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Development of the 1st Watch List under the Environmental Quality Standards Directive

Directive 2008/105/EC, as amended by Directive 2013/39/EU, in the field of water policy

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Abstract
According to Directive 2008/105/EC (the Environmental Quality Standards Directive, EQSD), a new mechanism is needed to provide high-quality monitoring information on the concentrations of polluting substances in the aquatic environment across the EU. The aim of this mechanism is to support the identification of priority substances for regulation under the Water Framework Directive. A restricted number of substances (up to 10) are to be included in a dynamic Watch List, remaining there for limited time. Three compounds, i.e. diclofenac, 17-beta-estradiol (E2), and 17-alpha-ethinylestradiol (EE2) have already been identified for inclusion in the first Watch List, for the specific purpose of better informing the determination of suitable risk reduction measures. Therefore, up to seven additional substances should be identified for inclusion.
This report describes the procedure to identify a short-list of substances, based on the suspected risk to or via the aquatic environment, as well as on the unavailability of sufficient monitoring data or data of sufficient quality to identify the risk posed by those substances, and to prioritise them at EU level. From the short-list, seven additional substances are proposed for inclusion in the first Watch List.

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Abbreviations

ADI	Acceptable Daily Intake
BCF	Bioaccumulation Factor
BMF	Biomagnification Factor
CIS	Common Implementation Strategy
dw	Drinking Water
EqP	Equilibrium Partitioning method
fw `	Freshwater
hh	Human Health
Koc	Organic carbon adsorption coefficient
LOD	Limit Of Detection
LOQ	Limit Of Quantification
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PPP	Plant Protection Products
PS	Priority Substance
RQ	Risk Quotient (PEC/PNEC)
sec pois	Secondary poisoning
sed	Sediment
TDI	Tolerable Daily Intake
TG n. 27	Reference no. 14
WFD	Water Framework Directive

1. Introduction

According to Directive 2008/105/EC (EQSD) [1], a new mechanism is needed to provide high-quality monitoring information on the concentrations of potentially polluting substances in the aquatic environment to support future prioritisation exercises in line with Article 16(2) of Directive 2000/60/EC (Water Framework Directive, WFD) [2], and thereby to improve the protection of the aquatic environment and of human health via the environment. The mechanism is aimed at emerging pollutants and other substances for which the available monitoring data are either insufficient or of insufficient quality for the purpose of identifying the risk posed across the EU. It involves creating a Watch List with a limited number of such substances and monitoring them EU-wide for up to 4 years. Frequent reviews of the list will ensure that substances are not monitored longer than necessary, and that substances for which a significant risk at EU level is confirmed are identified as candidate priority substances with as little delay as possible.

Article 8b of the EQSD sets out the information to be taken into account when identifying substances to include in the Watch List. The first list may contain a maximum of 10 substances or groups of substances. A suspected significant risk at Union level to, or via, the aquatic environment, and a lack of sufficient monitoring data are both regarded as conditions for a substance's selection. However, three compounds, i.e. diclofenac (CAS n. 15307-79-6), 17-beta-estradiol (E2) (CAS n. 50-28-2), and 17-alpha-ethinylestradiol (EE2) (CAS n. 57-63-3), have already been selected for inclusion in the first list in order to collect sufficient monitoring data for the determination of risk reduction measures. The Joint Research Centre (JRC) has been tasked with proposing 7 substances as candidates for the completion of the first Watch List and identifying analytical methods for their monitoring.

This report describes the procedure and criteria used to identify a short-list of substances, proposed for inclusion in the Watch list.

2. Initial List of Substances

Generally, the criteria for inclusion in the initial list of candidate substances was that i) the substance had been previously suspected of posing a significant risk to, or via, the aquatic environment, meaning there is reliable evidence of hazard and of a possible exposure to aquatic organisms and mammals and ii) there is not enough information to assess an EU-wide exposure for the substance, i.e. insufficient monitoring data or data of insufficient quality. Following these criteria, the initial list of substances selected as candidates for the Watch List comprises substances identified during the last review of the Priority Substances (PS) list, and substances directly proposed by MS and other stakeholders.

Table 1. Initial list of substances

CAS n.	Substance name	Source [a]
294-62-2	Cyclododecane	[4]
60207-90-1	Propiconazole	[4]
731-27-1	Tolylfluanid	[4]

1066-51-9	Amino-methyl phosphonic acid (AMPA)	[4]
25057-89-0	Bentazone	[4]
80-05-7	Bisphenol A	[4]
298-46-4	Carbamazepine	[4]
1897-45-6	Chlorothalonil	[4]
1333-82-0	Chromium trioxide	[4]
81103-11-9	Clarithromycin	[4]
1085-98-9	Dichlofluanid	[4]
60-00-4	Edetic Acid (EDTA)	[4]
1071-83-6	Glyphosate	[4]
15687-27-1	Ibuprofen	[4]
93-65-2; 7085-19-0	Mecoprop (MCPP)	[4]
1113-02-6	Omethoate	[4]
2303-17-5	Tri-allate	[4]
52-68-6	Trichlorfon	[4]
7440-66-6	Zinc and its compounds	[4]
57-12-5	Cyanide – free (HCN and CN-)	[4]
723-46-6	sulfamethoxazole	[4]
53-16-7	Estrone	[5-7]
128-37-0	2,6-di-tert-butyl-4-methylphenol	MS
50-00-0	Formaldehyde	MS
85-01-8; 90640-80-5	Phenanthrene	MS
52645-53-1	Permethrin	EEB
121-75-5	Malathion	EEB
61-82-5	Aminotriazole	NORMAN
83905-01-5	Azithromycin	NORMAN
5466-77-3	2-ethylhexyl 4-methoxycinnamate	NORMAN
83164-33-4	Diflufenican	NORMAN
82419-36-1	Ofloxacin	NORMAN
114-07-8	Erythromycin	NORMAN
115-86-6	Triphenyl phosphate	NORMAN
85721-33-1	Ciprofloxacin	NORMAN
87674-68-8/163515-14-8	Dimethenamid/ dimethenamid-P	NORMAN
2032-65-7	Methiocarb	NORMAN
19666-30-9	Oxadiazon	NORMAN
105827-78-9; 138261-41-3	Imidacloprid	[8-10]
153719-23-4	Thiametoxam	[8-10]
210880-92-5	Clothianidin	[8-10]
111988-49-9	Thiacloprid	[10]
135410-20-7/160430-64-8	Acetamiprid	[10]

[a] Sources indicated as reference [4] are those listed in Table 4.1 of that document.

2.1 Substances from the last review of the PS list

During the last review of the priority substances list in accordance with Article 16(2) of the WFD [2], 12 priority substances (PS) were added to the initial list of 33 PS in Annex X to that Directive. Both modelling- and monitoring-based exercises, starting from initial lists of 2014 and 316 substances, respectively, were performed during the prioritisation process [3]. Various criteria were applied as screening and short-listing tools, including risk characterisation based on hazard and exposure assessment using PEC to PNEC ratios. If the PEC/PNEC ratio was ≥ 1 on the basis of monitoring data for at least 3 Member States, the substance was generally recommended for EQS derivation, especially if it was also classified as PBT/vPvB/ED/CMR [3]. However, not all of those substances were ultimately prioritised, in several cases because hazard information was lacking or monitoring data were available for too few Member States.

Therefore, the substances short-listed during the last review of the PS but not finally proposed for prioritisation, for which a detailed dossier had been produced and sometimes EQS had been derived, were included in the Initial List of substances as candidates for the Watch List. These substances have been identified in Table 4.1 of the Prioritisation scoping report [4], and are also listed above in Table 1.

An exception is the substance musk xylene (CAS n. 81-15-2), which despite having been short-listed in the last prioritisation exercise, was not included in the current list of candidate substances because a ban has been imposed on its use in Europe. Firstly, the International Fragrance Association [11] decided in their 44th amendment a voluntary ban on the use of musk xylene in fragrance products. Secondly, the European Commission has issued a ban on musk xylene with a sunset date of 21/07/2014 [12].

