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COMMISSION STAFF WORKING PAPER

TECHNICAL BACKGROUND

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy

{COM(2011) 875 final}

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1. REVIEW PROCESS

1.1. Tasks

In summary, the main tasks of the technical review of the Priority Substances list under the Water Framework Directive (WFD[1]) were to prioritise possible new Priority Substances (PS), considering among others the substances in Annex III to the EQS Directive (EQSD[2]), to set appropriate EQS, and to review whether changes should be made to the EQS or status (as PS or Priority Hazardous Substances (PHS)) of existing PS. The outputs of the technical process were therefore a list of possible new substances, EQS for them and for some existing substances, and PHS classifications. In addition, and in the context of the subsequent impact assessment, the need for additional control measures for existing and new priority substances was investigated.

1.2. Participants in the review

The technical process of the review was developed by the WFD Common Implementation Strategy (CIS)[3, 4] Working Group E (Chemical Aspects, formerly called Priority Substances), operational since 2007 when it superseded the Expert Advisory Forum established in 2001. WG E contributed in various ways to the review of the EQS Directive, supporting the collection of data (including monitoring and hazard data and information on control measures), the prioritisation exercise, the update of the Technical Guidance Document on EQS (TGD-EQS) and the derivation of EQS. Two expert groups were set-up as sub-groups of WG E: the Expert-Group on the Technical Guidance Document EQS (EG-EQS), and the Sub-Group on Review of Priority Substances (SG-R). The membership of WG E and the two expert groups consists of Commission DGs, Member States and stakeholder organisations including a range of industry bodies and NGOs. A list of Members is available on the Register of Commission Expert Groups[5].

The SG-R was mandated to support the prioritisation, to propose the candidate substances to be included in the PS list, and to propose EQS for them in water, sediment and/or biota as appropriate. It also provided advice on the revision of water EQS and the development of sediment and biota EQS for existing PS. It was assisted in its work by Commission consultants INERIS and the International Office for Water. The outputs of SG-R's technical work were regularly presented and discussed in WG E meetings during the review process.

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1 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [OJ L327 of 22.12.2000]. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02000L0060-20090113:EN:NOT

2 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council [OJ L 348, 24.12.2008, p. 84–97]. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:348:0084:0097:EN:PDF

3 Common Implementation Strategy (CIS) http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy.pdf

4 CIS work programme 2011-2012 http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/implementation_documents/final_2010-2012/_EN_1.0_&a=d

5 http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=371, under "Sub-groups", "Priority Substances".

In support of the EQS-setting and revision processes, it was necessary to update the guidance document on EQS derivation. This was done by the EG-EQS in parallel with the prioritisation work. The EQS derivation and revision were then carried out according to the updated guidance. The guidance and the draft EQS were submitted to the Scientific Committee on Health and Environmental Risks (SCHER) for its opinion. Further details are provided in later sections.

1.3. Summary of approach and outcomes

1.3.1. Proposed Priority Substances

The prioritisation process took account of several information sources and arrived at a short-list of 19 substances, for which EQS were derived, though not all the substances appear in the proposal for the reasons explained in section 2.8.2.

During the review, particular consideration was given to the substances in Annex III to the EQSD. Section 2.9 explains how these substances ranked in relation to others shortlisted during the prioritisation process, and what led to their inclusion in or exclusion from the options and the final proposal.

Consideration was also given to substances that might pose a particular risk to drinking water supplies. Data were requested from WG E on concentrations of such substances in water bodies used for the abstraction of drinking water, and in drinking water itself. For none of the substances were the data conclusive. For this reason, no substances were identified that would require the setting of a standard specific to water bodies used for the abstraction of drinking water. Section 2.10 provides more details.

For all the proposed priority substances, consideration was given to their hazardousness (in particular as judged under other legislation) and the exposure of the aquatic environment (and humans via the aquatic environment) to them in order to determine whether they should be classified as PHS. Six were identified as PHS. The considerations for each substance are summarised in section 4.2.2.

1.3.2. Existing PS

A review of new risk assessments of the existing PS led to the conclusion that the EQS for seven substances should be revised and/or established for biota instead of water. Details are provided in section 3.3.

New information that might affect the status of existing PS was also reviewed, and this led to the proposal that two existing substances be reclassified as PHS, as outlined in section 4.2.1.

2. PROCESS FOR PRIORITISATION OF NEW PRIORITY SUBSTANCES

2.1. Background

According to WFD Article 16(1), the Commission should identify priority substances (PS) among those presenting a significant risk to or via the aquatic environment, including such risks to waters used for the abstraction of drinking water. Article 16(2) establishes that the identification of PS should be based on

1. Risk assessment carried out under the chemicals, pesticides (plant protection products) and biocides legislation (Regulation (EEC) No.793/93, Directive 91/414/EEC (now Regulation (EC) No 1107/2009) and Directive 98/8/EC respectively)

2. Targeted risk assessments focusing on aquatic ecotoxicity and on human toxicity via the aquatic environment

3. Simplified risk-based assessment procedure based on scientific principles taking particular account of

    - Evidence regarding the intrinsic hazard of the substances,
    - Evidence from monitoring of widespread contamination
    - Other elements that may indicate widespread contamination such as production volumes and use patterns

At the time the first identification of PS was carried out (list of 33 PS established in 2001 by Decision 2455/2001/EC), very few risk assessment were available under the chemicals, pesticides and biocides legislation. The COMMPS (**combined monitoring-based and modelling-based priority setting)** procedure[6] was developed as a simplified risk-based assessment that combined the available information on the intrinsic hazard of substances (first bullet under point 3 above) with estimates of exposure based on monitoring information (second bullet under point 3 above) and modelling information derived from production volumes and use patterns (third bullet under point 3 above).

The current situation is very different from ten years ago in that the implementation of the legislations on chemicals, pesticides and biocides has progressed substantially. Risk assessments have been concluded for many substances and need to be taken into account when identifying priority substances under the WFD. In addition, risk assessments are available in draft stage for a number of substances and other substances have undergone voluntary risk assessments.

At the time of development COMMPS was welcomed as a pragmatic approach towards prioritisation. The Scientific Committee on Toxicity, Ecotoxicity and the Environment published an opinion on COMMPS[7] that identified a number of elements for improvement in the future. This opinion and the discussions among Commission services, Member States and stakeholder experts were considered in the development of an improved methodology for prioritisation. This was developed (starting in 2007) by the Working Group E on Chemical Aspects under the WFD Common Implementation Strategy (CIS).

The following sections explain how the three bases for PS identification presented in WFD Article 16(2) have determined the methodology used in the current review.

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6 http://ec.europa.eu/environment/water/water-dangersub/lib_pri_substances.htm

7 Opinion on the revised proposal for a List of Priority Substances in the Context of the Water Framework Directive (COMMPS Procedure) prepared by the Fraunhofer-Institut (Germany) - Final report Opinion adopted at the 11th CSTEE plenary meeting on the 28th of September 1999. http://ec.europa.eu/health/ph_risk/committees/sct/docshtml/sct_out49_en.htm

2.2. Overall approach to prioritisation

The overall approach was based on the criteria set out in the WFD Article 16(2) and built on the experience gained with the COMMPS procedure (see below). It is recognised that there is no single approach that is best for prioritisation, all have their advantages and disadvantages. A combination of different approaches was considered the best to identify candidates for the priority list.

The approaches were based on the following, which were developed as parallel prioritisation processes and subjected to expert review:

- Risk assessment carried out under the chemicals, pesticides and biocides legislation
- Targeted risk assessments focusing on aquatic ecotoxicity and on human toxicity via the aquatic environment
- Simplified risk-based assessment procedure based on scientific principles taking particular account of
  - Evidence regarding the intrinsic hazard of the substances, and
  - Evidence from monitoring of widespread environmental contamination and
  - Other elements that may indicate widespread contamination such as production volumes and use patterns
- Priority Hazardous Substances criteria (PBT or equivalent level of concern), including Substances of Very High Concern under REACH and POP criteria
- Other sources of information
  - Substances of concern at Member State level
  - Annex III of EQSD Directive 2008/105/EC

The processes led to separate but complementary lists of substances. The lists or at least the highest-priority substances on each list were amalgamated and subjected to a short-listing procedure involving further expert review. The range of processes took advantage of the most relevant available information. Inevitably there was some overlap between the lists, despite the independence of the processes, and this made the case for prioritising some substances particularly strong. The individual processes and the short-listing procedure are illustrated in Figure 1 and described in the following sections. The short-listed substances were subject to a detailed expert review on the basis of dossiers prepared by the Commission and Member States experts in the Sub-Group on Review.

The following sections describe more in detail the different sources of prioritisation and how the short-listing was carried out.

