of LOQs for non-quantified samples 0.0006 – 0.05 µg/L, which would indicate a good sensitivity on monitoring regarding the PNEC=1 µg/L. However, these data are not EU-representative since 2 MS (FR and IT) are overrepresented holding together about 89.7% of all samples. In addition, recent exposure data (after 2020) are lacking in the

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
								dataset. In WISE data rare exceedances were observed in one MS and RQ<1. Additional exposure data were provided by AT, FI, IT, SE. The additional data showed occasional exceedances in 3 MS. According to PECs data RQ>1.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
Azole Fungicides		131983-72-7 **Triticonazole**	Azole fungicide used as PPP	(R) Suspected toxic to reproduction (ECHA, 2023)	Approved as PPP (EU Pesticides database, expiry 15/03/2025)	CQC ad hoc – Switzerland (from NORMAN) **1 µg/L**	LC–MS/MS; LOQ=0.0136 µg/L, Chitescu et al. (2015)	No available data (WISE 2023, EEA). Additional information or data from AT, IT, SE, DE, FI and NORMAN. PECs available. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
Industrial	**Group of 6PPD and 6PPD-quinone**	793-24-8 **6PPD**	Industrial tyre rubber antioxidant	Very toxic to aquatic life with long lasting effects (H400, H410).		**0.37 µg/L** PNEC freshwater Source ECHA; 0.48 µg/l (RIVM, 2007); 0.045 µg/l (PNEC predicted, NORMAN)	UHPLC (LOQ= 35 ng/L) (Cao et al., 2022)	No available data (WISE 2023, EEA). Additional data from SE and DE. Details provided in the factsheet.
		2754428-18-5 **6PPD-quinone**	Industrial transformation product of 6PPD	Very toxic to aquatic life with long lasting effects (H400, H410).		**0.37 µg/L** PNEC freshwater Source ECHA	LC-MS/MS LOQ <10 ng/L Tian et al. (2022). UHPLC (LOQ 23 ng/L) (Cao et al., 2022)	No available data (WISE 2023, EEA). Additional data from SE and DE. Details provided in the factsheet.
Pharmaceuticals	Group of antiarrhythmic medicines: Amiodarone Dronedarone	1951-25-3 Amiodarone	Pharmaceutical - antiarrhythmic medicine	high chronic toxicity (Janusinfo, SE)	Authorised for use in the European Union	1.2 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN) and (FASS) **0.24 µg/L** (RIVM, 2020)	SPE LC-ESI-MS/MS, LOQ = 0.185 µg/L, Grabic et al. (2012); SPE-LC-MS/MS LOQ = 0.01 µg/L, Source: NL experts (personal communication)	No available data (WISE 2023, EEA). PECs from literature. Details provided in the factsheet.
		141625-93-6 Dronedarone	Pharmaceutical - antiarrhythmic medicine	Very toxic to aquatic life with long lasting effects, suspected of	Authorised for use in the European Union.	**0.4 µg/l** ad hoc EQS List Swiss Ecotoxcentre (from NORMAN) and (from FASS)	UPLC-MS/MS, LOQ= 0.1 µg/L, Castro et al. (2018)	No available data (WISE 2023, EEA). PECs from literature. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
				damaging fertility or the unborn child, may cause harm to breast-fed children, is suspected of causing cancer				
	Citalopram	59729-33-8	Pharmaceutical (serotonin-selective reuptake inhibitor) for treating depression and anxiety	Stockholm's list of environmentally harmful APIs	Authorised for use in the European Union (human) according to EMA	**6.4 µg/L**; (LANUV, 2016)	LC-MS/MS. LOQ = 0.0059 ng/L, Roveri et al. (2021)	No available data (WISE 2023, EEA). Additional data from SE. From literature PECs available. Details provided in the factsheet.
	Disulfiram	97-77-8	Pharmaceutical - chronic alcoholism	Very toxic to aquatic life with long lasting effects	Authorised for use in the European Union (human) according to EMA	**0.02 µg/l** ad hoc EQS List Swiss Ecotoxcentre (from NORMAN); 0.0264 µg/l, ECHA	UHPLC-QTOF-HRMS LOD 0.015 µg/l Massano et al., (2023)	No available data (WISE 2023, EEA). Additional data were not provided so far.
	Fluoxetine	54910-89-3	Pharmaceutical (prozac) to treat depression, obsessive-compulsive disorders and	Stockholm's list of environmentally harmful APIs	Authorised for use in the European Union (human and veterinary) according to EMA	**0.012 µg/L** Oakes et al., 2010 (UBA); 0.1 µg/L (NORMAN from US-EPA (2018)	LOQs = 0.02 µg/l DE experts (personal communication); UHPLC-QTOF-HRMS LOD 0.005 µg/l Massano et al.,	WISE 2023 (EEA): 181 samples (all non-quantified) taken at 31 sites in 2 MS (NL and SE) during the period 2016-

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
			bulimia nervosa (an eating disorder) within the European Union.			AQUIRE database); 1.12 µg/L (RIVM, 2011)	(2023)	2021. Range of LOQs 0.0011 - 1 µg/L. Only about 26% of samples are processed with methods having LOQs ≤ 0.01 µg/L, indicating an insufficient sensitivity on monitoring regarding PNEC = 0.012 µg/L. In addition, the data are not EU-representative. In conclusion: the quality of available data does not support a proper statistical analysis of MECs. Additional data from SE. From literature MECs and PECs. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
	Gemfibrozil	25812-30-0	Pharmaceutical Treatment of abnormal blood lipid levels	According to the classification provided by companies to ECHA in REACH registrations is suspected of causing cancer, suspected of impairing fertility or the unborn child and is harmful to aquatic life with long lasting effects	Authorised for use in the European Union.	**0.5 µg/l** Ecotox Knowledgebase (from NORMAN); 1.5 µg/l, Pfizer (from Agerstrand and Ruden 2010) (FASS-Gemgibrozil-Pfizer)	SPE followed by UHPLC- QqLIT-MS (river water), LOQ= 0.0034 µg/l, Mandaric et al. (2017)	No available data (WISE 2023, EEA). Additional information or data from AT, SE, DE and NORMAN. From literature MECs found. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
	Propranolol	525-66-6	Pharmaceutical - antihypertensive	Very high chronic toxicity (Janusinfo, SE)	Authorised This medicine is authorised for use in the European Union.	**0.02** µg/l Vestel et al. (2016); RIVM (2020) 0.16 µg/L Swiss Ecotoxcentre (2013); 0.23 µg/L ERA document AstraZeneca (2023)	LC-MS/MS, LOQ = 0.0072 ng/L, Roveri et al. (2021)	WISE 2023 (EEA): 397 samples (30.5% quantified) taken at 49 sites in 4 MS during 2018-2021. Range of LOQs 0.0011 - 0.03 µg/L which indicates a sufficient sensitivity of monitoring compared to the PNEC=0.02 µg/L. The data are not EU representative since 2 MS (BE and NL) are overrepresented holding together 95% of all samples. In addition, the available data lacking info about exposure after 2021. The data showed higher quantification rate, exceedances in 2 MS and an overall RQ(P95)=4.7

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
								according to PNEC=0.02 µg/L. Additional information or data received from AT, DE, SE, NORMAN, AstraZeneca. The additional data from MS showed a high quantification frequency and some exceedances. The data from AstraZeneca showed RQ>1.
PPP	**Abamectin**	Abamectin (CAS N. 71751-41-2) is a mixture of ≥ 80% avermectin B1a (CAS N. 65195-55-3) and < 20% avermectin B1b (CAS N. 65195-56-4).	PPP (insecticide and anthelmintic) Pharmaceutical (anthelmintic, veterinary only) Avermectin family	PPP with restricted use Pharmaceutical with only veterinary use (cattle) for the treatment of gastro-intestinal nematodes, lungworms and nasal	Approved in EU as PPP 31/03/2038 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK This substance was previously approved for use as a biocide in the EEA and/or Switzerland, and	0.00035 µg/L Sources: 2011, E.C. Assessment Report. Same PNEC in NORMAN **0.001 µg/L** RIVM (2008) and SYKE (2011)	LC-MS/MS, LOQ = 0.05 µg/L, E.C. Assessment Report (2011) and EPA report (2014); LC-MS/MS LOQ= 0.0005 µg/L NL experts (personal communication)	No available data (WISE 2023, EEA). Additional info from SE. PECs from EFSA. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
				bots Suspected to be toxic to reproduction (ECHA) Very toxic to aquatic life with long lasting effects and is suspected of damaging the unborn child (H400, H410, H361d)	this approval has now expired, for: controlling insects, ants, etc Pharmaceutical with only veterinary use (cattle) for the treatment of gastro-intestinal nematodes, lungworms and nasal bots			
	Amisulbrom	348635-87-0	Fungicide	Suspected to be carcinogenic (ECHA)	Approved as PPP (EU Pesticides database, expiry **30/09/2024**) National authorisation AT,BE,BG,CY,CZ,DE,EE,EL,ES,FI,FR,HR,HU,IE,IT,LT,LU,LV,NL,PL,PT,RO,SE,SI,SK	**0.229 µg/L** (UBA, 2020) 1.39 µg/L (CQC ad hoc – Switzerland, taken from NORMAN)	LC-MS/MS, Detection limit 0.019 µg/L Reporting limit 0.10 µg/L, Sjerps et al. (2019)	No available data (WISE 2023, EEA). Additional info or data from IT and SE. PECs from EFSA. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
	Cyprodinil	121552-61-2	PPP (anilinopyrimidine fungicide)	Candidate for substitution very toxic to aquatic life with long-lasting effects	Approved in EU as PPP 15/03/2025 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK	0.75 µg/L UBA (2020); 0.16 µg/L RIVM (2023); 0.33 µg/L Swiss Ecotoxcentre (2016) and NORMAN; **0.026 µg/L** (0.03) INERIS (2011)	HPLC-UV LOQ = 0.10 µg/L EFSA, (2005); LC-MS/MS LOQ = 0.01 µg/L Source: NL experts (personal communication)	WISE 2023 (EEA): 17188 samples (22.3% quantified) taken at 1334 sites in 4 MS (CY, IT, NL, SE) during the period 2015-2020. The data are not EU-representative since 2 MS are overrepresented holding together about 99% of all samples. In addition, the available data do not describe recent exposure (after 2020). The WISE data showed exceeding concentrations in 2 reporting MS. Additional data from SE showed exceedances and presence of concern. PECs (EFSA) showed RQ>1. Details provided in the factsheet.

Type of substance	Substance name	CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data
PPP	**Etoxazole**	153233-91-1	PPP (acaricide and insecticide)	Candidate for substitution Very toxic to aquatic life with long lasting effects	Approved in EU as PPP 31/01/2028 National authorisation BE,BG,EL,ES,HR,HU,IT,NL,PT	0.013 µg/L (NORMAN, from ad hoc EQS List Swiss Ecotoxcentre) **0.0004 µg/L** (RIVM, 2014)	LC-MS/MS, LOQ = 0.10 µg/L, EFSA Journal (2017); GC-MS/MS, LOQ = 0.0003 µg/L Source: NL experts (personal communication)	No available data (WISE 2023, EEA). Additional info or data from AT and SE. PECs from EFSA. Details provided in the factsheet.
Sunscreen agents	**Ethylhexyl salicylate (octisalate) (sunscreen)**	118-60-05	Cosmetic products	Very toxic to aquatic life with long lasting effects Potential endocrine disruptor (CoRAP)	Authorised in cosmetic products in EU, maximum 5 % concentration	**0.168 µg/L** ECHA (2023)	SPE-HPLC-QqQ-MS/MS method to determine UV filters in surface water. LOQ = 0.0019 µg/L, Swiss Ecotox Centre (Personal communication); SPE-HPLC-ESI-MS/MS, LOD= 0.0001 µg, Tsui et al. (2014)	No available data (WISE 2023, EEA). Additional data from SE. Details provided in the factsheet.

Source: EC-JRC

Table 2. Substances not selected as most suitable candidates for the 5th WL due to uncertainties regarding the analytical methods and/or PNEC values. PPP: Plant Protection Products, Limit of Quantification (LOQ), Predicted No-Effect Concentration (PNEC), PNEC (ENV): PNEC environmental.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
Biocides	Group of Rodenticides (Brodifacoum, 56073-10-0; Bromadiolone, 28772-56-7; Difenacoum, 56073-07-5)	Rodenticides used as biocides (Kotthoff M et al., 2019; Regnery J et al., 2019)	PBT Toxic to Reproduction (R) It is very toxic to aquatic life with long lasting effects	Brodifacoum ECHA Validity of approval until 30/06/2024 –to be extended	Brodifacoum PNECbiota=0.01 µg/kg/bw	HPLC with fluorescence detection to determine the concentration of brodifacoum in tissue samples. The method detection limit was 0.01 µg/g=10 µg/kg. (Booth et al., 2012). Not adequate LC-MS with a detection limit of 1×10-5% (0.1ppm) =100 µg/kg. not adequate Freshwater fish liver and SPM, LOQ for Difenacoum 0.2, for Bromadiolone 2 µg/kg using UHPLC-HRMS-MS/MS	Exposure data not available (WISE 2023, EEA)	Monitoring is suggested in SPM, sediment or biota. No analytical method with low LOQ
			PBT Toxic to Reproduction (R) It is very toxic to aquatic life with long lasting effects	Bromadiolone ECHA Validity of approval until 30/06/2024 –to be extended	Bromadiolone PNEC biota =0.0056 µg/kg			
			P, vP, BT Toxic to Reproduction (R) It is very toxic to aquatic life with long lasting effects	Difenacoum ECHA Validity of approval until 30/06/2024 – to be extended	Difenacoum PNECbiota=0.03 µg/kg bw/day			