2.2 Substances proposed by MS and other stakeholders and/or flagged in the literature

Member States representatives and other stakeholders which are part of the WFD Common Implementation Strategy (CIS) Working Group Chemicals were invited to propose substances for the Watch List based on the experience gained in the implementation of monitoring programs under the WFD, and previous prioritization schemes followed in Europe. The proposed substances are listed in Table 1, as well as some substances flagged in the literature as being of possible concern.

The estrogenic hormone estrone (E1) is a product of E2 oxidation and although it has lower estrogen receptor binding/transactivation potency than E2 *in vitro* [5,6], it is usually found at higher concentrations (by a factor of about 10) in WWTP effluents and surface waters [5,6,7]. Because of its chemical similarity, E1 is usually analysed together with E2 and EE2.

Other substances proposed for inclusion in the initial candidate list were 2,6-di-tert-butyl-4-methylphenol (UV stabilizer and fuel antioxidant), formaldehyde, phenanthrene, the insecticides permethrin and malathion, and five neonicotinoids. Three of these neonicotinoids (imidacloprid, thiametoxam, clothianidin) have been recently subject to a moratorium on their use for two years by the European Commission following evidence that they are harmful to pollinators and other insects [8]. These substances have a half-life in soil that can reach three years, which makes it possible for them to persist in the environment even after the ban [9]. Two additional neonicotinoids thiacloprid and acetamiprid have also been proposed for the Watch List. Although these two substances are less toxic

than imidacloprid, thiametoxam and clothianidin [10], they may still represent a risk if there is an increase in their use to replace the restricted neonicotinoids.

Furthermore, the initial list also includes the top-ranked substances in "Category 2" [1] of the NORMAN Prioritisation scheme, including the antibiotics azithromycin, ofloxacin, erythromycin and ciprofloxacin, the plant protection products aminotriazole, diflufenican, dimethenamid, methiocarb and oxadiazon, the flame retardant triphenyl phosphate and the sun screen ingredient 2-ethylhexyl 4-methoxycinnamate.

2.3 Criteria for De-Selection of Substances

From the initial list of 43 candidate substances for the Watch List, a criterion was defined to de-select substances with sufficient monitoring data available to conclude on a European-wide risk, i.e. with monitoring data from at least four MS. This is because a threshold for availability of monitoring data relating to at least four MS has been proposed as a criterion for including substances in the monitoring-based ranking of the next prioritization exercise [13]. Therefore, such substances are considered to have sufficient monitoring data for a possible prioritisation and were therefore excluded from the Watch List. To identify the number of MS for which monitoring data are available, the period 2006-2014 was considered, and three databases were searched, i) WATERBASE, hosted by the European Environment Agency (EEA) and containing official monitoring data, aggregated by year, gathered under the State of the Environment (SoE) reports by MS, ii) IPCheM, with regard to the monitoring data compiled during the previous prioritisation exercise and iii) NORMAN database containing monitoring data from official sources, projects and literature.

The selection criteria for consideration of monitoring data were the following:

1. Clear indication of the sampling site (site name, code, etc)
2. Clear identification of the analysed substance (determinand)
3. Clear identification of the measurement unit
4. Samples collected from 2006 on
5. Either LOD or LOQ (at least one) clearly reported
6. Identification of the analysed fraction (only for NORMAN, such information was not available for WATERBASE)
7. LOD or LOQ ≤ substance-specific limits[2] when the value is reported to be below LOD or LOQ[3]
8. LOD or LOQ < PNEC when the value is reported to be below LOD or LOQ[3]

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[1] The substances have been selected on the basis of the occurrence data available in the NORMAN EMPODAT database and they fulfil the following criteria: a) hazard assessment is based on experimental data (AF maximum 50 for the derivation of the Lowest PNEC, mostly based on existing Assessment Reports) AND b) there is at least 1 site with exceedance of the Lowest PNEC (evidence of a potential risk) AND c) further monitoring data are needed for better assessment of exposure and risk at the European scale.

[2] Two substance-specific limits were calculated as the 99th percentile of all LOD and LOQ values for a certain substance (for NORMAN database separate limits were calculated for the dissolved fraction and for the "whole water" fraction)

[3] In WATERBASE data are aggregated by year, but information is available on the number of samples collected and the number of samples resulting below the LOQ. Hence these criteria were only applied if all samples were reported to be below LOQ.

2.4 Dataset Filtered

After the application of the above criteria, 16 substances have been de-selected based on availability of sufficient monitoring data. These substances are estrone, propiconazole, AMPA, bentazone, bisphenol A, carbamazepine, chlorothalonil, glyphosate, ibuprofen, mecoprop, omethoate, zinc, sulfamethoxazole, phenanthrene, permethrin and malathion. Monitoring data were available for dimethenamid from four MS, and only dimethenamid-P was considered for further assessment in this exercise. Therefore, a final number of 28 substances were taken forward for the purpose of ranking according to the risk they pose to the environment.

3. Methodology for Ranking of Substances

3.1 Overall Methodology

A risk assessment of all the substances in the filtered dataset was done by combining the substance-specific hazard data and information on exposure to the substance in or via the aquatic environment. According to the substance's physico-chemical properties, the receptors and compartments at risk were identified and an assessment done for each route of exposure, including the estimation of specific PEC and PNEC values, as summarized in Figure 1. In general, the criteria to identify the required assessments followed those specified in the Technical Guidance No. 27 of the Common Implementation Strategy (CIS) of the WFD [14].

The risk for direct toxicity to pelagic organisms from the presence of substances in the water column was always assessed, considering both a PEC_{fw} and a $PNEC_{fw}$ for surface water.

Depending on the sorption potential of a substance, a risk assessment for the sediment compartment was performed, i.e. whenever the organic carbon adsorption coefficient trigger value (Log K_{oc} or Log K_{ow}) ≥ 3, by estimating a PEC_{sed} and the $PNEC_{sed}$.

For the protection of organisms from secondary poisoning, an assessment was made for those substances with a potential to bioaccumulate, using as trigger values bioconcentration factors (BCF) $\geq$ 100 or Log $K_{ow} \geq 3$ and the substance being not readily biodegradable [15]. In this case, a PEC_{biota} was considered and a $PNEC_{biota,\ sec\ pois}$ was estimated for top predators, as well as a $PNEC_{biota,\ hh}$ to assess the risk for human health arising from the consumption of fishery products.

Finally, an effect assessment was conducted for all substances regarding the protection of human health from consumption of drinking water, by estimating a $PNEC_{dw,\ hh}$ to be compared to the PEC_{fw}.

After estimating all the above PEC and PNEC values, risk quotients (PEC/PNEC) were calculated for the different compartment and receptor scenarios. The highest risk quotient calculated for a substance was used in the final ranking of substances (from highest to lowest risk).

