EUROPEAN COMMISSION

Brussels, 31.1.2012
SEC(2011) 1547 final

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy

{COM(2011) 876 final}
{SEC(2011) 1546 final}

Disclaimer: This impact assessment commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Overview

The Commission proposal which this Impact Assessment concerns addresses the control of pollution of surface water bodies by Priority Substances (PS) - chemicals presenting a significant risk to or via the aquatic environment at EU level - . The Water Framework Directive (WFD) 2000/60/EC[1] (Article 16(4)) requires that the list of PS be reviewed at least every four years. Technical work on the review began in 2007. It aimed to identify substances that should be added to the list through a prioritisation exercise, to set environmental quality standards (EQS)[2] for them, and to review the EQS for and status of the existing PS. As the technical work was in its final stages in 2010, work on the impact assessment began with the commencement of a study by the consultancy Entec[3]. The consultant drafted individual substance impacts reports taking into account the conclusions of the technical work[4], and these were drawn upon for a large part of this Impact Assessment Report.

In the course of reviewing the PS list, possible improvements in the functioning of the Environmental Quality Standards Directive (EQSD) 2008/105/EC[5] were identified, and a possible mechanism for improving the identification of additional PS in future reviews, and these are included as separate sets of options. The preferred option is therefore a package of options.

The roadmap for the assessment was drafted in March and finalised in October 2010.

1.2. Impact Assessment Steering Group (IASG)

Meetings of the IASG were held in February 2010, March, April and May 2011, with a fifth and final meeting on 18 May 2011. The following DGs attended one or more of the meetings: the Secretariat General (SG), AGRI, ENTR, JRC, MARE, REGIO, RTD, and SANCO. DG ENTR and DG SANCO also attended meetings of the working groups doing the technical work and contributing to the impact assessment study (see section 1.3).

1.3. Expertise for the technical process

The technical work for the review, i.e. principally the prioritisation and EQS setting, was led by DG ENV and the JRC and carried out by a range of experts. These included members of

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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 An EQS is defined as the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment' (WFD Article 2.35)

3 Study Contract No 070307/2009/547548/SER/D1

4 For the existing substances under review, some of the supporting information for the study was prepared by a second consultancy, WRc (with input from Milieu).

5 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 [OJ L 348, 24.12.2008, p. 84] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0105:EN:NOT

the Chemical Aspects Working Group E under the WFD Common Implementation Strategy (CIS)[6], in particular two sub-groups of WG E, and the consultancy INERIS (with input from the Institute of Water, IoW). The membership of WG E and the two sub-groups consists of Commission DGs, Member States (MS) and stakeholder organisations including a range of European industry associations (AESGP, AISE, Business Europe, CEFIC, CEPI, CONCAWE, COPA-COGECA, ECPA, EFPIA, EUCETSA, EUDA, EUREAU, EURELECTRIC, EUROFER, EUROMETAUX, EUROMINES) and NGOs (EEB, Greenpeace, OSPAR , WWF). Annex VII gives the full names and sectors.

WG E contributed significantly to the review by supporting the collection of data (including monitoring and hazard data), the prioritisation process for identifying new substances, the update of the Technical Guidance Document on EQS setting, and the derivation of EQS. The two sub-groups of WG E that carried out much of the work were the Expert Group on the Technical Guidance Document EQS (EG-EQS), and the Sub-Group on Review of Priority Substances (SG-R), both chaired by the JRC. The WG E industry stakeholder groups involved their most relevant member companies, generally represented by technical experts, in the sub-group discussions, particularly as the selection procedure reached its final stages and EQS were developed.

The draft EQS were submitted to the Scientific Committee on Health and Environmental Risks (SCHER)[7] for its opinion.

1.4. Stakeholder consultation

1.4.1. Stakeholders and nature of consultation

The members of WG E – i.e. all MS and the most relevant stakeholder organisations - were kept informed of the progress on the technical work in the sub-groups throughout the review process. They contributed information to that process and provided information to the consultancy Entec for the impact assessment study. They were consulted twice on the methodology and twice on the draft substance impacts reports.

The penultimate drafts of the substance impacts reports were also sent to additional selected stakeholders in a targeted stakeholder consultation, to cover organisations (see Annex VII) not already (fully) represented on WG E. In view of the wide range of organisations/sectors already involved in WG E, their involvement throughout the process, and the technical nature of the review, it was judged appropriate to target additional consultation to selected additional organisations rather than to conduct a full public consultation. Other DGs were asked to propose organisations whose interests might require additional representation, and those targeted included groups representing the fishing/aquaculture and transportation industries, medical professionals and users/consumers. Output from a public internet consultation would likely have been of a very general nature, and unlikely to add to the feedback already gathered by other means. For example, in the Flash Eurobarometer on water in 2009, 75% of EU citizens identified chemical pollution of water as a threat to the water environment, a higher

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6 http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy.pdf

7 The SCHER is one of the Scientific Committees providing the Commission with independent advice. It is made up of 17 scientists. More information at http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm

proportion than for any other threat. In the 2011 Environment Eurobarometer[8] water pollution was most frequently identified as one of the top five environmental concerns.

1.4.2. Consultation outputs

The involvement of WG E and its sub-groups in the technical process from its inception allowed the represented MS and organisations to inform the selection of new PS and the EQS setting, for example by highlighting substances of concern or relevant toxicity studies. The general view of MS and stakeholders in WG E is that the results of the technical work have a sound scientific basis despite some differences of opinion between industry and MS experts – as for example highlighted to the SCHER for its consideration.

The development of the options was informed by discussion on issues including the appropriateness of setting sediment and biota standards, and the difficulty for MS of dealing with "ubiquitous PBTs". Some stakeholder views on specific options are mentioned in the relevant sections. The need to interface effectively with other legislation (see Annex VI) was emphasised.

1.5. The Impact Assessment Board

This Impact Assessment Report was discussed by the Impact Assessment Board on 22 June 2011, leading to a positive opinion with comments. The Board commented in its overall assessment that the findings of the IA should be presented more clearly. For this reason, the material in the report has been substantially reorganised and supplemented, to some extent using information from the existing annexes. The overview (section 1.1) makes clearer what the options cover; the policy context (section 2.1) elaborates on the current assessment of the River Basin Management Plans; the baseline has been more clearly presented (see point 2 below); the introductory parts of section 5.2 explain in more detail the analysis of costs and benefits of the substance options and the uncertainties involved; and specific reference is made to SMEs. Finally, the preferred policy package is compared to the baseline in section 5.8.2.

The Board provided five main groups of recommendations. These have been acted upon as follows:

(1) Better present the scale of the problem and the experience with implementation of the relevant provisions of the WFD

Risks to health and the environment from the candidate substances, and current levels of use and production, have been summarised in a new table in section 2.2.3. This section also explains the prioritisation process in more detail. The participation of interested businesses is elaborated in section 1.3, and additional references to stakeholder views on individual substances have been made in section 5. Information on substitutes has been included in the (adapted) tables in section 5.2. Preliminary information on the use by MS of provisions for exemptions in the WFD is presented in section 2.1.

(2) Provide a more coherent baseline scenario and clearly explain the role of other existing policy instruments

[8] http://ec.europa.eu/environment/working_en.htm

The section on the baseline (2.5.1) has been expanded to explain better how other legislation including REACH and the Biocidal Products Directive could affect the baseline, and influences on the baseline in the substance options are summarised in the tables in section 5.2. Other references to the relationship between the WFD and REACH are made in sections 2.1 and 4.2.1. The numbers of MS that have set national standards for the candidate PS are now given in the table in section 2.2.3 (the details can still be found in Annex VI) and comment is made on the likelihood that other MS would follow. The information on exemptions in section 2.1 distinguishes between applications on the basis of disproportionate costs and those on other grounds.

(3) Present expected costs and benefits in a more systematic and transparent way

The report attempts to be more explicit about the cost estimates (separately for business and public authorities), the uncertainties around them and the process for collecting and validating them (sections 5.2.1, 5.2.2 and the adapted tables and text on the individual substance options in section 5.2). The issue of disproportionate costs, including the relevance of socio-economic assessment under other legislation, is addressed in sections 5.2.1.2 and 5.3. The benefits of the proposal have been brought out more clearly by stressing the contribution made by the WFD to providing monitoring data in sections 2.5.1 and 5.2, by summarising the risks posed by the candidate substances in section 2.2.3, and by clarifying what is already included in the baseline (particularly in the tables in section 5.2).

(4) Assess impacts on SMEs

The implications of the substance options for SMEs are indicated in section 5.2.1.2 and the sections in 5.2 analysing the individual substance options (especially the adapted tables). The compliance strategies of MS are mentioned in section 5.3, and reference to the likelihood of MS exempting SMEs on grounds of disproportionate costs is made in section 5.2.1.2.

(5) Include a clear overview of costs and benefits of the retained policy package

The report explains better in section 4.2.1 how measures could be triggered by the proposal, and stresses in sections 2.5.1 and 5.2 the value of the monitoring data delivered under the WFD. Comparison of the options with the baseline has been made more consistent. The benefits and costs of the preferred package of options are summarised in section 5.8.2, and the section on distributional impacts elaborates on several points, including the possible impact of high production and use coinciding in particular MS.

Additional technical comments by the Board have been addressed throughout the report.

The Board's request that the absence of a public internet consultation be better explained has been addressed in section 1.4.1. The views of stakeholders have been more extensively incorporated in the report. The Executive Summary has been complemented with a summary of the costs and benefits of the preferred package of options.

2. PROBLEM DEFINITION

2.1. Introduction: policy context/background

The WFD acknowledges the existence of considerable pressures on the aquatic environment, including that from chemical pollution, and the need for sustainable water management. Its

environmental objectives include the achievement of good chemical and ecological status for surface and groundwater bodies, and the prevention of deterioration. The Directive is implemented at the level of river basin districts (RBDs). MS were required to adopt by 2009 a River Basin Management Plan (RBMP) based *inter alia* on a pressures and impact analysis and the results of monitoring, and a programme of measures for each district.

To meet good chemical status, water bodies must meet the EQS set for the PS. The current 33 PS include a range of industrial chemicals, pesticides and metals/metal compounds. Some PS are identified as Priority Hazardous Substances (PHS) because of their persistence, bioaccumulation and/or toxicity or equivalent level of concern, criteria consistent with the criteria for Substances of Very High Concern (SVHCs) under REACH. MS are required to monitor the PS in surface water bodies, and to report exceedances of the EQS. The objective of good ecological status requires that for chemicals identified as substances of concern at local/river-basin/national level but not as PS at EU level, standards have to be set at national level. These chemicals are known as River Basin Specific Pollutants (RBSPs). The WFD requires the adoption of measures to control the discharges, emissions and losses of PS and PHS to the aquatic environment – progressive reduction in the case of PS, cessation or phasing out in the case of PHS.

The WFD (Article 16(4)) requires the Commission to review the list of PS at least every four years, and the EQSD (Article 8) requires the Commission to report the outcome of its first review to the European Parliament in 2011. As part of the review, the Commission has to consider inter alia the substances in Annex III of the Directive for possible inclusion in the list. It is also required to identify, if appropriate, new PS or PHS, and to set EQS for surface water, sediment or biota[9] as appropriate, and to review the existing PS. The proposed new substances and changes to existing substances are expected to be taken into account in the 2015 updated RBMPs and programmes of measures.

Member States' first RBMPs, and their progress on complying with the EQS for the existing PS, are currently being assessed. However, because the end of the first RBMP cycle (i.e. in 2015) has not yet been reached, and the EQSD did not come properly into play until mid 2010, it would be premature to conclude on the success of the MS in meeting the chemical status objective in 2015. However, the preliminary assessment shows that significant percentages of water bodies are currently failing to achieve the objective of good chemical status (e.g. 28% of surface water bodies in BE, 29% in CZ, 16% in FR, 24% in NL).

Indeed, the analysis of the RBMPs done so far shows that many MS will use the provisions to apply exemptions from meeting the 2015 chemical status objective on socio-economic grounds, either to allow extension of the deadlines (WFD Article 4(4)) or, less frequently, to lower the environmental objectives (WFD Article 4(5)). In the first RBMPs, at least 15 MS are applying exemptions, and between them they are using all the main grounds, i.e. technical unfeasibility, disproportionate costs, or natural conditions not allowing timely improvement – in that order, i.e. technical unfeasibility is cited more than twice as often as disproportionate costs, which is cited in turn more than twice as frequently as natural conditions. It can be concluded that in many MS there will be a delay in reaching the EQS for some substances, meaning that those substances could pose a risk to or via the aquatic environment for a longer period, although the precise risk cannot be quantified.

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[9] Biota refers to any groups of living aquatic organisms that can be analysed and used as indicators of pollution such as fish, mussels, invertebrates, etc.

Despite the current failures - largely for substances that persist in the environment and/or undergo long-range transport - there is evidence that the concentrations of some PS, e.g. Mercury, have decreased in some countries, e.g. DE, since they were first listed in 2001[10], even though the EQS were not set until 2008. Listing in itself appears to have contributed to increased awareness of the need to take control measures, and, importantly, is providing the monitoring data required to assess the effectiveness of the measures. Timely compliance with the EQS in the EQSD is expected to increase as technical advances are made.

2.2. What is the issue or problem requiring action?

2.2.1. General points

It is clear from monitoring data that chemical pollution of water bodies remains an important issue to be tackled at all levels. Tens of thousands of chemicals are used daily in the EU for multiple purposes[11]. Some are active at very low concentrations and therefore difficult to detect in water. Substances of concern may be of synthetic or natural origin, and be produced deliberately or unintentionally. They may be released into the aquatic environment, directly or indirectly, during one or more phases of their lifecycle, from production through use to disposal. They may show high direct toxicity to the aquatic environment (microbial, plant or animal life) and/or pose a risk principally via secondary poisoning because of their persistence and bioaccumulation, e.g. in humans via the consumption of fish and shellfish. Their effects may be acute and/or chronic. For example, the presence of brominated diphenyl ethers (BDEs) (existing PS) in cord blood has been linked in epidemiological studies with neurodevelopmental effects in infants; and neurodevelopmental effects, altered habituation patterns, hyperactivity, learning and memory deficits have been seen in animal studies with BDEs (Herbstman *et al* 2010; Costa *et al* 2011).

2.2.2. Summary of main issues/problems

In the context of the required review, and noting already the need to consider particularly the substances in Annex III of the EQS Directive, the main issues to take into account are

(i) the availability of new information about risks caused by existing PS and new chemicals,

(ii) the fact that some of the most harmful chemicals already on the PS list or proposed for addition are ubiquitous persistent, bioaccumulative and toxic (PBT) substances and, despite being already heavily regulated, will produce widespread failures of the objective of good chemical status for many years due to their intrinsic characteristics, especially if the EQS is set in biota instead of water to improve detection, and

(iii) the fact that there is a paucity of fit-for-purpose monitoring data on which to base assessment of exposure[12] and thus the prioritisation of new PS in future reviews.

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[10] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 destablishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC [OJ L331 of 15.12.2001, p.1]

[11] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Chemicals_management_statistics

[12] In the context of risk assessment "exposure" refers to the amount of contaminant (dose) that an individual or the population will receive. This is compared with the predicted no-effect concentration to perform the risk assessment.

2.2.3. New information on risks to environment and human health

A range of new information was reviewed, including data on ecotoxicity, environmental concentrations, production and use, and assessments of persistence, bioaccumulation, carcinogenicity, mutagenicity, reprotoxicity and endocrine disrupting potential. This information pointed to concerns regarding a number of substances not yet identified as PS, and to a need to review the status and/or EQS of some existing PS. It also pointed to the need to consider deriving EQS for the identified substances in a specific matrix[13].

The selection of possible new PS was conducted using the approaches outlined in WFD Article 16(2). These included taking account of risk assessments under other legislation (in particular the chemicals, plant protection product (PPP) and biocides legislation), and the assessment of intrinsic hazard and exposure according to a simplified risk-based assessment. As part of the latter, parallel monitoring and modelling-based risk ranking exercises were undertaken, starting with lists of approximately 1000 and 2000 substances, respectively. The prioritisation led to a list of 15 possible new PS. Some information on them is provided in the table below. Further information (including the EQSs derived) is provided in Annexes II and V. Although several other substances were acknowledged to be of concern, the risk was judged lower or the evidence for listing them at this point was not as strong or complete.

Many of the 15 substances (e.g. Dioxins, HBCDD, PFOS) are persistent and/or bioaccumulative as well as toxic, and are therefore likely to remain in the environment for decades and/or affect birds and/or mammals including humans via secondary poisoning. A number of others (e.g. Cypermethrin, Dichlorvos) are characterised by their acute toxicity. For some toxic substances, chronic effects may be more important than acute effects, depending upon how the concentrations of the substance in water vary, and upon the organisms affected. Some of the substances show evidence of probable or possible carcinogenicity in humans (e.g. Dioxins, Dicofol), others are known or suspected endocrine disruptors (e.g. Heptachlor, the Estradiols).

National standards exist for some of the substances in a number of MS; further details are provided in Annex II. The monitoring database referred to was compiled for the review.