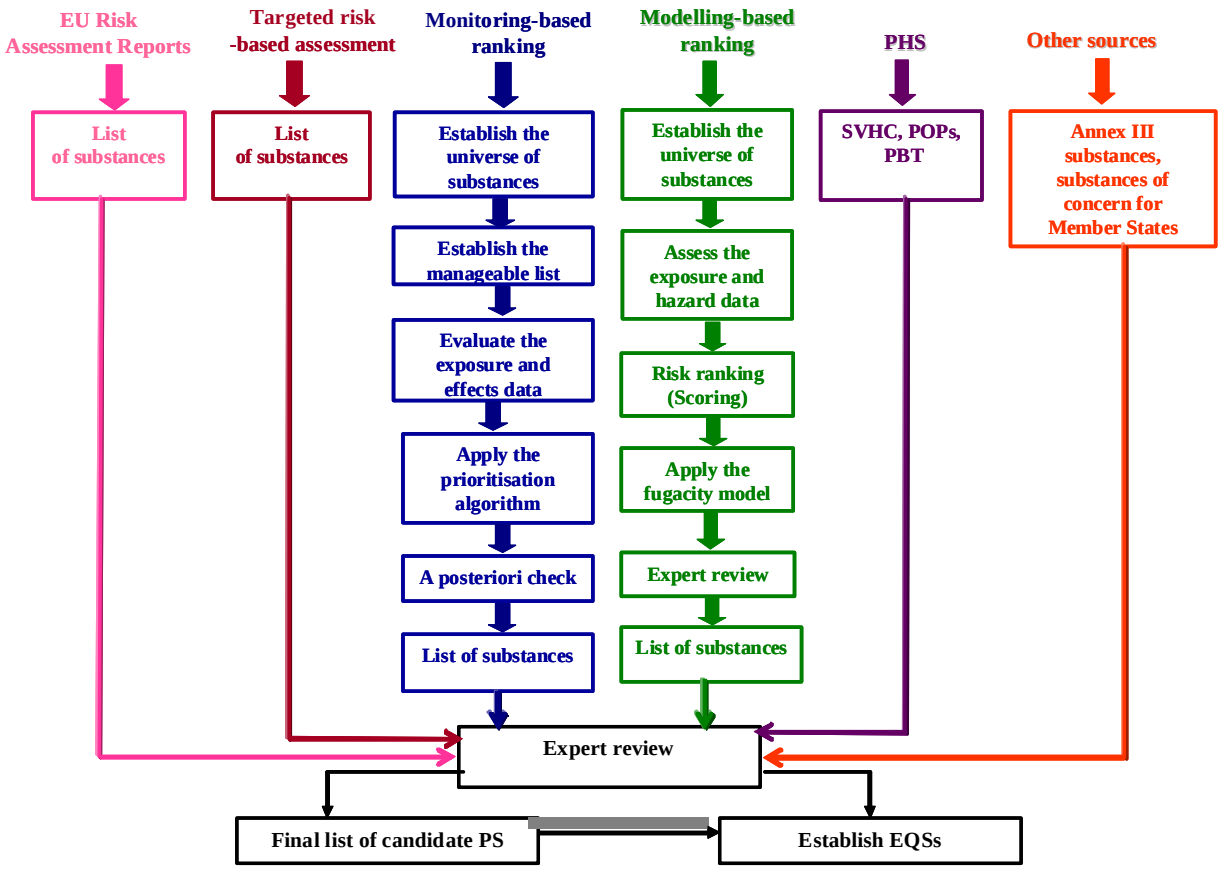

Figure 1: Overall approach to prioritisation

2.3. Risk assessment carried out under the chemicals, plant protection products and biocides legislation[8]

2.3.1. Existing Substances Regulation (EEC) No.793/93

From 1994 to 2009, a total of 4 priority lists comprising 141 substances were drawn up by the Commission in consultation with Member States to carry out risk assessments under Regulation (EEC) No.793/93 (see http://esis.jrc.ec.europa.eu/). Risk assessment reports were concluded for 102 substances. Among those, and without counting existing PS, 49 pose identified risks to or via the aquatic environment and for 35 a Commission Recommendation to reduce risk has been published in the Official Journal.

The risk assessment reports (RAR) for existing chemicals that included a conclusion iii[9] for the aquatic environment were screened to extract the Predicted Environmental Concentrations (PECs), Predicted No Effect Concentrations (PNECs) and risk ratios.

The following criteria were applied when considering whether to further consider the substance:

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8 The information on this section reflects the situation at the time of performing the review (mid 2009).

9 Conclusion (iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

- The default option was to select the substance for further review in view of the conclusion iii on risks to or via the aquatic environment.

- Only final RARs were considered. Draft RAR were not deemed sufficient to consider the substance further.

- If the risk assessment clearly indicated that the conclusion iii was reached for a local scenario or for only a few sites, and the scenario was not likely to be present in a significant number of river basins in the EU, the substance was not considered further. If the risk was labelled "local" but related to widespread uses then it was deemed appropriate to identify the substance for further review. In case of doubt about whether the use was widespread or not the substance was kept for further review.

The assessment concluded with 12 substances selected for preparation of detailed dossiers out of the 49 substances with conclusion iii for the aquatic environment.

2.3.2. Plant Protection Products legislation Directive 91/414/EEC (Regulation (EC) No 1107/2009)

As at 23 June 2009, 334 active substances were included in Annex I of Directive 91/414/EEC, i.e. authorised for use in plant protection products, and 766 active substances had been subject to a non-inclusion decision. Annex I of Directive 91/414/EEC identifies 151 of the 334 active substances authorised as needing risk reduction measures due to the risk to surface waters.

The Sub-Group on Review decided not to investigate further those plant protection products (PPPs) that have been authorised, and are therefore included in Annex I to Directive 91/414/EEC, but for which there is no other source of information for prioritisation, i.e. they are not ranked high in either the monitoring-based or the modelling-based approach, nor identified as a PBT, POP, SVHC or Annex III substance. PPPs subject to a non-inclusion decision under Directive 91/414/EEC and not ranking high in any of the ranking exercises were also not investigated further.

The Sub-Group considered information on the peak concentrations of the PPPs in the monitoring database in order to ensure that the averaging involved in the PEC calculation in the monitoring-based prioritisation did not overlook important information on short-lived high concentrations.

The risk assessments for the remaining 11 PPPs were screened to extract the relevant information. The Toxicity Exposure Ratios (TERs) were used to rank the PPPs as far as the available information allowed. Eight out of the 11 PPPs ranked high in the modelling-based prioritisation and 4 out of 11 ranked high or very high in the monitoring-based prioritisation. Methiocarb (aka mercaptodimethur) and Deltamethrin ranked very high in the monitoring-based prioritisation but were proposed for de-selection because the available monitoring information was not sufficiently representative of an EU risk and had not been identified by any other prioritisation process.

2.3.3. Biocides legislation Directive 98/8/EC

At the time of short-listing there were 29 active substances in Annex I of Directive 98/8/EC, i.e. authorised for use. Of those, the annex identifies risks to the aquatic environment in 13 cases. Around 300 active substances were under review at that moment.

The same criteria were applied to biocides as to PPPs, i.e. no further investigation was proposed if the substance was not ranked high in any of the ranking exercises and they were not identified as a PBT, POP, SVHC or Annex III substance.

Only one substance remained after applying these criteria: Tolylfluanid, which is also authorised as a PPP. Its risk assessment under the biocides legislation was examined and the substance was further investigated.

2.4. Targeted risk assessments focusing on aquatic ecotoxicity and on human toxicity via the aquatic environment

On the basis that voluntary risk assessments had been concluded by industry on Copper and by the UK on PFOS, in both cases showing conclusion iii for the aquatic environment for some scenarios and uses, these substances were further reviewed.

2.5. Simplified risk-based assessment procedure based on scientific principles

A simplified assessment procedure was developed for the current prioritisation by the Sub-Group on Review, largely building on the experience of COMMPS and the opinion on this methodology received from the Scientific Committee on Toxicity, Ecotoxicity and the Environment[10] (SCTEE, now Scientific Committee on Health and Environmental Risks – SCHER).

The Sub-Group decided to run the following 2 methodologies in parallel:

– A **monitoring-based methodology** elaborated by DG Environment's consultant INERIS-IOW, and

– A **modelling-based methodology** developed by the Sub-Group based mainly on an UK methodology modified and implemented by the JRC

The methodologies complement each other, as the SCTEE recognised in its opinion[11]. Both incorporate information on the intrinsic hazard of substances, i.e. first bullet under point 3 in section 2.1 above. The monitoring-based methodology builds on the second bullet under point 3 in section 2.1 above and the modelling-based methodology on the third bullet under point 3.

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[10] Opinion of the SCTEE adopted on 28 September 1999, available at http://ec.europa.eu/health/ph_risk/committees/sct/docshtml/sct_out49_en.htm

[11] "Monitoring data provide an excellent basis, from direct observation, to get information on European environmental conditions. However, monitoring data cannot be used as the single scoring method because the available information is incomplete and only covers a set of substances which were considered "relevant" in the past. Thus, the current monitoring information is biased by previous decisions on which substances should be monitored. (…) Therefore, it is important to incorporate a second system, to allow inclusion in the final list, of substances with a high potential risk for aquatic organisms for which no monitoring information is available to date." Cf. Opinion of the SCTEE of 28.09.1999.

2.5.1. Monitoring-based prioritisation

As recognised by the SCTEE, the monitoring-based approach is an excellent basis for prioritisation as it provides direct evidence of the presence of substances in the environment.

A preliminary monitoring-based prioritisation was conducted in 2008 leading to the compilation of a database and a first-stage ranking report. Following extensive discussions, gaps and improvements were identified and a second data collection and an improved prioritisation methodology were implemented. A monitoring-based list of substances was then proposed. The steps involved were: data gathering, selection of relevant substances to rank, definition and application of the criteria for ranking, development and application of the algorithm for ranking, additional checks, and identification of the final monitoring-based list of substances. These are described in detail below.

2.5.1.1. Creation of the database

The monitoring-based ranking used raw monitoring data collected in EU Member States (all except Malta) and other European countries (Norway and Switzerland). Minimum information criteria for use of the data in the prioritisation were defined. With each analysis, 22 mandatory pieces of information were required, and a large set of additional information if available. The Sub-Group developed a template for the data collection which was implemented in a data-collection tool. This tool was used by almost every country to prepare its dataset: gather individual data, check for completeness, and export the resulting dataset for submission to the Commission. In the received datasets, various validity checks were implemented before the data were gathered in a central database.