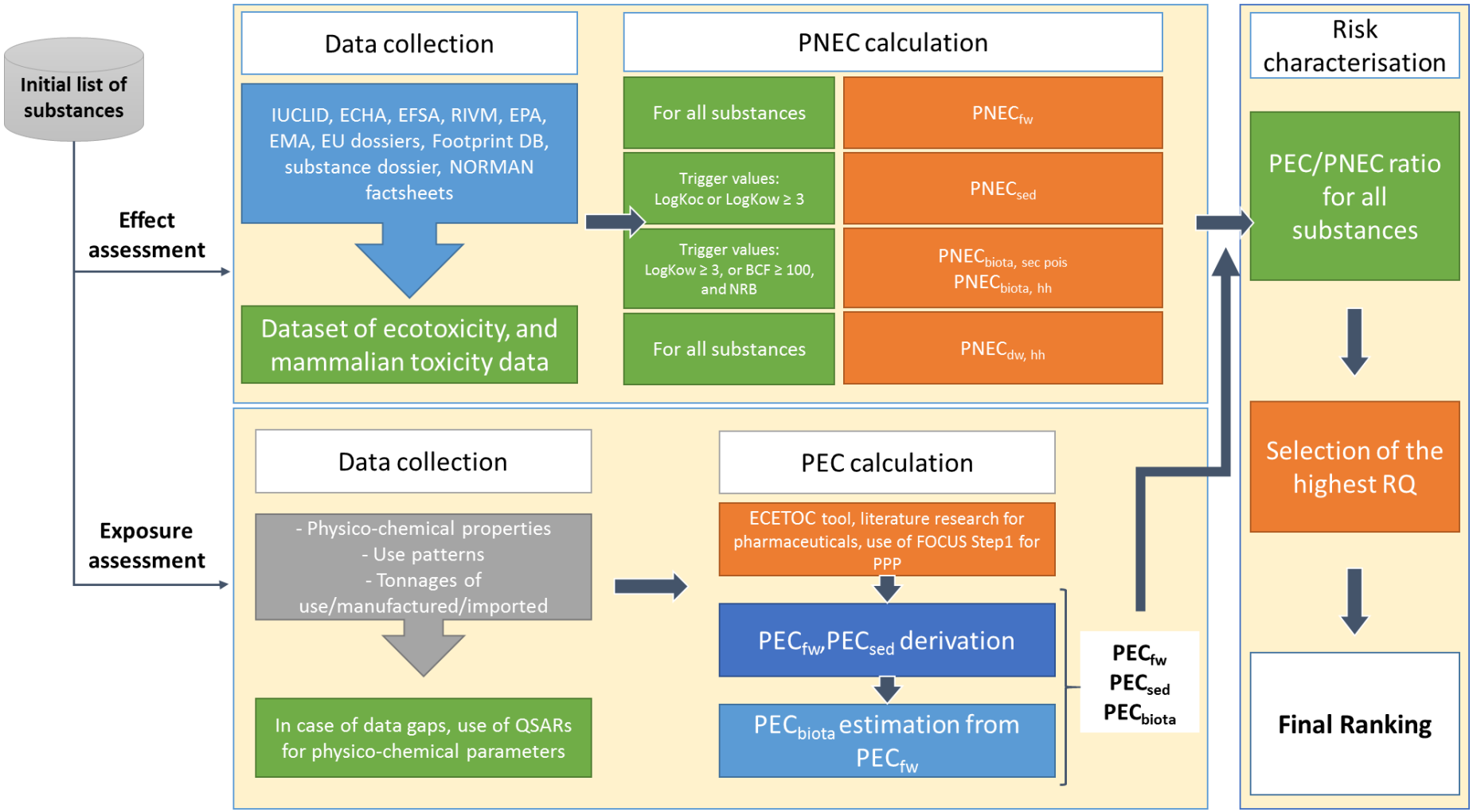

Figure 1. Overall methodology for the ranking of substances

3.2 Data Collection

For the collection of data, information was retrieved from several databases and reports, including IUCLID, ECHA, EFSA, RIVM, EMA, EU-Review reports, EU-RAR, EU Pesticides DB, Footprint Pesticides Properties DB, EPA, substances dossiers prepared during the last prioritisation exercise and substances factsheets provided by NORMAN. The relevance and reliability of the data retrieved from the above sources was deemed acceptable for the purpose of this exercise, since it was considered that the data had been reviewed by a competent authority, and no further review of the original study reports was conducted.

Data collected for the exposure assessment and PEC calculation comprised physical and chemical properties (molecular weight, water solubility, vapour pressure, biodegradability, sorption potential and bioaccumulation potential), tonnage (of use, manufacture and import) and Environmental Release Category (ERC) codes.

The collection of hazard data for the aquatic and sediment compartments included acute and chronic ecotoxicity (typically the most sensitive LC/EC50 or NOEC/EC10 endpoints). Regarding mammalian or human toxicity effects from oral exposure, data were collected for repeated dose toxicity, carcinogenicity, mutagenicity and effects on reproduction, focusing on typical endpoints such as NOAL, DNEL, ADI and TDI values.

3.3 Hazard assessment – estimation of PNEC values

3.3.1 PNEC for direct toxicity to freshwater organisms

Chemical risk assessment in the water compartment is relevant for the protection of organisms inhabiting the water column. Therefore, the protection threshold concentrations $PNEC_{fw}$ have been estimated for all substances.

For the estimation of the $PNEC_{fw}$, a deterministic approach has been used by selecting the most stringent valuable endpoint from the available aquatic toxicity data, and applying an assessment factor (AF), which was chosen based on the guidelines for the derivation of the $QS_{fw,\,eco}$ retrieved from the TG n. 27 - CIS WFD [14]. However, for some substances for which the PNEC was retrieved directly from other sources, a probabilistic method was used.

3.3.2 PNEC for the toxicity to benthic species

The threshold safety value for the protection of benthic organisms $PNEC_{sed}$ has been derived for those substances with a potential for sorption into the sediment compartment using as trigger values: logKoc or LogKow ≥ 3. The $PNEC_{sed}$ has been calculated following the TG n. 27- CIS WFD [14] and the ECHA Guidance (2012) [16], using equation A.

$$PNEC_{sed} = \frac{K_{\text{sed-water}}}{RHO_{sed}} \times PNEC_{fw} \times 1000 \qquad (A)$$

RHO_{sed} is the bulk density of wet sediment, $K_{sed\text{-}water}$ is the partition coefficient between sediment and water and 1000 is the conversion factor from m^3 to litre.

3.3.3 PNEC for the toxicity to top predators from secondary poisoning

The WFD provides for the protection of top predators such as birds and mammals from risks of secondary poisoning arising from the consumption of aquatic organisms from lower trophic levels contaminated with toxic substances.

A $PNEC_{biota,\ sec\ pois}$ has been derived for all substances with a potential to bioaccumulate, as indicated under section 3.1.

The derivation of a $PNEC_{biota,\ sec\ pois}$ started from toxicological endpoints reporting on dietary and oral exposure such as the no-observed adverse effect level (NOAEL) or no observed effect concentration for ingestion ($NOEC_{oral}$). Since the $PNEC_{biota,\ sec\ pois}$ is expressed as concentration in food, conversion factors from NOAEL to NOEC have been used, for bird and mammalian toxicity studies, following the TG n. 27 - CIS WFD [14].

3.3.4 PNEC for hazard to human health via consumption of fishery products

Regarding the protection of human health from the consumption of contaminated fishery products, a $PNEC_{biota,\ hh}$ has been derived in a similar manner as the $QS_{biota,\ hh\ food}$ in the TG n. 27 - CIS WFD [14], by using endpoints such as the acceptable daily intake (ADI), tolerable daily intake (TDI) or $NOAEL_{oral}$ (divided by an AF).

$$PNEC_{biota,\ hh} = \frac{0.1 \times TL \times 70}{0.115} \qquad \text{(B)}$$

The $PNEC_{biota,\ hh}$ is expressed in $\mu g \cdot kg^{-1}$, and uses a default value of human body weight of 70 kg, and a daily consumption of fishery products of 0.115 kg. In addition, it is assumed that fishery products make up no more than 10% of the threshold level value ($0.1 \times TL$) [14].

3.3.5 PNEC for hazard to human health via drinking water consumption

Drinking water is a possible route of human exposure to substances in water, and protection threshold concentrations $PNEC_{dw,\ hh}$ have been derived for all substances, based on human toxicity data. If available, WHO [17] or EU [18] drinking water standards have been used as the $PNEC_{dw,\ hh}$ values for that substance.