Table summarising information on the 15 possible new PS:

Substance	Type/Use	Concern	State of play in MS
17 alpha-ethinylestradiol (EE2)	Pharmaceutical; synthetic steroid hormone used mainly in oral contraceptives. No production data available. Approx 32 million women in EU use EE2-based contraception.	Endocrine disruptive; prolonged exposure to low concentrations of EE2 has been shown to cause sex changes, alterations in reproductive capacity, and ultimately population collapse in fish (Kidd et al, 2007)	Monitoring database contains data from 3 countries, 2 showing exceedance of EQS, 1 likely exceedance; literature predicts exceedances more widely.
17 beta-estradiol (E2)	Steroid hormone: excreted naturally (approx 90%) in human and livestock urine but also (<10%) as a result of pharmaceutical use (of which 90% from HRT).	Endocrine disruptive; chronic studies show effects on sexual development and fecundity in fish.	Monitoring database (2 countries) and literature show exceedance of EQS.
Aclonifen	Herbicide, used on a range	Toxic to a range of aquatic	National standard

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

	of arable crops. Use > 1000 tonnes/yr.	organisms.	exists in SE. 3 countries in monitoring database, FR data predominant and showing exceedance. Authorised in 18 MS.
Bifenox	Herbicide, used to kill broadleaf weeds in cereal crops and grassland. Use > 200 tonnes/yr.	Toxic to a range of aquatic organisms.	3 countries in monitoring database; FR data predominant and showing exceedance. Authorised in 19 MS.
Cybutryne (Irgarol®)	Biocide used as antifouling agent in coatings for boat hulls etc. Use approx 10 tonnes/yr.	Toxic; degrades only slowly and main degradation product (M1) also toxic; persists in sediments.	National standard exists in SE. 4 countries in monitoring database; exceedance or near exceedance of EQS in 3.
Cypermethrin	Insecticidal pyrethroid plant protection product (PPP) and biocide, used in arable farming, salmon farming, sheep dipping and wood preservation. Use up to 100 tonnes/yr.	Toxic to a range of aquatic organisms. Benthic invertebrates vulnerable because cypermethrin binds to sediment[14]. Use in the marine environment is authorised in a few countries of the world but prohibited in Canada[15] where suspicion exists regarding a possible link with the death of lobsters [16], the sensitivity of which has been assessed (e.g. Burridge et al 2000).	National standards exist in 2 MS (DK, UK). 3 of 5 countries in monitoring database show exceedance of EQS; analytical method may have missed others.
Dichlorvos	Organophosphorus insecticide and biocide, used in grain/nut stores, insecticidal sprays/strips. Use – a few kg to a few tonnes/yr in different MS; probably closer to lower figure since 2008 when decision on non-authorisation as PPP took effect.	Toxic particularly to aquatic invertebrates and fish; possibly carcinogenic to humans. (No longer authorised as PPP.)	National standards exist in 4 MS (BE, DE, IT, NL); IE simply monitors. Monitoring database shows exceedance of EQS in 7 of 9 MS; analytical method may have missed others.
Diclofenac	Pharmaceutical, used as NSAID. Average consumption 0.46 g/person/yr.	Toxic, directly (e.g. chronic studies show effects on gills and kidneys in fish), and via secondary poisoning, e.g. vultures in India affected by veterinary use in cattle.	Monitoring and predictions show exceedances of the EQS in water in 7 MS
Dicofol	Organochlorine PPP, until recently authorised for use on fruit and vegetable crops. Possibly residual use.	Toxic; similar to DDT, recommended for designation as POP (Stockholm Convention); possibly carcinogenic to humans, possibly endocrine disruptive.	Monitoring database shows failure of EQS in ES and FR, likely elsewhere.
Dioxins (and	Dioxins: by-products of	PBTs, POPs (Stockholm Convention	National standards

14 http://www.scotland.gov.uk/Publications/2002/08/15170/9409

15 http://www.worldwildlife.org/what/globalmarkets/aquaculture/WWFBinaryitem8842.pdf

16 http://www.cbc.ca/news/canada/new-brunswick/story/2010/02/18/nb-aquaculture-pesticide-bay-of-fundy-lobster-deaths-658.html
http://quoddytides.com/salmon10-8-10.html,

dioxin-like PCBs)	thermal combustion PCBs: chlorinated organic compounds formerly used to manufacture electrical equipment etc.; some also produced by combustion.	and CLRTAP). Some congeners probably carcinogenic to humans; other possible effects include endocrine disruption, impairment of immune system, nervous system, reproduction. Limits already set for presence in feed and food. Baltic salmon not for export because dioxin limits exceeded.	exist in 3 MS (DK, IT, SE). IE simply monitors. Several MS report likely exceedance of EQS.
HBCDD	Industrial chemical, used as flame retardant, especially in polystyrene, including insulation boards. Use up to 10000 tonnes/yr.	PBT, SVHC under REACH, recommended POP. Possibly toxic to reproduction in humans.	National standards exist in 2 MS (DK, SE). Monitoring data mainly from literature show exceedances of EQS.
Heptachlor/ Heptachlor epoxide	Organochlorine insecticide, no longer authorised but secondary emissions possible.	POP; very toxic to aquatic organisms; possibly/probably carcinogenic to humans, possibly endocrine disruptive..	National standards exist in 6 MS (AT, BE, IT, RO, NL, DE); CY and IE simply monitor. Monitoring database shows exceedance of biota EQS in at least 3 out of 6 MS and of corresponding water EQS in at least 6 out of 12 MS; analytical method may have missed others
PFOS	Industrial chemical, used in hydraulic aviation fluids, photography, electroplating. Use – 100s of tonnes in 2000, less since 2008 but present in many existing products, especially textiles.	PBT, POP. Toxic to animals especially mammals. Possible carcinogen in humans; possible effects on thyroid function..	National standards exist in 3 MS (CZ, DK, SE). 4 countries in monitoring database, all showing exceedance of EQS
Quinoxyfen	Fungicide, used mainly on cereals, grape vines. Use approx 70 tonnes/yr.	PBT and vPvB properties. Accumulates particularly in sediments.	Monitoring data from 2 MS; some exceedances of EQS in FR. Authorised in 17 MS.
Terbutryn	Biocide, used especially in coatings for buildings, as preservative. Use approx 200 tonnes/yr.	Toxic especially to algae and aquatic plants..	National standards exist in 2 MS (BG, CZ). 5 countries out of 9 in monitoring database show exceedance of EQS

The reasons for reviewing the EQS and/or status for some existing PS (Anthracene, PolyBDEs, DEHP, Lead, Naphthalene, Nickel, PAHs, Fluoranthene and Trifluralin) are explained in Annex II. In most cases, a (revised) EU Risk Assessment Report (RAR) had become available since the existing EQS was established.

2.2.4. Specific difficulties with ubiquitous persistent, bioaccumulative and toxic (PBT) chemicals

2.2.4.1. Introduction

By definition, PBTs persist in the environment, bioaccumulate in the trophic chain and are toxic. They are classified in the WFD as Priority Hazardous Substances (PHS). Some are Persistent Organic Pollutants (POPs) capable of causing long-range transboundary pollution. They are largely ubiquitous and are found even in remote areas, far away from any human activity (e.g. BDEs in remote alpine lakes in Austria; brominated flame retardants, organohalogens and perfluorinated compounds in the Arctic – see AMAP 2009).

The measures already taken regarding several existing PBTs have reduced emissions significantly. In addition, the REACH Regulation is now providing a mechanism to identify PBTs as substances of very high concern (SVHC) and, where they are included in Annex XIV, they become subject to authorisation, which ensures their progressive substitution on the market with less hazardous substances, where this is economically and technically feasible. However, their existing concentrations, particularly in sediment and/or biota, could still pose a risk to the aquatic environment and/or to human health via the aquatic environment, and natural recovery will generally take decades.

Because of their properties, regulation of these substances under the WFD poses particular problems. Three issues or sub-problems need to be considered, as follows. Full explanation is provided in Annex III.

2.2.4.2. Presentational issues related to large proportion of EQS failures

Surface waters are assessed in the WFD for their overall chemical status against all the EQS for PS, including the ubiquitous PBTs. Maps have to be produced for the RBMPs showing the chemical status of each RBD. A bad situation for some chemicals can therefore hide positive situations for other substances. The maps may then be dominated by failures about which little more, if anything, can be done from the water management perspective.

It is obviously important that the extent of the PBT problem be clarified and acknowledged, not hidden. However, the influence of these substances on the assessment made under the WFD seems disproportionate in relation to the possibilities for the policy to deliver reductions in their environmental concentrations within the WFD timeframe.

2.2.4.3. Choice of monitoring matrix for compliance checking

The EQSD includes the flexibility for MS to choose the matrix to monitor the PS. For most PS, EQS for water are given in Annex I of the EQSD, but MS can choose to develop and use sediment and/or biota standards that offer at least the same level of protection as those provided for water. For three substances (Mercury, Hexachlorobenzene and Hexachlorobutadiene), EQS for biota are given in the EQSD[17] that MS have to use unless they develop and apply a water standard that offers the same level of protection as the biota

[17] These substances are hydrophobic and bioaccumulative and therefore the preferred matrix for monitoring is biota; their concentrations in water are so low that are rarely measurable using state of the art analytical techniques. The main exposure route posing a risk is secondary poisoning, i.e. risks to human health via ingestion of contaminated fish or shellfish.

standard. Most of the ubiquitous PBTs (and some other substances) are very hydrophobic. It is therefore difficult to monitor them in water. The analytical techniques available are rarely sensitive enough to reliably detect concentrations of the order of the EQS, as the EQS is itself very close to (or below) the limit of determination. This means that where the results of an analysis are below the limit of determination, the concentration in the sample may still be higher than the EQS. Commission Directive 2009/90/EC requires MS to use analytical techniques that meet certain minimum quality requirements in relation to the EQS, but it also establishes that if the analytical techniques don't meet those minimum criteria, the best available techniques not entailing excessive costs should be used. Because of this clause, some MS are applying water standards for certain substances even though they are not able to monitor at the level of that EQS. This allows them to conclude that "there is no problem", even though the application of a sediment or biota standard (set at more measurable concentrations) might reveal extensive failure. Although legally possible within the current legislative set-up, it is clearly unacceptable that water bodies are categorised as having "good chemical status" while they contain elevated values in sediment and/or biota that pose a risk to or via the aquatic environment, and unacceptable that the use of different methods by different MS leads to different reporting of similar situations.

The tendency for MS to monitor in water is clear from the data gathered for the prioritisation database; only 11 MS provided data for biota, only 12 for sediment, but all 27 for water.

Knowledge and methodologies to develop EQS for sediment and biota have evolved significantly, and it is now possible to derive standards for these matrices (SCHER, 2010). However, this expertise is not available in all MS. Although this issue of the choice of matrix applies most obviously to substances identified as ubiquitous PBTs, it may apply to others as well.

2.2.4.4. Reduced monitoring effort for ubiquitous PBTs

An additional issue that has been raised by MS in relation to these substances is the monitoring requirements. The WFD (Annex V) and EQSD set minimum monitoring requirements which are adapted to the RBMP cycle. For ubiquitous PBTs, any change in environmental concentrations that might occur as a result of measures is likely to occur over the long term (unless remediation is carried out) and therefore a lower monitoring frequency would seem justified and possibly also a reduction in the number of monitoring sites. If MS choose to use a sediment or biota standard, the default monitoring frequency is already lower. The issue is how, for ubiquitous PBTs, the monitoring frequency can be optimised to minimise the administrative burden while still yielding sufficient information.

2.2.5. Knowledge base

2.2.5.1. Introduction

The process of identifying PS and setting EQS for them relies on the availability of a range of information. Data are needed on

- Intrinsic properties of the substances and their (eco)toxicological effects
- Exposure, i.e. environmental concentrations, preferably measured but otherwise reliably modelled on the basis of production volumes, use patterns and/or emissions.

Although a vast amount of monitoring data was gathered for the current review of the PS list, constituting a very significant improvement in relation to the last prioritisation exercise, and

although other sources of information including modelling were used in the prioritisation process (as recommended by the Scientific Committee on Toxicity, Ecotoxicity and the Environment[18] following the previous exercise) to avoid missing substances not already monitored, the process was to some extent still hampered by the relative paucity of monitoring data for some substances, including the unevenness of data collection across the EU. This prevented the proper assessment of the risk posed by some substances that otherwise might have been considered for prioritisation. There is a vicious circle: unless a substance is already regulated, it is unlikely to be widely monitored – but if it is not monitored and the environmental concentrations cannot be reliably modelled either, estimation of the risk posed to and via the aquatic environment at EU level may not be robust enough to justify regulation. Since the listing of a substance implies an obligation to monitor (i.e. an administrative cost) and to take measures, it is not efficient to list substances that don't pose a risk; at the same time, uncertainty could lead to some substances not being identified as PS that should be. The situation is particularly difficult for emerging pollutants (see Annex III).

Another issue of concern for some substances is the quality of the monitoring data that are available. As indicated in section 2.2.4.3 on the issue of the monitoring matrix, certain substances occur at very low concentrations below the determination limit of the available analytical methods, but potentially still above the no-effect level. Despite monitoring, uncertainty may therefore remain regarding whether the concentrations in the environment are likely to be harmful. The monitoring data for a number of PPPs (which are active at very low concentrations because of their high toxicity) are often inadequate in this respect, since the determination limit is higher than the no-effect level.

Although research is an obvious source of information on new risks, the information is usually scattered and does not provide an EU picture; it is therefore not always sufficient for prioritisation.

2.2.5.2. Specific problems to address

The main issues that need to be addressed are therefore the

- lack of a clear mechanism for collecting information at EU level, i.e. although Article 3 of Decision 2455/2001/EC specifies that "MS shall ensure that the substance and exposure-related data needed for the implementation of the COMMPS procedure are made available", some MS provide a lot of data and some very little;
- lack of EU representativeness of monitoring data, e.g.. 80% of the database compiled for the present review comes from two MS; data for many substances (more than 800 out of the 1150) come from 3 countries or fewer; only for 30 substances do data come from more than 18 countries;
- need for more consistent implementation by MS of WFD pressures and impacts analysis – which should act as a common driver for the monitoring of substances posing a risk;
- bias towards monitoring pollutants that are already regulated, meaning that for certain substances, in particular the emerging pollutants, monitoring data are sparse, even though evidence exists that among them there are a number that may pose a risk;
- quality of the monitoring data, i.e. the need for analytical techniques to be used that are sufficiently sensitive to determine concentrations at the no-effect level, so that the monitoring data are "fit for (the) purpose" of prioritisation.

[18] Former Scientific Committee replaced by SCHER

2.3. What are the underlying drivers of the problem?

For the possible new PS identified in the current review, the fact that there is a need to regulate them under the WFD probably results in part from imperfection in the models and assumptions used in the implementation of the upstream legislation controlling their authorisation and use. The WFD acts in that respect as a "safety net".

In the specific case of pharmaceuticals, one significant source of emissions is the disposal of unused pharmaceuticals. Although EU legislation obliges MS to establish take-back schemes, it does not impose reporting obligations or efficiency targets. There are therefore no comprehensive data on the functioning of the schemes, despite a recent survey by the European Federation of Pharmaceutical Industries and Associations (EFPIA). What is clear, though, is that a significant quantity of unused drugs are discarded into the sink or toilet and therefore end up in surface waters; 10 to 43% of interviewees in different MS discard medicines in this way (Knappe, 2008). The amount of pharmaceuticals collected in various European countries varies significantly, generally in the range of 10 to 100 tonnes per million inhabitants per annum. The rate is very high in Switzerland followed by Ireland, Luxembourg, Sweden and France (EEA 2010).

Improper disposal could be a significant source of pollution by Diclofenac given its high usage and potentially high quantities of unused doses (due to end of treatment, medication change, non-compliance with prescription, or expiry). One 10-tablet blister of a typical 50 mg dose can pollute up to 5 million litres of water with concentrations above the EQS, i.e. a volume equivalent to the waste water generated daily by a town of 20 000 inhabitants. Improper disposal of unused EE2 could also be a significant source of pollution, considering that a single blister of pills for one menstrual cycle with the most common dose of 30 μg has the potential to pollute to concentrations above the EQS 24 million litres of water, equivalent to the waste water generated daily by a city of 100 000 inhabitants.

For the existing PS, the need for reassessment arises because knowledge at the time they were listed did not support sufficiently stringent EQS, nor proper status (as PHS).

More generally, chemical pollution of the environment, including of the aquatic environment, is almost certainly aggravated by the fact that users of the chemicals do not bear the cost of pollution, i.e. there is a market failure. Related to this is the fact that conventional urban waste water treatment is not capable of adequately removing all the pollutants, and installing tertiary treatment on a widespread basis would be expensive.

In relation to the problems described for ubiquitous PBTs, it is clear that historic pollution accounts for much of the contamination that exists and therefore for the difficulties faced by MS in achieving good chemical status. The relatively uniform (with respect to type of PS) requirements of the WFD and EQSD appear to aggravate those difficulties.

The difference in choice of EQS (and monitoring) matrix made by MS that results in very different assessments for the same substance (especially ubiquitous PBTs) arises in part because the EQSD and the Commission Directive 2009/90/EC on technical specifications for chemical analysis do not provide enough guidance to limit the choice.

Finally, the paucity of high-quality and fit-for-purpose monitoring data to support the prioritisation exercise appears to result principally from the absence of a clear, targeted mechanism to gather such data.

2.4. Who is affected by the problems identified, in what ways and to what extent?

As acknowledged in the WFD, water is not a commercial product like any other but, rather, a heritage which must be protected. At the same time, it is indeed a key economic resource. The increasing economic development of Europe has not only increased the dependence on water resources but also in many areas created more intensive pressures on them, in particular on their quality. Many surface waters are used as sources of drinking water (60% of the water abstracted in the EU for the production of drinking water comes from surface water) and of water for a range of domestic, industrial, agricultural and aquacultural purposes. They also serve as receptors for waste including industrial and domestic sewage effluents, and many receive a range of pollution from diffuse sources such as run-off from urban and agricultural areas, leachate from landfills and mine workings, and atmospheric deposition.

Where the objective of good chemical status is not met, the concentrations of at least some PS in the relevant water bodies are likely to be above no-effect levels and therefore a risk to the aquatic environment and/or to human health through the aquatic environment, for example via the consumption of drinking water, fish or shellfish. Achieving good status is likely to become increasingly challenging in the context of climate change, which is likely to result in more frequent incidences of low river flows and depleted lakes and reservoirs (EC, 2009) therefore leading to a higher concentration of pollutants.

Surface waters *in situ* that support a healthy aquatic ecology are key for biodiversity. Around 70% of the protected habitats and species in EU legislation are water related. Chemical pollution can reduce the richness of the aquatic ecosystem and, consequently, its functionality, hence decreasing its resilience, its capacity to handle pollution (Cardinale 2011). At the same time, the amenity value of water bodies as features of the landscape that support recreational activities such as angling, swimming and boating is reduced.

The potential effects of the 15 possible new PS are outlined in section 2.2.3 (see also Annexes II and V for details). Because those effects, and likewise the effects of the existing PS, are relevant to society as a whole, they are obviously also directly or indirectly relevant to industry. The industry sectors that produce or use the possible new PS are indicated in the "Type/Use" column of the table in section 2.2.3. In addition to them, the water and sewerage treatment industry is inevitably concerned by the presence of chemical substances (in general) in water bodies. In the context of implementing the EQSD, it is the Member State Competent Authorities on whom the obligation to meet the EQS for PS falls.

2.5. How would the problem evolve, all things being equal?

The three main problems identified would be expected, if no proposal were made, to evolve as described below.

2.5.1. New information on risks to environment and human health

For the substances identified in this review (existing and new PS), the baseline situation, in terms of production, use and emissions, is in most cases subject to significant uncertainty for several reasons. The most important is that several pieces of legislation are already in place

that will or may have an impact on the use and emissions of some of the substances in the coming years, and therefore on their concentrations in the aquatic environment. The most important of these are the WFD Programmes of Measures, the PPP legislation including the Directive on the sustainable use of pesticides, .the REACH Regulation, industrial emissions policy, and the legislation on biocides, pharmaceuticals, waste and POPs. Some information on which substances are subject to the legislation, and on the implications, is provided here; further details are in the tables in section 5.2 and in Annexes V and VI.