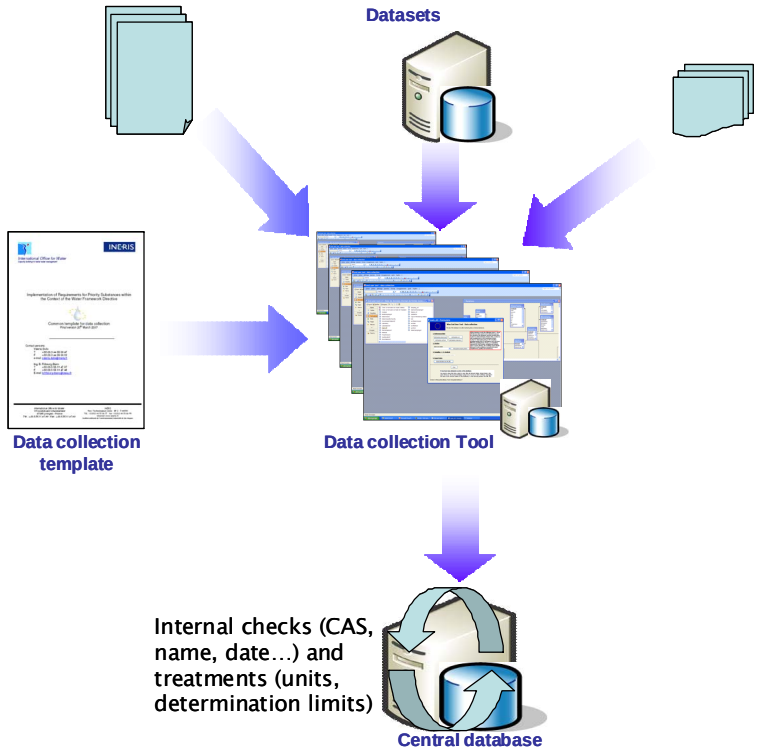
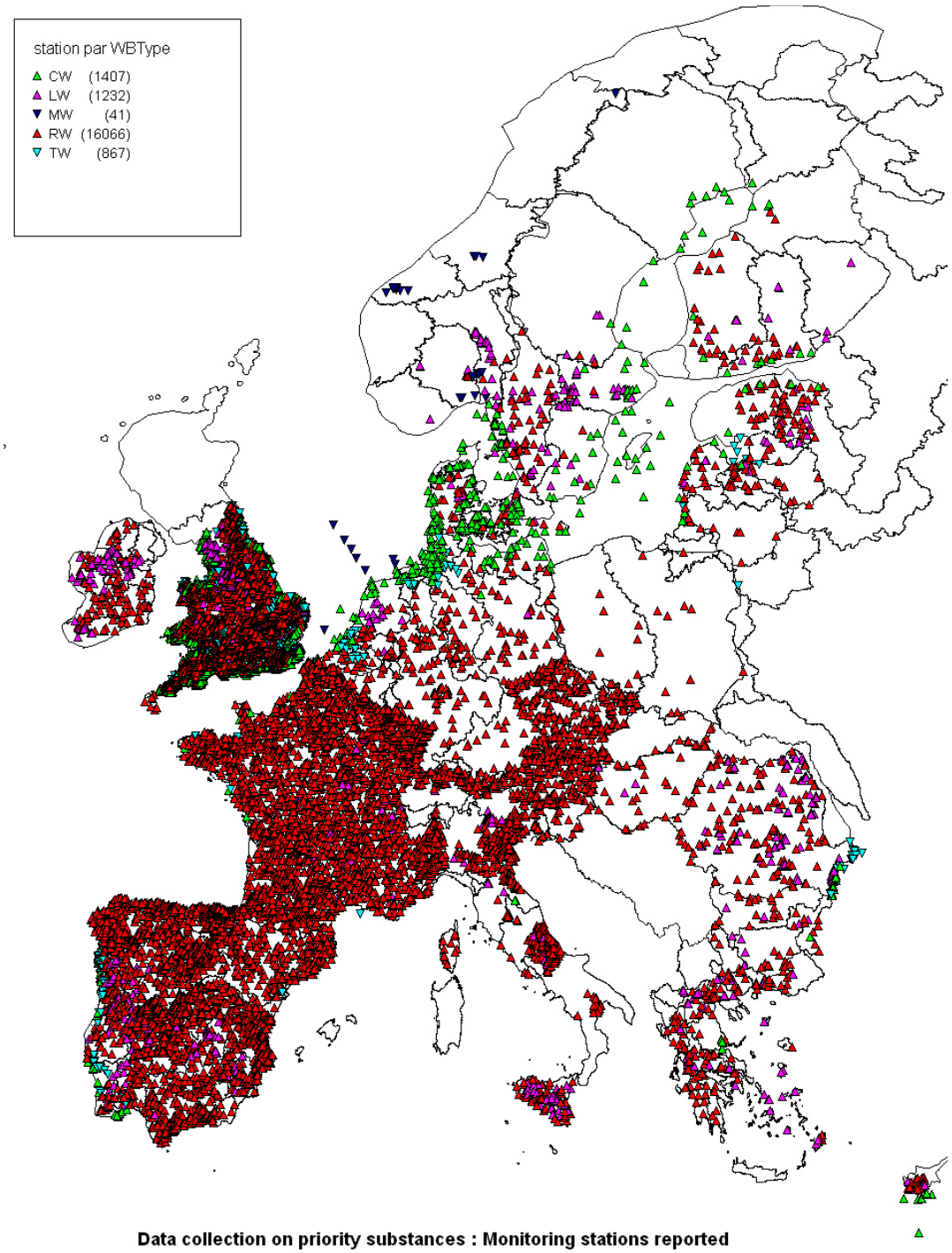


Figure 2: Data collection, template, tool and database

Many differences in presentation and content were found, including the use of more than 150 different units. Some preliminary treatment was therefore necessary, e.g. to express all results in µg/l for water analyses and µg/kg for sediment and biota analyses.

Overall, 14.6 million analyses from 19 900 stations in 28 countries and covering 1151 substances were reported.[12] All 4 WFD surface water categories (rivers, lakes, transitional and coastal waters) were represented, river stations being predominant as illustrated in the following map (**Figure 3**).

[12] This compares with 750 000 analyses from the EU15 for water and sediment in the database compiled for the COMMPS procedure.



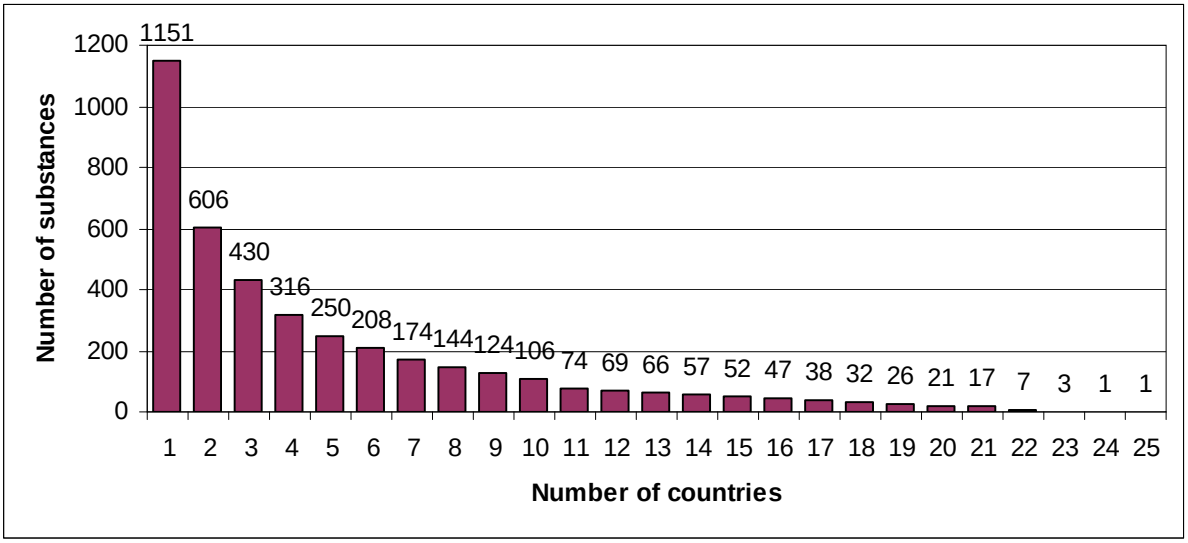
Data collection on priority substances : Monitoring stations reported

Data were provided on three fractions of water, four fractions of sediment and eight fractions of biota, water data being by far the most dominant.

2.5.1.2. Selection of substances for ranking

Considering the tight schedule and the available resources, it was not possible to use the complete dataset. In addition, Figure 4 on the number of countries that reported data on the various substances (independent of fraction) shows that most substances were reported on by only a small number of countries, hence not necessarily representative of the situation in the EU.

Figure 4: Number of countries reporting data per substance



Since the WFD intends that PS be of EU-wide concern, the ranking step was restricted to substances monitored in at least 4 countries, i.e. to 316 substances.

2.5.1.3. Criteria for ranking: consideration of exposure and effects data

The prioritisation took account of the combination of:

- exposure data (Predicted Environmental Concentration) expressed as a single concentration, based on the available EU monitoring data, and
- effect data (Predicted No Effect Concentration) selected from the literature for the sole purpose of prioritisation.

The exposure data were calculated from the monitoring data as arithmetic means at the level of each monitoring station for each analysed fraction (whole water, dissolved metals in water, sediment below 2mm, below 63µm, below 20µm, fish and invertebrates), and then as 90th percentiles of the means from all stations. If collected data are representative of the EU situation, 90% of the stations would be expected to experience average concentrations below this value, i.e. below the PEC. In terms of risk assessment, this implies that if the PEC is below the PNEC, 90% of the station locations are, on average, expected to present safe concentrations. In practice, difficulties arise because of measurements that are below the analytical determination limit. Two PEC calculations were consequently calculated, one using only quantified values (PEC1), the other using all available data (PEC2). In the latter data below the determination limit was replaced by half its value as recommended by the QA/QC Directive (2009/90/EC)[13].

Two PEC/PNEC risk ratios could then be derived for each fraction (where data were available). In some cases the results may have reflected insufficient analytical performance rather than real risk. It was therefore necessary to assess the relevance of the ratios. This was done first by discarding cases where the risk based on PEC2 was >1 whilst that based on

[13] Commission Directive on technical specifications for chemical analysis and monitoring of water status, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:201:0036:0038:EN:PDF

PEC1 was <1, second by checking that PEC1 > PEC2, and third by considering for ranking in the monitoring-based prioritisation only the substances where the number of quantified analyses is more than 2% of the total number of analyses.

The effect data considered were ecotoxicity data for the different fractions covered by the monitoring data. They were obtained during an extensive literature review in the spring of 2009. For water, direct ecotoxicity was considered and a PNEC calculated using the original Technical Guidance Document on Risk Assessment. For sediment, PNEC values were calculated by applying the Equilibrium Partitioning method using $PNEC_{water}$ and K_{oc} as input parameters. For biota, risk of secondary poisoning for predators and risk to human health via consumption of contaminated aquatic biota were assessed and the PNEC based on the higher risk.

Drinking water standards were compared with the PECs to provide an indication of the removal efficiency that might be required to produce drinking water. For metals, PNECs in water and biota were proposed, based on substance factsheets or on the relevant RARs.

2.5.1.4. Prioritisation algorithm

For each fraction, five risk-ratio categories were defined: Very High, High, Medium, not Applicable and Low[14]. The overall priority is defined by the maximum priority amongst the calculated risk ratios for all fractions.

Specific cases were made for substances relevant to drinking water, where drinking water standards or guidelines were considered in place of the PNEC for the ratio calculation. Specific cases were also made for PCBs, where results for total PCBs were compared to results on each individual PCB, and to the sum of these individuals. Specific case is also made for dioxins/furans where the sum of all dioxin like substances is made using the Toxic Equivalent Factor (TEF) approach.

2.5.1.5. Additional checks

Substances in the very high and high categories were selected for additional checks[15]. Since not all fractions needed to be classified in these categories to make the substance rank high or very high, it was important to check the EU representativeness of the monitoring data for the fraction(s) leading to this ranking. Additional checks on the quality and reliability of the monitoring data were also done to ensure that the selection had a solid basis. As a result of these checks, some substances were identified as candidates for de-selection.

In particular, when the substance was not monitored by at least 3 countries in the determinant fraction resulting in high or very high risk, the substance was identified as candidate for de-listing subject to a final consideration. Non-quantified analyses for which the limit of determination was more than twice the PNEC were considered unreliable. The PEC values and risk ratios were recalculated without these data and if the substance was no longer ranked as very high or high it was identified as a candidate for de-selection, also subject to a final consideration.

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14 See INERIS-IOW (2009), annex IX for exact definition

15 See INERIS-IOW (2009), annex XII

2.5.1.6. List of substances prioritised through monitoring

After application of the algorithm and the additional checks, a list of 36 organic compounds and 4 metals was obtained, 19 of these identified for de-selection.