When a WHO drinking water standard was not available, the $PNEC_{dw,\ hh}$ was calculated according to the following equation C, retrieved from the TG n. 27 - CIS WFD [14].

$$PNEC_{\text{dw, hh}} = \frac{0.1 \times TL_{hh} \times bw}{uptake_{dw}} \qquad \text{(C)}$$

A human body weight (bw) of 70 kg and a daily uptake of drinking water ($uptake_{dw}$) of 2 litres were used. A fraction of 0.1 of the human toxicological standard (TL_{hh}, usually the acceptable daily intake (ADI) or the tolerable daily intake (TDI)) is allocated to intake of the substance via drinking water.

3.4 Exposure assessment – estimation of PEC values

Regarding the exposure assessment, information on tonnage and use pattern for all substances was searched for. To facilitate the ranking of substances based on risk, it was attempted to use a similar method for the PEC calculation for all substances, the ECETOC PEC calculation tool based on EUSES [19] This tool requires tonnage information, as well as usage information as input values. Unfortunately, the required input information was not available for all substances, and additional models were required, as detailed below. When more than one PEC value was calculated by different methods, the worst case value was generally used for the ranking of substances.

3.4.1 PEC for freshwater

Tonnages and usage information were retrieved from IUCLID for six substances, and for additional seven substances from the last prioritisation exercise. Thus, for these thirteen substances, the ECETOC tool was used for the PEC calculation with the respective ERC codes (when more than one use was reported, the ERC corresponding to the worst-case scenario was selected for the calculation).

Unfortunately, the required input information for the remaining substances was not sufficient to run the model, and additional methods were sought for the PEC calculation depending on the availability of input data.

For two substances the PEC was retrieved from European Union Risk Assessment Reports (EU-RAR), while for eight pesticides, the PEC was calculated with the model FOCUS Step 1 [20]. Finally, for four antibiotics, given the unavailability of information on production or sales, PEC values were retrieved from the literature. For the antibiotic Erythromycin, two PEC_{fw} values were available, one was retrieved from the literature, while the second was calculated with ECETOC with the worst case being selected for the ranking (see discussion in Section 5). A summary of the sources of information and the models used for the PEC calculation are given in Table 2.

Table 2. Data sources and methods used for PEC calculation.

CAS n.	Substance name	Tonnage source	ERC code used	PEC calculation method
128-37-0	2,6-di-tert-butyl-4-methylphenol	IUCLID	ERC8d [a]	ECETOC [b]
135410-20-7/ 160430-64-8	Acetamiprid	-	-	FOCUS Step 1
61-82-5	Aminotriazole	Last prioritization exercise	ERC8d	ECETOC [b]
83905-01-5	Azithromycin	-	-	[21]
1333-82-0	Chromium trioxide	-	-	EU-RAR
85721-33-1	Ciprofloxacin	-	-	[21]
81103-11-9	Clarithromycin	-	-	[21]
210880-92-5	Clothianidin	-	-	FOCUS Step 1
57-12-5	Cyanide- free (HCN and CN-	-	-	-
294-62-2	Cyclododecane	IUCLID	ERC6a	ECETOC [b]

1085-98-9	Dichlofluanid	Last prioritization exercise	ERC8b	ECETOC [b]
83164-33-4	Diflufenican	-	-	FOCUS Step 1 [c]
163515-14-8	Dimethenamid-P	-	-	FOCUS Step 1
60-00-4	Edetic Acid (EDTA)	IUCLID	ERC10b [a]	ECETOC [b]
114-07-8	Erythromycin	IUCLID	ERC8a	ECETOC [b]
5466-77-3	2-ethylhexyl 4-methoxycinnamate	Last prioritization exercise	ERC8a	ECETOC [b]
50-00-0	Formaldehyde	IUCLID	ERC8d [a]	ECETOC [b]
105827-78-9/ 138261-41-3	Imidacloprid	-	-	FOCUS Step 1
2032-65-7	Methiocarb	Last prioritization exercise	ERC8d	ECETOC [b]
82419-36-1	Ofloxacin	-	-	[22]
19666-30-9	Oxadiazon	-	-	FOCUS Step 1 [c]
111988-49-9	Thiacloprid	-	-	FOCUS Step 1
153719-23-4	Thiamethoxam	-	-	FOCUS Step 1
731-27-1	Tolylfluanid	Last prioritization exercise	ERC8b	ECETOC [b]
2303-17-5	Tri-allate	Last prioritization exercise	ERC8d	ECETOC [b]
52-68-6	Trichlorfon	Last prioritization exercise	ERC8a	ECETOC [b]
115-86-6	Triphenyl phosphate	IUCLID	ERC8a [a]	ECETOC [b]

[a] Worst-case use scenario was selected among many others

[b] Koc value were used, in addition to default input values

[c] Output from FOCUS Step 1 retrieved from EFSA conclusion report

3.4.2 PEC for sediment

For the calculation of the PEC_{sed} ECETOC results were used whenever available, and for pesticides the results were retrieved from Focus Step 1. Similar to the PEC_{fw}, PEC_{sed} values for chromium trioxide were retrieved from the EU-RAR. For those pharmaceutical substances passing the trigger value Log Koc and Log Kow ≥3, the sediment equilibrium partition method (EqP) was used considering the PEC_{fw}. The $PEC_{sed\text{-}ww}$ in terms of wet weight (ww) was calculated using equation D:

$$PEC_{sed-ww} = \frac{K_{sed\text{-}water}}{RHO_{sed}} \times \mathrm{PEC_{fw}} \times 1000 \qquad (D)$$

Since the final PEC_{sed} was calculated in terms of dry weight, a conversion step was required, by using the following equations E and F.

$$CONVsed = \frac{RHO_{sed}}{Fsolid_{Sed} \times RHOsolid} \qquad (E)$$

$$PEC_{Sed} = CONVsed \times PEC_{sed-ww} \qquad (F)$$

For the calculation of $K_{Sed\text{-}water}$, the following equation G was used.

$$K_{sed-water} = Fair_{sed} \times K_{air-water} + Fwater_{sed} + Fsolid_{sed} \times \frac{Kp_{Sed}}{1000} \times RHO_{solid} \qquad (G)$$

Default values for RHO_{solid}, $Fwater_{sed}$, $Fsolid_{sed}$ and Foc_{sed} were taken from TG n. 27 - CIS WFD [14].

3.4.3 PEC for biota

For the calculation of the PEC_{biota} the following equation H was used [23].

$$PEC_{biota} = PEC_{fw} \times BCF \times BMF \qquad (H)$$

BCF values were retrieved when available or, for 5 substances, calculated from QSARS.
Default BMF values were retrieved from TG n. 27 - CIS WFD [14].

3.5 Final Ranking

Risk quotients (RQ) were estimated for all the relevant receptors at risk, i.e. RQ_{fw}, RQ_{sed}, $RQ_{biota,\ sec\ pois}$, $RQ_{biota,\ hh}$, $RQ_{dw,\ hh}$, and are available in the substances fact sheets, in Annex I. The highest RQ for the different compartments and/or receptors was selected for the final ranking of substances (Table 3).

4. Results

4.1 Overview of the exposure, hazard and risk assessment

The overall results from the estimated PEC and PNEC values, as well as the different RQ are summarized in Table 3. Substances are already ranked from the highest to the lowest RQ. To be noted that for the two substances with the lowest ranking, ofloxacin and EDTA, their risk quotient was below 1, suggesting there is no risk.