Decisions under the other legislation are likely to lead to decreased emissions to water or no change. In some cases, decisions are awaited on status (e.g. as a POP) or on continued authorisation (e.g. as a biocide), and they might go either way. For example, a decision not to exclude a particular biocide from Annex I to the Biocidal Products Directive in the current review would mean no change. Further, even where a decision is made to restrict use, the measure might have greater or lesser effect depending upon its scope. In the example of the biocides, exclusion might not apply to all of the currently authorised product types. Even though recommendations exist regarding the non-authorisation or POP designation of some substances, the final decisions cannot be considered foregone conclusions.

Legislation in baseline	**Developments/general implications**	**Relevant substances/specific implications**
WFD Programmes of Measures in MS	MS currently defining measures for existing PS and RBSP on basis of 2009 RBMPs and Programmes of Measures. Due to be operational by end 2012; reporting of impacts in 2015.	All existing and proposed PS – uncertainty regarding the implementation of MS measures for existing PS and relevant RBSPs, and the possibility that the measures might affect more than the targeted substances, including (other) possible new PS. Of 15 proposed PS, 10 are RBSP, therefore already subject to measures (see Annex VI), but in 8 cases in only 1 to 3 MS.
Plant Protection Products (PPP) legislation, especially the Sustainable Use of Pesticides Directive but Regulation (EC) No 2009/1107	National Action Plans due by end 2012; measures - to be introduced 2013-2015 – not yet defined. Authorisation of individual active substances subject to periodic review; new information could change authorisation, and the Regulation also contains new criteria regarding PBT/vPvB substances.	Aclonifen, Bifenox, Cypermethrin, Quinoxyfen, - uncertainty regarding measures from NAPs and/or outcome of authorisation review. Increasing likelihood of MS specifying buffer strips as well as other measures under Sustainable Use Directive; could decrease concentrations in water bodies. Aclonifen - EU-level requirement since 2008 for buffer strips. Quinoxyfen – authorisation under Directive 91/414/EEC due to be reviewed in 2014 under the Regulation; conditions or withdrawal possible. (PPP legislation also relevant to Dichlorvos, Dicofol, Terbutryn, Trifluralin – but these are no longer authorised as PPPs.)
Biocidal Products Directive 98/8/EC	Review programme ongoing covering 23 different types of biocides – could lead to change or withdrawal of authorisations. Tigher restrictions on industrial use of creosote due to take effect May 2013.	Cybutryne (1 product type), Cypermethrin (3 product types, Dichlorvos (1 product type), Terbutryn (3 product types) – uncertainty regarding outcome of review. Creosote restrictions relevant to Anthracene, Fluoranthene, Naphthalene, PAHs.
REACH Regulation	Registration process ongoing; may bring new information and potential action,	Existing PS: Anthracene, DEHP, Fluoranthene, Lead, Naphthalene, Nickel, PAHs;

	even in the near future, on existing/proposed PS. In addition, substances may be added to SVHC candidate list and then Annex XIV (the authorisation list) with a sunset date but possible exemptions for specified uses. REACH cannot affect emissions from existing products.	Proposed PS: HBCDD, PFOS – uncertainty regarding extent/impact of possible regulation for reasons given below. Registration dossiers for the existing PS still to be assessed. DEHP and HBCDD – in Annex XIV, sunset date 2015; not yet known which uses will be authorised. (Leaching from existing products containing these substances not directly affected, e.g. of DEHP from existing textiles, furniture and PVC construction materials such as flooring, roofing, piping; of HBCDD from insulation materials *in situ* and on disposal; but extent could change depending upon how long new use continues.) PFOS – in Annex XVII; not certain how quickly technical advances will allow substitution of PFOS for the derogated uses Anthracene (and related oils, pastes) and coal tar pitch high temperature (relevant to Anthracene, Fluoranthene, Naphthalene, PAHs) are on the SVHC candidate list. Not certain what the outcome of their further review will be.
POPs legislation: Stockholm Convention[19], POPs Protocol to UNECE CLRTAP[20], and Regulation (EC) No 850/2004[21]	Under Stockholm Convention, for existing and new POPs, measures must be taken to either eliminate production and use (some exemptions possible) (Annex A), restrict production and use (Annex B), or reduce unintentional releases with the goal of eliminating them altogether (Annex C). Measures and/or exemptions could change.	Existing POPs - uncertainty regarding implementation/effectiveness of measures especially where complete phase-out of use not yet possible: Existing PS: some polyBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE) (Annex A); Proposed PS: Heptachlor, PCBs (Annex A), PFOS (Annex B), Dioxins (Annex C) Measures for the BDEs and PFOS were agreed in 2010 and should significantly reduce emissions to the aquatic environment, but timeline for substitution of PFOS uncertain Possible POPs – uncertainty regarding listing: Trifluralin (existing PS), Dicofol and HBCDD (proposed PS) EC Regulation addresses some other substances, i.e. PAHs are subject to release reduction provisions (relevant also to anthracene, fluoranthene, naphthaleme.)
Industrial emissions Directive 2010/75/EC (IED) – recast of Integrated Pollution Prevention and Control (IPPC) Directive	IED regulates industrial emissions to water and other environmental media including by integrated permitting for a wide range of industrial sectors, with emission controls based on Best Available Techniques (BAT). Implementation of IED as of 2011 likely to strengthen BAT and could therefore affect baseline for industrial chemicals discharged by industries	Potentially all substances but particularly industrial chemicals discharged by industries, i.e.: Existing PS: Anthracene, DEHP, Fluoranthene, Naphthalene, Nickel, Lead, PAHs. Proposed PS: Dioxins and DL-PCBs, HBCDD, PFOS - uncertainty regarding changes to BAT implementation given that transposition date of IED likely not to be uniform, renewal of permits likely to follow different timetables, and new

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

20 http://www.unece.org/env/lrtap/pops_h1.htm

21 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:229:0005:0022:EN:PDF

		approach to BAT not effective until 2014..
Waste legislation – several acts and decisions	Latest Commission implementation report on EU waste legislation recognises progress but also important gaps. Further progress likely – could affect emissions to water from waste handling and/or disposal.	Several substances could be affected. – uncertainty regarding specific measures. As an example, most recently, the Commission has announced that it intends to propose limits on the amount of the two POPs (polyBDEs and PFOS) in waste[22].
Pharmaceutical legislation	Commission study to be launched 2011 building on existing information on the impact of pharmaceuticals on the aquatic environment. The impact of this Commission initiative is uncertain but could be significant in the long term.	Diclofenac, E2, EE2. – uncertainty regarding MS action on take-back schemes and outcome of Commission study.
Other legislation	Rotterdam Convention: a substance listed in Annex III becomes subject to the Prior Informed Consent (PIC) procedure[23].	A recommendation to include PFOS, pentaBDE and octaBDE in Annex III will be considered in 2013 – uncertainty regarding outcome. (PCBs, heptachlor and some other existing PS are already listed.)

With regard to the Programmes of Measures and the RBSPs covered under ecological status, it is clear that although 10 of the 15 proposed PS are designated as RBSPs, this only applies in a few MS. This suggests that only a few MS would act on those substances in the absence of a proposal to list them as PS[24], although it is not possible to predict which substances the MS will identify as RBSPs in their updated RBMPs in 2015. Less action could mean more frequent exceedance of no-effect levels. In the few MS where proposed PS have already been designated as RBSPs, a reduction in the risk to and/or via the aquatic environment would be expected, depending upon the extent to which measures are taken to reduce concentrations below their current levels and on the level of the quality standard set by the MS. As has been found for other RBSPs, considerable variation between MS is observed, both in terms of the magnitude of the standard and the chosen matrix (see Table in Annex VI), meaning that without the harmonised EQS derived for each substance as a PS, different baselines would likely be seen in the different MS. Some of the standards are significantly less stringent than being proposed here.

In the absence of a proposal to list the possible new PS in the EQSD, the baseline scenario would include almost no monitoring of those substances in the aquatic environment. Most would only be monitored in the few MS where they are listed as RBSPs. Under the Stockholm Convention there are some non-binding recommendations for the monitoring of POPs; and Regulation (EC) No 850/2004 Article 9 requires "appropriate programmes and mechanisms" to be established for the regular provision of comparable monitoring data on the presence of Dioxins and PCBs in the environment, though no specifications are given. The limited extent of baseline monitoring of the proposed PS would make it difficult to judge the effectiveness of the measures being taken under the Programmes of Measures or other (non-WFD) EU legislation, and thus to adjust them if necessary, and difficult to determine where remediation might be necessary. In addition, if the proposed PS were not listed as such,

22 http://ec.europa.eu/environment/waste/studies/pdf/POP_Waste_2011.pdf

23 http://www.pic.int/Procedures/PICProcedure/tabid/1364/language/en-US/Default.aspx

24 This is based on information from 19 MS. Although it is early to extract conclusions from the RBMPs (their assessment is on-going), it is clear that there is a wide diversity of methodologies and likely an implementation gap in the identification of substances of river basin importance in the context of ecological status.

decisions taken under the other relevant legislation might take less note of the risk to the aquatic environment and thus not lead to such effective measures.

If no proposal were made to change the EQS of the existing PS where new information indicates that they should be more stringent, these substances could pose an unrecognised ongoing risk. In the case of Nickel, it was recognised at the time the original EQS was set that it was probably not protective enough and would have to be revised. If the status of DEHP were not changed, too little attention might be paid to emissions of this reprotoxic substance into the aquatic environment from existing uses; the change is appropriate for an existing PS (by definition posing a risk to or via the aquatic environment) recently included in Annex XIV of REACH. If the status of Trifluralin were not changed, there would be no effect on primary emissions since Trifluralin has not been approved for use as a plant protection product (PPP) in the EU since 2007, but the EU position in the POPs negotiations could be compromised, and there would be no strong driver to carry out sediment remediation.

2.5.2. Specific difficulties with ubiquitous persistent, bioaccumulative and toxic chemicals

This issue relates to the functioning of the EQSD and is therefore not affected directly by other legislation other than the Directive 2009/90/EC on technical specifications for chemical analysis.

If there were no change, widespread pollution by some of the existing ubiquitous PBTs could hide improvements achieved for other substances in the second RBMP. In addition, if some of the policy options related to substances were realised in the legislation (introducing stricter EQS for some existing ubiquitous PBTs and adding some new ubiquitous PBTs to the list of PHS), the second RBMP maps would likely show a worse picture than the first, giving. the impression that the chemical status in most if not all MS was getting worse rather than improving. MS would, among other things, be faced with the significant administrative burden of having to explain and justify this in the plans and during the WFD public-participation process. The extent of this problem would depend on the option chosen for the substances.

As regards the choice of the matrix, the current legislation does not provide any incentive to improve the information base by choosing the most appropriate matrix for substances such as ubiquitous PBTs. In the absence of a proposal to change the situation, MS could continue to monitor in water even when another matrix would be more suitable. There would continue to be many false "good chemical status" reports, harmonisation would not be achieved, and there would be less scope for identifying and possibly remediating highly contaminated sites.

As regards the monitoring effort, departure from the minimum requirements in the WFD requires technical justification that some MS may not be in a position to elaborate. MS would continue to monitor on the basis of the minimum requirements in WFD Annex V and in EQSD Article 3. These requirements might not be the most efficient for ubiquitous PBTs. This would result in a waste of resources.

2.5.3. Knowledge base

Although the availability of monitoring data for the current prioritisation was much better than for the first exercise, i.e. a much more substantial database was compiled this time, there were still limitations.

For future exercises, the implementation of REACH and the PPP Regulation of 2009 hold the promise of providing some assistance, although neither is likely to lead to the provision of targeted, EU-wide monitoring data relating for example to emerging pollutants.

REACH implementation is likely to generate a wealth of information on intrinsic properties and effects; a mechanism will need to be put in place to access and use it for the prioritisation. On the exposure side, the REACH evaluation tool allows requests to industry for monitoring data for certain substances, but this mechanism will not provide systematic representative information across the EU. It might be a useful source of information but only to complement EU-wide monitoring. In any case, this only refers to substances covered under the scope of REACH and will not cover all emissions (e.g. those emitted from existing consumer products).

The second RBMP is expected to provide more information than the first on MS monitoring of RBSPs, but the extent of this is not yet clear. Indications from the first RBMP reporting are that most of the MS have identified a very limited number of specific pollutants. There is also no clear mechanism for the data itself to be reported at EU level. Unless the situation changes, reporting will be voluntary, and although it could go into an EU database, it might still not be fit for purpose for the reasons explained in section 2.2.5.

2.6. Does the EU have the right to act?

Water pollution has a very important transboundary character. 60% of the EU territory lies in shared river basins (EC, 2007). Because of this, and because many substances that cause pollution are used across the EU anyway, it is appropriate to set harmonised EQS for them at EU level where a significant risk to or via the aquatic environment is identified. Apart from the wider protection, a more level playing field is ensured than when only a few MS set an EQS or the national EQS are very different.

The Union's policy for controlling the pollution of surface waters is set out in Article 16 of the WFD. Articles 16(4) and (8) of the WFD provide for the list of PS to be reviewed every four years and the EQS within two years after the inclusion of new substances on the list. Article 8 of the EQSD provides for the review of the PS list combining in the same proposal the identification of the substances and the EQS. As regards the problems of ubiquitous PBTs and the knowledge base, the proposals concern action aimed at improving the functioning of the existing legislation.

3. OBJECTIVES

The obligations under the WFD are referred to in previous sections. In line with those, the general objectives of the proposal are the following:

- Reduce the risks to or via the aquatic environment posed by certain substances
- Improve the functioning of the EQSD
- Provide adequate tools to improve the future identification of substances of concern to or via the aquatic environment at EU level.

The specific objectives are the following:

- Consider the latest scientific knowledge in the review of existing PS
- Identify new PS and set EQS for them

- Ensure improved knowledge, through monitoring, of the risks posed by existing and proposed PS and the effectiveness of measures taken to reduce or eliminate emissions
- Improve communication of the progress on water quality under the WFD
- Strengthen the current legislation on the choice of the most suitable matrix for monitoring
- Reduce the administrative costs for MS by providing additional flexibility in the monitoring of ubiquitous PBTs while maintaining the effectiveness of the monitoring
- Provide a mechanism to improve the knowledge base and make future identification of PS more effective

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

4. POLICY OPTIONS

4.1. Overview

The options presented in this section address one or more of the problems and objectives presented in sections 2.2 and 3. The table below shows the correspondence between the options and the problems, sub-problems and objectives:

Problem	Sub-problem	General objective	Specific objectives	Options
New information on risks to environment and human health	Existing substances	Reduce the risks to or via the aquatic environment posed by certain substances	Consider the latest scientific knowledge Ensure improved knowledge through monitoring	A2
	Proposed substances		Identify new substances that pose risks and set EQS for them Ensure improved knowledge through monitoring	A3a-A3c
Specific difficulties with ubiquitous PBTs	Presentational issues	Improve the functioning of the EQSD	Improve communication of progress on water quality under the WFD	B2a-B2b
	Choice of matrix		Strengthen the current legislation on the choice of the most suitable matrix for monitoring	B3a-B3b
	Monitoring effort		Reduce the administrative costs for MS by providing additional flexibility in the monitoring of ubiquitous PBTs	B4a-B4b
Knowledge base	-	Provide adequate tools to improve the identification of substances of concern	Provide a mechanism to improve the knowledge base and make future identification of PS more effective	C2-C3

The sets of options relating to ubiquitous PBTs and the knowledge base are independent of the substance options and of each other.

4.2. Policy options in relation to the substances

4.2.1. Introduction

The policy options considered in this section refer to the inclusion of substances as PS in Annex X of the WFD, the (re)determination of the status (PS or PHS) of the PS, and the revision or establishment of EU-wide EQS for them. If a substance is identified as a PS but

not a PHS, it can still be used, but the EQS should be met. For PHS, the WFD foresees the cessation and phase-out of discharges, emissions and losses to water in the long-term. This will usually require substitution or at least severe restrictions on use.

Article 16 (6, 7, 8) of the WFD establishes the obligation for the Commission to propose control measures at EU level to achieve the emission objectives for PS and PHS (For the latter, cessation and phase-out should occur within 20 years of the adoption of such measures). Measures may involve process controls (including emission controls for point sources) and product controls. However, several existing EU policies, for example for industrial chemicals, PPPs, biocides and veterinary medicines, include mechanisms and criteria that can be used to a greater or lesser extent to develop and decide on such controls to address the risks identified by the WFD. It would not be appropriate for the Commission to propose alternative controls for specific substances on the basis of the WFD. This would create unnecessary double regulation. Therefore, the options do not specify measures. They assume that the other EU policies will establish the most appropriate controls and that measures might also be taken at MS level, as required by WFD Article 11(3)(k). When the first PS list was established, existing legislation was also seen as providing sufficient tools to enable appropriate measures.

As explained in section 2.5.1, a number of the measures that might reduce emissions to water of certain existing or proposed PS, such as authorisation for limited uses under REACH or withdrawal of an authorisation under the biocides or PPP legislation, or the establishment of additional mitigation measures during use, are likely to be taken under the baseline. However, some might be triggered or accelerated as a result of PS designation or EQS revision under the WFD, or as a result of feedback from the monitoring conducted under the WFD – this being an obligation for the substances listed as PS. The interaction of the WFD/EQSD with other legislation is explained further at the end of Annex VI.

4.2.2. The options A1, A2 and A3 (a)-(c)

Option A1 is the no-policy-change option; the baseline is explained in section 2.5. The other options relating to substances are presented in the table below. They are fully based on the outcome of the technical work presented in sections 1 and 2.2.3. They are cumulative on the basis of theoretically increasing impacts, starting with existing PS, adding newly identified substances except pharmaceuticals, and finally adding pharmaceuticals (last because they have not hitherto been regulated under the WFD). Existing PS not included in option A2 would not be affected. The first option including newly identified substances (option A3a) includes substances listed in Annex III of the EQSD, which there is an explicit legal obligation to review. The outcomes of the technical review of the Annex III substances are explained in the Commission Staff Working Paper SEC(2011)1544 (European Commission 2011). Effectively five (if Dioxins and Dioxin-like PCBs are counted as 2) of the 13 Annex III substances were identified by the technical process.

Option	**Substance**	**Change or establishment of EQS in water?**	**Biota EQS proposed?**	**Change from PS or identified as PHS?**
Option A2: Change EQS and/or status of existing PS	Anthracene	Y (minor)	N	N
	Poly-BDE	Y (significant[25])	Y	N
	DEHP	N	N	Y

[25] If change is higher than one order of magnitude.