Table 1: List of substances prioritised through monitoring

No.	SubstanceName	CAS
1	Heptachlor epoxide	1024-57-3
2	Heptachlor	76-44-8
3	Permethrin*	52645-53-1
4	Cyanides	57-12-5
5	Malathion*	121-75-5
6	Methiocarb*	2032-65-7
7	Cypermethrin	52315-07-8
8	Deltamethrin*	52918-63-5
9	Parathion	56-38-2
10	Dichlorvos	62-73-7
11	Dichlorodiphenyl dichloroethane - o,p'	53-19-0
12	Tetrabutyltin compounds*	
13	Triphenyltin compounds*	
14	Dicofol*	115-32-2
15	Fenitrothion*	122-14-5

No.	SubstanceName	CAS
28	Mevinphos	7786-34-7
29	Chloroacetic acid*	79-11-8
30	Methidathion*	950-37-8
31	Monobutyl tin compounds	
32	2,4-Dichlorophenol*	120-83-2
33	Dioxins/Furans	
	Dioxins/Furans/PCB dioxin-like	
34	PCBs	
	PCBs - worst case 3 approaches	
	2',3,4,4',5'-Pentachlorobiphenyl	31508-00-6
	2,3,3',4,4'-Pentachlorobiphenyl	32598-14-4
	2,2',4,4',5,5'-Hexachlorobiphenyl	35065-27-1
	2,2',3,4,4',5'-Hexachlorobiphenyl	35065-28-2
	2,2',3,4,4',5,5'-Heptachlorobiphenyl	35065-29-3
	2,2',5,5'-Tetrachlorobiphenyl	35693-99-3

No.	SubstanceName	CAS
16	Diazinon*	333-41-5
17	Omethoate	1113-02-6
18	Nitrite	14797-65-0
19	Phoxime	14816-18-3
20	Chloroxuron	1982-47-4
21	Azinphos-ethyl	2642-71-9
22	Pirimiphos-methyl*	29232-93-7
23	Trichlorfon*	52-68-6
24	2,2',4,4'-Tetrabromodiphenyl ether*	5436-43-1
25	Fenthion	55-38-9
26	Chlorpyrifos-methyl	5598-13-0
27	Methoxychlor	72-43-5

No.	SubstanceName	CAS
	2,3,3',4,4',5-Hexachlorobiphenyl	38380-08-4
	2,4,4'-Trichlorobiphenyl*	7012-37-5
	2,2',4,5,5'-Pentachlorobiphenyl	37680-73-2
	3,3',4,4'-Tetrachlorobiphenyl	32598-13-3
	PAHs	
35	Pyrene	129-00-0
36	Benzo(a)anthracene	56-55-3
	Metals	
37	Arsenic (and mineral compounds)*	7440-38-2
38	Selenium*	7782-49-2
39	Uranium*	7440-61-1
40	Vanadium*	7440-62-2

* candidate for de-listing

The Sub-Group on Review agreed that, due to the limitations in the monitoring data, substances identified for de-selection should not be subject to further scrutiny in this review if their presence in the list of candidate substances was due only to monitoring-based prioritisation.

Dicofol and Trichlorfon ranked high also in the modelling-based prioritisation. Dicofol is also a PBT and/or vPvB and is in Annex III of the EQSD. Tetrabutyltin compounds were identified as PBT and/or vPvB. Arsenic is a SVHC under REACH. 3,3',4,4'-Tetrachlorobiphenyl (PCB 77) is a POP. Therefore these five substances were retained for further scrutiny.

2,2',4,4'-Tetrabromodiphenyl ether ranked high in the monitoring-based prioritisation but was deleted from the list of candidate substances because it is an existing PS (brominated diphenylether congener BDE-47).

The other substances out of the 19 that were identified as candidates for de-selection were not considered further.

The PAHs ranking high in the monitoring-based ranking (pyrene and Benzo(a)anthracene) were also not proposed for further consideration as PAHs are already included in the PS list.

The remaining substances were then considered alongside those in the other lists of candidate substances for prioritisation.

Twelve substances were identified for which the ratio between the PEC and the drinking water standards was high, i.e. substances for which high treatment removal efficiency would be necessary, and which might therefore cause failure of the drinking water standard at the tap. These were not immediately scrutinised further unless other sources of prioritisation were relevant. The issue of substances that might pose a risk to drinking water supplies is addressed in section 2.10.

The detailed information collected for the monitoring-based prioritisation, and the quantity of analyses collected allowed a more complex approach than COMMPS, and consequently gave more representative results. However, the methodology used to select the substances was based on the arithmetic mean by station and did not consider seasonal emission patterns. This was identified as a limitation of the methodology that could be addressed in future exercises.

2.5.2. Modelling-based prioritisation

The modelling-based ranking involved the following steps: identification of a starting list of substances, data collection (exposure and hazard assessment), application of the ranking methodology, definition of a final modelling-based list of substances. These steps, which were carried out by the Joint Research Centre (JRC), are described below.

2.5.2.1. Starting list: Universe of chemicals

The first step in the modelling based approach was to define the list of substances to which to apply the ranking methodology. Various sources where used: monitoring data from Member States (MS), substances proposed by the European Parliament (EP) for further investigation, stakeholders, research consortia, international organisations, and several EU lists of substances of possible concern such as PBTs, possible endocrine disruptors, plant protection products, etc. All these lists were merged together to form a combined list of 2034 compounds. Metals were excluded from this list as the majority of the tools developed for the estimation of physical, chemical and toxicological properties have been developed to deal with organic compounds rather than metals.

Simplified **M**olecular **I**nput **L**ine **E**ntry **S**pecification (SMILES) codes (descriptions of molecular structure in short ASCII strings) were generated for 1872 substances for use in the modelling.

2.5.2.2. Data collection: Exposure and hazard assessment

Each substance was subjected to a hazard assessment following the REACH Guidance on Information Requirements and Chemical Safety Assessment. It comprised four criteria: Persistence, Bioaccumulation, Toxicity and Endocrine Disrupting properties. When a criterion was fulfilled, a score of 1 was given and the scores were added. If a substance was vPvB, a score of 4 was attributed. In the absence of sufficient information to conclude, QSAR models were used as surrogates.

The assessment of persistence (P) was made using BIOWIN (1727 substances of which 691 were P) or BIOHCWIN (142 substances of which 41 were P) from the EPIsuite, whilst to estimate very P (vP), the OECD Pov and LRTP screening tools were used.

To assess bioaccumulation (B), measurements of the BioConcentration Factor (BCF) in aquatic species were preferred, and B was attributed when 2000<BCF<5000 L/kg, very B (vB) when BCF>5000 L/kg, whereas if the Log Kow <=4,5 and no specific mechanism of uptake was identified, the substance was considered as neither B nor vB. Experimental BCF was used but in the absence of data, other information was used in a weight-of-evidence approach, including worst-case QSAR estimated values based on three modelling approaches.

To assess toxicity (T), REACH Annex XIII criteria were used: either a long-term no-observed effect concentration (NOEC) of less than 0.01mg/l, or the substance was identified as carcinogenic, mutagenic or toxic for reproduction, or the substance had chronic toxicity effects identified by a risk phrase under Directive 67/548/EEC. Acute studies provided evidence of T but this needed to be complemented by chronic tests on fish, daphnia or algae. In their absence, the screening was finalised by applying four QSAR models generated by the ADMET modeller software to derive acute aquatic toxicity, T being assigned if 3 of the 4 QSARs agreed on T classification.

The above scores were summed to obtain a hazard score. The exposure was then assessed through collection of data on use of the substances in products using the IUCLID database and SPIN. The IUCLID database (http://iuclid.echa.europa.eu/) contains data collected through an obligation on producers and importers of high-production-volume chemicals and low-production-volume chemicals. The SPIN database contains data from Nordic countries on the use of substances in products (http://www.spin2000.net) and was used when no data were found in IUCLID, applying an extrapolation factor to derive a European tonnage. Use patterns were applied to generate release indices. When several uses were possible, the most dispersive was selected. An exposure score was then attributed. Only 737 substances could be assessed due to limitations in the data availability.

The exposure score was combined with the hazard score to derive a risk score, and only the 78 substances classified at the top of the resulting matrix were selected.

2.5.2.3. Risk ranking

The subset of 78 substances selected for their risk score were classified using a risk ratio approach. Predicted Environmental Concentrations (PEC) were calculated using two approaches: a multimedia model and a tiered approach developed by ECETOC to calculate the exposure and related risks to consumers, workers and the environment caused by chemicals. Predicted No Effect Concentrations (PNECs) were also calculated, using experimental data where possible. PEC/PNEC ratios were then used to rank the substances.

2.5.2.4. List of substances prioritised through modelling

The list of 78 substances is presented in the following table. Some of these substances were also selected by the monitoring based prioritisation.

Table 2: List of substances prioritised through modelling

CAS	Name
101-05-3	Anilazine
107-64-2	Dimethyldioctadecylammonium chloride
1085-98-9	Dichlofluanide
1120-36-1	Tetradecene
115-32-2	Dicofol
1163-19-5	Bis(pentabromophenyl) ether
118-74-1	Hexachlorobenzene
118-82-1	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol
119-47-1	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol
120-82-1	1,2,4-trichlorobenzene
1222-05-5	4,6,6,7,8,8-hexamethyl-1,3,4,6,7,8-hexahydrocyclopenta[g]isochromene
122-34-9	simazine
128-69-8	isochromeno[4',5',6':6,5,10]anthra[2,1,9-def]isochromene-1,3,8,10-tetrone
133-49-3	pentachlorobenzenethiol
13356-08-6	bis(tris(2-methyl-2-phenylpropyl)tin) oxide
135-91-1	4,4'-methylenebis[N,N-diethylaniline]
13680-35-8	4,4'-methylenebis[2,6-diethylaniline]
1461-25-2	tetrabutyltin
1582-09-8	trifluralin
1861-40-1	benfluralin
1897-45-6	chlorothalonil
1912-24-9	atrazine
2082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
21725-46-2	cyanazine
21850-44-2	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]
2303-17-5	tri-allate
2312-35-8	propargite
25103-58-6	tert-dodecanethiol
25637-99-4	hexabromocyclododecane
2921-88-2	chlorpyrifos
294-62-2	cyclododecane
31565-23-8	di(tert-dodecyl) pentasulphide
31570-04-4	tris(2,4-ditert-butylphenyl) phosphite
3194-55-6	1,2,5,6,9,10-hexabromocyclodecane
32534-81-9	diphenyl ether, pentabromo derivative
32536-52-0	diphenyl ether, octabromo derivative
3520-72-7	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]
38521-51-6	2,3,4,5,6,alpha-hexabromotoluene
3861-47-0	4-cyano-2,6-diiodophenyl octanoate
42576-02-3	methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate

CAS	Name
469-61-4	[3R-(3alpha,3abeta,7beta,8aalpha)]-2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulene
470-90-6	chlorfenvinphos
4979-32-2	N,N-dicyclohexylbenzothiazole-2-sulphenamide
50-29-3	clofenotane
5102-83-0	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]
5216-25-1	alpha,alpha,alpha,4-tetrachlorotoluene
52315-07-8	alpha-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
52434-90-9	1,3,5-tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
52-68-6	trichlorfon
52740-90-6	1-amino-N-(3-bromo-9,10-dihydro-9,10-dioxo-2-anthryl)-9,10-dihydro-9,10-dioxoanthracene-2-carboxamide
5468-75-7	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]
55283-68-6	ethalfluralin
5567-15-7	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]
5598-13-0	chlorpyrifos-methyl
56-35-9	bis(tributyltin) oxide
5915-41-3	terbuthylazine
60207-90-1	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
61213-25-0	3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one
629-59-4	tetradecane
63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro
64131-85-7	O,O,O-tris(4-nitrophenyl) thiophosphate
6683-19-8	3-{[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoyl]oxy}-2,2-bis({[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoyl]oxy}methyl)propyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoate
67747-09-5	N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]-1H-imidazole-1-carboxamide
67774-74-7	undecylbenzene
68442-68-2	4-(1-phenylethyl)-N-[4-(1-phenylethyl)phenyl]aniline
7287-19-6	prometryn
731-27-1	N-{[dichloro(fluoro)methyl]sulfanyl}-N',N'-dimethyl-N-(4-methylphenyl)sulfuric diamide
732-26-3	2,4,6-tri-tert-butylphenol
74070-46-5	2-chloro-6-nitro-3-phenoxyaniline
77-47-4	hexachlorocyclopentadiene
79-94-7	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
81-15-2	5-tert-butyl-2,4,6-trinitro-m-xylene
834-12-8	ametryn
84852-53-9	1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]
87-68-3	hexachlorobuta-1,3-diene
886-50-0	terbutryn
93-46-9	N,N'-di-2-naphthyl-p-phenylenediamine
96-69-5	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol

2.6. Priority hazardous substances criteria

PHS are a subset of PS that are identified as being "toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern" (WFD article 2(29)). In this context, the substances identified by the following processes and legislations are relevant:

2.6.1. REACH Substances of Very High Concern (SVHC)

At the time of initial listing for the PS review, 15 had been identified, 3 of them already PS; overall, in 2008 and 2009, 32 substances were proposed as SVHC, many of them already PS or PHS. Two were not relevant to the aquatic environment. The remaining 12 substances[16] were retained on the PS candidate list until it was decided not to consider further substances proposed for SVHC classification on the basis of CMR properties only unless there was evidence that the substances were relevant for the aquatic environment. Acrylamide, Benzylbutylphthalate (BBP), 4,4`-diaminodiphenylmethane (MDA), 2,4-dinitrotoluene, Arsenic and its mineral compounds, Chromium and its compounds and Cobalt and its compounds were then not investigated further.

2.6.2. Persistent Organic Pollutants (POPs) under the Stockholm Convention

At the time of initial listing for the PS review, 12 substances were on the POPs list and 9 more were in the process of being added after the agreement at the Conference of the Parties in May 2009, i.e. a total of 21 substances, 10 of them not PS. Of the 13[17] identified as POPs by the end of 2009, only those prioritised also by other processes were considered further, to avoid looking at substances which are not relevant for the aquatic environment in the EU.

2.6.3. Substances identified as Persistent, Bio-accumulative and Toxic (PBTs) under Regulation (EEC) No.793/93

At the time of initial listing for the PS review, 27 substances had been identified, 9 of them not PS. PBT properties were taken into consideration in the modelling-based prioritisation. Out of the 13 PBT/vPvB substances included on the list of candidate substances in the modelling exercise, 9 substances ranked high, one of which ranked high also in the monitoring-based prioritisation (Tetrabutyltin compounds). Tetramethyllead was not considered further because it is no longer produced in the EU and because Lead and its compounds are already PS; Nitrofen was not considered further because it is only used as an intermediate in the production of Aminofen (CAS 14861-17-7) by only one producer and its use as a PPP in the EU has been banned since 1988. Bis(tributyltin)oxide (TBTO) was not considered further because Tributyltin compounds are already PS. Coal tar pitch, distillates, pyrene fraction had already been de-listed from the monitoring-based prioritisation on the grounds that PAHs are already PS.

2.7. Other sources for identification of candidates for prioritisation

Annex III to the EQSD identifies 13 substances that the Commission was required to review to decide whether to propose them for inclusion in the PS list. The consideration of these substances is described in more detail in section 2.9.

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16 Salts and compounds of arsenic, cobalt and chromium are grouped into three groups.

17 PCBs counted as 1

In addition, Member States and stakeholders in WG E were given the opportunity to identify and provide the evidence of additional substances of concern that were causing pollution problems, likely putting at risk the achievement of the WFD objectives, and that were not being considered through any of the prioritisation routes. The following substances were proposed:

- Germany proposed consideration of PFOS (already considered)
- Sweden proposed consideration of Irgarol (active substance Cybutryne)
- The EEB, supported by several Member States, proposed consideration of seven pharmaceuticals (including some with endocrine disruptive properties).

Technical reports and literature references were provided. It was decided that detailed dossiers would be prepared for all of these.

2.8. Approach to shortlisting

2.8.1. Short-listing from the first candidate list

The *initial* lists from the above prioritisation processes were amalgamated to produce a list of a few hundred candidate substances. Further short-listing was achieved by applying of a number of selective criteria, most of them already mentioned under the individual headings above. The short-listing was undertaken by the Sub-Group on Review. Efforts were made to consider all the available evidence when deciding on whether to take forward each substance.

The selective criteria were, in summary, as follows:

- Substances ranking high or very high in the monitoring-based prioritisation for which the ranking was due to data from less than 3 countries for the determinant fraction were excluded because their selection was deemed non-representative. This led to the exclusion of 14 substances.
- No further investigation was undertaken of PPPs/biocides that had been authorised under the PPP legislation, but which had not been prioritised by any other process; or that had been subject to a non-inclusion decision under Directive 91/414/EEC or Directive 98/8/EC and did not rank high in any of the ranking exercises. This step led to the exclusion of 168 substances from further investigation.
- Substances that were identified due to assessments under the existing chemicals Regulation (EEC) No.793/93/EC, were generally not considered further if the conclusion (iii) in the risk assessment report regarding risks to or via the aquatic environment was reached for a local scenario or for only a few sites, and the scenario was not likely to be present in a significant number of river basins in the EU. Out of the 49 substances with conclusion iii for the aquatic environment, 12 were further investigated.
- Voluntary risk assessments on copper and on PFOS, for which the results showed conclusion (iii) for aquatic environment for some scenarios and uses, led to further consideration of those substances.

- No further investigation was undertaken of REACH SVHC for which the reason to propose this classification was their CMR properties alone, i.e. for which there was no other source of prioritisation that showed that exposure through water was relevant. This meant that 7 substances that had been identified were not further investigated.

- No further investigation was undertaken of POPs where there was no other source of prioritisation.

- To arrive at a manageable list, the 10 highest-ranking substances from the monitoring and modelling-based prioritisation processes were selected, along with the substances identified for further review from the risk assessment reports, as well as the substances indentified from the other sources (PBTs, SVHC, POPs, Annex III lists). Some substances were selected based on more than one criterion.

A list of 51 substances for preparation of dossiers was arrived at and proposed to the Sub-Group on Review. To this list were added the 8 substances (Cybutryne and 7 pharmaceuticals) proposed as substances of concern to Member States, resulting in a shortlist of 59 substances (or groups of substances).

Discussions within the Sub-Group at its meeting in January 2010 led to the elimination of 15 of these substances or groups of substances for a range of reasons, e.g. because:

- the risk assessment report identified risks to the aquatic environment, but sufficient risk reduction measures had been implemented and there was evidence they were effective at local level.

- it appeared that risks to or via the aquatic environment were likely to be local only and best handled at national level.

- industry provided new data on production volumes that led to lower ranking in the modelling-based prioritisation exercise.

Heptachlor and Heptachlor epoxide, the two isomers of HBCDD and 17 alpha-ethinylestradiol and 17 alpha/beta estradiol were considered together for the preparation of dossiers, meaning that there was a short-list of 41 dossiers to be prepared for detailed review.

2.8.2. Preparation of substance dossiers and further short-listing

For the 41 short-listed substances or groups of substances, substance-specific data sheets (substance dossiers) were prepared to facilitate further discussion and detailed review. A template for these was agreed by the Sub-Group. Member State volunteers or the Commission consultant INERIS were tasked with acting as rapporteur for individual dossiers, and consulted closely with associated MS and stakeholders. The dossiers collated available information on the identity, regulation/legislation, properties, environmental occurrence, and toxicity of the substances.

Once the dossiers had been prepared, the Sub-Group met to consider which substances it should recommend for EQS derivation and inclusion in the revised PS list. A summary document was prepared to structure and facilitate the discussions, including to highlight areas

of uncertainty or contention including points that had been flagged by rapporteurs or associated MS/stakeholders.

From the 41 substances or groups of substances, the Sub-Group arrived at a short-list of 20 substances for further consideration, 16 of which they recommended for EQS derivation, 3 of which they considered required further information before a recommendation could be made, and one of which should be considered under the review of the existing PS. On the remaining substances they concluded that there was not sufficient evidence to take them forward in the current review.

The criteria used to decide on each substance were their toxic properties and/or available PEC/PNEC ratios. If a substance was either PBT/vPvB/ED/CMR and/or the PEC/PNEC ratio was >=1, it was generally recommended for EQS derivation, unless its regulatory situation suggested this might or would not be necessary. Conversely, if a substance was not PBT/vPvB/ED/CMR and did not have a PEC/PNEC ratio >=1, it was generally put aside.

More information was judged necessary on 17 beta-estradiol, ibuprofen and zinc for the following reasons.

An industry study on the PNEC for 17 beta-estradiol was due in the near future that should be considered before concluding that the PEC/PNEC ratio was >1. The industry study was delivered and did not change the conclusion. Therefore, the substance was finally taken forward for EQS derivation.

On Ibuprofen, the SCHER was asked whether a particular study that had been used as a key study to derive a tentative EQS could be used as sufficient basis for the EQS. The SCHER's response was that other supporting studies were needed, and therefore Ibuprofen was not proposed for prioritisation.

On Zinc, further analysis of the monitoring data (and risk ratios) was considered necessary. This was performed and presented to the WG E. On this basis, a survey was performed among Member States experts that concluded that a large majority did not support the prioritisation of Zinc at this stage. The results of the assessment of the monitoring data were not conclusive because subject to a significant degree of uncertainty, arising from three main sources:

- The fact that most of the monitoring data were for total Zinc, instead of dissolved Zinc as required for the risk assessment
- Monitoring data on the supporting physico-chemical parameters needed for the estimation of bioavailability were not available. Default parameters had to be used which introduced a significant degree of uncertainty.
- Information on natural background concentrations was scarce.

On this basis, it was decided not to pursue the prioritisation of Zinc but to gather monitoring data of better quality for the purpose of risk assessment and refine the analysis in a future review of the list of priority substances. Although Zinc is not proposed for prioritisation, an EQS was derived for it (and assessed by the SCHER) which could be used by MS as a national standard, thus improving harmonisation.