Table 3. Results from the risk-based ranking of substances using the highest risk quotient calculated for each substance

ID Rank	CAS n.	Substance	$PNEC_{fw}$ (mg/L)	$PNEC_{sed}$ (mg/kg dw)	$PNEC_{biota, sec\ pois}$ (mg/kg food)	$PNEC_{biota, hh}$ (mg/kg food)	$PNEC_{dw, hh}$ (mg/L)	PEC_{fw} (mg/L)	SOURCE of PEC_{fw}	PEC_{sed} (mg/kg)	SOURCE of PEC_{sed}	PEC_{biota} ($mg/kg_{wet\ fish}$)	Highest RQ for ranking	
1	52-68-6	Trichlorfon	9.60E-07	N. R.	N.R.	N.R.	0.158	0.0313	ECETOC	N.R.	N.R.	N.R.	32604	RQ_{fw}
2	294-62-2	Cyclododecane	N.A.	N.A.	5	15.217	0.875	0.4677	ECETOC	306.44	ECETOC	87459.90	17492	$RQ_{biota, sec\ pois}$
3	61-82-5	Aminotriazole	8.00E-05	N. R.	N.R.	N.R.	0.004	0.73	ECETOC	N.R.	N.R.	N.R.	9125	RQ_{fw}
4	2032-65-7	Methiocarb	1.00E-05	0.001	0.591	0.791	0.046	0.044	ECETOC	4.54	ECETOC	3.34	8798	RQ_{sed}
5	5466-77-3	2-ethylhexyl 4-methoxycinnamate	2.70E-05	0.002	N.R.	N.R.	7.875	0.0063	ECETOC	8.39	ECETOC	N.R.	4665	RQ_{sed}
6	163515-14-8	Dimethenamid-P	2.00E-04	0.001	N.R.	N.R.	0.070	0.281	FOCUS Step 1	0.465	FOCUS Step 1	N.R.	1405	RQ_{fw}
7	83164-33-4	Diflufenican	1.00E-05	0.020	16.7	12.174	0.700	0.012	FOCUS Step 1	0.22	FOCUS Step 1	19.15	1200	RQ_{fw}
8	19666-30-9	Oxadiazon	8.80E-05	0.050	0.24	0.219	0.013	0.09863	FOCUS Step 1	1.19	FOCUS Step 1	239.67	1120	RQ_{fw}
9	2303-17-5	Tri-allate	1.30E-03	0.006	1.67	1.522	0.088	0.013	ECETOC	5.44	ECETOC	18.20	933	RQ_{sed}
10	111988-49-9	Thiacloprid	1.00E-04	N. R.	N.R.	N.R.	0.035	0.085	FOCUS Step 1	N.R.	N.R.	N.R.	850	RQ_{fw}
11	128-37-0	2,6-di-tert-butyl-4-methylphenol	3.16E-03	1.290	16.7	15.217	0.875	0.423	ECETOC	347.64	ECETOC	10575	694	$RQ_{biota,hh}$
12	105827-78-9/ 138261-41-3	Imidacloprid	2.09E-04	N. R.	N.R.	N.R.	0.210	0.062	FOCUS Step 1	N.R.	N.R.	N.R.	296	RQ_{fw}
13	114-07-8	Erythromycin	4.00E-05	0.001	no info	0.043	0.002	0.00526	ECETOC	0.32	ECETOC	0.26	264	RQ_{sed}
14	210880-92-5	Clothianidin	7.20E-05	N. R.	N.R.	N.R.	0.340	0.014	FOCUS Step 1	N.R.	N.R.	N.R.	194	RQ_{fw}
15	1333-82-0	Chromium trioxide	3.40E-03	6.800	17	0.055	0.003	0.35	EU-RAR	0.152	EU-RAR	0.98	111	$RQ_{dw, hh}$
16	153719-23-4	Thiamethoxam	1.00E-03	N. R.	N.R.	N.R.	0.091	0.08	FOCUS Step 1	N.R.	N.R.	N.R.	80	RQ_{fw}
17	135410-20-7/ 160430-64-8	Acetamiprid	5.00E-04	N. R.	N.R.	N.R.	0.245	0.034	FOCUS Step 1	N.R.	N.R.	N.R.	68	RQ_{fw}
18	1085-98-9	Dichlofluanid	2.65E-04	0.018	3.3	21.304	1.225	0.00531	ECETOC	0.73	ECETOC	0.38	40.17	RQ_{sed}
19	50-00-0	Formaldehyde	4.70E-01	2.440	N.R.	N.R.	0.525	13.53	ECETOC	N.R.	ECETOC	N.R.	28.8	RQ_{fw}
20	115-86-6	Triphenyl phosphate	3.70E-03	0.240	N.R.	N.R.	0.140	0.015	ECETOC	5.49	ECETOC	N.R.	22.9	RQ_{sed}
22	81103-11-9	Clarithromycin	6.00E-05	N. R.	No info	0.012	0.001	0.000345	Literature	N. R.	N. R.	0.02	5.75	RQ_{fw}
23	731-27-1	Tolylfluanid	1.96E-04	0.058	8	6.087	0.350	0.00097	ECETOC	0.22	ECETOC	0.07	4.95	RQ_{fw}
24	85721-33-1	Ciprofloxacin	8.90E-05	0.272	N.R.	N.R.	0.006	0.000278	Literature	0.85	EqP	N.R.	3.12	RQ_{fw}
25	83905-01-5	Azithromycin	9.00E-05	0.014	no info	0.103	0.006	0.000093	Literature	0.014	EqP	0.02	1.03	RQ_{fw}
26	82419-36-1	Ofloxacin	1.30E-04	N. R.	N.R.	N.R.	no info	0.00009	Literature	N. R.	N. R.	N.R.	0.69	RQ_{fw}
27	60-00-4	Edetic Acid (EDTA)	2.20E+00	118.6	N.R.	N.R.	0.6	0.2486	ECETOC	26.93	ECETOC	N.R.	0.41	$RQ_{dw, hh}$
28	57-12-5	Cyanide-free	5.00E-05	N. R.	N. R.	N. R.	0.05	-	-	-	-	-	-	-

N.R. Not required, N.A. Not available

5. Recommendations

The current exercise has attempted to quantify the risk associated to the substances in the candidate list, for which a lack of EU-wide monitoring data has been identified that would inhibit them from being proposed as priority substances in Europe.

Therefore, it is recommended that the ranking based on RQ is considered as a criterion for selection into the first Watch List. However, there are some issues with the PEC calculation for some substances that may need to be considered for the final decision, as described below.

i) Trichlorfon: this substance has been banned as a PPP and currently it is still used as veterinary pharmaceutical. For the PEC calculation, only a pre-banning tonnage was available, and no PEC value was available from the literature. For this reason, the available tonnage value was used for the PEC calculation, even though it is likely an overestimation, and an ERC code applicable to veterinary pharmaceuticals was selected (ERC8a). It should be noted that six MS have derived an EQS for trichlorfon, but it is unclear whether monitoring data were collected for at least 4MS for the time period 2006-2014, in which case the substance could be automatically considered under the monitoring-based exercise of the next PS review;

ii) Dimethenamid-P: dimethenamid is a herbicide that has been banned in 2006 [24] and has since been replaced by its active isomer dimethenamid-P. The PNEC values were estimated based on combined data from dimethenamid and dimethenamid-P, since the toxicological reference values established for dimethenamid have been considered applicable to dimethenamid-P by EFSA [25];

iii) Erythromycin: this pharmaceutical substance is registered in IUCLID with tonnage value given for an intermediate use (associated code ERC6a). By using ECETOC and ERC6a code to estimate the PEC value, an extremely high PEC_{sed} (50.89 mg/kg), and therefore a considerable risk, would be calculated for this substance, which would become the highest ranked in this exercise. However, the high PEC_{sed} value seemed an overestimated value and therefore, it was decided to use a different ERC code, applicable to pharmaceuticals, i.e. ERC8a. The PEC values obtained with the latter code (Table 3) were more similar to the PEC available from literature by using a spatially explicit model, further validated with monitoring data [26];

iv) Tolylfluanid and dichlofluanid: both substances have been banned as PPP but currently they are still used as biocides. For the PEC calculation, only pre-banning tonnages were available, and no PEC values were available from the literature. For this reason, the available tonnage values were used for the PEC calculations, even though they are likely an overestimation, and an ERC code applicable to biocides (ERC8b) was used;