Option	Substance	Change or establishment of EQS in water?	Biota EQS proposed?	Change from PS or identified as PHS?
	Lead	Y (minor)	N	N
	Naphthalene	Y (minor)	N	N
	Nickel	Y (significant)	N	N
	PAHs			
	Benzo(a)pyrene	Y (significant)	Y	N
	Benzo(b)fluoranthene	Y (significant)		
	Benzo(k)fluoranthene	Y (significant)		
	Indeno(1,2,3-cd)pyrene	Y (significant)		
	Benzo(g,h,i)perylene	Y (significant)	N	
	Fluoranthene	Y (significant)	Y	N
	Trifluralin	N	N	Y
Option A3a: Existing-PS changes plus Annex III substances	Dicofol	Y	Y	Y
	PFOS	Y	Y	Y
	Quinoxyfen	Y	N	Y
	Dioxins and DL-PCBs	N	Y	Y
Option A3b: Existing-PS changes plus Annex III substances plus other new substances excluding pharmaceuticals	Aclonifen	Y	N	N
	Bifenox	Y	N	N
	Cybutryne	Y	N	N
	Cypermethrin	Y	N	N
	Dichlorvos	Y	N	N
	HBCDD	Y	Y	Y
	Heptachlor/ heptachlor epoxide	Y	Y	Y
	Terbutryn	Y	N	N
Option A3c: Existing-PS changes plus Annex III substances plus other new substances including pharmaceuticals	17 alpha-ethinylestradiol	Y	N	N
	17 beta-estradiol	Y	N	N
	Diclofenac	Y	N	N

Details of the proposed EQS are provided in Annex II.

4.3. Policy options in relation to the specific difficulties with ubiquitous PBTs

There are three sub-problems under this heading, with their own objectives. Options have been structured as follows:

Option	Presentation	Choice of matrix	Monitoring effort
B1	No change (presentation of all PS results together)	No change (choice is fully free)	No change (minimum frequency but some flexibility if technically justified)
B2a	Allow separate presentation of ubiquitous PBTs		
B2b	Take ubiquitous PBTs out of chemical status		
B3a		Conditioned to meeting or coming closest to the minimum performance criteria of Commission Directive 2009/90/EC	
B3b		Fixed choice for each substance	
B4a			Introduce reduced monitoring obligations for ubiquitous PBTs if certain specified conditions are met
B4b			Introduce reduced monitoring obligations for ubiquitous PBTs

			(unconditional)

The issues and options are largely independent and therefore any combination of options (one per sub-problem or column) is possible. The following substances have been identified as ubiquitous PBTs: BDEs, Mercury, Tributyltin (TBT), PAHs (existing PS) and Dioxins/DL-PCBs; Heptachlor and heptachlor epoxide, HBCDD, PFOS (possible new PS).

4.3.1. Option B1: No change

This option would mean continuing as now. The baseline is explained in section 2.5.

4.3.2. Option B2a presentation: Allow separate presentation of ubiquitous PBTs

This option identifies a number of substances that are ubiquitous PBTs at EU level and allows MS to present the assessment for some or all of these substances separately (e.g. in separate maps) from that for the rest of the PS in the RBMPs, although the chemical and overall status assessment would still need to include them.

4.3.3. Option B2b presentation: Take ubiquitous PBTs out of chemical status

This option would mean that the assessment of chemical status would no longer need to include the levels of these substances, good chemical status could be met on the basis of meeting the obligations only for the other PS. This would mean taking the substances out of WFD Annex X and EQSD Annex I. There would not be a legally binding EU-wide EQS.

The obligation to monitor and report according to EQSD Article 3.3 would be kept in order to ensure that there were at least a trend assessment of the concentrations of these chemicals. No other legislative tool provides for their monitoring in the aquatic environment at EU level.

4.3.4. Option B3a choice of matrix: Leave flexibility but link the choice to requirements of Directive 2009/90/EC

A preferred matrix/matrices for monitoring and compliance checking for each substance would be identified (as it is one of the outcomes of the technical process)[26]. The choice of matrix would still be left to the MS except in cases where

- the available analytical technique fulfils the performance criteria of Directive 2009/90/EC in one matrix and not in the other(s), or
- no analytical technique meets the performance criteria but the technique for one matrix performs significantly better than that for the other matrix/matrices,

and there is an EQS available at EU level for at least the matrix where the analytical technique performs according to the criteria in Directive 2009/90/EC or performs better than in the other matrix/matrices. In this case MS would have to use the matrix for which Directive 2009/90/EC is fulfilled or for which the analytical technique performs significantly better in relation to the criteria in Directive 2009/90/EC.

[26] As explained in the problem definition section, options B3a and B3b are most obviously relevant to ubiquitous PBTs but would apply to all PS.

A common example would be the case of a hydrophobic and bioaccumulative substance where the EQS in water is very low and an EQS for biota has been derived. The best available analytical technique for water does not fulfil the requirements of Directive 2009/90/EC, but it does for biota. In that case, MS would have to use the biota standard.

The assessment of the relative performance of the analytical methods would be left to the MS, possibly with some technical guidance to be developed at EU level, if needed to complement the criteria given in Commission Directive 2009/90/EC.

4.3.5. Option B3b choice of matrix: Fix the preferred matrix for each substance

The choice of matrix for monitoring and compliance checking would be fixed at EU level for each substance, reflecting the outcome of the expert work (see Annex II).

4.3.6. Option B4a monitoring: Introduce reduced monitoring obligations for ubiquitous PBTs if certain specified conditions are met

Criteria for reducing the monitoring effort for the substances identified as ubiquitous PBTs would be established in the legislation, i.e. criteria for applying the flexibilities in the WFD and EQSD as regards monitoring frequencies (based on "technical knowledge and expert judgement") and for reducing the number of sites at which the ubiquitous PBTs need to be monitored. This reduced monitoring effort could apply without further justification only if there were enough information on the presence of the substance in water bodies (in particular in sediment and/or biota), i.e. there were a robust baseline of monitoring information. This reduced monitoring would be without prejudice to the need to undertake more detailed monitoring if local measures had to be taken and their effectiveness had then to be assessed.

4.3.7. Option B4b monitoring: Introduce reduced monitoring obligations for ubiquitous PBTs (unconditional)

Allow reduced monitoring (frequency and number of sites) for ubiquitous PBTs compared with the general requirements for other PS. In this option the reduced monitoring effort could be applied without preconditions.

4.4. Policy options in relation to improving the knowledge base

4.4.1. Option C1: No change

This option would mean continuing as now. The baseline is explained in section 2.5.

4.4.2. Options C2 and C3: Establishment of a watch list

These options would involve establishing a watch list. The aim would be to ensure targeted monitoring across the EU of substances of possible concern, for example, emerging pollutants, to provide a database of high-quality information fit for the purpose of subsequent prioritisation exercises under the WFD. Two approaches would be possible, a watch list without a legal obligation, or a watch list with a legal obligation. The list would be "dynamic" with substances being regularly added and removed. Approximately 20 would be on the list at any one time, monitored by MS at 250-300 representative sites across the EU according to agreed technical guidelines for monitoring (site selection, sampling and analysis), with results being reported to the Water Information System for Europe (WISE).

The technical details including the structures that would be involved in supporting the operation of the watch list are described in Annex III.

4.4.3. Option C2: Establish a watch list without legal obligation

This option would entail establishing a watch list on the basis of a voluntary system of monitoring and reporting. The well-established informal decision-making process of the CIS would be used. This has been operating well since 2001 and involves decision making by the WFD Water Directors, hence ensuring political support in the MS. The technical proposals on the selection of substances to monitor and the guidelines for monitoring would be forwarded to the Water Directors for endorsement at one of their twice-yearly meetings.

4.4.4. Option C3: Establish a watch list with legal obligation

This option would entail establishing a watch list through a legally binding instrument. This would involve a legal provision that establishes the watch list in generic terms in the legislation, with the obligation for MS to monitor and report to the Commission, and a mandate for the Commission to develop the list of substances. The list would be adopted by Commission Decision.

The structures involved in the technical work and data collection would be the same as in option C2, including the use of the CIS WGE/CMEP groups and the WISE reporting system. The technical guidelines for the monitoring process would still be developed informally. There is considerable experience in the CIS of developing informal guidance for endorsement by the Water Directors. This procedure reduces significantly the administrative burden but has proven efficient with high rates of uptake of the guidelines by the MS.

Alternative options to formally adopt the technical guidelines for the monitoring would entail a heavier and longer administrative procedure that would, because of the need for substance-specific updates, reduce the usefulness of the watch list, limiting the frequency of renewal and thus its effectiveness at meeting the objective of "improving the knowledge base". Formal adoption of technical guidelines would also not be consistent with what the Commission and the MS have been doing over the past 10 years for the implementation of the WFD and the related Directives (Floods, Groundwater, EQSD), a system that is highly appreciated as effective and not entailing excessive administrative costs (see for example conclusions of Water Directors meeting of December 2008 and CIS Work Programme 2010-2012[27]).

In the consultation phase it was a consensus view of the MS that the development of the technical work should be done using existing structures.

5. ANALYSIS OF IMPACTS AND COMPARISON OF THE OPTIONS

5.1. Introduction

The different sets of options (A, B and C) address different problems and are of a different nature. For this reason, this section sets out the analysis of impacts for the options in set A,

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

then a comparison of those options; then does the same for the options in sets B and C. The criteria for comparison of the options have been adapted to the nature of the options. In all cases, an assessment has been made as regards effectiveness at reaching the general and specific objectives set out in section 3. The options are compared relative to the "no-change" options A1, B1 and C1; the baseline is explained in section 2.5.

5.2. Analysis of impacts of the substance options

5.2.1. General considerations as regards costs and benefits of the substance options

Annex IV includes a summary of the approach used to assess the impacts.

Although specific measures are not proposed in the options at either EU or MS level, as explained in section 4.2.1, considerable efforts were made to obtain quantitative information regarding the impacts of potential measures. However, little quantitative information was received for many of the substances, even on the potential economic costs (see section 5.2.2). In view of this and of the uncertainty regarding the measures that might be applied, a largely qualitative approach was taken in the analysis. This appears proportionate considering the limited direct effects of the proposed options, the fact that the decision processes regarding action under other sectoral EU legislation usually include a socio-economic analysis, and the fact that MS can apply exemptions regarding attainment of the environmental objectives under the WFD (see section 5.2.1.2).

Nevertheless, to the extent possible, information on the scale of the benefits and costs is presented under the various options.

It should be borne in mind that the Treaty establishes as one of the pillars of EU environmental policy the control of pollution at source. This principle gives priority to upstream controls on the assumption that, in general, rectification at source is more cost-effective than end-of-pipe solutions. The importance of considering upstream measures was highlighted by MS and stakeholders during the consultation; they also stressed the need to consider the feasibility of phasing out certain substances that are currently in use and others that are produced unintentionally.

5.2.1.1. Benefits

This section presents quantitative and qualitative information on the main generic benefits expected from the substance options A2 to A3c. The magnitude would depend on the ambition of the options. Positive impacts specific to the proposals for individual substances are presented in later parts of section 5.2 on the specific impacts of the individual substance options.

Since the options do not specify measures, the assessment of the potential benefits of measures themselves (as compared with the benefits of monitoring) can only be based on the potential measures that might be taken at EU or MS level as a result of the proposal. Realisation of some of the benefits would be in the long-term. Benefits to health are extremely difficult to quantify, being dependent on many factors in addition to exposure and intrinsic hazard.

Environmental benefits

- Regular monitoring and consequently increased knowledge of the extent of water pollution, particularly valuable to assess the effectiveness of the measures taken under the WFD and other sectoral legislation to limit the emissions; this benefit would not be achieved under the other sectoral legislation alone. It should be noted that monitoring of the substances in option A2 already occurs, and that EQS for them already exist, but that changes in the EQS matrix for some of those substances would be expected to improve the quality of the monitoring data.

- The triggering of measures, including by feedback from monitoring, to limit chemical emissions, with consequent improvements in biodiversity that will result in a more resilient aquatic ecosystem, enhancing its capacity to deliver ecosystem services such as the processing of excess nutrients (Cardinale 2011). Recent studies from the JRC have estimated the monetary value of the removal of nitrogen performed naturally by healthy river ecosystems in the EU as being of the order of 373 million € per year (JRC, 2011).

- Wider benefits to biodiversity, i.e. beyond the immediate aquatic ecosystem, in view of the extensive interactions between different ecosystems and organisms, including through migration.

- Cleaner sediments (including as a result of remediation informed by monitoring) meaning less potential for re-dissolution in the water column and reduced uptake of harmful substances by plants and animals.

Economic benefits

- Moving towards a level playing-field for industry across the EU as regards the driver for the authorisation of discharges, compared to the current situation where MS establish their own EQS for some of the candidate PS. National EQS for some substances differ by several orders of magnitude (e.g. 2 orders of magnitude in the case of Dichlorvos, 3 orders of magnitude in the case of Heptachlor, one order of magnitude in the case of Terbutryn).

- Reduced treatment costs for drinking water and industrial process water. E.g. in the context of the 2006 impact assessment, based on data from 3 MS, estimated unit costs for removal of pesticides were 0.028 €/m3 (Ecolas, 2005). Based on data from BE, DE, NL and UK, that study estimated that 74% of surface waters used for the production of drinking water exceeded regularly the standard of 0.1 µg/l. Latest data from EUREAU suggest that the value of 74% is probably overestimating the percentage of water bodies that show regular exceedances, but in any case the costs are considerable. According to Eurostat (2011, env_watq2_1), around 20 900 million cubic metres of surface water are abstracted in the EU for drinking water production. Using these figures, the following table presents estimated annual costs of treatment for three different scenarios:

Percentage of surface water bodies used for the abstraction of drinking water that exceed regularly the standard for pesticides	30%	50%	70%
Estimated treatment cost (million € per year)	175	292	409

- Cleaner sediment implying cheaper management of waste from dredging. Around 200 million cubic metres of sediment are dredged every year in the EU (SedNet, 2004). Management costs are heavily dependent on the sediment quality and vary from 1 to 45 €/m^3. Assuming that 10% of the material is contaminated (value from the Port of

Rotterdam) and hence requires higher disposal costs in the range of 10 to 30 €/m^3, the annual expenditure in handling contaminated dredged material is in the order of 200 to 600 million € per year. The potential cost savings in the long term are therefore significant.

- The potential for healthier, more productive commercial fisheries and aquaculture.
- Fostering of innovation to find substitutes for PHS.

Social and public health benefits

- More information for the public on the quality of the aquatic environment;
- Reduced bioaccumulation of many hazardous chemicals in humans, reduced exposure (occupational and other) if less hazardous substitutes are used;
- Potential improvements in quality of fish and shellfish from commercial fisheries, aquaculture and recreational fishing.
- Improved amenity value of water bodies (tourism, angling, etc), and reduced exposure for humans using them for bathing, surfing and other water sports;
- Cleaner water for livestock where surface water is used directly, resulting in reduced accumulation in meat and milk, hence reduced human exposure to hazardous substances, likewise, less accumulation in meat from game drinking surface waters directly;
- Reduced potential for accumulation of hazardous substances in crops when untreated surface water is used for irrigation.

5.2.1.2. Costs

The most important costs fall into the "economic" category. If significant social or environmental costs (beyond water) are involved they are mentioned in later sections.

The obligation to monitor PS means that additional monitoring costs would apply to all the substance options except option A2 which relates only to existing PS. These were estimated on the basis of figures provided by MS for the existing PS (see Annex IV), and are given in the relevant sections. The Standard Cost Model was not used for these estimates because of the availability of data from the MS, which allowed the analysis to be tailored more realistically.

Since the options do not specify measures, the assessment of the other potential costs of the options can only be based on potential measures that might be taken at EU or MS level as a result of the proposal.

The substances proposed as PHS, with the exception of Quinoxyfen, are already regulated under other sectoral EU legislation, and in some cases subject to (or likely to become subject to) international conventions, in ways that should eventually achieve the cessation or phase-out of emissions, subject to the availability of substitutes where needed. Therefore their designation as PHS is not expected to lead to any significant impacts on the market (both in terms of users and producers) beyond the baseline.

For the other substances proposed for addition to the PS list or a more stringent EQS, measures beyond the baseline might be taken under the other EU legislation, but these and their costs cannot be predicted. However, the chemicals (REACH), biocides and PPP legislation contains provisions for authorisation decisions to take account of socio-economic (including environmental) factors. Where measures are taken at MS level, it is important to note that, although PS are selected from among those posing a risk at EU level, local pollution and circumstances can vary substantially and with them the costs of the measures. For example, the treatment required at an Urban Waste Water Treatment Plant (UWWTP) will be determined by the characteristics of the receiving water body, its uses and other discharges. It should be noted that the majority of UWWTPs provide only "simple treatment", but that MS are already obliged to upgrade certain plants to secondary treatment according to Article 4 of the Urban Waste Water Treatment Directive and that the cost of doing this cannot be attributed to the options in this IA.

In this context it is also important to note that, if the relevant conditions are fulfilled (on the basis of local assessment), MS may rely on certain exemptions, i.e. if measures to achieve the WFD objectives are technically unfeasible, disproportionately expensive, or would take longer than the WFD deadlines due to natural processes, or if the origin of the problem is transboundary, exemptions under WFD Article 4(4) (extension of deadlines) and 4(5) (lowering of objectives) may be used for specific water bodies if all conditions listed in those Articles are fulfilled. This provides MS with a legal safety net to deal with specific situations in which the costs of achieving the environmental objectives would significantly exceed the benefits – it is for MS to carry out this assessment. Guidance on applying exemptions is available[28]. Although exemptions relate to WFD environmental objectives and thus to the obligations on MS, they can potentially indirectly apply to emissions by individual operators. Whether MS would be able to take the operators' position into account would depend upon the justification provided, since the overall exemption would have to be justified to the public.

As indicated in section 5.2.1, little quantitative information was received for many of the substances. It seemed inappropriate to attempt a quantitative analysis combining those data with the uncertain policy outcomes, bearing in mind the other points above. A largely qualitative approach was therefore taken to assessing the costs of the options, except in relation to the monitoring obligation.

The additional monitoring costs would be borne by MS.

On the basis of the information obtained, the impacts on EU companies (see the following sections and especially section 5.7) would be expected to be relatively small and not to affect the competitiveness of individual MS or overall EU competitiveness. As indicated in section 2.6, the setting of EQS at EU level should create a more level playing field for the MS than when only a few MS set an EQS or the national EQS are very different. As stated above, exemptions applied by MS could indirectly apply to companies and thus keep costs within proportionate limits. Other reasons for not expecting impacts on competitiveness are that relatively few substances are involved compared with the total number on the market; substitution is not seen as a likely requirement (beyond the baseline) for most of the substances in the options, either because they are already heavily regulated and will have to be substituted anyway or because they are not designated as PHS and their use will generally be able to continue; most of the producers involved are large (even multinational) and have an

[28] European Commission, 2009b

extensive product portfolio; substitutes generally exist where necessary (further information appears under the individual options below), and the need for measures to control emissions to the aquatic environment from many of the substances is also acknowledged in other parts of the world, e.g. in at least Australia[29], Canada (see footnote 15) and the USA[30] regarding Cypermethrin, in at least the USA regarding pharmaceuticals[31] (although no standards have so far been set), worldwide regarding the designated POPs. Although Quinoxyfen use is currently still authorised in Australia, the instructions for use are strong on the need to avoid any emissions to water.