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
Industrial	Three alkylphenols (4-tert-butylphenol, 98-54-4; phenol, dodecyl-, branched, 121158-58-5 and p-(1,1-dimethylpropyl)phenol, 80-46-6)	Industrial products with different applications	4-tert-butylphenol: Suspected to be Toxic to Reproduction, Endocrine Disrupting. phenol, dodecyl-, branched: Toxic to Reproduction, Endocrine Disrupting. 1,1-dimethylpropyl)phenol, Endocrine Disrupting, (ECHA)		4-tert-butylphenol: no new sediment toxicity data or PNEC are available in ECHA. PNECsed=270 µg/kg (DW; ECHA) phenol, dodecyl-, branched: no new sediment toxicity data or PNEC are available in ECHA. PNECsed=226 µg/kg (DW; ECHA) 1,1-dimethylpropyl) phenol: New PNEC For CAS 80-46-6 $PNEC_{fw\ sediment}$ of 0.105 mg/kg wet weight =105 µg/kg by Equilibrium partitioning. Source: Environmental	For sediments, for CAS 98-54-4 and CAS 80-46-6 Heemken et al 2001: Extracted by Accelerated Solvent Extraction with *n*-hexane/ acetone. Following a clean-up by HPLC, using GC–MSD. LOQ 0.5µg/kg Source: Heemken et al, 2001	Exposure data not available (WISE 2023, EEA)	Monitoring is suggested in sediments.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
					risk evaluation report: 4-tert-pentylphenol (CAS no. 80-46-6)			
	Benzotriazole 95-14-7	Industrial Pharmaceutical (drug precursor)	Under assessment as Persistent, Bioaccumulative and Toxic Under assessment as Endocrine Disrupting Toxic to aquatic life with long lasting effects		19 µg/L AA-EQS – Swiss Ecotox Center proposal for: Benzotriazole. 2016 Same value from RIVM and UBA	Not found, to be double checked or asked to experts	WISE 2023 (EEA): available data from 2 MS (FR and NL) for 2016-2020; overall 7496 samples (43.6% quantified). The data are not EU-representative. According to the initial tentative risk screening there is a low concern.	Uncertainties re the analytical method.
	Bromate 15541-45-4	Industrial			There is an EQS proposal from 2015 from the Ecotoxcentre, AA-EQS=50 µg/L Based on a recent risk-assessment of RIVM, leading to a health advisory level of 1 µg/L		Exposure data not available (WISE 2023, EEA)	Uncertainties re the analytical method and PNEC value.
	Group of Chloroanilines: 4-Chloroaniline, 106-	4-Chloroaniline: Industrial (ECHA) Use in the	PT, possible M, C (ECHA) Not in Annex III		0.05 µg/L (prioritisation exercise RBSP-	Isocratic reversed-phase HPLC (RPHPLC)	Scarce exposure data available from	Uncertainties re the PNEC value.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	47-8; 3,4-dichloroaniline, 95-76-1	production of urea insecticides and herbicides, pigments, pharmaceuticals and cosmetic products (WHO, 2003)	inventory (ECHA) Officially recognised in the EU as Carcinogenic (Harmonised C&L) It is very toxic to aquatic life with long lasting effects (ECHA)		ECOSTAT, UBA, 2014) 0.22 µg/L (NL legal standard AA- EQS, RIVM, 2009) 0.57 µg/L (MPCeco, water, RIVM, 2009) 1 µg/L (INERIS, 2011)	(LOD 0.036 µg/L) (Börnick et al., 2001) LC-MS/MS (0.00013 µg/L) (Rimayi et al., 2019)	2-3 MS but with insufficient sensitivity of monitoring (WISE 2023, EEA). Possible higher concern according to the tentative risk screening.	
		3,4-dichloroaniline: Industrial (ECHA) It is exclusively used as an intermediate in the chemical industry for the synthesis of 3,4-dichlorophenyliso cyanate, the herbicide propanil and an azo dye for polyester fabrics (UC = 3 and for the production of phenylureaherbici des (diuron, linuron) and the bactericide trichlorocarbanilid e by further sites	P, vP, T Endocrine disruptor (INERIS) Not in Annex III inventory (ECHA) It is very toxic to aquatic life with long lasting effects (ECHA)		0.02 µg/L (monitoring exercise INERIS, 2012) additional AF of 10 since it is ED according to INERIS 0.2 µg/L (water) and 0.039 mg/kg ww (sediment) (Risk Assessment Report, JRC, 2006) 3 µg/L (NL QS, RIVM, 1998)	Isocratic reversed-phase HPLC (RPHPLC) (LOD 0.033 µg/L) (Börnick et al., 2001) LC-MS/MS (LOD µg/L 0.0052) (USGS, 2012)		Uncertainties re the PNEC value.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
		(EU, RAR, DE 2006).						
	Free Cyanide CN- 57-12-5 HCN 74-90-8	Industrial product Inorganic biocide	T (ECHA) HCN does not display properties of environmental persistence or bioaccumulation, although it is highly toxic to aquatic organisms. It does not meet the criteria for classification as PBT		0.26 µg/L (JRC Factsheet 2015-2018/WFD-UK TAG report, 2012) 5 µg/L (freshwater ECHA dossier) 0.5 µg/L (JRC Dossier, 2015) 0.04 (PNECaqua, ECHA) AA-EQS = 0.22 µg/L, derived by SSD, RIVM, NL	Continuous Flow Analysis (CFA) method according to ISO 14403-2:2012 modified LOQ < 0.3 µg/L (Fraunhofer Institute, 2018)	WISE 2021 (EEA): In inland surface water (dissolved fraction) 158 samples (4.4% quantified) from 61 sites in 3 MS (2015 - 2019). For non-quantified samples, the range of LOQs is 0.002 – 0.57 µg/L. The sensitivity of monitoring is acceptable. The data are not EU-representative. Concern in some of the reporting MS according to the initial risk screening.	Uncertainties re the analytical method.
	Lithium 7439-93-2	Industrial Pharmaceutical			PNEC freshwater= 1.65 mg/L PNEC marine water= 0.165 mg/L Secondary poisoning: no		In WISE 2023 (EEA): 2559 samples (total and dissolved; overall 85.9% quantified) from 76 sites in 3 MS (2010 - 2020). Range of LOQs	A more reliable PNEC value is needed.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
					potential for bioaccumulation PNEC sediment (freshwater)= 44.2 mg/kg sediment dw PNEC sediment (marine water)= 4.42 mg/kg sediment dw PBT assessment does not apply (ECHA) Based on a recent risk-assessment of RIVM, leading to a health advisory level of 7.7 µg/L)		0.001 – 10 µg/L (non-quantified samples). The sensitivity of monitoring is acceptable. The data are not EU-representative. Tentative statistics of MECs (µg/L): Median9.8 P95=64.5 P99=129 Possible concern according to the initial risk screening.	
	Melamine, including variants as Cyanuric acid and HMMM 108-78-1	Industrial Starting material for the manufacture of synthetic resins	Suspected to be Carcinogenic Under assessment as Persistent, Bioaccumulative and Toxic		360 µg/L INERIS and NORMAN 525 µg/L RIVM		No available data in WISE 2023 (EEA)	Uncertainties re the analytical method.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	Group of Siloxanes: (octamethylcyclotetrasiloxane D4 (CAS N. 556-67-2), decamethylcyclopentasiloxane D5 (CAS N. 541-02-6) and dodecamethylcyclohexasiloxane D6 (CAS N. 540-97-6))	Industrial and cosmetic products	D4 ECHA Suspected to be Toxic to Reproduction, Under assessment as POP, PBT, vPvB report 2018 link D5 ECHA link Persistent, Bioaccumulative and Toxic. PBT, vPvB report 2018 D6 ECHA link Persistent, Bioaccumulative and Toxic, PBT, vPvB. report 2018	Restriction as group for Hydrocarbyl siloxanes: ON GOING ECHA's assessment of regulatory needs, report 2022 link Inclusion of D6 to the previous restriction scope 21-Jan-2021 report	D4 PNEC sed=0.015 µg/kg dw (SE, 2018) D5 PNECsed=2.2 mg/kg dw (EA, 2009) 11 mg/kg dw (ECHA) D6 PNECsed=13 mg/kg dw (ECHA) 7.5 mg/kg (EA, 2009)	GC-MS/MS LOQ, D5=0.08 ng/g dry weight LOQ, D6=0.04 ng/g dry weight Source Sang-Yoon Lee et al., (2017) https://doi.org/10.1016/j.envpol.2018.01.051	Exposure data not available (WISE 2023, EEA). Silicones Europe (CES) - CEFIC has provided extended information for MECs and PECs of siloxanes in different environmental matrices and analysis of published monitoring data and associated risk screening.	Monitoring is suggested in SPM. Awaiting ECHA restriction/ban.
Pharmaceuticals	Allopurinol and its metabolite oxipurinol 315-30-0 and 2465-59-0	Human medicine to treat gout	PT (allopurinol) (suspected Janusinfo, SE)	Authorised for use in the European Union	Allopurinol: 20.6 µg/L (PNEC-predicted, NORMAN) Oxipurinol: 14 µg/L (AA-EQS, UBA, 2023) 57.6 µg/L (PNEC-predicted, NORMAN)	LC-MS/MS-analysis LOQ surface water = 5 ng/L (allopurinol) 25 ng/L (oxipurinol) (Funke et al., 2015)	Exposure data not available (WISE 2023, EEA)	Uncertainties in the PNEC value.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	Atovaquon 95233-18-4	Pharmaceutical Antimalaria medicine	Very toxic to aquatic life and is very toxic to aquatic life with long lasting effects.	Authorised for use in the European Union	0.00083 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN) and (FASS)		Exposure data not available (WISE 2023, EEA)	Monitoring is suggested in sediments. Uncertainties re the analytical method.
	Gabapentin 60142-96-3	Human medicine - antiepileptic		Authorised for use in the European Union	1 mg/L (AA-QS, UBA, 2020) 10 µg/L (JD-UQN proposal, NORMAN) NORMAN: link estimated from UBA PNECfw=1000 µg/L PNECmw=100 µg/L PNEC fw sed= 7872 µg/kg dw	HPLC-MS/MS LOQ = 5 ng/L (Fonseca et al., 2020)	Exposure data not available (WISE 2023, EEA)	Uncertainties re the PNEC value.
	Irbesartan 138402-11-6	Human medicine - Antihypertensive		Authorised for use in the European Union	Chronic quality standard 700 µg/L (Ecotoxcentre, CH 2013)		Exposure data not available (WISE 2023, EEA)	Uncertainties re the PNEC value.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	Orlistat 86829-58-2	Human medicine - Treatment of obese (very overweight) patients. Orlistat blocks gastrointestinal lipases (enzymes that digest fat).	Very toxic to aquatic life with long lasting effects	Authorised for use in the European Union	0.16 µg/l ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)		Exposure data not available (WISE 2023, EEA)	On hold, maybe in the next WL The experts should be consulted for the analytical method.
	Synthetic progestins Norethisterone and Levonorgestrel	Norethisterone 68-22-4	ED PBT, possible C, R, ED (modelling exercise) P(3/3) B(3/3) T(3/3) Stockholm County Council Potentially persistent, low potential for bioaccumulation and very high chronic toxicity. Moderate/high environmental risk (Janusinfo, SE) This substance may damage fertility or the unborn child, is	Authorised for use in the European Union	0.0005 µg/L (Janusinfo SE, Fass, SE) 0.0354 µg/L (Prioritisation exercise, 2016) 0.51 µg/L (freshwater, ECHA) 10 µg/kg sediment dw (sediment freshwater, ECHA) 0.0148 (Zhou et al., 2019)	LC-MS/MS (0.00001 µg/L) (Vulliet et al., 2011)	No available data in the WISE 2023 (EEA)	On hold, waiting for a validated EBM (for both substances).

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
			very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is suspected of causing cancer and may cause harm to breast-fed children. (ECHA) R, a majority of data submitters agree this substance is Toxic to Reproduction (ECHA)					
	Levonorgestrel 797-63-7		PT, ED Levonorgestrel very high chronic toxicity. High risk of environmental impact (Janusinfo, SE) This substance may damage fertility or the unborn child, is suspected of causing cancer, is harmful in contact with skin, is harmful if	Authorised for use in the European Union	0.00001 µg/L (Janusinfo SE, Fass, SE, 2017) 0.000016 µg/L (FASS text of Bayer AG, 2020)	HPLC-MS/MS (LOQ 0.00009 µg/L) (Avar et al., 2015) LC-MS/MS (MDL 0.00033 µg/L) (Vulliet et al., 2011) 0.000025 µg/L (Teigeler et al., 2021)	No available data in the WISE 2023 (EEA)	

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
			inhaled, may cause harm to breast-fed children and is harmful if swallowed R, a majority of data submitters agree this substance is Toxic to Reproduction (ECHA) Substances predicted as likely to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity					
	Sitagliptin 486460-32-6	Pharmaceutical (antidiabetic, type-2 diabetes)		Authorised for use in the European Union	84 µg/L ad hoc EQS List Swiss Ecotoxcentre (from NORMAN)		Exposure data not available (WISE 2023, EEA)	On hold, maybe in the next WL. It is monitored but the method has not been provided yet to the JRC.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
PPP and or biocide	Halosulfuron – methyl 100784-20-1	PPP (Herbicide)	Candidate for substitution Toxic to Reproduction (ECHA) Very toxic to aquatic life and is very toxic to aquatic life with long lasting effects	Approved in EU as PPP 31/03/2025 National authorisation BG,EL,FR,HU,IT,PT	0.051 µg/L (P-PNEC pred) from NORMAN		Exposure data not available (WISE 2023, EEA)	The PNEC value is predicted.
	Folpet	Fungicide used as PPP and Biocide	It is suspected to be carcinogenic (ECHA https://echa.europa.eu/substance-information/-/substanceinfo/100.004.627), carcinogenic (INERIS). Toxic to aquatic life (Folpet PT9 Assessment Report, 2014).	Biocide and Fungicide (ECHA, 2023a). This substance is approved for use as a biocide in the EEA and/or Switzerland, for product preservation, preservation films, preservation of fibres, leather, rubber, or polymers. Approved as PPP in EU, expiry of approval 15/02/2025 Authorized at national level in:	1.9 µg/L Folpet PT9 Assessment Report, 2014 1.95 µg/L UBA RAC	High-Performance Liquid Chromatography with ultraviolet (UV) detection (HPLC-UV) and external standard LOQ is 0.02 µg/L (Folpet PT9 Assessment Report, 2014).	In WISE 2023 (EEA): Available 5006 samples (37.6% quantified) taken at 262 sites in 3 MS (CY, IT, NL) during 2016-2020. Range of LOQs 0.01 - 2 µg/L. Good sensitivity of monitoring regarding the tentative PNEC=1.9 µg/L. The data are not EU representative since are only from 3 MS and IT holds about 91% of all samples. A low concern according to the tentative initial risk screening.	It undergoes hydrolysis and it is questionable whether it can be detected in surface water.

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
				AT,BE,BG,CY,CZ, DE,DK,ES,FR,HU, IE,LU,MT,NL,PL,R O,SE,SI,SK.			Additional information sent by DE, SE and NORMAN. Additional monitoring data sent by AT and IT. Details provided in the factsheet	
	Imazamox 114311-32-9	PPP (Herbicide)	Candidate for substitution Suspected to be Toxic to Reproduction (ECHA) Very toxic to aquatic life, is very toxic to aquatic life with long lasting effects	Approved in EU as PPP 31/01/2025 National authorisation AT,BE,BG,CY,CZ, DE,EE,EL,ES,FI,F R,HR,HU,IE,IT,LT, LV,MT,NL,PL,PT, RO,SE,SI,SK	120 µg/L RIVM 0.45 µg/L ad hoc EQS List Swiss Ecotoxcentre (NORMAN database)		Exposure data not available (WISE 2023, EEA)	Uncertainties on the PNEC value.
UV Filters	Phenolbenzotriazoles (UV-Filters) UV 320, 3846-71-7	UV filters, Industrial Cosmetics and sunscreens	PBT vPBT Suspected of causing cancer The OSPAR List of Substances of Possible Concern	SVHC now requiring authorisation before it is used (Annex XIV of REACH).	PNECfw 0.01416 µg/L (predicted QSAR NORMAN database)	LC/LC-MS/MS (Brorström-Lundén et al., 2011)	Exposure data not available (WISE 2023, EEA)	Most of the PNEC values are based on modelling data (QSAR).