v) No available information on production and sales were available for the antibiotics clarithromycin, ciprofloxacin, azithromycin and ofloxacin. For this reason, ECETOC could not be used with the corresponding ERC code for the calculation of the PEC, and literature values were used instead [21,22]. Based on the limited monitoring data in the NORMAN database, there is an indication of PNEC exceedance from measured concentration values for these

substances. There is growing concern that the development of antimicrobial resistance (AMR) is resulting in a continuous decline in therapeutic capability against infectious diseases caused by bacterial pathogens [27]. The development of resistance has been attributed to a large extent to the excess use and the misuse of antibiotics. However, the selection and enrichment of resistant mutants in the environment, as a result of the presence of antibiotics at low concentrations due to excretion and improper disposal, is an issue requiring further investigation [28]. Although some papers would suggest that low concentration of antibiotics could induce resistance and be linked to the transfer of the antibiotic resistance gene (ARG) [29, 30], the lack of high quality monitoring data is one of the bottlenecks to draw a conclusion on the relationship between concentration and resistance. Therefore, given the potential risk that antimicrobial resistance poses to human health and the current difficulty in the calculation of a modelled PEC (and RQ), it would be advisable to gather wider information on exposure to these substances in the environment, some of which may in any case have direct toxic effects.

vi) Free cyanides: Even though there is monitoring available data for total cyanides from > 4 MS, there is insufficient information with regards to the most bioavailable cyanide species. Furthermore, no tonnage in Europe was available in IUCLID for free cyanides and therefore ECETOC could not be used for PEC calculation. Moreover, no PEC value could be found in the literature. Improved monitoring strategies focused on free cyanide would facilitate the estimation of environmental concentrations, particularly considering the concern for drinking water exposure and the available drinking water standard in Europe for cyanides [18].

It is recommended that in addition to diclofenac, E2 and EE2, already proposed for the Watch List, the list also includes the five substances with the highest risk (all with a RQ>4000), as determined in this exercise and described in Table 3 (trichlorfon, cyclododecane, aminotriazole, methiocarb and 2-ethylhexyl 4-methoxycinnamate). It is also recommended that erythromycin be included, as the highest ranking antibiotic, given the pressing need to gather more data on the environmental occurrence of this group of substances. The specific concerns and uncertainties regarding free cyanides justify our recommendation of this substance for inclusion.

Even though E1 has been excluded from the list of candidate substances due to availability of monitoring data, it is a transformation product of E2 and is a considerable contributor to estrogenic activity in the aquatic environment. Therefore, it is recommended that E1 be analysed together with E2 to gather data for risk management following the reasons for inclusion of E2 into the Watch List. Both substances may be analysed with the same method in the same run, by GC-MS or LC-MS, without considerable additional burden.

In conclusion, the ten substances recommended for the first Watch List are listed below, subject to the availability of the analytical methodology to monitor them:

Diclofenac
17-Beta-estradiol (E2)
17-Alpha-ethinylestradiol (EE2)
Trichlorfon
Cyclododecane
Aminotriazole
Methiocarb
2-ethylhexyl 4-methoxycinnamate
Erythromycin
Cyanide-free

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Annex I – Information on exposure, hazard and risk

Trichlorfon (CAS N. 52-68-6)

USE PATTERN	
Uses:	Insecticide used as veterinary pharmaceutical
Banned uses:	PPP (Commission Decision, C (2007)2096)
Tonnes/year:	From previous exercise: 1050 (year 2000)
Spatial usage (by MS):	Not known

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
2 (FR, NL)	NORMAN, 2014	$MEC_{95,\ whole}$: 0.428 µg/L	6 MS (RBSP EQS ECOSTAT – UBA report)

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Daphnia magna*, 48 h, EC_{50}	0.00096 mg/L	1000	9.60E-07 mg/L	Footprint Pesticides Database	In the EFSA conclusion, the study was considered of poor quality, however similar results were reported in the U.S. EPA ECOTOX DB
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI (provisional)	0.045 mg/kg bw/day	-	0.158 mg/L	EFSA conclusion, 2006 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
32604.17	N.R.	N.R.	N.R.	0.20

Cyclododecane (CAS N. 294-62-2)

USE PATTERN	
Uses:	Industrial use resulting in manufacture of another substance (use of intermediates)
Banned uses:	**-**
Tonnes/year:	Confidential (IUCLID,2013)
Spatial usage (by MS):	Not known

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
None	-	-	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	-	-	-	N.A.	ECHA, 2013	Due to the fact that no effects have been seen at concentrations below solubility, it is not possible to calculate $PNEC_{fw}$
$PNEC_{sed}$	-	-	-	N.A.	-	See comment above.
$PNEC_{biota,sec\ pois}$	Rats, repeated dose toxicity, c.f. 10, 29 d, NOAEL	150 mg/kg bw/day	300	5 mg/kg food	ECHA, 2013	-
$PNEC_{biota,\ hh}$	DNEL, from repeated dose toxicity, oral, NOAEL 150 mg/kg bw/day, AF 600	0.25 mg/kg bw/day	-	15.217 mg/kg bw/day	ECHA, 2013 (for NOAEL value)	DNEL value used for PNEC calculation, please see section 3.3.4
$PNEC_{dw,\ hh}$	DNEL, same as above	0.25 mg/kg bw/day	-	0.875 mg/kg bw/day	ECHA, 2013 (for NOAEL value)	DNEL value used for PNEC calculation, please see section 3.3.5

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
N.A.	N.A.	**17491.98**	5747.36	0.53

Aminotriazole (CAS N. 61-82-5)

USE PATTERN	
Uses:	Herbicide (PPP)
Banned uses:	
Tonnes/year:	From previous exercise: 22550 (year 1994)
Spatial usage (by MS):	Authorized in BE, EL, ES, FR, HU, IT, LU, NL, PT, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
1 (FR)	NORMAN, 2014	$MEC_{95,\ whole}$: 0.873 µg/L	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Navicula pelliculosa*, 120 h, NOEC	8.00E-04 mg/L	10	8.00E-05 mg/L	INERIS, 2011	Three NOEC values from the three main trophic levels (fish, aquatic invertebrates, algae)
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI	0.001 mg/kg bw/day	-	0.004 mg/L	EU Review Report, 2001 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
9125	N.R.	N.R.	N.R.	208.57

Methiocarb (CAS N. 2032-65-7)

USE PATTERN	
Uses:	Insecticide, Molluscicide, Repellant (PPP)
Banned uses:	-
Tonnes/year:	From previous exercise: 1500 (year 2000)
Spatial usage (by MS):	Authorised in: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, NL, PL, PT, RO, SI, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
2 (FR, NL, UK)	NORMAN, 2014 IPCheM	$MEC_{95, whole}$: 0.0585 µg/L (NORMAN) MEC_{95}: 0.095 µg/L (IPCheM)	1 (RBSP EQS ECOSTAT – UBA report)

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Daphnia magna*, 21 d, NOEC	0.0001 mg/L	10	1.00E-05 mg/L	EFSA Conclusion, 2010 DAR, 2004	Three NOEC values from the three main trophic levels (fish, aquatic invertebrates, algae)
$PNEC_{sed}$	-	-	-	0.001 mg/kg dw	Equilibrium partitioning method	See section 3.3.2, and 3.4.2 eq. E-F-G, for calculation
$PNEC_{biota,sec\ pois}$	Dog, 90 d, c.f. 40, NOAEL	1.33 mg/kg bw/day	90	0.591 mg/kg food	EFSA Conclusion, 2010 (for NOAEL)	See section 3.3.3. for calculation
$PNEC_{biota,\ hh}$	ADI	0.013 mg/kg bw/day	-	0.791 mg/kg food	EFSA Conclusion, 2010 (for ADI)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	ADI	0.013 mg/kg bw/day	-	0.046 mg/L	EFSA Conclusion, 2010 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
4400	**8798.45**	5.65	4.22	0.97