Additional costs to producers could include: the cost of (further) reducing point-source emissions at a production site, temporary loss of overall sales volume while shifting to a substitute product, the cost of investing in the development and production of a substitute.

Costs to users/consumers would also be expected to be relatively small, consisting of the possible additional cost of substitute products, or an increase in the cost of water if water companies pass on the - proportionate - costs of additional treatment, or of cleaner energy.

Small and medium-sized enterprises (SMEs) that might be affected by the options include pesticide and coating formulators, textiles and plastics companies, construction companies, dockyards, ship owners, fishermen, arable and salmon farmers, pharmacies, waste management companies, and water companies. However, with the exception of the water companies, as explained further in the context of options A2 and A3c, they would not be expected to face significant costs beyond the baseline. As noted above in the context of EU companies generally, substitution is not seen as a likely requirement for most of the substances, and where it is, it would in most cases be required in the baseline, and subject to the availability of substitutes. Impacts on SMEs relevant to the individual substances are mentioned under the options below.

5.2.2. Uncertainties in the analysis of the substance options

Uncertainties in the analysis of the benefits and costs of the substance options derive from:

- Uncertainties in the exceedance of the proposed EQS in each MS, especially where the prioritisation was based primarily on modelling;
- Uncertainties in the baseline measures;
- Uncertainties in the measures that would be taken to meet the EQS and, if applicable, phase-out requirements;
- Incomplete production and use data, e.g. production volume and location, associated employment; use in some MS;
- Limited estimates, if any, of the costs of reducing emissions from industrial point sources and of removing pollutants at UWWTPs;
- Relative paucity of data regarding the cost and possible impacts of substitutes, where relevant;

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29 http://www.apvma.gov.au/products/review/docs/sheep_ectoparsiticide_prelim_report_vol_2.pdf

30 http://www.swrcb.ca.gov/rwqcb5/water_issues/tmdl/central_valley_projects/central_valley_pesticides/criteria_method/cypermethrin/2011mar_cypermethrin_draft.pdf

31 http://water.epa.gov/scitech/swguidance/ppcp/index.cfm

- Difficulty in attributing benefits to action on particular substances and in quantifying them.

Not all the uncertainties apply to all the substances, or to the same extent. Notable substance-specific uncertainties are given in the tables in the sections that follow, and/or in the factsheets in Annex V.

The uncertainties exist despite the substantial effort that went into compiling the monitoring database used for the prioritisation, and despite the comprehensive consultation carried out (see section 1.4) to gather the necessary data and information to underpin the analysis.

During the consultation, MS and stakeholders in WG E stressed that unrealistic extrapolations and attempts at quantitative estimates should not be done. This view was expressed in relation to, among other aspects, estimating the baseline concentrations where monitoring data were not available, and the supporting study did not pursue an early proposal to calculate concentrations on the basis of surface water volumes to quantify the possible exceedance of the proposed EQS in "missing" MS. The approach of using case studies to support the assessment of impacts (see Annex IV) was designed to some extent to overcome this.

Still, a few stakeholders considered that the extent of the monitoring data for some substances (Cypermethrin, EE2, Quinoxyfen) did not justify prioritisation. For Cypermethrin, 3 out of 5 MS in the database showed exceedances of the EQS, and many additional samples below the determination limit in those and other MS may also have been above the EQS. Although sheep dipping used to be one of the main uses of Cypermethrin in the UK (the MS showing the greatest number of exceedances), this should no longer be the case, but no data are available showing that exceedances don't still occur from other uses. Cypermethrin was ranked high in the modelling as well as the monitoring-based prioritisation. For EE2, the data for 3 countries in the monitoring database were complemented by literature data. Quinoxyfen was reviewed because of its EQSD Annex III status, and although only 2 MS provided monitoring data (most from FR, showing isolated exceedances), this PPP is authorised in 17 MS and is a PBT. Further explanation regarding the monitoring and modelling-based prioritisation processes is provided in the Commission Staff Working Paper SEC(2011)1544 (European Commission 2011).

Although the starting point for consultation was the membership of WG E, therefore mainly stakeholder groups, several individual companies were contacted also directly by the Commission and/or Entec. Indeed, for a number of the substances included in the options, individual companies participated in the WG E and Sub-Group meetings and provided some input directly to the technical work on EQS derivation. However, despite repeated requests for information for the substance impacts reports, and consultation on them, the amount and quality of data and information received from MS and stakeholders was limited.

5.2.3. Analysis of impacts of Option A2: Change EQS and/or status of existing PS

The impacts of this option over and above the baseline include those associated with changes to (i) the EQS (ii) the monitoring matrix and (iii) the status of the substances. Specific analysis for each substance is presented later in this section.

5.2.3.1. Change in the EQS

Impacts could result from the potential need to take measures to meet a more stringent EQS for some of the PS. The measures required and the sectors involved would depend on the

substance. The costs would depend on the type of measure and on the scale of action, which would depend upon the extent of EQS exceedance.

5.2.3.2. Change in the EQS matrix

Biota monitoring is more expensive per sample/analysis, but fewer sampling locations are needed and a lower frequency (annual according to EQSD Art 3(2)(c), cf. monthly according to WFD Annex V) due to the integrative character of biota. The impact of this option on monitoring costs is therefore estimated to be neutral, although there would be some adaptation costs for MS which have not previously monitored routinely in biota. Currently the choice of matrix is left to MS and therefore it is not appropriate to attribute such adaptation costs to this option.

As regards benefits, establishing a biota standard at EU level for the substances for which it is the most appropriate matrix due to their persistence and bioaccumulation potential would encourage MS to monitor in biota, improve knowledge of the extent of the problem (including the possible need for sediment remediation), and allow better evaluation of the effectiveness of measures, thereby providing a better basis for improved protection. The encouragement for MS to monitor in the most suitable matrix, would come from: their no longer needing to develop their own standard, for which many lack the expertise. Differences between MS would also be reduced (a preliminary assessment of national EQS in 14 MS shows that the national EQS for 35 substances differ by at least 2 orders of magnitude between the country with the lowest and the highest EQS).

5.2.3.3. Change in status

The impacts of this change would be in relation to the stricter regulation that applies to PHS cf. PS, i.e. the need to cease discharges, emissions and losses of the substance to water within 20 years of the adoption of the relevant measures at Community level.

5.2.3.4. Summary of specific impacts per substance

The table below summarises the specific impacts per substance. More details are provided in the factsheets in Annex V. Monitoring of these substances is in the baseline, but the information obtained on Fluoranthene, PAHs and PolyBDEs would be expected to improve with the expected shift from water to biota monitoring.

#	**Substance (main uses)**	**Baseline* and proposed change**	**Summary of significant specific impacts**	**Remarks re substitution, SMEs, notable uncertainties**
2	**Anthracene** (Main use as component of coal tar pitch; some use in pure form in pyrotechnics. Produced during combustion, therefore many sources, including metal industry.)	PHS; possible inclusion in REACH Annex XIV; IED, waste legislation; POPs Regulation – could all reduce emissions. Change: MAC-EQS	**Positive:** Improved coherence with chemical policy, i.e. with the outcomes of the risk assessment under Regulation (EC) No 793/93. Greater attention to reducing point source emissions due to more stringent MAC-EQS. **Negative:** No significant negative impacts expected as change is not major.	Emissions (partly natural) cannot be completely eliminated. Local negative impacts on SMEs cannot be discounted but unlikely to be significant given small magnitude of change; no information provided by stakeholders. Uncertainty re authorisation; extent of failure of current MAC.
5	**Poly-BDE** (Main use as flame retardants in polymers and	PHS; POPs (4 congeners); REACH; IED; waste legislation (new limits	**Positive:** Encouragement to MS to monitor in biota instead of monitoring (ineffectively) in water,	Most impacts in baseline. Substitutes exist. As regards SMEs: Possible local impacts on water

	textiles; only deca BDE still authorised, and no longer in electrical/electronic products.)	proposed); possible inclusion of penta and octa BDEs in Rotterdam Convention – could all reduce emissions. Change: EQS, matrix	therefore better information for improved protection (see section 5.2.3.2).. **Negative:** Widespread presence makes it very difficult to reduce further the emissions, discharges and losses. Potential local impacts, including if sediment remediation is needed.	companies and landfill operators. Uncertainties re extent of EQS failure in MS due to inadequate analytical sensitivity; inclusion in Rotterdam Convention; effect of more stringent EQS on decaBDE use (and import).
12	**DEHP** (Main use as plasticiser in polymers, especially PVC, including in construction products and medical equipment.)	PS; included in REACH Annex XIV, sunset 2015 (substitution in baseline); IED; waste legislation – could all reduce emissions[32]. Change: Status	**Positive:** Coherence with REACH; particular consideration under REACH authorisation process of uses affecting aquatic environment. **Negative:** Classification as PHS not likely to have impacts beyond baseline as regards production and use. Widespread presence in existing construction materials makes it difficult to reduce further the discharges, emissions and losses. However, there might be local impacts if measures were taken at MS level.	Most impacts in baseline. Substitutes exist, but incomplete info on environmental and health impacts As regards SMEs: Possible impact on water companies (if required to increase removal rate of DEHP). Uncertainty re outcome of authorisation process under REACH.
20	**Lead** (Main use in batteries, accumulators, shot, ship keels, construction materials etc.)	PS: REACH (Evaluation of Registration dossier); IED; waste legislation – have potential to reduce emissions. Change: EQS	**Positive:** Alignment of EQS with latest science; use of a "bioavailable" EQS and monitoring of bioavailable Lead would provide better data, possibly useful to target remediation. **Negative:** Change to EQS not major (equivalent to a change from 7.2 to 6 µg/l total Lead,), therefore no significant impact expected.	Most impacts in baseline. Uncertainty re extent of failure of EQS in MS in absence of data on DOC. Local impacts, especially in areas with low DOC, cannot be discounted but no information provided by MS or stakeholders and not possible to estimate, though would be minor given small magnitude of change.
22	**Naphthalene** (Main use as chemical intermediate, produced from coal tar pitch. Produced during combustion, therefore many sources, including metal industry.)	PS; REACH (including possible addition of coal tar pitch high temperature to Annex XIV); IED; waste legislation; POPs Regulation – could all reduce emissions. Change: MAC-EQS	**Positive:** Improved coherence with chemical policy. Possibly greater attention to reducing point source emissions due to introduction of MAC-EQS. **Negative:** No important impact expected as change of Annual Average EQS (AA-EQS) is not major and MAC-EQS is two orders of	Emissions (partly natural) cannot be completely eliminated. Local negative impacts on SMEs cannot be discounted but no information provided by stakeholders and not possible to estimate. Uncertainty re authorisation, and re failure of proposed MAC.

[32] Since this impact assessment was drafted, a proposal has also been tabled by Denmark to place restrictions (under Annex XVII of REACH) on the placing on the market and use of certain articles containing DEHP and three other phthalates http://echa.europa.eu/documents/10162/17096/information_note_dk4phthalates_en.pdf

			magnitude higher than AA-EQS.	
23	**Nickel** (Main use in alloys, metal plating, batteries, steel manufacture.)	PS; REACH (Evaluation of Registration dossier); IED; waste legislation – have potential to reduce emissions. Change: EQS	**Positive:** Alignment of EQS with the latest science available. Reduced risk to or via the aquatic environment. Monitoring of bioavailable Nickel would provide better data. **Negative:** Significant tightening of the standard would lead to increased failure of EQS across EU, but variable among MS, driving upgrades in water treatment. (See text for details)	Local impacts possible on industrial SMEs and water companies. Costs to water companies/authorities and industry likely to be passed to consumers, directly or indirectly, within proportionate limits. Assessment uncertain due to lack of monitoring datasets that contain the necessary data for calculation of bioavailability and lack of information on natural background concentrations.
28	**PAHs** (Main use as component of coal tar pitch. Produced during combustion, therefore many sources, including metal industry.)	PHS; REACH (including possible addition of coal tar pitch high temperature to Annex XIV); IED; waste legislation; POPs Regulation - could all reduce emissions. Change: EQS and matrix for 4; MAC-EQS for Benzo(g,h,i)perylene	**Positive:** Improved coherence with chemical policy. Possibly greater attention to reducing point source emissions of some PAHs due to introduction of MAC-EQS. Biota standard would allow better assessment of the extent of the problem and of the effectiveness of measures. **Negative:** Dependent upon whether additional measures needed.	Emissions (partly natural) cannot be completely eliminated. Local negative impacts on SMEs cannot be discounted but no information provided by stakeholders and not possible to estimate. Uncertainty re authorisation of coal tar pitch and extent of failure of proposed EQS and MAC.
	Benzo(a)pyrene			
	Benzo(b)fluoranthene			
	Benzo(k)fluoranthene			
	Indeno(1,2,3-cd)pyrene			
	Benzo(g,h,i)perylene			
15	**Fluoranthene** (Main use as component of coal tar pitch. Not produced or used in pure form. Produced during combustion, therefore many sources, including metal industry.)	PS; REACH (including possible addition of coal tar pitch high temperature to Annex XIV); IED; waste legislation; POPs Regulation – could all reduce emissions. Change: EQS	**Positive:** Improved coherence with chemical policy. Biota standard would allow better assessment of the extent of the problem and of the effectiveness of measures . **Negative:** Shift to biota standard likely to result in a significant increase in failures. Potential local impacts if sediment remediation is needed.	Emissions (partly natural) cannot be completely eliminated. Local negative impacts on SMEs cannot be discounted but no information provided by stakeholders and not possible to estimate. Uncertainty re authorisation of coal tar pitch; extent of failure of current EQS.
33	**Trifluralin** (Use as herbicide no longer authorised.)	PS; Recommended POP; PPP legislation (recently excluded from Annex I of Dir 91/414/EEC) – emissions should be declining. Change: Status	**Positive:** Change of status would ensure coherence with latest scientific information and PPP policy. **Negative:** No significant negative impact expected as non-authorisation is already in the baseline.	Uncertainty re possible need for local remediation and re outcome of POPs negotiations. No negative impacts on SMEs expected, except possibly in the short term for producer in Hungary if production has to stop; POP designation likely in baseline anyway.

* WFD Programmes of Measures relevant in all cases; uncertain impacts. See Annex V for information on other relevant legislation in baseline.

The main positive and negative impacts of this option are summarised in the table in section 5.3.

The setting of a more stringent EQS for Nickel (2 μg/l bioavailable, corresponding to around 5.6 μg/l total dissolved, cf 20 μg/l total dissolved) would be likely to drive local upgrades of industrial and/or urban WWTPs, and better control of industrial discharges into urban sewer systems. The need would have to be assessed at local level, as the impact would depend on local conditions (nickel bioavailability and hence toxicity depends on environmental conditions such as pH, dissolved organic carbon and hardness, dilution of the discharges in the receiving water body, interactions with other discharges in the basin, etc). Application of a biotic ligand model (a tool to determine bioavailability on the basis of the environmental conditions) to available monitoring data shows potential significant failures in some countries: BE (4 to 56% of samples), DE (6 to 52%), IT (18 to 72%), RO (6 to 27%), SI (0.3 to 8%), the range depending upon the effect on bioavailable Nickel concentrations of the combination of environmental conditions . Datasets containing the necessary information to calculate bioavailability show negligible impact in SE, significant in the UK (9 to 26%). Estimates for the UK indicate that approximately 2% of the UWWTPs might need upgrading, requiring whole-life investment of the order of 2 billion € and attendant additional running costs. This is considered to be a worst case as the ambient concentrations of Nickel in the UK are among the highest in the EU. The estimate is based on a $EQS_{bioavailable}$ of 2 μg l^{-1}, and would be lower if an EQS of 4 μg l^{-1} were adopted as proposed by the industry stakeholder. This higher EQS could only be arrived at if it were accepted that the field data provided by the industry removed any uncertainty about the lowest no effect concentration derived in lower-tier studies, a position not agreed upon by the Sub-Group on PS as a whole. The importance of considering bioavailability and natural background concentrations was stressed by MS and stakeholders during consultation. Industry provided estimates suggesting that the number of industry installations that would fail to comply with an EQS of 2 μg l^{-1} would be significantly greater, depending upon the sector, than the number failing to comply with an EQS of 4 μg l^{-1}. For example, in 12 out of 16 sectors, no sites would be compliant at 2 μg l^{-1}, whereas at 4 μg l^{-1} only 3 sectors would be non-compliant at all sites. However, the estimates were not based on a full consideration of bioavailability and appear to represent a worst-case scenario.

Otherwise in this substance option, no significant costs would be expected for EU industry or for MS, as changes compared to the baseline are relatively minor. As in the case of some other substances, the outcome of the REACH authorisation process for DEHP, which is used as a plasticiser, largely in the manufacture of flexible PVC, cannot be predicted. The main industry stakeholder argued that DEHP should not be designated a PHS. However, the listing of DEHP in Annex XIV already implies eventual substitution and phase-out provided suitable alternative substances or technologies are economically and technically viable. This would be consistent with PHS designation and contribute to the WFD objective of phasing out emissions to the aquatic environment. However, as noted in the above table, DEHP is widespread in existing construction materials in situ. A high proportion of its use is indoor, for example in flooring and flexible water pipes, and this is considered to account for a high proportion of the emissions to water. Some outdoor use, for example in roofing materials, also contributes, but the PVC common in window frames, guttering and downpipes is, according to the information available, largely unplasticised (i.e. rigid) and therefore should not contribute. Although the REACH process is likely to achieve complete substitution in the end, meeting the WFD objective within its 20-year timeline could still imply a need to replace existing (in situ) construction materials. However, any such action would be subject to consideration of the costs. Exemptions regarding the 20 year deadline could be applied, as explained above, on the grounds of disproportionate costs or technical non-feasibility. The assessment of early (before end-of-life) replacement costs would need to take into account the

disposal/recycling costs, including those to the environment. The emissions of DEHP to the environment from incineration and landfill have been calculated in the EU Risk Assessment Report to be very low compared with those from use, but the cost of manufacturing replacement materials would also have to be considered. As noted above, guidance on applying exemptions is available[33].

Regarding other existing PS: On Trifluralin, comments were received from the main industry stakeholder questioning whether it should be designated a PHS in the absence of confirmation of POP classification, but it is clearly a PBT. On PAHs, over half of MS drew attention during the review to analytical difficulties with some PAHs because of their low EQS in water; the introduction of a biota EQS should help.