EQS fact sheets (EQS dossiers) based on the substance dossiers were prepared for 19 substances (the 17 indicated in Table 3 as "recommended for EQS derivation" plus Zinc and Ibuprofen, the latter only including a tentative EQS). The EQS derivation process is described in detail in section 3 of the present document.

In the process of development of the EQS dossiers, discussions took place about the reliability of the monitoring information on Cyanides. Most of the available monitoring data were for total Cyanides, whereas the toxicity data on the basis of which a PNEC had been derived were for free Cyanide (the form listed in Annex III of the EQSD). The conclusion of the discussions was that free Cyanide would not be proposed for prioritisation in this review. As for Zinc, further review of free Cyanide would benefit from the collection of targeted high-quality monitoring data. For this reason, both substances are candidates for inclusion in the proposed watch list.

Of the 19 substances shortlisted for EQS derivation, 16 appear in the proposal, although two are together, i.e. Dioxin-like PCBs are included with Dioxins. Non-dioxin-like PCBs are not included, on the grounds that there are insufficient data to reliably set an EQS.

Table 3 summarises the outcome of the discussions on the 41 dossiers.

Table 3: Outcome of expert discussion on the short-list of 41 dossiers

Substance	**Lead**
Recommended for EQS derivation	
17 alpha-ethinylestradiol (EE2)	COM
17 beta-estradiol (E2)	COM
Aclonifen	COM
Bifenox	COM
Cyanide – free (HCN and CN^-)	COM
Cybutryne (Irgarol®)	SE
Cypermethrin	NL
Dichlorvos	COM
Diclofenac	DE
Dicofol	COM
Dioxin (2,3,7,8 - Tetrachlorodibenzo-p dioxin,TCDD)	IT
Heptachlor/Heptachlor epoxide	COM
1,2,5,6,9,10-Hexabromocyclododecane (HBCDD)	SE

Substance	**Lead**
1,3,5,7,9,11-Hexabromocyclododecane (HBCDD)	
Perfluorooctane sulfonic acid and its salts (PFOS) and perfluorooctane sulfonyl fluoride	UK
Polychlorinated biphenyls (PCBs)	FR
Quinoxyfen	COM
Terbutryn	DE
To be considered under the review of existing PS	
Diphenyl ether, octabromo (octaBDE)	SE
Not enough evidence to take forward at present	
Amino-methyl phosphonic acid (AMPA)	FR
Bentazone	IT
Bisphenol A (4,4'-isopropylidenediphenol)	UK
Carbamazepin	DE
Chlorothalonil	NL
Chromium trioxide	UK
Clarithromycin	DE
Cyclododecane	SE
Dichlofluanid	COM
Edetic acid (EDTA)	COM
Glyphosate	FR
Ibuprofen	DE
Mecoprop (MCPP)	UK
Musk xylene	AT
Omethoate	COM
Propiconazole	DE

Substance	Lead
Sulfamethoxazole	DE
Tolylfluanid	FI
Tri-allate	UK
Trichlorfon	FR
Zinc and its compounds	UK

2.9. Annex III of EQSD substances

All 13 Annex III substances were incorporated in the modelling-based prioritisation. Monitoring data was also available for a number of the substances and the results of the monitoring-based prioritisation approach for those are presented in the INERIS Monitoring report in section VIII.3. Only a few Annex III substances were not already proposed for further consideration by other prioritisation processes.

The outcomes of the individual prioritisation processes and the conclusion of the overall prioritisation process regarding each of the Annex III substances are presented in Table 4.

Table 4: Conclusions of the individual and overall prioritisation processes regarding the Annex III substances

CAS	Substance	Conclusion
57-12-5	Cyanides (free)	Ranked very high in the monitoring based prioritisation. Risk ratio >1. Selected for EQS derivation but monitoring data largely for total rather than free cyanide, therefore not prioritised. Probable candidate for the proposed watch list.
60-00-4	Edetic acid (EDTA)	Risk assessment conclusion iii for aquatic environment, but evidence suggested risk ratio generally <1. Not selected for EQS derivation:
80-05-7	Bisphenol A (4,4'-isopropylidenediphenol)	2008 update of the risk assessment concluded no risk to aquatic environment. Outstanding controversy regarding effects on snails. Not selected, but evidence to be reviewed.
81-15-2	Musk xylene (5-tert-buthyl-2,4,5-trinitro-m-xylene)	Ranked high in modelling based prioritisation, PBT, SVHC. Insufficient evidence of a risk ratio>1. REACH Annex XIV listing will further reduce. Not selected.

CAS	Substance	Conclusion
115-32-2	Dicofol	Ranked high in both monitoring and modelling based prioritisation, PBT, recommended as POP. Selected for EQS derivation.
1066-51-9	Amino-methyl phosphonic acid (AMPA)	Identified in the INERIS report as potentially responsible for failures in the drinking water standard. Insufficient quantitative evidence of failure. Not selected.
1071-83-6	Glyphosate	Identified in the INERIS report as potentially responsible for failures in the drinking water standard. Insufficient quantitative evidence of failure. Not selected.
1336-36-3	Polychlorinated biphenyls (PCBs)	Ranked very high in the monitoring based prioritisation, PBT, POP. Selected for EQS derivation (but EQS derivation possible only for dioxin-like PCBs, along with dioxins; not enough data for non-dioxin-like PCBs)
1746-01-6	Dioxin (2,3,7,8 - Tetrachlorodibenzo-p dioxin,TCDD)	Ranked very high in the monitoring based prioritisation, POP. Selected for EQS derivation.
1763-23-1	Perfluorooctane sulfonic acid and its salts (PFOS) and perfluorooctane sulfonyl fluoride	Voluntary risk assessment identified risk to aquatic environment, PBT, POP. Selected for EQS derivation.
7085-19-0	Mecoprop (MCPP)	Inclusion decision (PPP Directive Annex I) does not indicate the need to take measures to limit the risk to the aquatic environment. Risk ratio < 1. Concern re failures in drinking water not supported by sufficient quantitative evidence. Not selected for EQS derivation.
25057-89-0	Bentazon	Inclusion decision does not indicate the need to take measures to limit the risk to the aquatic environment. Risk ratio < 1. Concern re failures in drinking water not supported by sufficient quantitative evidence. Not selected for EQS derivation.

CAS	Substance	Conclusion
124495-18-7	Quinoxyfen	Inclusion decision indicates the need to take measures to limit the risk to the aquatic environment. Isolated exceedance of tentative EQS but PBT properties. Selected for EQS derivation.

Detailed dossiers were prepared for all Annex III substances because of the explicit obligation in the EQS Directive to review them.

2.10. Approach to substances that might pose a specific risk to drinking-water supplies

In the monitoring-based ranking the PECs were compared with the drinking water standards. Raw water in the environment is not expected to comply with drinking water standards as water is treated before being distributed, and therefore some pollutants are removed. However, the review tried to identify substances for which the ratio between the PEC and the drinking water standard was particularly high, i.e. to identify substances for which high treatment removal efficiency would be necessary, and which might thus cause failure of the drinking water standard at the tap.

The substances ranking high in this approach to prioritisation, and the estimated treatment removal necessary to achieve the drinking water standard are presented in Table 5.

Table 5: Conclusions of the monitoring-based ranking regarding substances that might pose a risk to drinking water supplies

CAS	Substance Name	EQSD Annex III subst.	Estimated removal efficiency needed
7664-41-7	Ammonium compounds		99,96-99,97
100-00-5	1-Chloro-4-nitrobenzene		80-98
1066-51-9	Aminomethylphosphonic acid (AMPA)	X	89-92
1071-83-6	Glyphosate (incl trimesium aka sulfosate)	X	69-84
1698-60-8	Chloridazon		30-99,7
34123-59-6	Isoproturon		49-76
59-50-7	4-Chloro-3-methylphenol		31-60
75-01-4	Chloroethylene		86-99
7440-61-1	Uranium		96-97

It should be noted that this was a theoretical exercise as no information was available on whether the high concentrations were found in water bodies actually used or intended to be used in the future for the abstraction of drinking water. For this reason, additional information was requested from Member States and the drinking water industry, in particular regarding whether exceedances of the drinking water standards occur that are linked to elevated concentrations of these or other substances in water bodies. The information received was not conclusive in terms of the EU-wide representativeness of the problem. Therefore, no substance was proposed for prioritisation on this basis.

3. ENVIRONMENTAL QUALITY STANDARDS (EQS) DERIVATION AND REVISION

For all the substances proposed for listing in the revised PS list it was necessary to derive environmental quality standards (EQS) for inclusion in the amended EQS Directive. On the basis of new evidence, the EQS for some existing substances had to be revised.

The principles for setting EQSs are set out in Section 1.2.6 in Annex V of the WFD but the details necessary for practitioners to follow are lacking. The derivation and revision of EQS in the current review were done on the basis of updated guidance, produced as explained below. Although there is no formal obligation to follow the guidance, it presents best practice for EQS derivation.

3.1. Technical Guidance on Environmental Quality Standards derivation (TGD EQS)

For the first list of PS, EQS were established in EQSD on the basis of extensive technical work using the Manual on the Methodological Framework to derive Environmental Quality Standards for Priority Substances under the WFD prepared by the Fraunhofer Institute[18]. The work was supported by an Expert Advisory Forum established in 2001. For the present review it was necessary to update the guidance. The main elements of the update were identified on the basis of the 2004 opinion[19] of the Scientific Committee on Toxicity, Ecotoxicity and the Environment on the former guidance and on discussions among the Commission, Member States and stakeholder experts.

An Expert Group (EG-EQS) under WG E co-chaired by the JRC and the UK was established to update the guidance, which covers all receptors (humans, aquatic life, predators) and all media (water, sediments and biota) that might be put at risk from chemical pollution. The updated guidance builds on the earlier guidance but provides more detail in a number of important areas, e.g. how to deal with metals, and how to derive EQSs for sediment and biota. It also includes more detailed guidance on other aspects of standard setting that were not covered in the earlier document.

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[18] Lepper (2005) http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_background/manual_methodology/_EN_1.0_&a=d

[19] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on "The setting of the Environmental Quality Standards for the Priority Substances included in Annex X of Directive 20006/60/EC in accordance with Article 16 thereof". Adopted by CSTEE during the 43rd plenary meeting of 28 May 2004. (http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out230_en.pdf)

It addresses all the points raised by CSTEE, not only regarding metals, sediments and biota, but also for example regarding the derivation of EQSs for transitional and coastal waters, the reliability and relevancy of the data used to derive EQS, the use of higher tier assessment methods and data such as Species Sensitivity Distributions (SSDs) and mesocosm study data in the derivation of short-term exposure standards, i.e. MAC-EQS, consideration of uncertainties, and the objective of protecting human health.