2-ethylhexyl 4-methoxycinnamate (CAS N. 5466-77-3)

USE PATTERN	
Uses:	Sunscreen ingredient in personal care products
Banned uses:	-
Tonnes/year:	From previous exercise: 7500 (year 2000)
Spatial usage (by MS):	Widespread use (worldwide)[1]

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
1(DE)	NORMAN, 2014	$MEC_{95,\ whole}$: 0.398 µg/L	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Daphnia magna*, 48 h, EC_{50}	0.0271 mg/L	1000	2.70E-05 mg/L	ECHA, 2014	Two acute toxicity values (Fish and Daphnia), plus a NOEC value from an algae study.
$PNEC_{sed}$	-	-	10	0.002 mg/kg dw	Equilibrium partitioning method	AF of 10, because log Kow >5 (Technical Guidance No. 27 of the CIS for the WFD)
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	RB
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	RB
$PNEC_{dw,\ hh}$	DNEL, repeated dose toxicity, oral	2.25 mg/kg bw/day	-	7.875 mg/kg bw/day	ECHA, 2014 (for DNEL)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
233.33	**4665.08**	N.R.	N.R.	8.00E-04

[1]Update of Sunscreen Ingredients Nomination to NTP. Imogene Sevin, Ph.D. Technical Resources International, Inc., 2006

Dimethenamid-P (CAS N. 163515-14-8)

USE PATTERN	
Uses:	Dimethenamid banned as Herbicide, PPP (Commission Decision, C(2006) 6895). Replaced as herbicide by its active isomer, dimethenamid-P
Banned uses:	-
Tonnes/year:	-
Spatial usage (by MS):	AT, BE, BG, CZ, DE, EL, ES, FR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
1 (NL)	IPCheM	MEC_{site}: 0.01 µg/L	**-**

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Lemna gibba*, 14 d, NOEC	0.002 mg/L	10	2.00E-04 mg/L	INERIS, 2011	Dimethenamid and dimethenamid-P were assessed together.
$PNEC_{sed}$	-	-	-	0.001 mg/kg dw	INERIS, 2011	Equilibrium partitioning method
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI	0.02 mg/L	-	0.070 mg/L	INERIS, 2011	Same ADI for dimethenamid and dimethenamid-P

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
1405	581.25	N.R.	N.R.	4.01

Diflufenican (CAS N. 83164-33-4)

USE PATTERN	
Uses:	Herbicide (PPP)
Banned uses:	-
Tonnes/year:	-
Spatial usage (by MS):	Authorized in AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
3 (FR, DE, FI)	NORMAN, 2014 WATERBASE, 2014	$MEC_{95, whole}$: 0.09 µg/L $MEC_{95, dissolved}$: 0.152 µg/L (NORMAN) $MEC_{95, whole}$: 0.029 µg/L (WATERBASE)	1 (RBSP EQS ECOSTAT – UBA report)

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Scenedesmus subspicatus*, 72 h, NOEC	0.0001 mg/L	10	1.00E-05 mg/L	INERIS, 2012	-
$PNEC_{sed}$	*Chironomus riparius*, 28 d, NOEC	2 mg/kg	100	0.020 mg/kg dw	INERIS, 2012	One long term test available
$PNEC_{biota,sec\ pois}$	Rats, chronic toxicity, c.f. 20, 2 years, NOAEL	25 mg/kg day	30	16.7 mg/kg food	INERIS, 2012	-
$PNEC_{biota,\ hh}$	ADI	0.2 mg/kg bw/day	-	12.174 mg/kg food	EFSA Conclusion, 2007 (for ADI)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	ADI	0.2 mg/kg bw/day	-	0.7 mg/L	EFSA Conclusion, 2007 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
1200	10.89	1.15	1.57	0.02

Oxadiazon (CAS N. 19666-30-9)

USE PATTERN	
Uses:	Herbicide (PPP)
Banned uses:	-
Tonnes/year:	-
Spatial usage (by MS):	Authorized in BE, CY, ES, FR, IT, LU, PT, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
2 (FR, IT)	NORMAN, 2014 IPCheM	$MEC_{95, whole}$: 0.07 µg/L $MEC_{95, dissolved}$: 0.168 µg/L (NORMAN) MEC_{95}: 13.35 µg/L (IPCheM)	1 MS (RBSP EQS ECOSTAT – UBA report) EQS set (WRc, 2012)

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Oncorhyncus mykiss*, 60 d, NOEC	0.00088 mg/L	10	8.80E-05 mg/L	EFSA Conclusion, 2010 DAR, 2006	Three NOEC values from the three main trophic levels (fish, aquatic invertebrates, algae)
$PNEC_{sed}$	*Chironomus riparius*, 28 d, NOEC	5 mg/L	100	0.050 mg/kg dw	EFSA Conclusion, 2010	One long term test available
$PNEC_{biota,sec\ pois}$	Rats, chronic toxicity, c.f. 20, 2 years, NOAEL	0.36 mg/kg bw/day	30	0.24 mg/kg food	EFSA Conclusion, 2010 (for NOAEL)	See section 3.3.3. for calculation
$PNEC_{biota,\ hh}$	ADI	0.0036 mg/kg bw/day	-	0.219 mg/kg food	EFSA Conclusion, 2010 (for ADI)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	ADI	0.0036 mg/kg bw/day	-	0.013 mg/L	EFSA Conclusion, 2010 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
1120.80	23.80	998.63	1093.74	7.83

Tri-allate (CAS N. 2303-17-5)

USE PATTERN	
Uses:	Herbicide (PPP)
Banned uses:	-
Tonnes/year:	From previous exercise: 10150 (year 2003)
Spatial usage (by MS):	Authorized in AT, BE, CZ, FR, IE, IT, NL, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
2 (FR, NL)	$MEC_{95,\ whole}$: 0.1875 µg/L	NORMAN, 2014	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Daphnia magna*, 21 d, NOEC	0.013 mg/L	10	1.30E-03 mg/L	EFSA conclusion, 2008 DAR, 2007	Three NOEC values from the three main trophic levels (fish, aquatic invertebrates, algae)
$PNEC_{sed}$	*Chironomus riparius*, 28 d, NOEC	0.583	100	0.006 mg/kg	EFSA conclusion, 2008	One long term test available
$PNEC_{biota,sec\ pois}$	Rats, chronic toxicity, c.f. 20, 2 years, NOAEL	2.5 mg/kg bw/day	30	1.67 mg/kg food	EFSA conclusion, 2008 (for NOAEL)	See section 3.3.3. for calculation
$PNEC_{biota,\ hh}$	ADI	0.025 mg/kg bw/day	-	1.522 mg/kg food	EFSA conclusion, 2008 (for ADI)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	ADI	0.025 mg/kg bw/day		0.088 mg/L	EFSA conclusion, 2008 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
10.00	**933.10**	10.92	11.96	0.15

Thiacloprid (CAS N. 111988-49-9)

USE PATTERN	
Uses:	Insecticide (PPP)
Banned uses:	-
Tonnes/year:	-
Spatial usage (by MS):	Authorized in AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
1 (FI)	WATERBASE, 2014	All values < LOQ	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Chironomus riparius*, 28 d, NOEC	0.001 mg/L	10	1.00E-04 mg/L	EU LoE, 2004	Due to the mode of action of neonicotinoids, the lowest endpoint from the aquatic species tested corresponds to the midge *Chironomus riparius*. Therefore, it was selected for $PNEC_{fw}$ calculation.
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI	0.01 mg/kg bw/day	-	0.035 mg/L	EU Review Report, 2003 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
850.00	N.R.	N.R.	N.R.	2.43

2,6-di-tert-butyl-4-methylphenol (CAS N. 128-37-0)