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	Phenolbenzotriazoles (UV-Filters) UV 326, 3896-11-5		Under assessment as PBT (ECHA)		0.013 µg/L (predicted NORMAN database)		Exposure data not available (WISE 2023, EEA)	
	Phenolbenzotriazoles (UV-Filters) UV 327, 3864-99-1		Under assessment as PBT (ECHA	SVHC now requiring authorisation before it is used (Annex XIV of REACH).	PNECfw 91.1 µg/L (Wallberg et al. 2014) PNECfw 0.00668 µg/L (predicted QSAR NORMAN database)	LC/LC-MS/MS (Brorström-Lundén et al., 2011)	Exposure data not available (WISE 2023, EEA)	
	Phenolbenzotriazoles (UV-Filters) UV 328, 25973-55-1		PBT and POP (ECHA)	Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH)	10 µg/L (ECHA)	LC/LC-MS/MS (Brorström-Lundén et al., 2011)	Exposure data not available (WISE 2023, EEA)	
	Phenolbenzotriazoles (UV-Filters) UV 329, 3147-75-9		Under assessment as PBT (ECHA)		0.012 µg/L (predicted NORMAN database)		Exposure data not available (WISE 2023, EEA)	

Type of substance	Substance name/ CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
	Phenolbenzotriazoles (UV-Filters) UV 350, 36437-37-3		Under assessment as PBT (ECHA)	Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).	0.01342 µg/L (predicted QSAR NORMAN database)	LC/LC-MS/MS (Lu et al. 2016)	Exposure data not available (WISE 2023, EEA)	
	Phenolbenzotriazoles (UV-Filters) UV P, 2440-22-4		Under assessment as PBT (ECHA)		PNECfw 260 ng/L (ECHA)	LC/LC-MS/MS (Brorström-Lundén et al., 2011)	Exposure data not available (WISE 2023, EEA)	

Source: EC-JRC

Table 3. List of substances for which sufficient exposure data are available. PPP: Plant Protection Products, Limit of Quantification (LOQ), Predicted No-Effect Concentration (PNEC), Risk Quotient (RQ), Measured Environmental Concentrations (MEC).

Type of substance	Substance name and CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
PPP	Chlortoluron 15545-48-9	Phenylurea class of herbicides	Candidate for substitution. Suspected to be carcinogenic and toxic to reproduction (ECHA). Very toxic to aquatic life with long lasting effects. Suspected of causing cancer and damaging the unborn child	Approved in EU as PPP 15/08/2026. National authorisation AT,BE,BG,CZ,DE, EE,EL,ES,FR,HR, HU,IE,IT,LV,PL,PT ,RO,SI,SK	0.1 µg/L (INERIS, 2013) 0.4 µg/L (RIVM, 2009) 0.6 µg/L (Swiss ecotoxce ntre)		WISE 2023 (EEA): available data from 8 MS (BE, DE, EE, FR, HR, IT, NL, SI) for 2010-2020; overall 90711 samples (20.8% quantified). FR is overrepresented holding about 68.3% of all samples. Acceptable sensitivity of monitoring since LOQs 0.0003 - 0.2 µg/L (non-quantified samples) regarding the freshwater PNEC=0.1	The amount and quality of available monitoring data seem sufficient to perform a risk assessment.

Type of substance	Substance name and CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
							µg/L. Statistics of MECs (assuming a substitution by half of LOQ for non-quantified samples): Mean=0.067 µg/L; P95=0.05 µg/L; P99=2 µg/L. RQ(MEC(P95))=0.5 RQ(MEC(P99))=20 Exceedaances in 5 MS.	
PPP	MCPA 94-74-6	Herbicide	Phenoxy herbicide. Very toxic to aquatic life with long lasting effects.	Approved in EU as PPP 15/08/2026. National authorisation AT,BE,BG,CY,CZ, DE,DK,EE,EL,ES, FI,FR,HR,HU,IE,IT ,LT,LU,LV,MT,NL, NO,PL,PT,RO,SE, SI,SK	0.66 µg/L (Swiss Ecotoxce ntre) 0.5 µg/L (Valeur guideEau 2015 INERIS) 0.1 µg/L AA-QSwater _eco (INERIS) 1.4 µg/L RIVM		WISE 2023 (EEA): available data from 14 MS (BE, CY, DE, EE, EL, FI, FR, HR, IE, IT, LU, NL, SE, SK) for 2010-2020; overall 105160 samples (22.5% quantified). FR is overrepresented holding about 60.7% of all samples. Acceptable sensitivity of monitoring since LOQs 0.0005 - 0.1 µg/L (non-quantified samples) regarding the freshwater PNEC=0.1 µg/L. Statistics of MECs (assuming a substitution by half of LOQ for non-quantified samples): Mean=0.063 µg/L; P95=0.09 µg/L; P99=1.54 µg/L. RQ(MEC(P95))=0.9 RQ(MEC(P99))=1.54 Exceedances in 12 MS.	The amount and quality of available monitoring data seem sufficient to perform a risk assessment.

Type of substance	Substance name and CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
PPP	Metazachlor 657-24-9	Herbicide	Suspected to be carcinogenic (ECHA)	Approved in EU until 31/10/2026. Authorised at national level in AT,BE,BG,CY,CZ, DE,EE,EL,ES,FI,FR,HU,IE,IT,LT,LU, LV,MT,NL,PL,PT, RO,SI,SK	0.02 µg/L (AA-QSwater) INERIS 2011 0.02 µg/L (NORMAN and Ecotoxcentrum, 2015) (AA-Qswater)	LC-MS/MS 0.0017 µg/L (LOQ) (UFZ KGM 2019, Halbach et al 2021)	WISE 2023 (EEA): available data from 10 MS (BE, DE, EE, FI, FR, HR, IT, LU, NL, SE) for 2010-2020; overall 85315 samples (21.5% quantified). FR is overrepresented holding about 72% of all samples. Acceptable sensitivity of monitoring (LOQs 0.0004 - 0.04 µg/L) regarding the freshwater PNEC. Statistics of MECs (2016-2020 derived by KM method - ProUCL of the US EPA: Mean=0.0053 µg/L; P95=0.0214 µg/L; P99=0.056 µg/L. RQ(MEC(P95))=1.07 RQ(MEC(P99))=2.8 In 6 MS, the individual RQ(MEC(P95))>1. Exceedances in 8 MS. The additional info and monitoring data (AT, IT, DE, SE and NORMAN) showed exceedances and a presence of risk. The JRC proposed Metazachlor as a suitable candidate for the PS list or RBSP (CH and NORMAN expressed same opinion).	The amount and quality of available monitoring data seem sufficient to perform a risk assessment.

Type of substance	Substance name and CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
PPP	Metribuzin 21087-64-9	Herbicide	Candidate for substitution. Very toxic to aquatic life with long lasting effects	Approved in EU as PPP 15/02/2025. National authorisation AT,BE,BG,CY,CZ, DE,EE,EL,ES,FI,F R,HR,HU,IE,IT,LU, LV,MT,NL,NO,PL, PT,RO,SE,SI,SK	0.058 µg/L Swiss Ecotoxce ntre and NORMAN 0.584 µg/l (RAC UBA) 0.2 µg/L AA-EQS (UBA) 0.12 µg/L RIVM		WISE 2023 (EEA): available data from 10 MS (BE, CY, DE, EE, FI, FR, HR, IT, NL, SE) for 2010-2020; overall 90613 samples (13% quantified). FR is overrepresented holding about 60.8% of all samples (IT is presented with 31.6% of samples). Acceptable sensitivity of monitoring since LOQs 0.0015 - 0.05 µg/L (non-quantified samples) regarding the freshwater PNEC=0.058 µg/L. Statistics of MECs (assuming a substitution by half of LOQ for non-quantified samples): Mean=0.052 µg/L; P95=0.025 µg/L; P99=2 µg/L. RQ(MEC(P95))=0.43 RQ(MEC(P99))=34.5 Exceedances in 5 MS.	The amount and quality of available monitoring data seem sufficient to perform a risk assessment.
PPP	Pirimicarb 23103-98-2	Carbamate insecticide	Candidate for substitution. Suspected to be carcinogenic (ECHA). Very toxic to aquatic life with long lasting effects, it is suspected of causing cancer.	Approved in EU as PPP 15/03/2025. National authorisation AT,BE,CY,CZ,DE, DK,EL,ES,FR,HR, HU,IE,IT,LU,NL,N O,PL,PT,SE,SI,SK	0.09 µg/L AA-EQS (Swiss Ecotoxce ntre, UBA, NORMAN and RIVM		WISE 2023 (EEA): available data from 7 MS (BE, DE, FI, FR, IT, NL, SE) for 2010-2020; overall 80543 samples (8.6% quantified). FR is overrepresented holding about 68.1% of all samples. Acceptable	The amount and quality of available monitoring data seem sufficient to perform a risk assessment.

Type of substance	Substance name and CAS N.	Use	Hazard	Authorisation	PNEC	Analytical method	Exposure data	Reason for not inclusion
					0.17 µg/L (RAC UBA)		sensitivity of monitoring since LOQs 0.0002 - 0.05 µg/L (non-quantified samples) regarding the freshwater PNEC=0.09 µg/L. Statistics of MECs (assuming a substitution by half of LOQ for non-quantified samples): Mean=0.055 µg/L; P95=0.0125 µg/L; P99=0.24 µg/L. RQ(MEC(P95))=0.14 RQ(MEC(P99))=2.67 Exceedances in 4 MS.	

Source: EC-JRC

2.2.1. Substances fulfilling the criteria 1 and 3

In the first outline draft report of the 5th Watch List (WL), the JRC identified candidate substances based on criteria 1 and 3. Recommendations from MS and stakeholders have been analysed and taken into account in this revised report. To apply the first criterion, Table 7 of the 4th WL report (Gomez-Cortes et al., 2022), listing suitable candidate substances for which information on analytical method or Predicted No-Effect Concentration (PNEC) was missing, was scrutinised and additional information sought on the listed substances.

New information was available for alkylphenols, gemfibrozil, gabapentin, metazachlor and propranolol. For the alkylphenols, a new $PNEC_{sediment}$ and analytical methods for some of the substances were found. For gemfibrozil, a lower PNEC was found, and an analytical method for water is available. A PNEC was published for gabapentin in the Norman database.

The approval of metazachlor has been extended until 31/10/2026 (see Table 3). It was not included in the 4th WL because the approval was due to expire in 2022, however it was extended to allow for the renewal assessment to be completed. This substance has been measured in overall eleven MS with acceptable sensitivity of monitoring and based on the $PNEC_{freshwater}$, shows a Risk Quotient (RQ) above 1. Finally, for the pharmaceutical propranolol, a lower PNEC and a suitable analytical method are available.

The JRC has thus identified two out of those five substances as suitable candidates for the next WL, i.e. gemfibrozil and propranolol (see Table 1). For alkyphenols (see Table 2), as already indicated during the 4th WL discussion, sediment monitoring is recommended, which is currently not popular, while for gabapentin, the PNEC is only predicted and this would not fulfil the criterion on the reliability of the PNEC (see Table 2). For metazachlor, the availability of monitoring data from overall eleven MS makes it unnecessary to include it in the WL; and it should be a candidate for the next Priority Substance (PS) list. In the meantime, given the overall RQ above 1, MS should designate it as a River Basin-Specific Pollutant (RBSP).

Regarding the siloxanes, since the evaluation of the restriction of the group of hydrocarbyl siloxanes by ECHA is still ongoing, it would be better to wait for its finalisation, and for completion of the ongoing analysis of the linear siloxanes, which are under investigation for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT/vPvB) properties (see Table 2).

Free cyanide was identified as a suitable candidate for the 4th WL. The Netherlands has recently derived new risk limits for this substance (as shown in Table 2). An analytical method is available, with a Limit of Quantification (LOQ) < 0.3 µg/L, however it requires instrument modifications that might still not be feasible for some MS. Nevertheless, it is important to keep an eye on this substance for the next WL programme.

The synthetic progestins levonorgestrel and norethisterone were initially identified as among the most suitable candidates for inclusion in the 4th WL to be monitored in inland surface waters, but they were not shortlisted because the analytical method is not sensitive enough for monitoring levonorgestrel. Alternative methods such as bioassays or Effect-Based Methods (EBM) could be used to overcome the monitoring difficulties posed by the low PNEC values, but they still need further development. For this reason, these synthetic hormones will be considered for future WL updates. They are listed in Table 2 together with substances for which there are uncertainties regarding the analytical method and/or PNEC values.

Other substances listed in Table 1 were selected from literature (Sanseverino et al., 2018) (based on criterion 3) as follows:

1. Antibiotics and classes of antibiotics: The rationale for their inclusion is their contribution to Antimicrobial Resistance (AMR) as well as (in some cases) their hazard properties. Table AII1 (Annex II) lists antibiotics for which both PNEC-ENV (based on ecotoxicity data) and PNEC-(resistance selection) are available in the literature. The antibiotics identified as most suitable for the 5th WL are listed in Table 1. PNEC-(resistance selection) is the only PNEC for antibiotics that addresses their potential to result in AMR and it is the equivalent of the PNEC-MIC used in the previous WL reports. Although both terms refer to the same way of deriving a PNEC value addressing resistance, the definition PNEC-(resistance selection) was chosen to avoid possible misinterpretation. The value of PNEC–(resistance selection) is derived starting from Minimal Inhibitory Concentration (MIC) data retrieved from the EUCAST database and applying an assessment factor of 10 (Bengtsson-Palme and Larsson, 2016). To be fully protective of environmental ecosystems and human health, both PNEC (PNEC-ENV and PNEC-(resistance selection) should be derived, and the lower value should be used for the Environmental Risk Assessment (ERA).