5.2.4. Analysis of impacts of Option A3a: Existing-PS changes plus Annex III substances

As options for substances are cumulative, this option includes all impacts of option A2 plus those described in this section.

The additional monitoring costs (based on unit costs of 1-2.4 million € per substance, see Annex IV) are estimated at 4-9.6 million € per year (i.e. between 5 and 14% of the estimated current costs of monitoring of existing PS in EU 27, see Annex IV).

5.2.4.1. Summary of specific impacts per substance

The table below summarises the specific impacts per substance and section 2.2.3 outlines the main uses and reasons for concern. Other details are provided in Annex V. All the additional substances in this option are proposed as PHS. In all cases, the major positive impact (which would not be in the baseline) would be that WFD monitoring would provide information on the extent of the problem and the effectiveness of the measures taken. This would in turn provide feedback to other policies to inform further decision making, e.g. to improve the efficacy of measures (where necessary), and allow better targeting of sediment remediation.

Substance	Baseline*	Summary of significant specific impacts	Remarks re substitution, SMEs, notable uncertainties
Dicofol	POPs legislation could become relevant. Recently excluded from Annex I of Directive 91/414/EEC; emissions to water likely to fall.	**Positive:** See text above table. Coherence with and feedback to PPP policy. **Negative**: Potential local impacts if sediment remediation needed (more likely in ES, IT and/or FR than other MS).	Most impacts in baseline as authorisation recently withdrawn. Uncertainty re outcome of POPs negotiations, and re extent of failure of EQS in several MS due to inadequate sensitivity of analytical method. No negative impacts on SMEs expected.
PFOS	POPs legislation (Annex B) applies – restrictions on production and use. REACH – restrictions; IED; waste legislation (new limits proposed); will help to reduce emissions to water.	**Positive:** See text above table. Feedback to chemicals and waste policy. **Negative**: Potential local impacts if sediment remediation needed.	Most impacts in baseline. As regards SMEs: Possible local impacts on landfill operators though also likely to be in baseline. Uncertainty re timeline for availability of substitutes in aviation, photography, photolithography (temporary exemptions in baseline), and re extent of failure of EQS in some MS.
Quinoxyfen	Regulation (EC) No 1107/2009 criteria re	**Positive:** See text above table. Feedback to PPP policy. Benefits	Substitutes exist (including improved management practices), though question

[33] European Commission, 2009b

	PBTs could lead to wihdrawal of PPP authorisation in 2014. Sustainable Use of Pesticides Directive could lead to decrease in emissions to water.	for aquatic biodiversity. **Negative**: If authorisation withdrawn there would be substitution costs but not significant according to the available information. Largest impacts expected in MS with highest consumption (DE, ES, FR, IT), and in hops (due to there being fewer alternative products).	raised regarding possible increased risk of resistance development. As regards SMEs: possible impact on PPP formulators and retailers while market adjusts. Possible impact on arable farmers (including possible need to change management practices). Phase-out would rely on non-reauthorisation following scheduled review under PPP legislation, such that most impacts would in fact be in baseline. Uncertainy re outcome of that review, and re: extent of failure of EQS in absence of widespread monitoring to match widespread authorisation; possible decline in use as a result of resistance.
Dioxins and DL-PCBs	POPs legislation applies; IED and waste legislation – could all reduce emissions.	**Positive:** See text above table. Feedback to industrial emissions and waste policies Reduced risk of exceedance of food standard in fish. **Negative**: Potential for costs of cleaner energy to be passed on to consumers, within proportionate limits. Potential local impacts if sediment remediation needed.	Most impacts in baseline. Uncertainties re extent of failure in many MS due to insufficient senstivity of analytical method.

* WFD Programmes of Measures relevant in all cases; uncertain impacts. See Annex V for information on other relevant legislation in baseline.

The main positive and negative impacts of this option are summarised in the table in section 5.3.

In the case of Quinoxyfen, its authorisation for use under Directive 91/414/EEC (i.e. its inclusion in Annex I) expires in 2014 and it will need to be reviewed. The results of the prioritisation process under the WFD will be provided for the review process under the PPP policy, in order to inform future decisions. If the authorisation for using Quinoxyfen as a PPP were not renewed, there would be negative impacts on the producer and on formulators/retailers (although they could be totally or partially compensated by substitutes). There would also be impacts on farmers due to the need to find substitutes, but several are authorised and available, though apparently fewer for hops than for other crops. There is some concern that resistance to another group of fungicides used to prevent powdery mildew could increase (HGCA 2009). However, it should be noted in this context that the WFD allows 20 years for phase-out of emissions to be achieved, compatible with the timescales over which industry could be expected to develop additional products and/or strategies to overcome resistance problems. It should also be noted that alternative management practices in hops can be used effectively to minimise the need for PPP treatment. In view of the new criteria in Regulation (EC) No 1107/2009 regarding PBTs, withdrawal of authorisation, and therefore the impacts indicated here, would be expected to fall within the baseline. Indeed, achievement of the WFD phase-out objective would rely on a decision under the PPP Regulation to refuse reauthorisation, and designation as a PHS under the WFD does not prejudge the outcome of the PPP review. The main industry stakeholder questioned the listing of Quinoxyfen in view of the available monitoring data (see section 5.2.2).

Apart from monitoring costs, no other significant impact of this substance option is expected compared with the baseline.

5.2.5. Analysis of impacts of Option A3b: Existing-PS changes plus Annex III substances plus other new substances excluding pharmaceuticals

As options for substances are cumulative this option includes all impacts of options A2 and A3a plus those described in this section.

The additional (cumulative) monitoring costs (based on unit costs of 1-2.4 million € per substance, see Annex IV) are estimated at 12-28.8 million € per year (between 17 and 41% of the estimated current costs of monitoring of PS in EU 27, see Annex IV).

5.2.5.1. Summary of specific impacts per substance

The table below summarises the specific impacts per substance and section 2.2.3 outlines the main uses and reasons for concern. Other details are provided in Annex V. Of the additional substances in this option, two (HBCDD and heptachlor) are proposed as PHS. As in option A3a, WFD monitoring would provide information on the extent of the problem and the effectiveness of the measures taken. This would in turn provide feedback to other policies to inform further decision making, e.g. to improve the efficacy of measures (where necessary), and, in the case of the two proposed PHS, allow better targeting of sediment remediation. The option includes several PPPs and biocides. Collectively, therefore, the option would contribute to reducing the potential for the drinking water standard for total pesticides to be exceeded.

Substance	**Baseline***	**Summary of significant specific impacts**	**Remarks re substitution, SMEs, notable uncertainties**
Aclonifen	PPP legislation. Recent introduction of compulsory buffer strips under Directive 91/414/EEC, NAPs due under Sustainable Use Directive – could reduce emissions.	**Positive:** See text above table. Feedback to PPP policy. Benefits for aquatic biodiversity from enforciing the EQS. **Negative**: Stricter requirements might be needed locally to meet the EQS.	As regards SMEs: A need to take additional measures would affect arable farmers – but mostly in baseline. Uncertainty regarding extent of EQS exceedance in many MS due to lack of widespread monitoring and changes under PPP legislation.; uncertainty re peak concentrations.
Bifenox	PPP legislation: NAPs due under Sustainable Use Directive - buffer strips and other measures could reduce emissions.	**Positive:** See text above table. Feedback to PPP policy. Benefits for aquatic biodiversity from enforciing the EQS. **Negative**: Stricter requirements might be needed locally to meet the EQS.	As regards SMEs: A need to take additional measures would affect arable farmers – but mostly in baseline. Uncertainty regarding extent of EQS exceedance in many MS due to lack of widespread monitoring and changes under PPP legislation; uncertainty re peak concentrations.

Substance	Baseline*	Summary of significant specific impacts	Remarks re substitution, SMEs, notable uncertainties
Cybutryne	Biocidal Products Directive – under review; outcome could affect authorisation.	**Positive:** See text above table. Feed-back to biocides policy. Stimulation of innovation to find additional alternatives. Employment opportunities if more frequent mechanical cleaning/maintenance. Benefits for aquatic biodiversity from enforciing the EQS. **Negative**: Substitution costs if substitution is needed to meet the EQS. Labour costs if use more frequent mechanical cleaning/maintenance. Increased shipping fuel costs/CO_2 etc emissions if alternatives less effective. Additional costs might be passed on to consumers/passengers. Potential local impacts if sediment remediation is needed.	As regards SMEs: Possible impacts on coating formulators, dockyards, ship owners, fishermen, but low since not PHS. Limited number of available chemical substitutes. Toxicity possibly not much lower, or little studied. Natural biocides being investigated. Non-biocidal fouling release coatings (e.g. silicone-based) have been developed. Mechanical cleaning also possible. Uncertainties re outcome of biocidal products review, possible impact of national bans on use on small boats.
Cypermethrin	PPP legislation: NAPs due under Sustainable Use Directive - buffer strips and other measures could reduce emissions. Biocidal Products Directive – under review; outcome could affect authorisation.	**Positive:** See text above table. Feed-back to PPP and biocides policy. Benefits to biodiversity. Significant potential benefits to fisheries and angling. **Negative**: For its use on crops, stricter requirements might be needed locally as a result of WFD monitoring and the need to meet the EQS. Costs to textile factories of increased effluent treatment and costs of substitution if needed to meet the EQS, but none expected to be significant. Possible impact on use in sea-lice treatment by salmon farmers.	As regards SMEs: A need to take additional measures would affect arable farmers – but mostly in baseline. Salmon farmers could be affected though EQS exist in DKand UK. Alternatives available if needed, e.g. hydrogen peroxide in salmon farming, alternative PPPs in agriculture. Uncertainties re extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method; extent of failure in UK following ban on use in sheep dipping in UK; extent to which used for sheep dipping in other MS; likely trend in use in agriculture and forestry; outcome of biocidal products review.
Dichlorvos	Biocidal Products Directive – under review; outcome could affect authorisation. Recently excluded from Annex I of Directive 91/414/EEC	**Positive:** See text above table. Feedback to biocides policy Benefits for aquatic biodiversity from enforciing the EQS. **Negative**: Possible reduction in range of uses, e.g. to indoor use, but no significant impacts likely unless authorisation withdrawn, in which case in baseline.	As regards SMEs: Possible impacts on product formulators, but likely only as part of baseline. Uncertainties re extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method; and re outcome of biocidal products review.

Substance	Baseline*	Summary of significant specific impacts	Remarks re substitution, SMEs, notable uncertainties
HBCDD	POPs legislation could become relevant. Inclusion in Annex XIV of REACH could affect authorised uses. IED and waste legislation could reduce emissions to water.	**Positive:** See text above table. Feed-back to chemicals and waste policy. Potential improvements for aquaculture/fisheries/angling; potential for improving human health; stimulation of innovation; benefits to producers of alternatives including potential employment; employment in remediation work. **Negative**: Possible loss of employment at single production site in the EU, but likely to be in baseline. Potential local impacts if measures taken at local level to meet EQS or to remediate sediments. Po	Most impacts in baseline, including, e.g. impacts on product manufacturers, construction companies and landfill operators, among them some SMEs, Substitutes being developed, but uncertainties re timeline for availability (none yet for certain types of polystyrene, though in pipeline) and environmental and health impacts. Uncertainties also re designation as POP; possible authorised uses under Annex XIV of REACH; impacts of waste disposal route (incineration cf landfill).
Heptachlor/ heptachlor epoxide	POPs legislation (including ban under Regulation (EC) No 850/2004)) and exclusion from Annex I of Directive 91/414/EEC responsible for reducing emissions.	**Positive:** See text above table. Benefits for aquatic biodiversity from enforciing the EQS by, e.g. additional water treatment or sediment remediation, thence better protection of human health from secondary poisoning. **Negative**: Potential local impacts if additional water treatment or sediment remediation undertaken.	Uncertainty re extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method. No negative impacts on SMEs expected.
Terbutryn	Biocidal Products Directive – under review; outcome could affect authorisation. Excluded from Annex I of Directive 91/414/EEC within past 10 years.	**Positive:** See text above table. Feed back to the biocides policy. Benefits to biodiversity, and to angling. Sustainable Urban Drainage (SUDs) could have shared benefits, e.g. flood control, energy saving. Stimulation of innovation in construction to minimise need for biocidal coatings. **Negative**: Installation and maintenance of SUDs (variable costs depending upon type). Costs of substitutes if needed.	As regards SMEs: Possible impacts on coating formulators, construction industry, but low since not PHS. Limited information on substances that can be substituted on a like-for-like basis. Altenerative building and surface design possible, also mechanical cleaning. Uncertainties re outcome of biocidal products review; extent of failure of EQS now that no longer used as herbicide.

* WFD Programmes of Measures relevant in all cases; uncertain impacts. See Annex V for information on other relevant legislation in baseline.

The main positive and negative impacts of this option are summaried in the table in section 5.3.

The outcome of reviews under other policies could result in the restriction of certain uses for PPPs or biocides, hence triggering substitution costs. However, the data gathered do not allow quantitative assessment of costs. According to the information available, there are substitutes for all the substances, although for some this might be more difficult (in particular for Cybutryne and Terbutryn). Nevertheless, as they are not identified as PHS, listing would not necessarily imply substitution. For Cybutryne, the international nature of shipping and the relevance of the International Maritime Organisation's International Convention on the

Control of Harmful Anti-fouling Systems on Ships[34] might need to be considered if national measures were not sufficient to allow achievement of the EQS. For Cypermethrin, additional management measures might be needed locally in salmon farming to ensure that it could remain in the portfolio of sea-lice treatments, as it still is in Scotland despite a national EQS. It should be possible to manage without substitutes, but they exist for aquaculture (e.g. application of hydrogen peroxide) and agriculture (alternative pyrethroids) if needed, though some costs could arise in relation to vine weevil control in the (unlikely) event that Cypermethrin use could not continue (ADAS, 2010, HGCA 2009). The inclusion of Cypermethrin was questioned by the main industry stakeholder as explained in section 5.2.2.

5.2.6. Analysis of impacts of Option A3c: Existing-PS changes plus Annex III substances plus other new substances including pharmaceuticals

As options for substances are cumulative this option includes all impacts of options A2, A3a and A3b plus those described in this section.

The additional (cumulative) monitoring costs (based on unit costs of 1-2.4 million € per substance, see Annex IV) are estimated at 15-36 million € per year (between 22 and 52% of the estimated current costs of monitoring of PS in EU 27, see Annex IV).

5.2.6.1. Summary of specific impacts per substance

The three additional substances in this option are all pharmaceuticals, although one is also excreted naturally. The table below summarises the specific impacts for these substances and section 2.2.3 outlines the main uses as well as the reasons for concern. Other details are provided in the text below the table and in Annex V. For these substances, as in the other options, a significant benefit of PS status is that WFD monitoring would provide information on the extent of the problem and the effectiveness of any measures taken. This would in turn provide feedback to pharmaceuticals policy. Since pharmaceuticals have not hitherto been regulated under the WFD, their regulation would bring new elements into play, notably public health considerations. The three substances under consideration are different in character (uses, sources, alternatives) and therefore also from a regulatory point of view (see Annex VI).

Substance	**Baseline***	**Summary of significant specific impacts**	**Remarks re substitution, SMEs, notable uncertainties**
17 alpha-ethinylestradiol	Urban Waste Water Treatment Directive (UWWTD). Pharmaceuticals (including pharmacovigilance) legislation. Take-back schemes.	**Positive:** See text above table. Benefits for aquatic biodiversity, especially fish, from meeting the EQS, due to lower endocrine disruptive exposure. Benefits to commercial and recreational fishing. Lower risk of drinking water containing the substance hence potential savings in drinking water treatment. **Negative**: Potential local costs if additional waste water treatment undertaken. (See text below re possible costs.) Possible one-off costs in the longer term for pharmaceutical companies to switch to alternative products,	Substitute (progestogen) exists for contraceptive pill use that exhibits lower impacts on aquatic wildlife and higher removal rates in conventional waste water treatment plants, though not necessarily suited to all patients. Other contraceptive methods also available (though may be less effective). Doctor/patient choice maintained, but could be influenced by information about environmental impact. As regards SMEs: A possible shift in the long term towards substitute(s) (through changed prescription practices) would involve medical practices and pharmacies but would be unlikely to have any significant negative impacts.

[34] http://www.imo.org/about/conventions/listofconventions/pages/international-convention-on-the-control-of-harmful-anti-fouling-systems-on-ships-(afs).aspx

Substance	Baseline*	Summary of significant specific impacts	Remarks re substitution, SMEs, notable uncertainties
		but overall market maintained.	Expansion of take-back schemes could involve some costs but also some benefits for public authorities and waste-handlers. Water companies could face higher costs if additional waste water treatment required, but substitution and take-back expansion should benefit them and drinking water treatment costs can be reduced. Uncertainty regarding variation in EQS exceedance across MS.
17 beta-estradiol (E2)	Urban Waste Water Treatment Directive (UWWTD). Pharmaceuticals (including pharmacovigilance) legislation: Take-back schemes. Nitrates and pesticides legislation related to slurry spreading and buffer strips.	**Positive:** See text above table. Benefits for aquatic biodiversity, especially fish, from meeting the EQS, due to lower endocrine-disruptive exposure. Benefits to commercial and recreational fishing. Lower risk of drinking water containing the substance hence potential savings in drinking water treatment. **Negative**: Potential local costs if additional waste water treatment undertaken and/or livestock farmers need to fence water courses beyond the requirements under other legislation. (See text below re possible costs.)	Substitution of limited relevance. As regards SMEs: Livestcok farmers could face additional costs for fencing water courses. Expansion of take-back schemes (limited relevance for E2) could involve some costs but also some benefits for public authorities and waste-handlers. Water companies could face higher costs if additional waste water treatment required, but source-control measures should reduce the need for this and drinking water treatment costs can be reduced. Uncertainty regarding variation in EQS exceedance across MS.
Diclofenac	Pharmaceuticals (including pharmacovigilance) legislation: Take-back schemes.	**Positive:** See text above table. Benefits for aquatic and other biodiversity from meeting the EQS. Benefits to commercial and recreational fishing. **Negative**: Potential local costs if additional water treatment undertaken. (See text below re possible costs.) Possible one-off costs in the longer term for pharmaceutical companies to switch to alternative products, but overall market maintained.	Substitute NSAIDs exist with similar therapeutic efficacy that are easier to remove in UWWTPs. Doctor/patient choice maintained, but could be influenced by information about environmental impact. As regards SMEs: A possible shift in the long term towards substitute(s) (through changed prescription practices) would involve medical practices and pharmacies but would be unlikely to have any significant negative impacts. Expansion of take-back schemes could involve some costs but also some benefits for public authorities and waste-handlers. Water companies could face higher costs if additional treatment required, but substitution and take-back expansion should benefit them. Uncertainty regarding variation in EQS exceedance across MS.