USE PATTERN	
Uses:	Industrial uses, use in plastics, rubber products, adhesives, coatings, dyes, fuel (biodiesel), use for the formulation of PPP and biocides, use as laboratory reagent (ECHA, 2013)
Banned uses:	-
Tonnes/year:	Confidential (IUCLID, 2013)
Spatial usage (by MS):	Not known

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
None	-	-	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Daphnia magna*, 21 d, NOEC	0.316 mg/L	100	3.16E-03 mg/L	ECHA, 2013	In IUCLID, three different $PNEC_{fw}$ were reported. Two were calculated from QSAR estimations, and the source of the 3rd PNEC was unclear. Therefore, according to the ecotoxicological data available, a new $PNEC_{fw}$ was estimated in this report.
$PNEC_{sed}$	-	-	-	1.290 mg/kg dw	ECHA, 2013	Statistical extrapolation
$PNEC_{biota,sec\ pois}$	-	-	30	16.7 mg/kg food	ECHA, 2013	-
$PNEC_{biota,\ hh}$	DMEL	0.25 mg/kg bw/day	-	15.217 mg/kg food	ECHA, 2013 (for DMEL)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	DMEL	0.25 mg/kg bw/day	-	0.875 mg/L	ECHA, 2013 (for DMEL)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
133.86	284.99	633.23	**694.93**	0.48

Imidacloprid (CAS N. 105827-78-9/138261-41-3)

USE PATTERN	
Uses:	Insecticide (PPP)
Banned uses:	Restriction of uses (EU n. 485/2013)[2]
Tonnes/year:	-
Spatial usage (by MS):	Authorized in AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
3 (FR, PT, NL)	NORMAN, 2014 WATERBASE, 2014	$MEC_{95,\ whole}$: 0.08 µg/L $MEC_{95,\ dissolved}$: 0.114 µg/L (NORMAN)	1 MS (RBSP EQS ECOSTAT – UBA report) EQS set (WRc, 2012)

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Chironomus riparius*, 28 d, EC_{10}	0.00209 mg/L	10	2.09E-04 mg/L	EFSA Conclusion, 2008	Due to the mode of action of neonicotinoids, the lowest endpoint from the aquatic species tested corresponds to the midge *Chironomus riparius*. Therefore, it was selected for $PNEC_{fw}$ calculation.[3]
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI	0.06 mg/kg bw/day	-	0.210 mg/L	EFSA Conclusion, 2008 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
296.65	N.R.	N.R.	N.R.	0.30

[2] the uses as seed treatment and soil treatment of plant protection products containing imidacloprid should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing imidacloprid should be prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering.

[3] It was shown that the toxicity of imidacloprid towards aquatic invertebrates varies, with *D. magna* being less sensitive than others, for instance amphipod *Hyalella azteca* or midge *Chironomus tentans*, and having acute LC50 values in the same concentration range as fish (Jemec et al., Chemosphere 68 (2007) 1408–1418).

Erythromycin (CAS N. 114-07-8)

USE PATTERN	
Uses:	Pharmaceutical, Industrial use resulting in manufacture of another substance (use of intermediates) (ECHA, 2014)
Banned uses:	-
Tonnes/year:	Confidential (IUCLID, 2014)
Spatial usage (by MS):	Yes (http://www.drugs.com/international/erythromycin.html)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
2 (NL, CH)	NORMAN, 2014	All values < LOQ	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Synechococcus leopoldensis* IAM-M6, 144 h, EC_{50}	0.002 mg/L	50	4.00E-05 mg/l	NORMAN, 2014	-
$PNEC_{sed}$	-	-	-	0.001 mg/kg dw	Equilibrium partitioning method	See section 3.3.2, and 3.4.2 eq. E-F-G, for calculation
$PNEC_{biota,sec\ pois}$	-	-	-	No info	-	Mammalian toxicity values lacking.
$PNEC_{biota,\ hh}$	ADI	0.0007 mg/kg bw/day	-	0.043 mg/kg food	WHO report[4] (for ADI)	See section 3.3.4 for calculation
$PNEC_{dw,\ hh}$	ADI	0.0007 mg/kg bw/day	-	0.002 mg/L	WHO report[4] (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
131.50	**264.56**	No info	5.99	2.15

[4] http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=3938

Clothianidin (CAS N. 210880-92-5)

USE PATTERN	
Uses:	Insecticide (PPP)
Banned uses:	Restriction of uses (EU n. 485/2013)[5]
Tonnes/year:	-
Spatial usage (by MS):	Authorized in AT, BE, BG, CZ, DE, DK, EL, ES, FI, FR, HU, IE, IT, LT, NL, PL, PT, RO, SK, UK (EU Pesticides DB)

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
None	-	-	-

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Chironomus riparius*, 28 d, EC_{15}	0.00072 mg/L	10	7.20E-05 mg/L	EU Review Report, 2005	Due to the mode of action of neonicotinoids, the lowest endpoint from the aquatic species tested corresponds to the midge *Chironomus riparius*. Therefore, it was selected for $PNEC_{fw}$ calculation.
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota,\ hh}$	-	-	-	N.R.	-	-
$PNEC_{dw,\ hh}$	ADI	0.097 mg/kg bw/day		0.340 mg/L	EU Review Report, 2005 (for ADI)	See section 3.3.5 for calculation

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota,\ hh}$**	**$RQ_{dw,\ hh}$**
194.44	N.R.	N.R.	N.R.	0.04

[5] the uses as seed treatment and soil treatment of plant protection products containing clothianidin should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing clothianidin should be prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering

Cyanide-Free (CAS N. 57-12-5)

USE PATTERN	
Uses:	Industrial uses
Banned uses:	-
Tonnes/year:	-
Spatial usage (by MS):	Not known

MONITORING AND DESIGNATION AS RIVER BASIN SPECIFIC POLLUTANT			
n. of MS	**Source of monitoring data**	**MEC values**	**RBSP**
14 (CZ, SI, EL, FR, DE, AT, ES, GB, IE, NL, PL, RO, SK, IT) as cyanide	NORMAN, 2014 WATERBASE, 2014 IPCheM	$MEC_{95, whole}$: 1.07 µg/L $MEC_{95, dissolved}$: 5 µg/L (NORMAN) $MEC_{95, whole}$: 20 µg/L $MEC_{95, dissolved}$: 20 µg/L (WATERBASE) MEC_{95}: 14 µg/L (IPCheM)	10 MS (RBSP EQS ECOSTAT – UBA report) EQS set for cyanide ion and total (WRc, 2012)[6]

HAZARD ASSESSMENT						
PNEC	**Endpoint**	**Endpoint value**	**AF**	**PNEC value**	**Source**	**Comment**
$PNEC_{fw}$	*Lepomis macrochirus*, 289 d, LOEC	0.0052 mg/L	100	5.2E-05 (mg/L)	WFD - UK TAG Report (2012)	The AF value includes a factor of 2 to convert the LOEC to a NOEC.
$PNEC_{sed}$	-	-	-	N.R.	-	-
$PNEC_{biota,sec\ pois}$	-	-	-	N.R.	-	-
$PNEC_{biota, hh}$	-	-	-	N.R.	-	-
$PNEC_{dw, hh}$	-	-	-	0.05 (mg/L)	EU Drinking Water QS	Referred to cyanide

RISK QUOTIENTS				
RQ_{fw}	**RQ_{sed}**	**$RQ_{biota,sec\ pois}$**	**$RQ_{biota, hh}$**	**$RQ_{dw, hh}$**
-	-	-	-	-

[6] Comparative Study of Pressures and Measures in the Major River Basin Management Plans' - Task 2c (Comparison of Specific Pollutants and EQS): Final Report – WRc (2012) - Contract No. 070311/2011/603663/ETU/D1 with DG Environment, European Commission

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