2. Fungicides: These are proposed due to their wide use and their potential contribution to AMR. Although the 4th WL already included several fungicides, additional substances have been selected based on a list received from the European Environmental Agency (EEA) within the activity of the interagency mandate on "Azole-resistant Aspergillus", and from literature data. Table AII2 shows the list, which includes only those which are approved. Some of the fungicides should be excluded because the PNEC is only predicted, as is the case for posaconazole, triazoxide, parconazole, and the pharmaceutical econazole, unless additional information can be found/provided. Furthermore, the approval of amisulbrom as Plant Protection Product (PPP) is expected to expire in 2024. Therefore, it is important to verify if their PPP use will be re-approved. A possible link between the fungicide folpet and Parkinson's disease has been postulated (Paul et al., 2023) but EFSA did not find any indication of neurotoxic potential (EFSA, 2023). Although there are in many cases no monitoring data, and thus no complete basis for suspecting a risk, there is evidence that Aspergillus fungi have become resistant to many antifungal azoles and monitoring those azoles could help to identify the cause (Fisher et al., 2022). If these azoles are listed, it would make sense to include also the other azole compound (propiconazole) that, like epoxiconazole, was excluded from the 3rd WL at the last minute on the basis that its approval for use in PPP was coming to an end. The persistence of these substances would justify their monitoring, even though they are no longer approved in the EU for use as PPP, as is the case of epoxiconazole.

In relation to criterion 2, suggestions were made during the preparation of the 4th WL to consider including all the environmentally harmful active pharmaceutical ingredients (API) of Stockholm's list (citalopram, escitalopram, diazepam, felodipine, fluoxetine, flupentixol, glibenclamide, haloperidol, meclizine, oxazepam, risperidone, roxithromycin, sertraline, and tetracycline) in the WL. Another suggestion was to include sitagliptin (anti-diabetic medicine) (Table 1 and Table 2).

In conclusion, the JRC proposed as most suitable candidates in the first outline: two pesticides metazachlor and folpet; the antibiotics norfloxacin, oxytetracycline, tetracycline and tylosin; the pharmaceuticals gemfibrozil and propranolol; and a group of fungicides and azole-related substances including pharmaceuticals (climbazole, itraconazole and ketoconazole), PPPs (amisulbrom, cyazofamid, bromuconazole, difenoconazole, epoxiconazole, mefentrifluconazole and triticonazole); and the pharmaceuticals gemfibrozil and propranolol (Table 1, Table 2 and Table 3). After the first

round of comments on the outline of the 5th WL draft report and additional monitoring data provided by MS, following the WG Chemicals meeting[2], the list of candidates was updated.

Particularly, two substances, metazachlor and folpet were removed from the list of most suitable candidates for the 5th WL. For metazachlor, additional monitoring data were submitted by several MS (see details in Annex IV), supporting the conclusion that sufficient good monitoring data were available at EU level to perform a risk assessment analysis. Therefore, it has been moved to Table 3. Since the RQ is above 1, it is recommended to refine the Environmental Quality Standard (EQS) for metazachlor, and potentially shortlist it as a priority substance. Furthermore, as mentioned above, in the meantime, MS should designate it as a River Basin-Specific Pollutant (RBSP) if a risk is identified.

The other substance, folpet, is not proposed because the substance undergoes a quick hydrolysis, since 50% is hydrolysed in 1-3 hours at pH 5-7. Therefore, it is questionable if it can be detected in surface water. This substance is listed in Table 2 (further information for collected monitoring data could be found in Annex II (Table AII2) and Annex IV).

2.2.2. Substances recommended by the WG Chemicals to fulfil criterion 2

Additional substances were proposed by the WG Chemicals after circulating the first outline of the 5th WL draft report. A total of fifty-seven substances were suggested, as shown in Figure 1. These substances fall in several groups of substances, which classification is based on their use. The majority of them belong to the Plant Protection Products (PPP) followed by the pharmaceuticals, industrial products, sunscreens and UV-filters and biocides. The full list of substances is in the Annex IV, as Supplementary Information. This annex is a separated file from the report and uploaded to CIRCABC[3].

Among the substances proposed by the WG Chemicals, following the collection of hazard properties, monitoring data, Predicted No-Effect Concentration (PNEC) values and analytical methods, the JRC listed the following substances in different tables according to their suitability for the WL program. The substances prioritised as most suitable candidates for the 5th WL are cited below and listed in Table 1:

The industrial product 6PPD and its transformation product 6PPD-quinone,

Five pharmaceuticals (amiodarone, dronedarone, disulfiram, fluoxetine and citalopram),

Three PPP and/or biocides (abamectin, cyprodinil and etoxazole),

The sunscreen ethylhexyl salicylate (octisalate),

The azole fungicide propiconazole.

Furthermore, the substances for which sufficient exposure data were available and with good quality to draw a risk assessment analysis at EU level, were also excluded and listed in Table 3. This table lists five PPP candidate substances (chlortoluron, MCPA, metazachlor, metribuzin and pirimicarb) which have been monitored in more than 4 Member States (actually in considerably more than 4). For these substances, along with the presence of relevant information about hazard, authorization and PNEC values, it seems that sufficient monitoring data with acceptably good quality are available

[2] WG Chemicals meeting held on 17-18 October 2023 (CIRCABC https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/a733d128-8e44-4973-9b4b-60728e53b4da?p=1&n=10&sort=modified_DESC)

[3] CIRCABC link for the ANNEX IV: https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/5066a01b-d3c6-4b70-989f-801ca944bc88/details

which could allow performing a risk assessment. Therefore, the aforementioned substances were not proposed for inclusion in the 5th WL. All five PPP substances showed exceeding concentrations in several MS, and particularly the risk screening of metazachlor evidenced a presence of EU-wide risk. Finally, substances which are not authorised, were excluded while those which authorisation is about to expire are listed in Table 4. These substances could be suitable candidates in the next WL program, in case their authorisation is going to be renewed.

To note that the suggested pyrethroid insecticides (etofenprox, lambda-cyhalothrin, pyrethrin, tau-fluvalinate and tefluthrin) and Per- and Polyfluoroalkyl Substances (PFAS) (fluazinam, fluorochloridone, flutianil, isoxaflutole, pehnthopyrad, propyzamide, pyroxsulam, tefluthrin, tembotrione and trisuflusulfuron-methil) are not proposed for the 5th WL. These substances are listed in the Annex IV.

The rationale for their exclusion is because both pyrethroids and PFAS are currently in the proposal of the WFD review (EC, 2022). Due to their hazard properties and high concern, it would be envisaged to add them to the Priority Substance (PS) list in the next prioritisation exercise. For pyrethroids, it would be desirable to include them as a group and a cumulative risk assessment should be developed as recommended by the JRC, SCHEER and MS. While for PFAS, additional PFAS should be added in case the Relative Potency Factor (RPF) would be available, since in the proposal of the WFD review (EC, 2022) the EQS is expressed as Perfluorooctanoic Acid (PFOA) equivalent for the sum of twenty-four PFAS which contribution is based on their Relative Potency Factor (RPF).

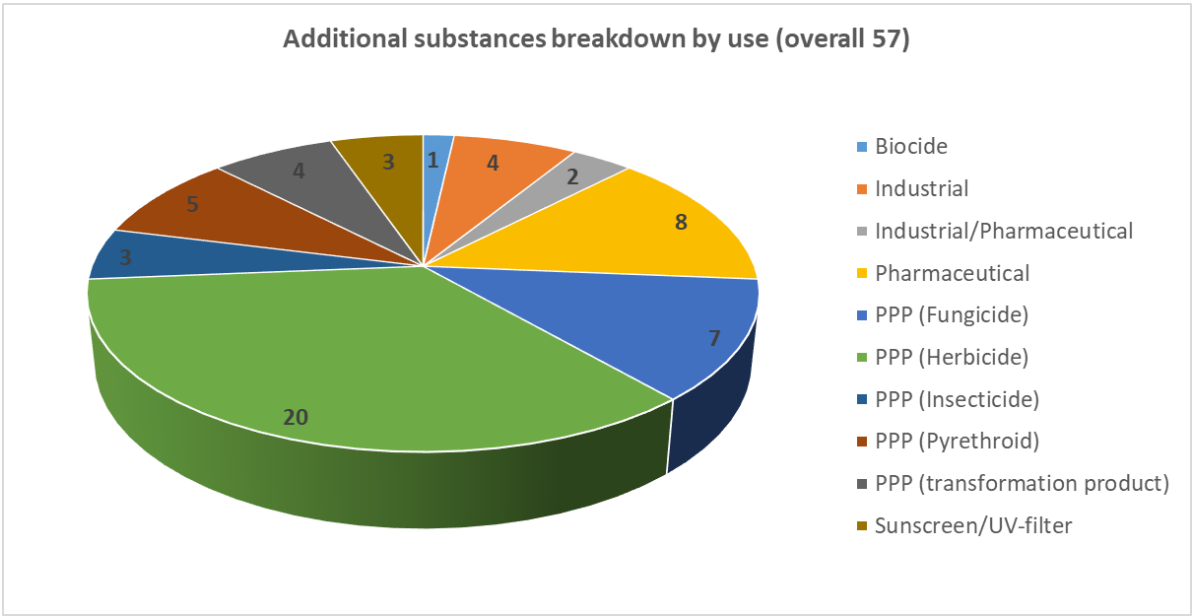

Figure 1. Distribution of the additional substances per group according to their use. The number indicates the amount of substances falling in each group. The full list of the substances is in Annex IV. PPP: Plant Protection Products. Source: EC-JRC

Table 4. List of substances proposed by WG Chemicals experts which are not selected because they are not authorised or due to the current expiry date of their authorisation. PPP: Plant Protection Products.

Substance name	CAS N.	Use	Authorisation	Information	Comment
Chloridazon-desphenyl	6339-19-1	PPP (herbicide, pyridazone – derivatives)	Chloridazone is not approved as PPP in EU since 31/12/2018	Metabolite of chloridazone	
Chloridazon-Methyl-desphenyl	17254-80-7	PPP (herbicide, pyridazone - derivatives)	Chloridazone is not approved as PPP in EU since 31/12/2018	Metabolite of chloridazone very toxic to aquatic life with long lasting effects	
Chlorothalonil	1897-45-6	PPP (fungicide)	Not approved as PPP in EU since 20/05/2019	PPP banned but is still detected in surface waters Suspected Carcinogenic (ECHA) Very toxic to aquatic life with long lasting effects, causes serious eye damage, is suspected of causing cancer	
Chlorothalonil metabolite R471811		PPP (fungicide)	Chlorothalonil is not approved as PPP in EU since 20/05/2019		
Fluazinam	79622-59-6	PPP (fungicide)	Approved in EU as PPP until 25/04/2026 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HU,IE,IT,LT,LU,LV,MT,NL,PL,PT,R O,SE,SI,SK	Suspected to be Toxic to Reproduction (ECHA) Very toxic to aquatic life with long lasting effects	EFSA Conclusion pending

Mecoprop-P	16484-77-8	PPP (herbicide)	Approved in EU as PPP until 15/05/2025 National authorisation AT,BE,BG,CY,CZ,DE,EE,EL,ES,FI,FR, HR,HU,IE,IT,LT,LU,LV,NL,NO,PL,PT, SI,SK	Very toxic to aquatic life with long lasting effects	EFSA Conclusion published. https://www.efsa.europa.eu/en/efsajournal/pub/8344 Decision on renewal pending – no proposal yet made.
Metolachlor	51218-45-2	PPP (herbicide)	Not approved as PPP in EU	Very toxic to aquatic life with long lasting effects	
Metolachlor (S-Metolachlor)	87392-12-9	PPP (herbicide)	S-Metolachlor not approved in EU since 22/01/2024	Very toxic to aquatic life with long lasting effects	
Metolachlor ESA	171118-09-5	Transformation product of PPP		Toxic to aquatic life with long lasting effects	
Metolachlor NOA	413173	Transformation product of PPP			
Metolachlor OXA	152019-73-3	Transformation product of PPP		Harmful to aquatic life with long lasting effects	
Metsulfuron-methyl	74223-64-6	PPP (sulfonylurea herbicide)	Approved in EU as PPP until 31/08/2026 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,NO, PL,PT,RO,SE,SI,SK	Candidate for substitution Very toxic to aquatic life and is very toxic to aquatic life with long lasting effects	Under renewal assessment by RMS

N,N-dimethyl sulfamid	3984-14-3	PPP (fungicide metabolite)	Not approved as PPP in Europe	Decomposition product of the fungicide tolylfluanide. In Germany, DMS was found in groundwaters and surface waters with typical concentrations in the range of 100–1000 ng/L and 50–90 ng/L, respectively (Schmidt 2008)	
Pendimethalin	40487-42-1	PPP (herbicide)	Approved in EU as PPP until 30/11/2024 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,PL, PT,RO,SI,SK	Candidate for substitution Suspected to be Toxic to Reproduction (ECHA) Very toxic to aquatic life, with long lasting effects	Decision on confirmatory data pending. and Under renewal assessment by RMS.
Tau-fluvalinate	102851-06-9	PPP (pyrethroid insecticide)	Approved in EU as PPP 31/08/2024 National authorisation AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI, FR,HR,HU,IT,LT,LU,LV,MT,NO,PL,PT, RO,SE,SI,SK	Very toxic to aquatic life, with long lasting effects (EFSA)	Under renewal assessment by RMS
Tembotrione	335104-84-2	PPP (herbicide)	Approved in EU as PPP until 31/07/2024 National authorisation AT,BE,BG,CY,CZ,DE,EL,ES,FR,HR,HU ,IT,LU,NL,PL,PT,RO,SI,SK	candidate for substitution Suspected to be Toxic to Reproduction (ECHA) Very toxic to aquatic life, with long lasting effects	Under renewal assessment by RMS
Terbuthylazin-2-hydroxy	66753-07-9	Transformation product of PPP		metabolite of terbuthylazine (expiry of approval 31/12/2024)	
Terbuthylazine	5915-41-3	PPP (herbidice)	Approved in EU as PPP until 31/12/2024 National authorisation AT,BE,BG,CY,CZ,DE,EL,ES,FR,HR,HU ,IE,IT,LU,MT,NL,PL,PT,RO,SI,SK	Very toxic to aquatic life, with long lasting effects	Under renewal assessment by RMS

Trisulfuron (formerly Triflusulfuron-methyl)	126535-15-7	PPP (sulfonylurea herbicide)	Triflusulfuron not approved in EU as PPP since 19/11/2023	Suspected to be carcinogenic (ECHA) Endocrine Disrupting properties (EFSA) Very toxic to aquatic life, with long lasting effects	

Source: EC-JRC

2.3. Rationale for the selection

This section further explains the rationale for the selection of the candidate substances fulfilling the criteria described in Section 2.1. Information on Predicted No-Effect Concentration (PNEC), analytical methods and exposure data are shown in Table 1, and more details are included in a separate document (Annex III, factsheets). An overview of the selected substances is presented in Figure 2 (in bold the most suitable candidates selected for the 5th WL). The substances are grouped according to their use or chemical structure (antibiotics, azole fungicides, industrial products, pharmaceuticals, Plant Protection Products (PPP), and sunscreen agents).