* WFD Programmes of Measures relevant in all cases; uncertain impacts. See Annex V for additional information on the baseline.

All three have been used for several years as pharmaceutical ingredients, and 17 beta-estradiol (E2) is also naturally excreted by humans and other mammals. The benefits deriving from their pharmaceutical application are reflected in their widespread use. However, they can pose a significant risk to the aquatic environment if their concentration is higher than the proposed environmental quality standard, as is found and has been indicated in section 2.2.3.

Although their addition to the PS list would be aimed principally at gathering monitoring data in the immediate future, this section presents measures that might be used by MS to address the potential environmental risk posed by them. It is not possible to assess the costs and

benefits of such measures in detail, as explained in section 5.2.1.1. However, some cost estimates are presented below.

Although one possible measure would be end-of-pipe treatment (improvement of UWWTPs). source-control measures might be more cost-effective. They could contribute to reducing the need for and cost of end-of-pipe treatment.

As mentioned in section 2.3, a significant source of emissions of pharmaceuticals, despite the existence of take-back schemes, is the disposal of unused products. In the absence of good knowledge regarding the functioning of these schemes, including of their set-up (e.g. whether financing is public, private or mixed), it is difficult to assess the impacts of change. However, the figures cited in section 2.3 suggest that there is room for improvement (as confirmed by the Pharmaceutical Group of the European Union). This could significantly reduce the emissions of Diclofenac and EE2.

Another approach to consider would be the promotion of more environmentally-friendly alternatives. For example, several Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) exist that could be used instead of Diclofenac, with similar therapeutic efficacy[35] but allowing easier removal in conventional UWWTPs (Roig 2010). Information to patients, doctors and pharmacists about the environmental impact of medicines could influence prescription if there were valid alternatives, as is the case for Diclofenac. In Stockholm (SE), an Environmental Classification System was established in 2005 that includes information to doctors, pharmacists and patients, leading to a significant impact on the prescription behaviour of health professionals, although comprehensive information on the success of the scheme is not available (Knappe 2008).

The oral pharmaceutical alternative to EE2-based oral contraceptives is the progestogen-based "mini-pill" which currently has an estimated market share of 8.5%. The efficiency of the contraception is identical (0.3 unintended pregnancies per 100 women). However, the EE2-based pill is not replaceable in all cases by the progestogen-based mini-pill.. Progestogens are also endocrine disrupting substances but the rate of removal in waste water treatment plants is significantly higher than for EE2 (Roig 2010; Chang. *et al*, 2011).

As regards E2, improved take-back schemes would be relevant to its pharmaceutical use, but the main measures would have to focus on reducing emissions due to natural human and livestock excretion which account for 90% of total emissions, e.g. improvements to UWWTPs and protection of water courses from livestock excreta; the former would reduce emissions also from the pharmaceutical uses.

As stated above, source control measures might be more efficient than end-of-pipe treatment. In selecting the most cost-effective measures MS would need to take into account the timing, in particular the fact that the EQS are not to be achieved in the short term, but only 10 years

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[35] To name a few aspirin, naproxen, ketorolac, ketoprofen, meloxicam, celecoxib, mefenamic acid, etoricoxib, indometacin, ibuprofen. See for example information at the National Health Service of England http://www.nhs.uk/Conditions/Anti-inflammatories-non-steroidal/Pages/Introduction.aspx and http://www.nhs.uk/Livewell/Pain/Pages/Whichpainkiller.aspx which presents various alternatives depending on the characteristics of the patient; the Prescription Guide of the Spanish Medicament Agency http://www.imedicinas.com/GPTage/Open.php?Y2ExMHNlMDFzYjAx that indicates that "differences in anti-inflammatory activity of different NSAIDs are small, but there is great variation in tolerance and response of each patient. Approximately 60% of patients respond to any NSAID, and 40% respond to one or another".

from now, and that there are possibilities for exemptions to extend the deadline on grounds of disproportionate cost or technical non-feasibility. As noted above, guidance on applying exemptions is available[36].

It is however not possible to estimate how much end-of-pipe treatment would be needed across the EU. This is very much dependent on local conditions. Nevertheless, some cost estimates for upgrading UWWTPs to remove E2 are available; they assume that no source-control measures are taken and in that respect represent worst-case scenarios.

- For England and Wales (UK), an estimate of 18 € per inhabitant per year was derived[37]. based on a modelling exercise using an EQS stricter than the one proposed (2.7 10^{-4} µg/l instead of 4.0 10^{-4} µg/l).
- For Switzerland, an increase of 5 to 25% in relation to conventional treatment costs depending upon the size of the plant has been estimated, resulting overall in 11-18 € per inhabitant per year depending on the number of plants to be upgraded (Abegglen *et al*, 2009).

These costs would fall on water companies (sometimes SMEs) but would likely be passed to consumers in full or in part in higher water bills, within proportionate limits. The increased treatment would result in a significant increase in energy use due to the increased treatment (equivalent to 1 million tons of CO_2 in England and Wales, an increase of 20% in relation to the current energy consumption in UWWTPs). On the other hand, the technologies used for the enhanced treatment would also eliminate many other pollutants and thus improve the quality of the discharge significantly, making it easier to treat water downstream for the production of drinking water and therefore implying potential savings. Additional benefits are discussed in section 5.2.1.1.

The cost of fencing to avoid livestock access to water courses is estimated at between 2 and 12 €/ha/year (quoted in Entec 2011); it is not possible to estimate how much fencing would be required in total. The costs could fall largely on livestock farmers (generally SMEs) but be attributed in part to requirements under other legislation such as the Nitrates Directive.

As mentioned above, not only the costs but also the benefits of applying measures (as noted in the table) are difficult to quantify. However, on the basis of the evidence for concern noted in section 2.2.3 and the generic benefits presented in section 5.2.1.1 including the value of a resilient aquatic ecosystem, significant benefits from meeting the EQS would be expected.

Uncertainties in the assessment of benefits and costs arise not only from uncertainties in the extent of exceedance of the EQS in different MS given the limited monitoring coverage and often inadequate analytical sensitivity, but also from the absence of information on production of the substances in the EU, and from the limited experience of reducing the environmental impact of pharmaceuticals in use. These uncertainties suggest that until further monitoring data have been gathered to inform the policy making, it would not be appropriate to propose measures at EU level; measures to influence prescription could in fact only be taken at MS level since there are currently no mechanisms in the EU legislation to do this. However, the evidence of pollution is considered sufficient to include E2, EE2 and Diclofenac in the list of

[36] European Commission, 2009b

[37] See Entec 2011, report for E2, Appendix B. Per capita cost calculated on the basis of average annual costs and 54 million inhabitants in England and Wales.

PS and to establish an EQS at EU level. In addition to reviewing the monitoring data, the Commission will explore in its study on the environmental impact of pharmaceuticals the need to provide mechanisms to address the issue at EU level.

During the consultation process the pharmaceutical industry expressed clearly its opposition to the inclusion of any pharmaceutical on the list of WFD priority substances, favouring a more holistic approach towards regulating the environmental impact of pharmaceutical products. On the other hand, the environmental NGOs favoured inclusion. No other stakeholder indicated a clear preference for one or another substance option, although comments were made regarding some individual substances, as reported above. The fact that all the substances reached this stage of the review reflected the existence of concern about them.

5.3. Comparison of the substance options

In the following table the options A1 to A3 are compared.

Effectiveness is compared on the basis of the objectives set out in section 3.The diversity of impacts covered by the different options does not allow an overall assessment of efficiency. As an alternative, the main positive and negative impacts of the options are presented in the table. The cost of monitoring the existing PS is estimated at 69m € per year (see Annex IV).

Option	**Effectiveness**	**Main positive impacts**	**Main negative impacts**
A1: No change	0		
A2: Existing PS	+ Improved knowledge of the extent of the risks from existing PS (through the setting of biota standards for poly-BDE, PAH and Fluoranthene). No improved knowledge of the risks posed by newly identified substances. Latest scientific information on the risks posed by additional substances not considered. Failure to optimise protection against identified risks from new substances not included in the PS list.	Better and more robust knowledge of the extent of the risks, coherence of the existing EQSs with the latest scientific and technical progress developed in the context of the chemicals policy, which would allow MS and other policies to take the necessary measures to reduce the risks caused by these substances to or via the aquatic environment. Improved protection of human health and aquatic biodiversity.	Potential significant costs to upgrade some industrial and UWWTPs (for Nickel), depending on local conditions. Costs would fall initially on water authorities/companies and industries but likely be passed to consumers, within proportionate limits.

Option	Effectiveness	Main positive impacts	Main negative impacts
A3a: Existing PS plus Annex III substances	++ Improved knowledge of the extent of the risks from existing PS (through the setting of biota standards for poly-BDE, PAH and Fluoranthene) Very limited improvement in knowledge of the risks posed by newly identified substances. Latest scientific information on the risks posed by several additional substances not considered. Failure to optimise protection against identified risks from several substances not included in the PS list.	As above plus: Information about the presence of and extent of the risk caused by the additional substances and about the effectiveness of largely baseline measures at reducing or phasing out emissions. Valuable data and information for decision making on targeted remediation and in the context of the PPP, chemicals, industrial emissions and waste policy. Additional protection of human health and aquatic biodiversity.	As above plus: Estimated additional monitoring costs of 4 – 9.6m € per year, which would fall on MS. Possible substitution costs for Quinoxyfen if not in baseline; could fall on the producers, formulators, farmers and/or consumers depending upon the substitute.
A3b: Existing PS plus Annex III plus other new excluding pharmaceuticals	+++ Improved knowledge of the extent of the risks from existing PS (through the setting of biota standards for poly-BDE, PAH and Fluoranthene) Significant improvement in knowledge of the risks posed by newly identified substances. Latest scientific information on the risks posed by pharmaceuticals not considered. No protection provided for identified risks from pharmaceuticals.	As above plus: Valuable data and information for decision making in the context of the biocides policy Additional protection of human health and aquatic biodiversity.	As above but: Estimated additional monitoring costs of 12 – 28.8m € per year, which would fall on MS; plus Possible costs to producers/formulators/consumers of substitutiing Cybutryne and Terbutryn (though not PHS); possible reduction in portfolio of treatment options for sea-lice in salmon farming if Cypermethrin could no longer be used for that purpose.
A3c: Existing PS plus Annex III plus other new including pharmaceuticals	++++ Improved knowledge of the extent of the risks from existing PS (through the setting of biota standards for poly-BDE, PAH and Fluoranthene) Very significant improvement in knowledge of the risks posed by newly identified substances. Latest scientific information on the risks fully considered. Protection optimised against identified risks from all the prioritised substances.	As above plus: Improved information on the extent of pollution by pharmaceuticlas, and EU-wide EQS as benchmarks for deciding measures at MS level. Additional protection of human health and aquatic biodiversity.	As above but: Estimated additional monitoring costs of 15 – 36m € per year, which would fall on MS; plus: Possible costs of additional UWWTP upgrades to remove E2 if locally required and not sufficient in option A2. Costs would fall initially on water authorities/companies but likely be passed to consumers, within proportionate limits. Costs for livestock fencing could fall on farmers.

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0) + means positive (number of + indicates magnitude)

No disproportionate costs have been identified at EU level, and option A3c achieves the objectives to the greatest extent as it contains the complete outcomes of the prioritisation process. Option A3c is therefore the preferred option.

If MS found that disproportioante costs would be incurred locally, the exemptions under the WFD could be used for particular water bodies if the conditions set out in the WFD were fulfilled, as explained in section 5.2.1.2. According to the available information, though, it is unlikely that such disproportionate costs would arise at many locations, except in the case of ubiquitous PBTs. MS would inevitably consider the implications for newly identified PS of their existing Programmes of Measures before considering the need for further measures. Some of them might already have been included as RBSPs or be affected by measures for other substances.

Option A3c ensures gathering of data to inform measures locally and possibly at EU level for all the prioritised substances. If the available information were not sufficient to decide on the need for measures at the time of adopting the Programmes of Measures , MS would be expected to identify, in their Programmes, the monitoring required to inform this decision, as well as the monitoring required to judge the effectiveness of any measures.The estimated monitoring costs are calculated linearly on the basis of a unit cost per substance (see Annex IV). This approach, which has the merit of simplicity, overestimates the costs for the options with the largest number of substances. These will have a better cost ratio per substance since sampling costs increase less steeply as the number of substances increases. Further, should upgrades to UWWTPs be required, or sediment remediation be undertaken, the costs per substance would decrease, i.e. they should not be multiplied by the number of substances. The benefits would extend beyond the targeted substances.

5.4. Analysis of impacts of options in relation to the ubiquitous PBTs

In the consultation phase, the identification of options to address the problems relating to ubiquitous PBTs was welcomed particularly by MS, but also by stakeholders.

5.4.1. Analysis of impacts of Option B2a on presentation: Give more flexibility on presentation

This is a relatively simple option that allows MS to adapt the presentation of the chemical status in the RBMP, separating ubiquitous PBTs and the rest of the substances. No significant costs are identified for this option. Some small costs might be involved in the production of different maps for the plans, but these are not considered significant. As regards potential negative impacts, as this option would not oblige MS to present PBTs separately, some discrepancy in presentation of the results between MS might occur.

In terms of benefits, the flexibility in the presentation would still maintain legal certainty as the definition of chemical status would not change. There would also be some administrative savings as MS would not need to justify in the RBMP the situation as regards ubiquitous PBTs, but would use the rationale provided in the EU legislation to present separately the information on these substances. It should be recalled that the RBMP are subject to compulsory public consultation.

5.4.2. Analysis of impacts of Option B2b on presentation: Take ubiquitous PBTs out of chemical status

This would represent a major change in the WFD and EQSD. It would reduce the level of environmental protection because there would be no EU EQS and no driver for taking measures.

The first implementation cycle of the WFD has not yet ended . Changing the goal posts before the 2015 deadline for achieving the objectives would create legal uncertainty. This option is also not fully consistent with the general objectives of the WFD to establish a high level of protection for the aquatic environment, as it would exempt some of the most dangerous substances from key obligations of the Directive. However, it would be a very straightforward way of addressing the problem of presentation.

The environmental NGOs expressed concern about both options B2a and B2b effectively because they considered that less attention would be given to the problem of ubiquitous PBTs. Most MS favoured option B2a.

5.4.3. Analysis of impacts of Option B3a on choice of matrix: Leave flexibility but link the choice to requirements of Directive 2009/90/EC

The main driver for the choice of the matrix should be the intrinsic properties of the substance and its environmental fate, together with the possibilities to effectively monitor the environmental concentrations to manage risks. However, flexibility in the choice of matrix is highly appreciated by MS. and factors such as tradition and experience in the MS, the expertise in the national laboratories and the maintenance of long time series of monitoring data could play a role. For example IT has a long tradition of monitoring sediments in coastal and transitional waters. Independently of the discussion about the appropriateness of setting standards at EU level for sediment and biota, some MS consider that water standards are useful in any case for the purpose of setting emission limits in the permits for waste water discharges, even when far below the sensitivity of state-of-the-art analytical techniques. Where it is possible to monitor reliably in any of the matrices, leaving MS the choice of the matrix allows them to take advantage of their experience and expertise.

This option, while also providing flexibility to adapt monitoring strategies quickly to progress in analytical techniques would at the same time lead to improved harmonisation of the assessment of chemical status. Adaptation costs might be faced by MS without experience in monitoring and analysing specific substances in certain matrices.

This option might introduce lack of legal clarity if there are no standard international analytical methods for certain substances, with internationally accepted analytical sensitivities. If this is the case, it will not be straightforward to assess which available method performs better and it could depend on the laboratory.

5.4.4. Analysis of impacts of Option B3b on choice of matrix: Fix the preferred matrix for each substance

A preferred matrix could be selected for each substance on the basis of the intrinsic properties and environmental fate and taking into account the performance of the best available monitoring technique. This would ensure a high level of harmonisation of the assessment of chemical status.

On the other hand, for some substances the preferred matrix is not clear cut and may depend on the local environment and nature of the emissions.

Adaptation costs might be faced by some MS without experience in monitoring and analysing specific substances in certain matrices. There would be no possibility to adapt quickly to

progress in analytical techniques that could improve the sensitivity in certain matrices. This could hinder progress in the development of analytical techniques for these other matrices.

One of the advantages of this option is the legal clarity it would provide, as the matrix would be fixed at EU level.

As implied above, more MS favoured maintaining some flexibility in the choice of matrix, although some favoured fixing the matrix in order to ensure comparability of results.

5.4.5. Analysis of impacts of Option B4a on monitoring: Introduce reduced monitoring obligations for ubiquitous PBTs if certain specified conditions are met

Costs could be saved because of reduced monitoring effort and reduced administrative burden for MS; the justification for the reduced effort would be in the EU legislation. The option could cover up to 8 ubiquitous PBTs (the 4 existing PS and 4 proposed), but the estimates in this section only cover the 4 existing (see section 5.7.1 for interactions between options).

It is estimated that the reduction in monitoring effort could save between 20 and 30% of the monitoring costs. This is a conservative estimate, since the default frequency in water is monthly (WFD Annex V) and in sediment and biota it is annually (EQSD Article 3.2c). The potential reduction in frequency of analysis for the water matrix is estimated to be from 12 samples per annum to 1 or 2 and for biota from 1 per annum to 1 every two or three years. This would give potential reductions of between 50% and 90%. In addition there could be additional savings by reducing the number of monitoring points to take into account the ubiquitous nature of the substances. However, taking into account the uncertainty as regards the availability of a robust monitoring baseline in all MS, the potential savings are reduced to an estimate of 20-30%. These savings are considered achievable in the short term.

If monitoring costs were reduced for all existing 4 ubiquitous PBTs in the 20-30% range, 0.8 to 2.9 million € per annum could be saved across the EU (between 1 and 4% of the overall estimated current costs of monitoring of PS).

The reduced administrative burden arising from not having to justify reduced monitoring effort for each of the substances is estimated at several man-days of work per RBMP. There are 176 RBDs. However, some countries have a strong national approach to implementating the WFD and would probably reuse the administrative effort for all or several of their RBDs (e.g. UK, IE, AT, PL, PT, NL). If this were taken into account, justification would be derived first hand for only about 120 RBDs. If applied to all 4 existing ubiquitous PBTs, the savings would amount to 1000 to 2500 man-days across the EU per RBMP cycle.