EG-EQS also sought to address technical issues highlighted in a paper by Bonnomet and Alvarez to the Expert Advisory Forum (8) in 2006, and to incorporate recent scientific thinking in the development of environmental standards e.g. those highlighted in a SETAC technical workshop held in the UK in 2006.

Since the guidance on EQS setting in Annex V of the WFD refers to guidance developed for Existing Substances and Biocides, part of the brief to the EG-EQS was to be consistent, as far as practicable, with guidance developed for REACH. The updated guidance highlights the role of existing risk assessments, e.g. those conducted under the PPP legislation, in setting EQSs.

The updated guidance was submitted to the Scientific Committee on Health and Environmental Risks (SCHER) for its opinion. The SCHER was largely supportive of the guidance, including of its handling of metal bioavailability. The TGD-EQS was slightly revised in response to specific comments, but the changes in the guidance did not affect significantly the methodology for EQS setting, and consequently did not affect the EQS that were already being developed on the basis of the draft updated guidance. A number of observations by the SCHER will be addressed in the longer term in future revisions of the guidance.

The final updated TGD-EQS was endorsed by the Water Directors of the Member States in May 2011.

3.2. Derivation of EQS for Proposed Priority Substances

As indicated above, EQS fact sheets (EQS dossiers) were prepared for 18 substances or groups of substances (the 19 shortlisted, excluding ibuprofen, for which only a tentative EQS was developed as a basis for the consultation with SCHER).

The rapporteurs were in some cases different from those which prepared the original substance dossiers. The template was the same as that for the substance dossiers; the sections related to the EQS were revised or completed for the first time.

Information extracted from grey literature was reported in the EQS dossiers where necessary and/or relevant but European and international peer-reviewed sources of information were given priority (e.g. European risk assessments for existing substances, PPPs and biocides, PBT evaluations, US-EPA assessments).

The EQS dossiers were considered initially by the associated Member States and stakeholders, then by the Sub-Group on Review as a whole. In most cases agreement on the proposed EQS was reached. However, in some cases, divergent views remained. The EQS dossiers were submitted to the SCHER for its opinion, in particular as to whether the EQS have been correctly and appropriately derived, in the light of the available information and the

TGD-EQS, and whether the most critical EQS (in terms of impact on environment/health) has been correctly identified.

Divergent views in the Sub-Group were highlighted in the requests to the SCHER. As explained above, in the case of ibuprofen, a critical but disputed study rather than an EQS dossier was submitted for an opinion on its relevance for EQS setting. The dossier for the non-dioxin-like PCBs was not submitted because there were not enough data to reliably derive an EQS.

In response to the SCHER opinion on aclonifen, the decision was taken not to designate it as a PHS, despite views to the contrary from the Sub-Group. The SCHER's comments on the cypermethrin dossier led to a check of the cited data and a number of corrections to citations but not to any change in the EQS, since the errors identified by the SCHER were not critical to the conclusions. The dicofol dossier was reviewed and some corrections made leading to an approximately 4-fold increase in the biota standard and corresponding (back-calculated) water EQS. In the EE2 and E2 dossiers, the marine annual average quality standards (AA-QS) were doubled as a result of adjusting the additional assessment factor from 10 to 5. Additional information and/or explanation was added to a number of the other EQS dossiers, most notably the dioxins dossier, but no other changes were made to EQS. For diclofenac, SCHER's opinion suggested that until there is greater certainty about the magnitude of a biota EQS, the water EQS should be considered the critical EQS; this will have to be reviewed. Similarly, a better acute toxicity dataset should in due course allow a Maximum Allowable Concentration (MAC) to be set.

In most of the dossiers, explanation has been added regarding the application of an additional assessment factor for the marine compared with the freshwater EQS. The additional assessment factors (not always 10) have been applied according to the revised TGD-EQS referred to above. The guidance, which is consistent with the approach under REACH, states that: the assessment factors provided for deriving the marine water QS are higher than those used for freshwater and that "this is justified by the need to account for the additional uncertainties associated with extrapolation for the marine ecosystem, especially the general under-representation in the experimental dataset of specific marine key taxa and possibly a greater species diversity". The guidance provides criteria for diverging from the provided default assessment factors. These criteria were used to determine the assessment factors and therefore the marine water QS for the substances in the PS review on a case-by-case basis.

3.3. Revision of EQS for Existing Priority Substances

Members of the Working Group E (WG E) were asked to indicate whether the EQS for any existing PS should be revised on the basis of new scientific information, and to comment on the need for standards in environmental compartments other than those for which they were already available. In addition, a systematic check was made of any updates to European risk assessment reports on existing PS (under the chemicals, biocides and PPP legislation).

On the basis of the findings, it was decided that the EQS for following substances should be reviewed.

Table 6: Rationale for reviewing EQS of existing PS

Existing substance	Rationale for reviewing EQS

Existing substance	Rationale for reviewing EQS
Anthracene, Fluoranthene, Naphthalene, PAH 5-6 rings	New information (Final EU RAR for Coal Tar Pitch, High Temperature, 2008)
Benzene	New information (Final EU RAR 2008) and Member State concern about carcinogenicity
Polybrominated diphenyl ethers	To include octaBDE (prioritised in the prioritisation process)
Lead	New information (EU VRAR 2008, SCHER review of VRAR 2009, first draft of Chemical Safety Report for REACH registration) and need to consider bioavailability
Mercury	Concern about the biota matrix to be monitored
Nickel	New information (EU RAR 2008, SCHER review of RAR 2009, and additional industry studies related to REACH registration) and need to consider bioavailability

The EQS for most of these substances were therefore revised according to the updated TGD-EQS, and the dossiers were submitted to the SCHER for its opinion.

For the substances reviewed in the light of the final RAR for Coal Tar Pitch, the new information led to the conclusion that for fluoranthene and four of the PAHs (i.e. excluding benzo(g,h,i)perylene, the critical matrix was biota. The Sub-Group proposed, for the four PAHs, use of the established food standard based on the toxicity of benzo(a)pyrene. This would also cover the risk from the non-carcinogenic PAH. For polyBDEs a biota standard was also proposed. In all these cases, calculation of a corresponding water standard led to values lower (in some cases much lower) than the existing water standard. For this reason, and because the back calculation is subject to some uncertainty, use of the biota standard appears appropriate.

The SCHER's comments led to review of the above EQS dossiers and some changes were made. In the anthracene and fluoranthene dossiers, the AA-QS for marine sediment were adjusted by eliminating the additional assessment factor of 5. In the naphthalene dossier, explanation was added for the choice of methodology and the retention of different assessment factors for the freshwater and marine sediment AA-QS. In the polyBDEs dossier, explanation was added for the choice of indicator congeners.

For benzene, industry brought new epidemiological and exposure information to the Sub-Group on Review, and it was concluded that the review would not be pursued further at this stage as there was no clear case for it.

For lead and nickel, the revision led to standards for the bioavailable metal. In the 2006 Commission proposal, these two standards were highlighted as preliminary, as the risk assessments were at the time not finalised. The SCHER opinion on the lead dossier prompted the addition of some clarifications, and the selection of an assessment factor of 4 for the

freshwater and marine sediment EQS, allowing presentation of a single value for each EQS rather than a range. The SCHER opinion on the nickel EQS dossier prompted additional in-depth and independent statistical analysis of some higher-tier data. There was a difference of opinion among the experts involved.

For mercury, a review of a large number of studies on secondary poisoning was undertaken by INERIS and made available to the SG-R. This work supports the use of fish as the main biota matrix for monitoring.

For 11 other substances, relevant updated risk assessments were identified, but a closer review led to the conclusion that revision of the EQS was not necessary at this stage.

4. PRIORITY HAZARDOUS SUBSTANCES (PHS) STATUS

4.1. Definition and criteria

"Hazardous substances" are defined in the WFD as substances or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern. Article 16 of the WFD determines that for Priority Hazardous Substances (PHS) measures should be aimed at the cessation or phasing-out of discharges and emissions and losses to the aquatic environment.

For the first list of priority substances (PS), the classification of PS as PHS was based largely on the PBT criteria listed in the Technical Guidance Document on Risk Assessment (ECB)[20] and in the proposal for the REACH Regulation. The classification of the 33 PS was done in two stages, i.e. 11 were classified definitely as PHS already in Decision 2455/2001/EC, but 14 were classified as possible PHS, subject to review – see Commission Working Document ENV 191000/01 final[21]. The procedure proposed was to group the PS according to their level of concern, taking particular account of their level of hazard. Reference was made to hazard classifications under other legislation, e.g. OSPAR Strategy, Council Directive 67/548/EEC, POPs Protocol under the UN-ECE CLRTAP, EU-RARs under Regulation (EEC) No. 793/93 and Council Directive 76/464/EEC and its five daughter directives. After grouping the substances, additional considerations were taken into account, including other relevant Community legislation or relevant international agreements, the production and use of the substance and the suspected endocrine disrupting potential of the substance.

In 2006, for the proposal on the EQS Directive, a further document setting out a list of characteristics that would justify PHS classification, including characteristics giving rise to an equivalent level of concern, was developed[22]. For 14 PS under review at that stage, it was

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20 European Commission Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Part I and Part II. European Communities, 2003.

21 http://ec.europa.eu/environment/water/water-dangersub/pdf/wd_env_191000_01_final.pdf

22 COM (2006) 397 and COM (2006) 398 Informal Background Document Identification of Priority Hazardous Substances (including Annex) http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_background/identificationpdf/_EN_1.0_&a=d

agreed to assess the aspect of "equivalent concern" on a case-by-case basis with the application of expert judgement and by ensuring, wherever possible, coherence with other relevant Community legislation. Decisions were made to confirm 9 of the 14 tentative PHS designations, such that 20 PS were finally designated as PHS. The criteria for equivalent concern were:

a) Very Persistent, Very Bioaccumulative (vPvB)-criteria;

b) Persistent Organic Pollutants (POP) (cf. Stockholm Convention);

c) Carcinogenic, mutagenic and toxic for reproduction (CMR);

d) Very Persistent, Very Toxic (vPvT) for substances with a high mobility;

e) Targeted risk assessments showing a particular risk for parts of the aquatic environment (in particular marine and groundwater).

Since that 2006 review, the REACH Regulation has become operational. The PBT criteria are laid down in Annex XIII, and there is a growing list of Substances of Very High Concern - SVHC as defined in Article 57 of REACH - which may be included in Annex XIV of the Regulation and thus become subject to authorisation.

It is reasonable, in view of Recital 28 of the EQSD and Article 2 (paragraphs 29 and 30) of the WFD, to harmonise the WFD approach with the approach taken under REACH, and therefore to use, as bases for identifying PHS, the criteria in REACH Annex XIII and Article 57 relating to PBTs and substances posing an equivalent level of concern. However, not all SVHC under REACH necessarily qualify as PHS, since not all are relevant to the aquatic environment, nor should the REACH criteria be considered exclusive, since REACH is not the main legislation for all chemicals (for example substances used in Plant Protection Products and pharmaceutical products are exempted from REACH authorisation), and its concerns do not necessarily encompass all the concerns arising under the WFD.