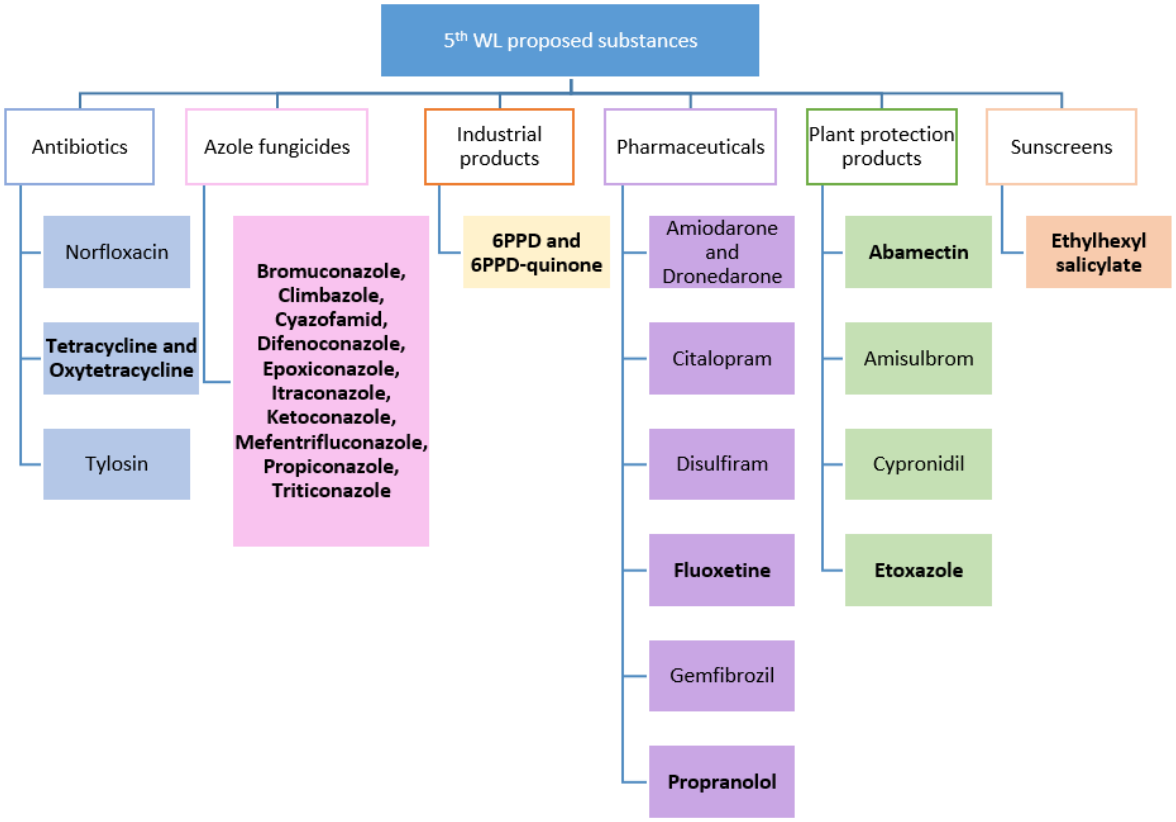

Figure 2. Illustration of the most suitable candidate substances for the next WL. In bold, the substances selected for the 5th WL. Source: EC-JRC

2.3.1. Antibiotics

Antibiotics are chemical agents that kill or inhibit the growth of microorganisms and are widely used in the treatment of bacterial diseases. They are toxic to aquatic life and can contribute to the spread of Antimicrobial Resistance (AMR) even at low, sub-lethal or sub-inhibitory concentrations, representing a risk to human health (Sanseverino et al., 2018).

Antibiotics are released into the environment mainly through Wastewater Treatment Plants (WWTP) and runoff and their concentrations in water, considered the main reservoir, range between 0.01 to 1 µg/L (Monteiro et al., 2010; Larsson, 2014; Kümmerer et al., 2003) with higher values reported for

effluents from antibiotic manufacturing sites (Larsson et al., 2007).

The selection of antibiotics is in line with the European One Health Action Plan against antimicrobial resistance (One Health approach 2023/C 220/01). In the current proposal following the review of the Water Framework Directive (WFD) and its daughter directives, three antibiotics previously on the WL are proposed to be included in the priority substances list (azythromycin, clarithromycin, erythromycin), and antimicrobial resistance genes are to be included in the WL as soon as suitable monitoring methods have been identified (COM/2022/540 final).

Measurement of antimicrobial resistance genes (ARGs) by quantitative Polymerase Chain Reaction (qPCR) and sequencing methods to be adopted as endpoints for the evaluation of risk assessment was also proposed in the 3rd and 4th WL reports by the JRC (Gomez Cortes et al., 2020 and 2022).

The four antibiotics proposed by the JRC for the 5th WL are norfloxacin (CAS 70458-96-7), tetracycline (CAS 60-54-8), oxytetracycline (CAS 79-57-2) and tylosin (CAS 1401-69-0). Reliable PNEC values are available for these substances as well as sensitive analytical methods to monitor them in surface water. They can be monitored using the same analytical method (LC-MS/MS) with limits of quantification ranging from 0.004 to 0.063 µg/L, depending on the substance.

For each antibiotic proposed by the JRC, both PNEC-ENV and PNEC-(resistance selection) have been collected in order to determine ecotoxicological and resistant selection, respectively.

Norfloxacin is a human medicine belonging to the class of quinolone antibiotics. It is authorised in the EU. This substance is suspected of impairing fertility or the unborn child (ECHA, 2023). The lowest PNEC value for this substance is 0.16 µg/L (Table 1). There are no available monitoring data for norfloxacin in WISE 2023 database (EEA). The JRC has received information about additional monitoring data from two MS and a stakeholder. The additional data for exposure showed occasional exceedances in effluents in one MS. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Tetracycline and Oxytetracycline are two antibiotics which belong to the class of tetracyclines and are authorised for human and veterinary use in the EU. Tetracycline is included in the Stockholm list of environmentally harmful Active Pharmaceutical Ingredients (API). It is potentially persistent and has very high acute toxicity (Janusinfo, 2023), while oxytetracycline is suspected of imparing fertility or the unborn child and may cause harm to breast-fed children (ECHA, 2023) and it is one of the most used antibiotics in aquaculture (Leal et al., 2019).

The lowest PNEC value for tetracycline is 0.09 µg/L and for oxytetracycline 0.5 µg/L (Table 1).

No monitoring data are available for tetracycline in the WISE 2023 database (EEA). Information on additional exposure data was received, so far, from two MS and a stakeholder (Table 1). The data provided by one MS showed some quantification frequency at sites but rare exceedances. Regarding the data from another MS, it seems that Limits of Quantification (LOQ) are higher than the proposed PNEC, while the stakeholder indicated that the available monitoring data are insufficient for a proper risk assessment (Table 1). However, MECs from effluents and surface water reported in a scientific publication showed exceedances (details are provided in the factsheet in Annex III).

For oxytetracycline there are monitoring data available from the WISE 2023 database (EEA): 86 samples (all non-quantified) taken at 29 sites in two MS during 2016-2019. The range of LOQ was 0.0025 - 2.5 µg/L. About 24.5% of samples are processed by analytical methods having LOQ > PNEC (0.5 µg/L). Thus, the available data are insufficient and not EU-representative. In addition, the quality of available data is not acceptable (insufficient sensitivity of monitoring and no recent data). The additional exposure data and information received, so far, from three MS and a stakeholder showed a low exposure risk (Table 1). The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Tylosin belongs to the class of macrolides and it is authorised for use in the EU as a veterinary medicine. This substance is very toxic to aquatic life with long lasting effects. It is suspected of causing cancer, and damaging the unborn child, according to ECHA. The lowest PNEC value for this substance is 1 µg/L (Table 1).

No monitoring data are available for tylosin in the WISE 2023 database (EEA). The JRC received information on additional monitoring data from two MS and a stakeholder, which showed a low risk. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Conclusion: The antibiotics norfloxacin, tetracycline, oxytetracycline and tylosin are proposed among the most suitable candidates for the 5th WL. JRC supports the inclusion of oxytetracycline because it is widely used in aquaculture and tetracyline was selected since it is in the Stockholm list of environmentally harmful Active Pharmaceutical Ingredients (API). Tetracycline and oxytetracycline are selected to be included in the 5th WL as a group of tetracyclines based on their contribution to AMR. Norfloxacin and tylosin are included as alternatives.

2.3.2. Azole Fungicides

Azole fungicides are proposed due to their wide use and their potential contribution to Antimicrobial Resistance (AMR). Although the 4th WL (EU/2022/1307) already includes a group of ten azole compounds, additional substances have been selected based on a list received from the EEA within the activity of the interagency mandate on "Azole-resistant Aspergillus", and from literature data (Table AII2). Since the duration of a continuous WL monitoring period for any individual substance may not exceed four years, the ten azole compounds added to the 3rd WL (EU/2020/1161) will be removed in 2024.

Some of the fungicides listed in Table AII2 will not be selected for the 5th WL because the Predicted No-Effect Concentration (PNEC) value is only predicted, as is the case for posaconazole, triazoxide, parconazole, and the pharmaceutical econazole, unless additional information can be found/provided by the experts.

Due to their antifungal properties, azole fungicides are extensively used as Plant Protection Products (PPP) and biocides. Europe is considered the dominant market for fungicides with major applications on grains and cereals, fruits (with particularly intensive use in viticulture), and vegetables. Consequently, fungicides can enter aquatic ecosystems via discharge from wastewater treatment plants following domestic and industrial use and indirectly from surface runoff, primarily from agricultural diffuse sources. Azole fungicides can be harmful to a broad range of non-target organisms and have also been studied for their possible endocrine-disrupting properties. Although there are in many cases no monitoring data, and thus no complete basis for suspecting a risk, there is evidence that Aspergillus fungi have become resistant to many antifungal azoles and monitoring those azoles could help to identify the cause.

The azole compounds are considered as grouped since they have a similar structure and common Mode of Action (MoA), they competitively inhibit the fungal CYP51- class cytochrome P450 superfamily enzyme 14α-sterol demethylase in a dose-dependent manner (Martinez-Matias et al., 2018).

The JRC has identified three azole fungicides approved in EU as antifungal medicines as shown in

Table 1 (climbazole CAS N. 38083-17-9, itraconazole CAS N. 84625-61-6 and ketoconazole CAS N. 65277-42-1) and seven azole fungicides approved in the EU as PPP and/or biocides (bromuconazole CAS N. 116255-48-2, cyazofamid CAS N. 120116-88-3, epoxiconazole CAS N. 133855-98-8, difenoconazole CAS N. 119446-68-3, mefentrifluconazole CAS N. 1417782-03-6 propiconazole CAS N. 60207-90-1 and triticonazole CAS N. 131983-72-7).

Considering the contribution of these substances to AMR, a PNEC-(resistance selection) can be retrieved in the literature for some azole fungicides used as pharmaceuticals as is the case of itraconazole (Bengtsson-Palme and Larsson, 2016).

Climbazole is a pharmaceutical authorised in the EU as antifungal agent for the treatment of human fungal skin infections. It is under assessment as Endocrine Disruptor (ED). A PNEC value of 0.11 µg/L and sensitive analytical methods are available (Table 1).

There are no available monitoring data for climbazole in WISE 2023 database (EEA). Information about additional exposure data, so far, was provided by three MS and a stakeholder. The additional monitoring data of MS showed a quantification rate but a low risk. According to the data available by the stakeholder the number of sites is insufficient for a proper risk evaluation. Moreover, one MS reported no availability of monitoring data. Climbazole is manufactured in and/or imported to the European Economic Area, at ≥ 10 to < 100 tonnes per annum.

Itraconazole is an antifungal medicine with human and veterinary uses authorised in EU for treating aspergillosis and candidiasis. A PNEC-(resistance selection) value (0.008 µg/L) and a sensitive analytical method are available. There are no available monitoring data for itraconazole in WISE 2023 database (EEA). Information about eventual exposure data was provided, so far, by one MS (data only from literature). Three other MS reported no availability of monitoring data (the SPM/sediment is recommended as most meaningful matrix by one MS). One stakeholder informed as well for no data availability. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Ketoconazole is a pharmaceutical authorised in EU as human and veterinary medicines to treat infections caused by dermatophytes and yeasts. Oral and topic formulations are available. This substance is toxic to Reproduction (R) according to ECHA. A PNEC value (0.05 µg/L) and sensitive analytical methods are available (Table 1).

There are no available monitoring data for ketoconazole in WISE 2023 database (EEA). Information about availability of additional monitoring data, so far, was received from three MS and a stakeholder. According to the stakeholder, the number and the quality of the available monitoring data are insufficient for a proper risk assessment. Concentrations occasionally exceeding the proposed PNEC were observed in one MS. The estimated range of use in EU is about 1 – 10 t/y (ECHA)

Bromuconazole is used in EU as PPP, the approval of this substance as PPPs has been recently renewed until 2027. Bromuconazole is very toxic to aquatic life with long lasting effects (ECHA, 2023). A PNEC value (0.015 µg/L) and sensitive analytical method are available (Table 1).

There are no available monitoring data in WISE 2023 database (EEA). Additional exposure data were received, so far, from two MS. The sensitivity of monitoring in one MS is insufficient, comparing with the proposed PNEC, so, the data do not allow a proper risk assessment. Provisionally, the data of one MS indicated no exceedances. Besides, three MS and a stakeholder informed about no availability of monitoring data. The PECs, estimated by FOCUS step 3 model (EFSA), exceed the proposed PNEC.

Cyazofamid is a cyanoimidazole fungicide approved in EU for use as PPP (expiry date 31/07/2036). It is very toxic to aquatic life with long lasting effects (ECHA). A PNEC value (0.13 µg/L) and analytical

methods are available, see Table 1.

There are no available monitoring data for cyazofamid in WISE 2023 database (EEA). The JRC has received, so far, information on additional monitoring data from four MS and a stakeholder. The additional monitoring data showed no exceedances. Some occasional exceedances according to the stakeholder. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Difenoconazole is approved as PPP (expiry 15/03/2026). It is very toxic to aquatic life with long-lasting effects and suspected of causing cancer. A PNEC value (0.36 µg/L) and sensitive analytical method are available (Table 1).

There are no available monitoring data for difenoconazole in WISE 2023 database (EEA). Information for additional monitoring data, so far, was received from five MS and a stakeholder. The additional monitoring data showed some exceedances in one MS. According to the stakeholder, the available data are insufficient for a proper risk assessment but showed a considerable frequency of quantification. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

Mefentrifluconazole is approved for use in EU as PPP (expiry 20/03/2029). According to the harmonised classification and labelling (ATP15) approved by the EU, this substance is very toxic to aquatic life with long lasting effects (ECHA). A PNEC value (1.6 µg/L) and sensitive analytical methods are available (Table 1).

There are no available monitoring data for mefentrifluconazole in WISE 2023 database (EEA). Additional monitoring data, so far, were provided by one MS. Another MS informed about no data availability. The additional monitoring data showed no exceedances.

Triticonazole is approved in EU for use as PPP (expiry 15/03/2025). A PNEC value (1 µg/L) and sensitive analytical method are available (Table 1).

There are no available monitoring data for triticonazole in WISE 2023 database (EEA). Information about additional monitoring data, so far, was received from five MS and a stakeholder. The additional monitoring data showed no exceedances but the PECs (EFSA) indicated a presence of risk. The estimated range of use in EU is about 1 – 10 t/y (ECHA).

The azole fungicides **propiconazole** and **epoxiconazole** were excluded from the 3rd WL at the last minute on the basis that their approval for use in PPP and biocidal products was close to the expiry date.

Propiconazole is not anymore approved as PPP, but it is approved as active substance in biocidal products at least until 2026, so it was reconsidered in this report. Propiconazole is toxic to reproduction and under assessment as ED (ECHA). A PNEC value of 1 µg/L is available for this substance (see the substance factsheet in Annex III).

Epoxiconazole is suspected to be carcinogenic and toxic to reproduction, and a majority of data submitters agree this substance is PBT (ECHA). A PNEC value (0.18 µg/L) is available for this substance. Both substances can be analysed by LC–MS/MS (see the substance factsheet in Annex III).

There are data available for propiconazole and epoxiconazole from WISE 2023 database (EEA).

For **propiconazole,** after the regulation undertaken in 2018, in WISE dataset 2023 (EEA) are available 26975 samples (16.2% quantified) taken at 2506 sites in 7 MS (DE, EE, FI, FR, IT, NL, SE) during the period 2019-2020. Range of LOQs for non-quantified samples 0.0006 – 0.05 µg/L, which would indicate a good sensitivity on monitoring regarding the tentative PNEC=1 µg/L. However, these

data are not EU-representative since 2 MS (FR and IT) are overrepresented holding together about 89.7% of all samples. In addition, recent exposure data (after 2020) are lacking in the WISE dataset. The data from WISE showed rarely exceedances in one MS and RQ<1.

Four MS provided additional monitoring data directly to the JRC (among them only AT was not presented in WISE dataset). The additional data showed some occasional exceedances in three MS. In addition, the Risk Quotients estimated by PECs are in a range 4.1 - 6.4, which indicating a concern.

For **epoxiconazole,** up to its regulation in 2020, in WISE dataset 2023 (EEA) are available 69894 samples (8.2% quantified) taken at 2225 sites in 9 MS (DE, EE, FI, FR, HR, IE, IT, NL, SE) during the period 2010-2020. Range of LOQ 0.002 – 0.05 µg/L for non-quantified samples. Good sensitivity on monitoring regarding the tentative PNEC = 0.18 µg/L. However, the data are not EU-representative since one MS (FR) is overrepresented holding about 86.7% of all samples and other 2 MS hold together about 11% of all data (i.e. 3 MS hold about 97.7% of reported samples). In addition, the available monitoring data do not include information about the recent exposure (after the restriction in 2020). Overall, the WISE data showed exceedances in one MS and RQ(P95)<1 considering data from all reporting MS.

Information about additional exposure data, so far, was provided to the JRC by five MS (among them only AT was not presented in WISE dataset) and a stakeholder. The additional data showed exceedances in one MS. According to the stakeholder, the available data showed high frequency of quantification and some exceedances at local level.

Conclusion: The JRC proposes the following ten azole fungicides as most suitable candidates for the 5th WL to be included as a group of substances: bromuconazole, climbazole, cyazofamid, difenoconazole, epoxiconazole, itraconazole, ketoconazole, mefentrifluconazole, propiconazole and triticonazole. The selection of the azoles is based on their hazard properties, potential contribution to the AMR and indication of potential risk estimated by MECs or PECs.

2.3.3. Industrial products

Among the additional substances proposed by Members of the WG Chemicals, after circulating the first draft-report for selection of substances for the 5th WL in 2023, the JRC has identified the industrial product N-1,3-Dimethylbutyl-N'-phenyl-p-phenylenediamine, 6PPD (CAS N: 793-24-8) and its transformation product 6PPD-quinone (CAS N. 2754428-18-5) as suitable candidates for the 5th WL. The selection is based on evidence for higher toxicity, particularly of the transformation product 6PPD-quinone in salmon, in a study by Tian et al. (2021; 2022). The toxicity of these substances has been reviewed by other authors (Chen et al., 2023; Brinkmann et al., 2022) concluding that sensitivity to acute exposure to 6PPD-quinone is highly variable across fish species in general, and salmonids specifically.

6PPD is used as tyre rubber antioxidant and it is very toxic to aquatic life with long lasting effects (H400, H410).

The PNEC value for 6PPD in freshwater is 0.37 µg/L (ECHA) and it can be analysed by LC-MS/MS together with its transformation product 6PPD-quinone (see Table 1).

There are no available monitoring data for 6PPD and 6PPD-quinone in WISE 2023 database (EEA). Additional monitoring data, so far, were provided to the JRC by two MS. The additional data for 6PPD-

quinone showed occasional exceedances in one MS (rainwater from a highway drain). 6PPD is manufactured in and / or imported to the European Economic Area at ≥ 10,000 to < 100,000 tonnes per annum.

Conclusion: 6PPD and its transformation product 6PPD-quinone are listed among the most suitable candidates for the 5th WL. Emerging concern has been raised in the last years for the release of these substances in the aquatic environment.

2.3.4. Pharmaceuticals

The JRC has identified a total of seven pharmaceuticals for possible inclusion in the list of most suitable substances for the 5th WL. Gemfibrozil (CAS N. 25812-30-0) and propranolol (CAS N. 525-66-6) were identified from previous Watch List (WL) reports, while amiodarone (CAS N. 1951-25-3), citalopram (CAS N. 59729-33-8), disulfiram (CAS N. 97-77-8), dronedarone (CAS N. 141625-93-6), and fluoxetine (CAS N. 54910-89-3) were selected among the additional substances proposed by Members of the WG Chemicals after circulating the first 5th WL draft report (see Table 1).

Amiodarone and **dronedarone** are authorised for use in EU as antiarrhythmic medicines. They belong to class III antiarrhythmic agents, which act by blocking potassium channels prolonging repolarisation. As a result, cardiac muscle cell excitability is reduced, preventing and treating abnormal heart rhythms.
Amiodarone has high chronic toxicity, while dronedarone is very toxic to aquatic life with long lasting effects, is suspected of impairing fertility or the unborn child, may cause harm to breast-fed children, is suspected of causing cancer and some data submitters indicate they consider this substance as toxic to reproduction.
The PNEC values for amiodarone and dronedarone are 0.24 µg/L and 0.4 µg/L, respectively (see Table 1). They can be analysed by LC-MS/MS with LOQs of 0.01 µg/L and 0.1 µg/L, respectively.
There are no available monitoring data for amiodarone and dronedarone in WISE 2023 database (EEA). However, the RQ(PEC) is higher than 1 (amiodarone) or approaching 1 (dronedarone).

Citalopram is a serotonin-selective reuptake inhibitor authorised in EU for treating depression and anxiety. This substance is included in the Stockholm's list of environmentally harmful Active Pharmaceutical Ingredients (API). It is very toxic to aquatic life with long lasting effects. The PNEC value (6.4 µg/L) and analytical method are available for this substance (LC-MS/MS) as shown in Table 1. There are no available monitoring data for citalopram in WISE 2023 database (EEA). Additional exposure data were provided by one MS showing no exceedances. However, RQ(PEC)>1.

Disulfiram is a medicine authorised in the EU for treating chronic alcoholism. It is very toxic to aquatic life with long lasting effects. A PNEC value of 0.02 µg/L and a sensitive analytical method (UPLC-MS/MS with LOQ = 0.1 µg/L) are available (see Table 1). There are no available monitoring data for disulfiram in WISE 2023 database (EEA). Additional monitoring data, so far, were not provided to the JRC (one MS informed about no available data). This substance is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum.

Fluoxetine is a pharmaceutical (Prozac) authorised for human and veterinary use in the EU to treat depression, obsessive-compulsive disorders and bulimia nervosa. This substance is included in the

Stockholm's list of environmentally harmful API. A PNEC value of 0.012 µg/L was provided by MS experts (Oakes et al., 2010) and a sensitive analytical method to monitor this substance in surface water is available (UHPLC-QTOF-HRMS, LOD = 0.005 µg/L) as shown in Table 1. Fluoxetine is potentially persistent with low potential for bioaccumulation and it has very high chronic toxicity (Janusinfo, SE).
There are available monitoring data from WISE 2023 database (EEA): 181 samples (all non-quantified) taken at 31 sites in 2 MS during the period 2016-2021. Range of LOQs 0.0011 - 1 µg/L for non-quantified samples. Only about 26% of samples are processed with methods having LOQs ≤ 0.01 µg/L, i.e. this would indicate an insufficient sensitivity on monitoring regarding the tentative PNEC = 0.012 µg/L. In addition, the data are not EU-representative. The quality of available data does not support a proper statistical analysis of MECs. Additional exposure data, so far, were provided to the JRC by one MS showing some exceedances in effluent waters. Literature MECs and PECs showed RQ>1.

Gemfibrozil is a pharmaceutical authorised in EU for the treatment of abnormal blood lipid levels. It is suspected of causing cancer, suspected of impairing fertility or the unborn child and it is harmful to aquatic life with long lasting effects (ECHA).
A PNEC value and analytical method are available. The JRC selected the value of 0.5 µg/L as the lowest one, however concern regarding the derivation of this value was expressed by Members of the WG Chemicals after circulating the first 5th WL draft report. An additional value is included for this substance (1.5 µg/L) as shown in Table 1. Gemfibrozil can be analysed in surface water by SPE followed by LC--MS/MS (LOQ = 0.0034 µg/L).
There are no available monitoring data in WISE 2023 database (EEA). Information about additional exposure data was provided to the JRC, so far, by three MS and a stakeholder. The additional monitoring data showed some quantification rate but no exceedances. MECs from two scientific articles showed RQ>1.

Propranolol is an antihypertensive pharmaceutical authorised for use in EU. It has very high chronic toxicity (Janusinfo, SE). A PNEC value is available for propranolol (0.02 µg/L). This substance can be measured in surface water LC-MS/MS (see Table 1).
There are available some monitoring data in WISE 2023 database (EEA): 397 samples (30.5% quantified) taken at 49 sites in 4 MS (BE, EE, NL, SE) during 2018-2021. However, the data are not EU representative since 2 MS are overrepresented holding together 95% of all samples. Range of LOQs 0.0011 - 0.03 µg/L for non-quantified samples, which indicates a sufficient sensitivity of monitoring compared to the tentative PNEC = 0.02 µg/L.
The available data from WISE showed higher quantification rate, exceedances in two MS and an overall RQ(P95)=4.7 according to the tentative PNEC=0.02 µg/L and assuming a substitution of non-quantified samples by ½ LOQ (details in the substance's factsheet).
Information about additional exposure data was provided to the JRC, so far, by three MS (among them AT and DE were not presented in WISE dataset) and two stakeholders (including AstraZeneca). Regarding the tentative PNEC = 0.02 µg/L, the additional exposure data showed high level of quantification frequency, exceedances and RQs > 1, i.e. a presence of risk (details in the substance's factsheet, Annex III).
For completeness, the analysis of exceedances and risk screening according to the initially proposed PNEC=0.16 µg/L are also presented in the propranolol's factsheet (Annex III).

Conclusion: Fluoxetine and propranolol have been selected to be included in the 5th WL. Fluoxetine is very toxic and is listed as harmful substance in the Stockholm's list of environmental harmful API. Propranolol has high toxicity and showed a higher quantification frequency and exceedances according to the available exposure data. Amiodarone, dronedarone, citalopram, disulfiram and gemfibrozil are listed as alternative substances for the 5th WL.

2.3.5. Plant Protection Products

The JRC investigated also other substances used as Plant Protection Products (PPP) in the EU as possible candidates for the 5th Watch List (WL) and identified a non-azole fungicide used as PPP in EU, amisulbrom CAS N. 348635-87-0. After circulating the first 5th WL draft report, the members of the WG Chemicals suggested additional substances used as PPP in the EU. Following the criteria described in Chapter 2.1 the JRC selected three additional substances: abamectin CAS N. 71751-41-2 ([4]), cyprodinil CAS N. 121552-61-2, and etoxazole 153233-91-1 as suitable candidates for the 5th WL.

Abamectin is an insecticide and anthelmintic approved in EU as PPP (expiry date 31/03/2038). Abamectin (CAS N. 71751-41-2) is a mixture of ≥ 80% avermectin B1a (CAS N. 65195-55-3) and < 20% avermectin B1b (CAS N. 65195-56-4). It was previously approved for use as a biocide in the EEA and/or CH for controlling insects, ants, etc., and this approval has now expired. However, it is authorised for veterinary use (cattle) for the treatment of gastro-intestinal nematodes, lungworms and nasal bots. Abamectin is very toxic to aquatic life with long lasting effects and is suspected to be toxic to reproduction and of damaging the unborn child (H400, H410, H361d, see Table 1). A very low PNEC value is available (0.001 µg/L). The substance can be monitored in surface water by LC-MS/MS(LOQ = 0.0005 µg/L). Monitoring data are not available for abamectin in WISE 2023 (EEA). Additional exposure data, so far, were provided to the JRC by one MS showing no detection. However, RQ(PEC)>1.

The avermectins are a group of antiparasitic agents that belong to the class of macrocyclic lactones. These compounds consist of 16-membered macrocyclic lactone derivatives and their metabolites (such as ivemectin, doramectin, emamectin, eprinomectin). They exhibit anthelmintic (anti-worm) and insecticidal properties, primarily used as veterinary medicine, and some derivatives are also used in human medicine. However, currently there are not reliable PNEC for the other avermectin substances. Therefore, the JRC, would recommend to include only abamectin as most suitable candidate substance for the 5th WL since it is the most widely used drug and pesticide among the avermectin group bearing in mind the other substances as potential candidate for the next WL program.

Amisulbrom is a fungicide belonging to the chemical family of sulphonamides (inhibitors of the mitochondrial respiratory chain). It is approved in EU as PPP (expiry date 30/09/2024). This substance is suspected to be carcinogenic (ECHA). A PNEC value is available (RAC = 0.229 µg/L) as well as a sensitive analytical method to monitor it in surface water (see Table 1). There are no available monitoring data for amisulbrom in WISE 2023 database (EEA). The JRC has received, so far, additional exposure data from two MS, which indicated no exceedances. However, RQ(PEC)>1.