Although substances having endocrine disrupting properties are covered in Article 57(f) of REACH, the Commission is currently developing criteria to assess endocrine disrupting substances and their properties, and for this reason, no attempt is being made during this review to classify proposed PS as PHS on the basis of their endocrine disrupting properties alone. The outcome of the Commission work is expected in 2013.

4.2. Review

4.2.1. Changes to existing Priority Substances

A questionnaire to members of Working Group E regarding whether there was new evidence that would provide grounds to reclassify some existing PS as PHS led to a number of suggestions. The technical grounds given were assessed by the Sub-Group on Review of the Priority Substances List (SG-R).

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http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_background/identification_annexpdf/_EN_1.0_&a=d

Of the five existing PS reviewed, two are proposed for possible reclassification to PHS, i.e. DEHP and Trifluralin.

Tables 7(a)-(e) summarise the evidence considered and the conclusions of the present review.

Table 7(a) PS No.12: Di (2-ethylhexyl)-phthalate (DEHP)

Conclusion of previous review	PBT criteria not met, though some borderline Widespread in environment, therefore humans exposed through whole lifetime These points might justify "equivalent level of concern" but EAF judged that there was not sufficient evidence of concern Some MS in favour of PHS status but no additional evidence provided
Technical grounds for PHS status	Reprotoxic. Cat IB in Annex VI Table 3.1 (harmonised classification and labelling of hazardous substances) of Regulation (EC) 1272/2008 (CLP) based on criteria in Annex I of the Regulation; Cat 2 in Annex VI Table 3.2 based on criteria in Annex VI of Directive 67/548/EEC. DEHP bioaccumulates in aquatic organisms. The BCF is =<2700, being 840 in fish and 2500 in mussels. The EU risk assessment (RAR, 2008, http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/dehpreport042.pdf) suggests need to limit risk of secondary poisoning in relation to food chains based on aquatic organisms, especially mussels, and a need to limit the risks to children in relation to exposure via the environment (taking account of existing risk reduction measures). Identified as substance of very high concern (SVHC) under REACH and listed in Annex XIV due to toxicity for reproduction, see: http://echa.europa.eu/doc/authorisation/annex_xiv_rec/subs_spec_background_docs/dehp.pdf#search="DEHP" and http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:044:0002:0006:EN:PDF Detected in sediment and biota in remote areas in southern Norway: http://www.klif.no/publikasjoner/2284/ta2284.pdf page 63.

Technical arguments against PHS status (CEFIC - ECPI)	Not PBT (RAR for under Regulation (EEC) No 793/93) Not PBT and not a risk for the marine environment at present exposure (OSPAR 2008) Reprotoxicity under Directive 67/548/EEC in place since 2001; not supported by Caunter et al 2004 study reviewed in RAR In REACH candidate list because of existing toxicity classification; all evidence will be reviewed; recent papers indicate that the exposure of children is similar to that of adults and the Margin of Safety means there is no need for concern Site-specific concentrations show no secondary poisoning risk Detection in sediment and biota at remote locations not a reason for PHS status (concentrations not a risk to aquatic organisms) COM WG on CLP concluded not dangerous to the environment Environmental concentrations are decreasing Biodilution (rather than biomagnification) occurs up the food chain.
Conclusions on the technical grounds	Appropriate to list as PHS given conclusions in the RAR and the inclusion of DEHP in Annex XIV of REACH (SVHC). The RAR (post-dating the COM WG on CLP) concluded that there was no concern for aquatic species exposed via the water phase, but that there was a need to limit the risk of secondary poisoning and the risks to children in relation to exposure via the environment (taking account of existing risk reduction measures).

Table 7(b) PS No. 20: Lead and its compounds

Conclusion of previous review	PBT assessment of metals difficult; in particular, P assessment not possible Comparison with Hg and Ni led to conclusion that there was not sufficient evidence that Pb posed an equivalent level of concern
Technical grounds for PHS status	Repr. 1A (H360: May damage fertility or the unborn child.) according to CLP for Pb compounds, some exceptions; and according to REACH self-classification for Pb metal powder, inorganic Pb compounds Carc 2 – according to REACH self classification for inorganic Pb compounds; IARC Carc 2A - on basis of 2B plus limited epidemiological evidence Damaging to IQ – threshold level for neurodevelopmental effects cannot be identified (methodological limitations?) Recent SCHER opinion on lead in drinking water[23] states that it sees no scientific basis for an increase in the drinking water standard for lead; a decrease in lead intake would reduce risk.
Technical arguments against PHS status (ILA-E)	Not PBT Pb metal and inorganic Pb not expected to be mutagenic under normal use and handling. (Note: data inconsistent, questions re relevance of exposure route/concentrations to *in vivo* circumstances) Insufficient epidemiological evidence to indicate that inorganic lead or lead compounds pose human cancer risk at most tissue sites studied.
Conclusions on the technical grounds	Conclusion that exposure of humans via surface waters minor in comparison with other routes, therefore not PHS despite intrinsic properties.

Table 7(c) PS No. 26: Octylphenol

Conclusion of previous review	Fulfils P and T criteria, not B No equivalent level of concern identified
Technical grounds for PHS status	Endocrine disruptive and same level of concern as nonylphenol (already PHS).

[23] http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_128.pdf

Technical arguments against PHS status (CEFIC - CEPAD)	OP is an intermediate, not remobilised from the final resin Current EQS (0.1 µg/l) conservative, cf REACH PNEC (0.632 µg/l) Environmental concentrations low; few exceedances of EQS; case-by-case management appropriate Reprotox study in rats (ref to be added) – no evidence of effects EQS is protective for endocrine effects (literature review) Presence of OP in NP not higher than approx 1%
Conclusions on the technical grounds	(No conclusion for the moment: ED criteria being developed by COM.)

Table 7(d) PS No. 31: Trichloro-benzenes

Conclusion of previous review	Lowest NOECs > T threshold, but uncertainty re mammalian toxicity Potential for long-range transport List I substance under Dir 76/464/EEC RAR under Reg (EEC) No.793/93 identified risks BUT, the Commission recommended that TCBs not be designated as PHS until the criteria for establishing 'an equivalent level of concern' were agreed and it could be demonstrated that the criteria are met by this substance.
Technical grounds for PHS status	PBT (Identified as PBT by the Technical Committee New and Existing Substances (TC NES) Subgroup on identification of PBT and vPvB Substances, EC). Proposed for investigation as POPs.
Technical arguments against PHS status (CEFIC - EuroChlor)	Does not satisfy PBT criteria. (van Wijk D et al (2006) 1,2,4-Trichlorobenzene marine risk assessment with special emphasis on the Osparcom region North Sea. Chemosphere **62**, 1294-1310) Not placed on REACH candidate list in 2010 because not identified as PBT Existing restrictions under Directive 2005/59/EC and registration only as intermediate under REACH mean little possibility of emission to aquatic environment
Conclusions on the technical grounds	Not a PBT; POP proposal apparently withdrawn. Not PHS.

Table 7(e) PS No. 33: Trifluralin

Conclusion of previous review	Fulfils B and T criteria but not P No equivalent level of concern identified
Technical grounds for PHS status	PBT (Identified as PBT by the TC NES Subgroup on identification of PBT and vPvB Substances, EC, 2006). Probable POP (Identified as fulfilling POP screening criteria by the TC NES Subgroup, EC, 2006; considered by EU delegation to UNECE CLRTAP Executive Board December 2010 to warrant POP designation.)

Technical arguments against PHS status (Dow Agro-Sciences)	PBT criteria not fulfilled in any single environmental compartment. CLRTAP process ongoing; conclusions on persistence should not be drawn until decision made. The Task Force (June 2010) "was not able to reach a consensus on trifluralin as a POP in the context of the Protocol…". At the Executive Board (December 2010) "it was suggested that the Working Group on Strategies and Review should consider any new scientific information with regard to trifluralin and/or PCA/PCP that might be submitted in time for its forty-ninth session in September 2011"
Conclusions on the technical grounds	PBT criteria met even if POP designation not confirmed. (P criterion for PBT is less stringent than for POP, i.e. 120d cf 180d in soil; PBT criteria do not have to be met in single compartment.). PHS.

4.2.2. Proposed new Priority Hazardous Substances

Table 8 summarises the conclusions of the present review.

Table 8: Proposed PHS

Substance	Rationale for PHS status
Dicofol	CLRTAP Working Group on Strategies and Review (Sept 2010) has recommended listing in POP protocol. Suspected to be endocrine disruptive.
Dioxins and Dioxin-like PCBs	Fulfils PBT criteria. Several congeners show endocrine disruptive properties. One congener carcinogenic.
PFOS	PBT; POP since August 2010. Reprotoxic (Cat 2)
HBCDD	CLRTAP Working Group on Strategies and Review (Sept 2010) has recommended listing in POP protocol
Heptachlor/Heptachlor epoxide	Fulfils PBT criteria. Suspected to be endocrine disruptive. IARC Group 2b – possibly carcinogenic to humans.
Quinoxyfen	Fulfils PBT criteria.

5. TECHNICAL BACKGROUND DOCUMENTS

Technical background documents listed below are available at:

http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_substances

The following documents are included:

- Results of the monitoring-based prioritisation:

INERIS-International Office for Water. Implementation of requirements on Priority substances within the Context of the Water Framework Directive (contract 07010401/2008/508122/ADA/D2). Prioritisation process: Monitoring-based ranking (September 2009).

- Results of the modelling-based prioritisation:

K. Daginnus, S. Gottardo, A. Mostrag-Szlichtyng, H. Wilkinson, P. Whitehouse, A. Paya-Pérez and J. M. Zaldívar (2010). A modelling approach for the prioritisation of chemicals under the Water Framework Directive. JRC Scientific and Technical Report EUR 24292 EN. http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/13548/1/prioritization_eur_february10_final.pdf

- Methodology for deriving EQS

Common Implementation Strategy for the Water Framework Directive (2011). Guidance document No 27. Technical Guidance for Deriving Environmental Quality Standards.

- EQS dossiers

23 substance specific dossiers summarising the derivation of the EQS.

- SCHER opinions on the Technical Guidance document and the EQS dossiers

The scientific opinion on the Technical Guidance for Deriving EQS and 24 scientific opinions on the EQS for the individual substances are available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/index_en.htm#id10

- Source screening and measures sheets

Updated source screening and measures screening sheets for the existing 33 PS and for 19 candidate PS

- Study supporting the impact assessment

Entec UK Ltd. Technical Support for the Impact Assessment of the Review of Priority Substances under Directive 2000/60/EC (Contract 070307/2009/547548/SER/D1):

Interim report (methodology) (November 2010)

29 substance-specific impact reports (April 2011)

Final report (including high-level analysis) (June 2011)