Cyprodinil is an anilinopyrimidine fungicide approved in EU for use as PPP (expiry date 15/03/2025). This substance is very toxic to aquatic life with long lasting effects, and it is a candidate for

[4] Abamectin (CAS N. 71751-41-2) is a mixture of ≥ 80% avermectin B1a (CAS N. 65195-55-3) and < 20% avermectin B1b (CAS N. 65195-56-4).

substitution. A PNEC value 0.026 µg/L and analytical methods are available (see Table 1). Monitoring data are available for cyprodinil in WISE 2023 (EEA): 17188 samples (22.3% quantified) taken at 1334 sites in 4 MS during the period 2015-2020. Range of LOQ 0.003 – 2 µg/L. About 86% of samples are processed with analytical methods having LOQ ≤ 0.026 µg/L, i.e. a sufficient sensitivity of monitoring regarding PNEC = 0.026 µg/L. The data are not EU-representative since 2 MS are overrepresented holding together about 99% of all samples. In addition, the available monitoring data do not include the recent years after 2020. One MS has provided additional monitoring data to the JRC (127 samples for 2016 and 359 samples for 2017-2018). According to the WISE data, RQ(MEC(P95)) = 0.77 (considering all reporting MS). The additional monitoring data showed exceedances and presence of concern since RQ(MEC(P95)) > 1. In addition, RQ(PEC)>1.

Etoxazole is an acaricide and insecticide approved in EU for use as PPP (expiry date 31/01/2028). It is approved as a candidate for substitution based on its bioaccumulative and toxic properties, meeting the criteria outlined in Regulation (EC) No 1107/2009, Annex II, points 3.7.2.2 and 3.7.2.3. Only uses on ornamental plants in permanent greenhouses shall be authorised. A very low PNEC value was found for this substance (0.0004 µg/L). For completeness, another PNEC value is also available (0.013 µg/L) as shown in Table 1 and an analytical method sensitive enough to monitor etoxazole in water at such low concentrations (LOQ = 0.0003 µg/L). There are no available monitoring data for etoxazole in the WISE 2023 database (EEA). Additional data, so far, were provided to the JRC by one MS but the monitoring was performed with insufficiently sensitive method regarding the PNEC=0.0004 µg/L. Another MS informed about "no use of this substance". However, RQ(PEC)>1.

Conclusion: The JRC has selected abamectin and etoxazole among the most suitable candidates for the 5th WL. They were selected due to their hazard properties. JRC recommends the inclusion of these substances due to their high toxicity. Amisulbrom and cyprodinil are included as alternatives. If no information about the approval renewal of amisulbrom is received, it will be moved to Table 4.

2.3.6. Sunscreen agents

The sunscreen agents avobenzone (CAS 70356-09-1), octocrylene (CAS 6197-30-4) and oxybenzone (CAS 131-57-7), were identified by the JRC in the 4th WL report (Gomez Cortes et al., 2022) and were included as group in the 4th WL (EU 2022/1307).

The sunscreen agent ethylhexyl salicylate (octisalate) CAS N. 118-60-5 was suggested by Members of the WG Chemicals after circulating the first version of the 5th WL draft report based on recently measured concentrations in Swiss lakes with bathing activity and frequency of use. Based on *D. magna* data, it has chronic effects in the same order of magnitude as octocrylene.

Octisalate is very toxic to aquatic life with long lasting effects and it is a potential endocrine disruptor (see Table 1). Moreover, it is included in Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation') as an ultraviolet radiation filter allowed for use in cosmetic products with a maximum concentration of 5 %. A PNEC value of 0.168 µg/L is available for this substance, and an analytical method is available (see Table 1) for monitoring this substance in surface water. It could be measured by LC-MS/MS together with the other sunscreen agents included in the 4th WL (EU 2022/1307). There are no available data for this substance in WISE 2023 database (EEA). Additional data, so far, were provided to the JRC by one MS showing no exceedances. Octisalate is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.

Conclusion: Octisalate is selected as it is very toxic to aquatic life with long lasting effects, it is a potential endocrine disruptor and it could be added to the group of sunscreen agents (avobenzone, octocrylene and oxybenzone) already listed in the current WL (EU 2022/1307).

3. Recommendations and Conclusions

Some substances were not considered for the current Watch List (WL) update because water is not the appropriate matrix for monitoring them, and monitoring in other matrices has so far not received much MS support in the context of the WL. The substances not selected (at least partly) for this reason include the alkylphenols, rodenticides and siloxanes. This should not be taken as an indication that they are of lesser potential concern. In the case of the rodenticides, the Predicted No-Effect Concentration (PNEC) value could be back calculated to water from biota when a reliable bioaccumulation factor (BCF) becomes available.

For certain azole fungicides, some Members of the WG Chemicals suggested SPM/sediment as the most appropriate matrix, since they show a log Kow value slightly higher than 3 (bromuconazole 3.24; climbazole 3.83; cyazofamide 3.2; difenoconazole 4.36; epoxiconazole 3.33; itraconazole 4.35-6.16-; ketoconazole 3.83; mefentrifluconazole 3.28; propiconazole 3.72; triticonazole 3.29). Since the available PNEC values and the monitoring data received from MS and stakeholders refer to water, JRC recommends measuring these substances in the water matrix to provide an overview of the azole fungicides in EU water bodies.

For other substances such as the synthetic hormones levonorgestrel and norethisterone, which have a very low PNEC value, no analytical method is yet available that is sensitive enough for monitoring them in water. The use of alternative methods such as Effect-Based Methods (EBM) would be an alternative, but they need validation. The JRC has committed to investigate them, however this task has had to be postponed due to the interlaboratory exercise for the estrogenicity EBM, included in the Commission proposal following up the WFD review. However, these substances would deserve more attention and the appropriate method (conventional or EBM) should be further investigated to allow their inclusion in the WL.

Free cyanide is not shortlisted for the 5th WL but should be considered again following efforts to facilitate the sharing of analytical capability.

Illicit drugs were evaluated for inclusion in the 4th WL report (Gomez Cortes et al., 2022) but they were not supported by the majority of MS experts. However, these substances occur in the aquatic environment and may pose a risk to aquatic organisms. In recent years, an increase in the concentrations of synthetic molecules such as fentanyl has been observed. Since there is no information on their concentrations at EU level the JRC recommends considering them in future WL updates.

Lithium was suggested by a MS, however it is not shortlisted because so far there is no evidence of concern, and a more reliable PNEC is needed. The EQS Technical Guidance No. 27 (EC, 2018) recommends incorporating bioavailability in the derivation of EQS for metals where possible. For this reason, the JRC gave priority to other substances this time.

Per- and Polyfluoroalkyl Substances (PFAS) as well as pyrethroid insecticides are considered of very high concern for human health and aquatic organisms, respectively. They could be added directly to the WFD as priority substances (PS) to join those already in the PS list. For PFAS with information on the relative potency factor (RPF), a cumulative risk assessment could already be carried out based on the EQS for the sum of 24.

In conclusion, following the criteria defined in Section 2.1 the JRC selected eight substances as most suitable candidates for the 5th WL. Seven substances are proposed as new candidates, while an additional substance (octisalate) is proposed to be included in the group of sunscreen agents already included in the 4th WL update (EU/2022/1307):

1- 6PPD and its transformation product 6PPD-quinone. 6PPD is a tyre rubber antioxidant product. Concern has been raised in recent years over the release and toxicity of these substances in the aquatic environment.
2- Abamectin is an insecticide and anthelminthic approved in the EU for PPP and veterinary uses. The JRC has selected it due to its hazard properties.
3- Etoxazole is an acaricide and insecticide approved in the EU for use as a PPP. The JRC supports its inclusion in the 5th WL due to its high toxicity.
4- Fluoxetine is a pharmaceutical (Prozac) authorised for human and veterinary uses. It is included in the Stockholm list of environmentally harmful Active Pharmaceutical Ingredients (API).
5- Group of azole fungicides. The JRC proposes the following ten azole fungicides as a group of substances, since the MoA is the same: bromuconazole, climbazole, cyazofamid, difenoconazole, epoxiconazole, itraconazole, ketoconazole, mefentrifluconazole, propiconazole and triticonazole. The choice of the azoles is based on their hazard properties, and potential contribution to Antimicrobial Resistance (AMR).
6- Propranolol is an antihypertensive pharmaceutical authorised for use in the EU. It has been selected due to its high ecotoxicity and because showed higher quantification rate and some exceedances according to the available exposure data.
7- Group of tetracycline-antibiotics (oxytetracycline and tetracycline). These substances are selected for their hazard properties and contribution to AMR. Oxytetracycline is widely used in aquaculture and tetracycline is in the Stockholm list of environmentally harmful API.
8- The sunscreen agent octisalate (ethylhexyl salicylate). The JRC proposes the inclusion of this substance in the 5th WL in the group of sunscreen agents (avobenzone, octocrylene and oxybenzone) already listed in the current WL (EU 2022/1307).

It is worth to mention that these substances should be monitored where potentially could be found, as the case for the 6PPD and its transformation product 6PPD-quinone. Indeed these two substances should be measured in surface waters, close to highway or very traffic area, similarly the antibiotics and pharmaceuticals in urban and farmer areas.

Furthermore, eight additional substances are included as alternatives: the antibiotics norfloxacin and tylosin; the fungicides amisulbrom and cyprodinil; the group of antiarrhythmic medicines amiodarone and dronedarone; and the pharmaceuticals citalopram disulfiram and gemfibrozil. However, the approval of amisulbrom expires in 2024. If no information on the renewal of this substance is received, it will be moved to Table 4.

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List of abbreviations and definitions

Abbreviations	Definitions
AA-QS	Annual Average Quality Standard
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredients
ARG	Antibiotic Resistance Genes
B	Bioaccumulative
C	Carcinogenicity
CQC	Chronic Quality Criterion
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EBM	Effect-Based Methods
EQS	Environmental Quality Standard
EQSD	Environmental Quality Standards Directive
ERA	Environmental Risk Assessment
FASS	Swedish environmental classification of pharmaceuticals (Fass.se)
INERIS	French National Institute for Industrial Environment and Risks
LC50	Lethal Concentration 50
LC-MS	Liquid Chromatography-Mass Spectrometry
LC-MS/MS	Liquid Chromatography-tandem Mass Spectrometry
LOQ	Limit of Quantification
M	Mutagenicity
MEC	Measured Environmental Concentration
MIC	Minimal Inhibitory Concentration
MoA	Mode of Action
MS	Member States
MSC	Minimal Selective Concentration

Abbreviations	Definitions
MTR	Maximum allowable risk level (NL)
P	Persistent
PEC	Predicted Environmental Concentrations
PFAS	Per- and Polyfluoroalkyl Substances
PFOA	Perfluorooctanoic acid
PNEC	Predicted No-Effect Concentration
PNEC-ENV	Predicted No-Effect Concentration-Environment
PPP	Plant Protection Products
PS	Priority Substances
qPCR	Quantitative Polymerase Chain Reaction
R	Reproductive Toxicity
RAC	Regulatory Acceptable Concentration (DE)
RBSP	River Basin-Specific Pollutant
RIVM	National Institute for Public Health and the Environment (NL)
RPF	Relative Potency Factor
RQ	Risk Quotient
SYKE	The Finnish Environment Institute
T	Toxicity
UBA	Germany's central environmental authority
WFD	Water Framework Directive
WL	Watch List

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Annexes

Annex I Sources of information

Exposure information

Exposure information was sought for all potential WL candidates from various sources but was not always found or was often very limited. Furthermore, not only data availability but also the quality of the collected data (if any) is crucially important to assess the risk that a given substance might pose. A summary of the monitoring data for each candidate substance in provided in Section 2.3 (Rationale for the selection) while details can be found in the dedicated factsheets (Annex III).

The relevant sources of monitoring data, used in the report, include the WISE database managed by the EEA (https://www.eea.europa.eu/data-and-maps/data/waterbase-water-quality-icm-2), the Naiades database (http://www.naiades.eaufrance.fr/acces-donnees#/physicochimie), reports and publications, and exposure data provided directly to the JRC by several MS.

Regarding the statistical analyses of Measured Environmental Concentrations (MECs), the JRC acknowledges that despite the constantly improving sensitivity of analytical techniques, any set of MECs may contain a proportion of non-detected or non-quantified samples. Thus, the usage of non-quantified samples in exposure datasets is a challenge when not all the limits of quantification (LOQs) of applied analytical methods are adequate in relation to the PNEC values.

In this report, the Data Scenario 2 (Sc2), which comprises all disaggregated raw data (all reported quantified and non-quantified samples), and the Data Scenario 3 (Sc3), containing quantified monitoring data plus non-quantified data for which ½ LOQ ≤ PNEC, have been used. The Sc3 is a more relevant data scenario for making a risk assessment according to the sub-group on review (SG-R) of the priority substances list (Carvalho et al., 2016; https://circabc.europa.eu/w/browse/52c8d8d3-906c-48b5-a75e-53013702b20a). When the substitution approach is feasible (EFSA, 2010; Shoari and Dube, 2018), then the non-quantified samples are set equal to half of the LOQ as stipulated in Directive 2009/90/EC. Other substitutions are also possible (for example at LOQ). If the level of censoring is high, then comprehensive mathematical techniques should be used for estimation of summary statistics (Gardner 2011; Helsel 2012; Shoari and Dube, 2018). In the report, the calculations of Risk Quotients (RQ) are mainly based on Scenario 2 data which are usually insufficient or have low quality, therefore should be considered as preliminary and tentative.

Hazard information

Hazard information was collected from various sources (Table AI1) for all the potential candidate substances.

First, EQS were collected from reports or online databases, or from literature, in particular if the methodology in the TGD EQS (2018) had been followed. Reports and publications provided directly to the JRC by MS were taken into account.

Second, PNEC values were collected, with a particular focus on the substances where no EQS value was available. Furthermore, PNEC values were searched for in the literature, with preference given to those used already in European monitoring campaigns or prioritisation exercises.

Third, PNECs were collected from the European Chemicals Agency (ECHA) dossiers and European Food Safety Authority (EFSA) risk assessment reports, when available.

Fourth, for pharmaceuticals, the Swedish Fass.se database was considered. In the case of antimicrobials, PNEC values were retrieved from the antimicrobial resistance (AMR) industry alliance list.

Fifth, literature was also screened for PNEC values.

Finally, for those substances where information was not available from any of the sources listed above, PNECs were calculated by the JRC using studies that were considered reliable or reliable with restrictions (as explained in the TGD-EQS (2018)).

Then, information about the PBT properties was retrieved from ECHA (industrial chemicals, pharmaceuticals and biocides) or EFSA (plant protection products, PPP), while Fass.se (SE) and Janusinfo, Stockholm County Council was the source for human pharmaceuticals. Carcinogenicity (C), Mutagenicity (M) and Reproductive Toxicity (R) categorisations (in accordance with the Globally Harmonised System of Classification and Labelling of Chemicals (GHS)) were extracted from ECHA dossiers. For ED substances, the Endocrine Disruptor Strategy (EDS) database and categorisation of the European Commission was used (EDS database, EC). Information retrieved from TDEX (the endocrine disruption exchange) as well as from research projects and peer reviewed articles was also considered for evaluating the ED properties of the substances. Concerning PPP, the information on CMR and PTB was retrieved from EFSA dossiers when available.

ECHA's information was used to identify substances for which there is an indication of concern.

Table AI1. Sources for EQS/PNEC values and hazard information.

Source	**Description**
AMR Industry alliance	Anti-Microbial pharmaceuticals, Science-Based PNEC Targets for Risk Assessments https://www.amrindustryalliance.org/wp-content/uploads/2023/02/AMR-Table-1-Update-20230222_corrected.pdf
ECHA	European Chemicals Agency https://echa.europa.eu/home
ECOTOX Database US EPA	USEPA ECOTOX Knowledgebase https://cfpub.epa.gov/ecotox/search.cfm
EDS database, EC	ECHA's endocrine disruptor (ED) assessment list. https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm https://echa.europa.eu/ed-assessment
EFSA	European Food Safety Authority https://www.efsa.europa.eu/en

ETOX UBA	Information System Ecotoxicology and Environmental Quality Targets https://webetox.uba.de/webETOX/index.do?language=en
EU Pesticides database	Plant protection products https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances
FASS	Swedish Environmental Classification System, Pharmaceuticals https://www.fass.se/LIF/startpage
INERIS	*French* National Institute for Industrial Environment and Risks, Portal chemical substances https://substances.ineris.fr/fr/
Janusinfo, Stockholm County Council	Pharmaceuticals https://www.janusinfo.se/environment
JRC	All substances
Norman	NORMAN Ecotoxicology Database — Lowest PNECs https://www.norman-network.com/nds/ecotox/lowestPnecsIndex.php?checkSelect=0;
Research articles and reports	All substances
RIVM	National Institute for Public Health and the Environment (NL) https://rvszoeksysteem.rivm.nl/Stoffen https://www.rivm.nl/
Swiss ECOTOX centre	Proposals for Quality Criteria for Surface Waters https://www.ecotoxcentre.ch/expert-service/quality-criteria/quality-criteria-for-surface-waters/
TDEX	The endocrine disruption exchange https://endocrinedisruption.org/
UBA	German Environment Agency - Umweltbundesamt https://www.umweltbundesamt.de/en

Source: EC-JRC

Analytical methods

A literature review of available analytical methods was carried out for the candidate substances. The JRC searched for analytical methods in reports and peer-reviewed papers. In these latter, the JRC verified that technical details are described. Where possible, the JRC uses the same terminology, preferably LOQ, to express the sensitivity of the method. In cases where the information is retrieved from peer-reviewed articles that use LOD (limit of detection) or MQL (method quantification limit), this is indicated. Furthermore, the matrix for which the analytical method has been validated, if other than water, is specified in the report and in the substance' factsheets (Annex III).

Table AI2. Sources for analytical methods.

Source	**Description**
Companies	Plant protection products and industrial products
ECHA	Publicly available assessment reports of the approved biocidal substances https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances and other substances https://echa.europa.eu
EFSA	Plant protection products https://www.efsa.europa.eu/en
Research articles and reports	All substances
USGS	Plant protection products and industrial products https://www.usgs.gov/
US EPA	Plant protection products https://www.epa.gov/

Source: EC-JRC

Annex II Tables

Table AII1: List of antibiotics identified from the literature for their possible contribution to antimicrobial resistance.

Group	Substance name /CAS number	PNEC (ENV = environmental, Concentration, fw = freshwater)	Uses	Status	Exposure data
Sulfonamides	Sulfamethazine 57-68-1	PNECfw = 30 µg/L (Oecotox centrum, 2016)	Veterinary	Approved	Not available
	Sulfadiazine 68-35-9	PNEC-ENV = 11 µg/L Source: AMR Industry Alliance	Veterinary	Approved	Not available
Tetracyclines	Tetracycline 60-54-8	PNEC-ENV = 3.2 µg/L PNEC-(resistance selection) = 1 µg/L Source: AMR Industry Alliance	Human and veterinary	Approved	Not available
	Oxytetracycline 79-57-2	PNEC-ENV = 47 µg/L PNEC-(resistance selection) = 0.5 µg/L Source: AMR Industry Alliance	Human and veterinary	Approved	A few data are available
Quinolones	Norfloxacin 70458-96-7	PNEC-ENV = 120 µg/L PNEC-(resistance selection) = 0.5 µg/L Source: AMR Industry Alliance	Human medicine	Approved	Not available
Macrolides	Roxithromycin 80214-83-1	PNEC-ENV = 6.8 µg/L PNEC-(resistance selection) = 1 µg/L Source: AMR Industry Alliance	Human medicine	Approved	Not available
	Tylosin 1401-69-0	PNEC-ENV = 1 µg/L PNEC- (resistance selection) =4 µg/L Source: AMR Industry Alliance	Veterinary	Approved	Not available

Source: EC-JRC

Table AII2: List of fungicides collected from the literature and recommended by the EEA

Group	Substance Name/ CAS number	PNEC	Uses	Status	Comment	Exposure data
Fungicides/ azole and	Climbazole CAS_38083-17-9	0.11 µg/L CQC ad hoc - Switzerland	Pharmaceutical			Not available
	Pyrisoxazole CAS_847749-37-5			Not clear	Not in the EU pesticides database / Not in ECHA.	Not available
	Posaconazole CAS_171228-49-2	P-PNEC predicted 0.0038 µg/L	Pharmaceutical	Authorised in the EU (noxafil), and as "generic medicine" (EMA)	To search for ecotox data for the PNEC derivation	Not available

related substances	Ketoconazole CAS_65277-42-1	0.1 µg/L (AF=10, 0.05 µg/L) Janusinfo SE **0.05 µg/L** (Vestel et al., 2016) 0.0081 µg/L (NORMAN)	Pharmaceutical	Authorised for use in the European Union for veterinary and human uses (EMA).	Ketoconazole is a pharmaceutical authorised in EU to treat infections caused by dermatophytes and yeasts. Ketoconazole is a medicine used to treat adults and children above the age of 12 years with Cushing's syndrome.	Not available
	Itraconazole	PNEC-resistance	Pharmaceutical	Authorised in		Not available

	CAS_84625-61-6	selection=**0.008 µg/L** (Bengtsson-Palme and Larsson, 2016); P-PNEC predicted 0.013 µg/L ToxTrAMs (2017) (from NORMAN)		Europe for veterinary and human uses		
	Epoxiconazole CAS_133855-98-8	0.2 µg/L Switzerland; **0.18 µg/L** INERIS, 2017; 0.46 µg/L (RAC, UBA) NL JG-MKN 0.19 µg/L, vastgesteld [EN: NL AA-EQS 0.19 µg/L, determined] Comment from NL 700 ng/L Check ECHA 2023	PPP	Suspected to be Carcinogenic Toxic to Reproduction A majority of data submitters agree this substance is PBT (https://echa.europa.eu/substance-information/-/substanceinfo/100.100.840)	Not approved as PPP	Not available
	Iprodione CAS_36734-19-7	0.35 µg/L (VGE –INERIS)			Not approved as PPP (Authorisation at national level NL?)	Not available
	Triazoxide CAS_72459-58-6	2.1 µg/L (DK comments) P-PNEC predicted 0.36 µg/L	PPP	Not approved as PPP according to the EU pesticides database. To verify, in 2019 EFSA reviewed the Maximum Residue Level (MRL) It was approved from 01/10/2011 to 30/09/2021.		Not available

	Parconazole hydrochloride CAS_62973-77-7	P-PNEC predicted 0.65 µg/L	Pharmaceutical			Not available
	Difenoconazole CAS_119446-68-3	**0.36 µg/L** UBA, provided by DE 0.56 µg/L PNEC chronic / AA-QSwater_eco (INERIS, 2013) 0.76 µg/L PNEC – RIVM	PPP	Approved as PPP (EU Pesticides database, expiry 15/03/2026)		Not available
	Triticonazole CAS_131983-72-7	1 µg/L CQC ad hoc - Switzerland	PPP	Approved as PPP (EU Pesticides database, expiry 15/03/2025)		Not available
	Prothioconazole CAS_178928-70-6	31 µg/L (DK comments) P-PNEC predicted 1.03 µg/L	PPP	Approved as PPP (EU Pesticides database, expiry 15/08/2025)		Not available
	Cyazofamid CAS_120116-88-3	0.13 µg/L (RIVM, 2006) CQC ad hoc – Switzerland 1.1 µg/L	PPP	Approved as PPP (EU Pesticides database, expiry 31/07/2036)		Not available
	Amisulbrom CAS_348635-87-0	RAC = **0.229 µg/L** (UBA, 2017) 1.39 µg/L (CQC ad hoc – Switzerland, taken from NORMAN)	PPP	Approved as PPP (EU Pesticides database, expiry 30/09/2024)		Not available
	Bromuconazole CAS_116255-48-2	1.5 µg/L CQC ad hoc - Switzerland **0.015 µg/L** RIVM indicative value (MTR)	PPP	Approved as PPP (EU Pesticides database, expiry 30/04/2027)		Not available
	Econazole nitrate CAS_24169-02-6	0.43 µg/L PNEC predicted (NORMAN)				Not available
	Mefentrifluconazole	1.6 µg/L	PPP	Approved as	Still search for	Not available

	CAS_1417782-03-6	(Registration report, 2018)		PPP (EU Pesticides database, expiry 20/03/2029)	ecotox data	
	Fenbuconazole CAS_114369-43-6	2.3 µg/L INERIS			Not approved as PPP in EU	Not available
	Folpet (N-(trichloromethylthio) phthalimide) CAS 133-07-3	1.9 µg/L Folpet PT9 Assessment Report, 2014 1.95 µg/L UBA RAC	PPP and Biocide	Approved as PPP in EU, expiry of approval 15/02/2025 Authorized at national level in: AT,BE,BG,CY,CZ, DE,DK,ES,FR,HU, IE,LU,MT,NL,PL,R O,SE,SI,SK. [EU Pesticides database] Approved for use as PPP in EU [EU/2023/918] and as biocide in EU [PT6 (EU) 2015/1757] [PT 7-9 (EU) 2015/1758] MRL in EU [EU/2023/1042] Banned as active substance in cosmetics in EU: Included in ANNEX II LIST OF		In WISE 2023 (EEA): Available 5006 samples (37.6% quantified) taken at 262 sites in 3 MS (CY, IT, NL) during 2016-2020. Range of LOQs 0.01 - 2 µg/L. Good sensitivity of monitoring regarding the tentative PNEC=1.9 µg/L. The data are not EU representative since are only from 3 MS and IT holds about 91% of all samples. Tentative statistics on measured concentrations based on raw data: Median = 0.02 µg/L Mean = 0.2 µg/L Max = 1 µg/L A low concern according to the initial risk screening.

				SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS [EC/1223/2009]		Additional information sent by DE, SE and NORMAN. Additional monitoring data sent by AT and IT.
	Rabenzazole CAS 40341-04-6					Not available

Source: EC-JRC

Annex III Factsheets (included in a separate document).

Annex IV Supplementary Information

An excel file with supplementary information is available in CIRCABC ([5]).

Folpet

The monitoring data available for this substance in WISE database are presented in Table 2.

Additional information or exposure data were provided to the JRC as follows:

AT: 140 samples (all non-detected) taken at 20 sites in 2015; LOD=0.04 µg/L; LOQ=0.08 µg/L; MECs ≤ 0.04 µg/L. Provisionally, the data indicated no risk (tentative PNEC=1.9 µg/L).

IT: aggregated information based on 5276 samples (only 1 quantified; concentration = 0.02 µg/L) taken annually at 202 – 253 sites in the period 2019 – 2021. LOQ = 0.02 µg/L. Good sensitivity on monitoring concerning the PNEC=1.9 µg/L. All concentrations ≤ 0.02 µg/L. Provisionally, the data indicated no exceedances.

IT: 8771 samples (all non-quantified) taken at 285 sites during 2019-2022. Good sensitivity of monitoring (range of LOQs 0.005 – 0.05 µg/L) regarding the tentative PNEC=1.9 µg/L. Mean = 0.017 µg/L and Max = 0.05 µg/L. No exceedances.

SE: no data available

DE: According to available monitoring data for surface water (LOQ = 0.03 µg/l) the concentrations are below LOQ, which do not indicate the relevance of this compound for the WL. The substance undergoes hydrolysis and the analytical standards are not stable during chemical analysis.

NORMAN:
Data available in EMPODAT are from 3 countries (France, Netherlands and Ireland). The monitoring data available are insufficient. The available data show low frequency of quantification and values below the PNEC.
It should be noted that Folpet is not stable. If it is included as part of the WL, then the transformation products should also be monitored.

Metazachlor

The monitoring data available for this substance in WISE database are presented in Table 3.

Additional information or exposure data were provided to the JRC as follows:

[5] Supplemental information for Annex IV is available in CIRCABC: Excel file included in CIRCABC: https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/5066a01b-d3c6-4b70-989f-801ca944bc88/details

AT: 512 samples (507 non-detected and 5 quantified) taken at 59 sites in 2015 and 2021; LOD=0.09 µg/L; LOQ=0.09 µg/L; Insufficient sensitivity on monitoring regarding the PNEC=0.02 µg/L. All quantified samples exceed the PNEC=0.02 µg/L; Mean = 0.45 µg/L (only quantified samples); Max = 1.4 µg/L. Provisionally, the data showed exceedances and indicated some risk.

IT: aggregated information based on 10290 samples (130 quantified; 19 quantified concentrations > 0.1 µg/L) taken annually at 536 – 710 sites in the period 2019 – 2021. LOQ=0.01 µg/L. Good sensitivity on monitoring regarding the PNEC=0.02 µg/L. Annual mean of Median concentrations = 0.023 µg/L (only quantified samples). Range of Max concentrations 0.28 - 0.59 µg/L. Provisionally, the data showed exceedances and indicated some risk.

SE: 567 samples (26 detected and 405 quantified) taken at 48 sites during 2015 – 2018 from monitoring exercises in agricultural areas. Range of LODs 0.0001 – 0.001 µg/L; range of LOQs 0.0002 - 0.002 µg/L. 103 quantified samples exceed the PNEC=0.02 µg/L; Mean = 0.024 µg/L (only detected and quantified samples); Max = 0.72 µg/L. Provisionally, the data indicated many exceedances and a presence of risk.

DE:
There is sufficient data available to assess the risk, so there is no need to include the substance on the WL.
In Germany, this substance is a RBSP with an AA-EQS of 0.4 µg/l, which is exceeded in several water bodies. From an ecotoxicological perspective, the PNEC of 0.02 µg/l appears to be meaningful.

NORMAN:
Cat 1 compound under NORMAN prioritisation framework. Data available from 12 countries, 169 sites and > 1000 analysis. High FQ (FQ_analysis: 50%. Exceedance of PNEC observed at 43% of the investigated sites). In line with the recommendation by JRC, metazachlor should be designated as PS or at least as RBSP

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