5.4.6. Analysis of impacts of Option B4b on monitoring: Introduce reduced monitoring obligations for ubiquitous PBTs (unconditional)

In the long term, the reductions in monitoring costs and administrative burden would likely be the same as those under option B4a. However, the absence of a requirement for a robust baseline could reduce the monitoring costs still further in the short term. At the same time, it would mean that certain undesirable trends or hotspots could be overlooked. Although the ubiquitous nature of the pollution from these substances means that differences between MS are likely not to be significant overall, local differences for some substances could be large (e.g. in water bodies that were/are subject to direct emissions compared with water bodies that are impacted by atmospheric deposition).

MS were generally in favour of reducing the monitoring obligation for ubiquitous PBTs. The few MS who expressed a preference for one or other option were approximately equal in number.

5.5. Comparison of options in relation to the ubiquitous PBTs

In the following table, options B1, B2a and B2b, options B1, B3a and B3b, and options B1, B4a and B4b are compared in their respective sets with regard to their effectiveness, efficiency and consistency, taking account of the objectives in section 3 and the existing legislation.

Option	**Effectiveness**	**Efficiency**	**Consistency**	**Overall mark**
B1: No change	0	0	0	0
Options on presentation				
B2a: More flexibility on presentation	++ Avoids presentational issue although formally chemical status would still be affected by the ubiquitous PBTs.	++ Efficient as no major costs involved and reduced administrative burden for MS.	+ Retains coherence with the objectives of the WFD, providing more flexibility in terms of presentation of information on status.	+++++
B2b: Take ubiquitous PBTs out of chemical status	+ Avoids presentational issue completely but undermines the objective of reducing the risks posed by certain substances.	++ Efficient as no major costs involved and reduced administrative burden for MS.	-- Incoherent with the overall objectives of the WFD and of chemicals policy.	+
Options on monitoring matrix				
B3a: Leave flexibility but link the choice of matrix with requirements of Directive 2009/90/EC	++ Strong driver for using the most appropriate matrix. Contributes to improved knowledge of the risks of substances and effectiveness of measures. Possible to take into account local situation. Possible lack of legal certainty if no international analytical standards.	+ Retention of some flexibility would allow MS to adapt to local circumstances and tradition/experience. Moderate adaptation costs for some MS.	+ Reinforces the role of Directive 2009/90/EC. Contributes to improved assessment of effectiveness of measures taken by other policies.	++++
B3b: Fix the preferred matrix for each substance	++ Strong driver for using the most appropriate matrix. Contributes to improved knowledge of the risks of substances and effectiveness of measures. Difficult choice in some cases. Not possible to take into account local situations. Legal certainty.	- Higher adaptation costs for MS that have no tradition/experience to monitor in biota.	≈ Less flexible to adapt to scientific and technical progress in analytical techniques. Could hinder progress in analytical techniques for other matrices.	+
Options on reduced monitoring				

Option	Effectiveness	Efficiency	Consistency	Overall mark
B4a: Reduced monitoring obligations if certain specified conditions are met	+ Reduces administrative burden and monitoring costs for MS.	+ Ensures that a robust monitoring baseline is available, hence contributing to good knowledge of the risks to or via the aquatic environment of ubiquitous PBTs.	≈	++
B4b: Reduced monitoring obligations (unconditional)	+ Reduces administrative burden and monitoring costs for MS.	≈ Does not guarantee a robust monitoring baseline in all MS, therefore not ensuring a good knowledge of the risks to or via the aquatic environment of ubiquitous PBTs.	≈	+

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): ++ strongly positive; + positive; – – strongly negative; – negative; ≈ marginal/neutral

Therefore the preferred options are B2a, B3a and B4a.

5.6. Analysis of impacts of options to improve the knowledge base

5.6.1. Analysis of impacts of Option C2: Establish a watch list without legal obligation.

Monitoring costs would be the most important costs associated with this option: estimated at 2 to 4 million € per year for the EU (between 3 and 6% of the overall estimated current costs of monitoring of PS, see Annex IV). These cost estimates were considered reasonable by MS and the JRC.

There would be some administrative costs to develop the technical specifications for monitoring. These would arise from the need to hold meetings of MS and stakeholder experts (estimated 3 per year with 40 participants) and additional work of an average of 10 working days per substance. This would result in additional administrative costs of 0.2 million € per year. These figures are based on the experience of the Chemical Monitoring and Emerging Pollutants (CMEP) sub-group. In fact, the costs attributable to the option would be lower as the CMEP group would meet anyway to deliver on the CIS work programme.

The lack of a legal obligation would produce uncertainties in the outcome due to pressures on MS to prioritise legal obligations in their budgets. This is evidenced by the fact that the rate of reporting to the EEA of new voluntary data streams is low, e.g. emissions to water, only 6 MS reporting fully according to specifications, 10 MS have not reported at all.

Further, participating MS would unfairly carry the costs, and due to non-participants it might not be possible to draw an EU picture and therefore the usefulness of the expenditure would decline significantly.

5.6.2. Analysis of impacts of Option C3: Establish a watch list with legal obligation

The costs of this option would be similar to those for option C2. However, there would be some additional costs for comitology and administration within the Commission.

The legal obligation would make the outcome more certain to meet the objectives, i.e. to provide EU-wide datasets, and ensure fairer sharing of the costs among MS.

Both MS and stakeholders supported the idea of the watch list, a few indicating their preference as regards the formal status (2 for legal obligation, 3 for voluntary approach, 5 no position).

5.7. Comparison of the options to improve the knowledge base

Option	Effectiveness	Efficiency	Overall mark
C1: No change	0	0	0
C2: Establish a watch list without legal obligation	+ Increased knowledge but likely to suffer important data gaps (incomplete coverage of MS) and lack of adherence to technical specifications due to the voluntary character.	+ Value for money (i.e. return on MS administrative - including monitoring - costs) limited by the likelihood of data gaps.	++
C3: Establish a watch list with legal obligation	++ Increased knowledge and likely to cover all or most of the EU countries in a harmonised way (i.e. following the technical specifications)	++ Very high efficiency (i.e. return on MS adminstrative – including monitoring - costs) as the watch list would provide targeted high-quality EU datasets that would be fit for purpose for PS prioritisation.	++++

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): ++ strongly positive; + positive; overall mark is sum of individual magnitudes.

Therefore the preferred option is C3.

5.8. Cumulative impacts, interactions across the various options and significant distributional effects

5.8.1. Interactions and cumulative impacts

There are a number of links between the various options.

- As regards the substances:
  - Options including new substances imply a net increase in monitoring costs (for public authorities) of 4-9.6 million € per year for option A3a, 12-28.8 million € for option A3b and 15-36 million € for option A3c. Although the same unit costs have been used for all options, it is likely that the options with a larger number of substances would benefit from smaller unit costs per substance, as costs such as sampling increase less steeply as the number of substances increases.
  - There are two substances for which end-of-pipe measures (in particular advanced treatment of urban waste water) have been identified as potentially effective and possibly requiring local implementation (Nickel and E2). Since there would likely be an overlap between the locations (with high population density) requiring upgrade of UWWTPs under option A2 (for Nickel) and under option A3c (for E2), the costs would not be additive. If these measures were implemented for Nickel and E2 they would also have a positive impact on reducing the emissions of other pollutants

covered in this impact assessment (e.g. Lead, DEHP, BDEs, HBCDD), other existing PS (Mercury, Cadmium, Nonylphenol, etc) and many other pollutants, representing good value for the investment by public authorities or private companies (and indirectly the consumers).

- As regards options for substances and ubiquitous PBTs:
  - The establishment of biota standards for the ubiquitous PBTs among the existing PS (those identified in option A2 but included in all the substance options), and the change from water to biota monitoring that options B3a or b would imply for those substances would result in higher rates of failure of EQSs. This would however provide a more accurate picture of the risks posed by those substances and of the effectiveness of measures taken, and would allow MS to take better-informed decisions on the need to undertake remediation at contaminated sites.
  - The extent to which the options addressing presentational aspects of ubiquitous PBTs would have an impact would depend upon the choice of substance option; the impact would be greater, the more cumulative the substance option, since it would relate not only to stricter EQS for existing substances but also additional ubiquitous PBTs.
  - If the ubiquitous PBTs were taken out of the chemical status assessment (option B2b), the general objective of reducing the risks posed by substances would be affected, as the WFD would not constitute a driver for improvement anymore.
  - If any of the substance options A3 were selected, the option B4 on reduced monitoring efforts would provide cost savings for the 2 to 4 additional new ubiquitous PBTs (2 substances in option A3a and 4 in options A3b or A3c). The savings would be realised immediately in the case of option B4b or in the longer term in case of B4a, as for the latter a monitoring baseline would need to be established. The potential cost savings are estimated to be in the range of those calculated for the existing 4 ubiquitous PBTs (0.8 to 2.9 million € per annum across the EU).
- As regards options for ubiquitous PBTs and for improving the knowledge base:
  - New monitoring costs due to the watch list (2-4 million € per year) would likely be (at least partly, possibly totally in the long term) compensated by the estimated reductions in the monitoring costs for ubiquitous PBTs (0.8 to 2.9 million € per year in the short term, additional similar amount in the long term). The value for money, though, would be significantly greater for the watch list.
- As regards the sub-options for ubiquitous PBTs: Although the sub-options on presentation, monitoring matrix and frequency are independent,
  - providing flexibility in presentation or taking ubiquitous PBTs out of the chemical status assessment could make it easier for MS to accept a shift towards more biota monitoring (whichever monitoring option applied); conversely, greater harmonisation of the monitoring matrix would be likely to lead to more comparable approaches to presentation under the flexible presentation option.
  - taking the ubiquitous PBTs out of the chemical status assessment would already reduce the monitoring obligation to that required for trend monitoring. Therefore the additional impact of adopting one of the options on reduced monitoring frequency would be lower than if the ubiquitous PBTs had not been taken out of chemical status.
  - fixing monitoring in the biota matrix would already reduce the monitoring frequency if MS were previously monitoring in water. Therefore the additional impact of adopting one of the options on reduced monitoring frequency would be lower than if the matrix had not been fixed in biota.

5.8.2. Cumulative impacts of the package of preferred options

Taking account of the interactions outlined above and the information summarised in sections 5.3, 5.5 and 5.7, the preferred options (all substances - A3c; flexible presentation for ubiquitous PBTs – B2a; choice of matrix linked to analytical sensitivity – B3a; conditional reduced monitoring for ubiquitous PBTs – B4a; and a watch list with legal obligation – C3) would be likely to have the following main benefits:

- all the latest scientific information reviewed would be taken into account;
- MS would be encouraged to monitor in biota when most appropriate;
- a more accurate picture would be obtained of pollution by ubiquitous PBTs;
- there would be a significant improvement in knowledge of the risks posed by all 15 of the prioritised substances and the ubiquitous PBTs among the existing PS, and of the effectiveness of measures for these substances, allowing introduction/improvement of measures at EU and MS level, better targeting of sediment remediation, and optimisation of protection from identified risks - thus leading to benefits to biodiversity and human health;
- measures applied to reduce the risks from some substances (e.g. Nickel) would be seen to reduce the risks from others (e.g. E2) as well;
- the harmonisation of EQS for more substances would provide a more level playing field for businesses in different MS;
- the administrative burden associated with explaining the failure of the chemical status objective as a result of ubiquitous PBTs would be reduced, and the public would receive clearer information; and
- savings of approx 0.8-2.9 m € per annum on monitoring ubiquitous PBTs would be expected, which could be invested in improving the information base for future prioritisation exercises, i.e. the watch list;

and the following main costs:

- estimated additional monitoring costs, to public authorities, of 15 – 36m € per year for the whole of the EU;
- costs to public authorities and private companies, likely passed to consumers, of additional UWWT to remove Nickel and E2, costs to industry to reduce point source industrial emissions of Nickel, and costs to livestock farmers to install fencing to keep animals away from water courses to reduce E2 emissions to water, although some of those costs could fall under other legislation and would be within proportionate limits; estimates for the UK (which has among the highest Nickel concentrations in the EU) are: whole-life costs of the order of 2 billion € to meet a 2 μg l^{-1} $EQS_{bioavailable}$ for Nickel by upgrading 2% of UWWTPs (fewer if EQS at 4 μg l^{-1}), and less than 19 billion € (upgrade of fewer than 9% of UWWTPs, 20-year lifetime cost which is in net present value) to meet a 4 10^{-4} μg l^{-1} EQS for E2, plus attendant running costs (noting that the costs for Nickel and E2 would not be fully additive);; the cost of fencing to avoid livestock access to water courses is estimated at between 2 and 12 €/ha/year (it is not possible to estimate how much fencing would be required in total, and at least some of the costs would fall under other legislation);
- the possible costs, unkown but not likely to be significant, of substituting Quinoxyfen, if authorisation not anyway withdrawn under the PPP legislation; these could fall on the producers, formulators, farmers and/or consumers depending upon the substitute;
- approx 2-4 m € per annum to operate the watch-list.

Overall, the preferred options would achieve the most objectives with the greatest efficiency while ensuring coherence with the existing legislation.

5.8.3. Distributional effects of the package of preferred options

The most significant distributional effects of the preferred options can be summarised as follows. However, it should be remembered that there is uncertainty about how many effects would be in the baseline. Generic environmental and health benefits are not referred to here. Most of the distributional effects relate to the preferred substance option (A3c) rather than the options addressing the other general objectives, although some relating to the latter are noted in the final bullet.

- Sector-specific
  - Since several agricultural PPPs are included in the preferred option, effects on PPP producers and formulators, and on farmers, could be higher than in many other sectors, although many of the effects would be in the baseline anyway because of introduction of new requirements under the Sustainable Use of Pesticides Directive. Effects relating to the producer of Trifluralin (in HU, for export) and to the producer, formulators and users of Quinoxyfen could be the most significant. Farmers could also bear costs associated with fencing watercourses to reduce E2 emissions (see above). On the other hand, farmers could benefit from improved ecosystem services.
  - The preferred substance option would involve including pharmaceuticals in the PS list for the first time, but none of the three pharmaceuticals is proposed as a PHS and no measures are proposed at EU level. Nevertheless, there could be an impact on the pharmaceutical sector in the long term if measures at MS level were taken to influence prescription and promote pharmaceutical alternatives with lesser environmental impact.
  - The commercial fisheries and aquaculture sectors could be affected positively by improved water quality and fish health. The introduction of an EQS for Cypermethrin could require some salmon farmers to use alternative management methods to apply the substance or substitutes. The introduction of an EQS for Cybutryne could lead to changes in maintenance practices for ship owners.
  - The commercial leisure sector (angling, boating) could be similarly affected.
  - The water sector (public and/or private) would be affected by any of the substance options because of the possible need to upgrade some UWWTPs to meet the EQS for substances discharged via this route, in particular E2 and Nickel. Other substances would be impacted, e.g. DEHP, HBCDD.
  - The waste sector would likely have to address end-of-life aspects of some products containing the proposed PS, e.g. HBCDD, and there might be implications (in relation to other substances too, e.g. PFOS, BDEs) for the handling of landfill leachate.
  - There could be indirect impacts on the construction sector from the requirement to meet an EQS for Terbutryn (although relevant measures are unlikely) and to phase out emissions of HBCDD to the aquatic environment.
  - Impacts in a number of other industry sectors would be expected to be already in the baseline: e.g. energy generation and metal production (in relation to stricter EQS for PAHs in particular), transport (in relation to the need to find a substitute for PFOS in aviation), textiles/polymers (in relation to BDEs, DEHP and HBCDD). However, measures to meet the stricter EQS for Nickel could involve the relevant industry sectors (e.g. alloys, metal plating, batteries, pigments, other chemicals, stainless steel production, mining).

- Impacts in the public sector would most obviously relate to monitoring costs, but some public sector investment might be involved also in infrastructure, in particular the upgrading of UWWTPs where these are in public ownership (see above), possibly also in the context of landfill-site management. Sustainable Urban Drainage systems (SUDS) targeting urban run-off might also receive public investment but would also have other benefits (flood risk management). Although there might need to be some public investment in awareness-raising relevant to pharmaceuticals prescription and disposal, spending on health care might be reduced in the longer term.
- Impacts on the public at large would likely include the passing on of any additional water treatment costs (urban and industrial waste water) or costs of cleaner energy, and the additional direct or indirect costs of substitutes, if needed. They could also include encouragement to change behaviour, e.g. in relation to the disposal of unused pharmaceuticals. Significant impacts on employment in industry would not be expected (see producer section below). Some employment opportunities might arise in sediment remediation and mechanical cleaning as a substitute for biocidal coatings.

- Producer and user-specific:
  - The overall impacts on producers are difficult to assess, because, despite extensive consultation, it has not been possible in many cases to determine who they are (therefore the size and resilience/capacity for diversification of the enterprise, although most of those identified are large) or where production is located, even whether it occurs within the EU. The production of some substances (Dichlorvos, Heptachlor, PFOS) no longer occurs in the EU. Dichlorvos and PFOS are manufactured in India and China, respectively and imported. There could be impacts on a producer (Israel-based) of HBCDD in NL which employs approximately 90 workers in the production of brominated compounds, and a producer of Trifluralin (for export) in HU. It is not clear whether Dicofol is still produced in IT, nor whether the production of Quinoxyfen by a large US-based company occurs in the EU. Cybutryne may be produced in CH by a large DE-based company; Terbutryn production occurs in part outside the EU. It should be remembered that most substitution costs, including those relating to employment, would be in the baseline.
  - There could be impacts on formulators of some PPPs and biocides, including the formulators of biocidal coatings, since there are EU formulators for most of these substances and they are not necessarily restricted to the MS where the substances are used. However, other (existing and/or new) products would be likely to take the place of substances whose use had to decrease or cease, and these could in theory be handled by the same formulators.
  - Impacts on the users of the products/formulations could occur as described for the sectors in the first main bullet.

- MS- and region-specific
  - The possible geographical impacts on producers and formulators are covered under the previous point. An additional observation is that trade (import, export) with third countries is unlikely to be affected significantly beyond the baseline for most substances. This is because, of the substances known to be relevant, i.e. proposed PHS that are currently imported into the EU or manufactured in the EU for export, most (DEHP, Dicofol, HBCDD, Heptachlor, PFOS, Trifluralin) are already and/or are expected to be further restricted under the baseline. An exception could be Quinoxyfen, depending upon where it is manufactured (information not available).

- Regulation of the PPPs would most likely affect all MS, but to different extents influenced by factors including crop type and value, production area, and production intensity. The MS with the largest use of agricultural PPPs are FR, IT, ES, DE, UK, PT; those with the most intense use are BE and NL (EC, 2006), and this list could be indicative of the MS that would likely be among the most affected by the preferred substance option, which includes several PPPs. Indeed, FR is noted to have the largest consumption of two of the PPPs, i.e. Aclonifen and Bifenox, and is also among the highest users of Quinoxyfen and Cypermethrin. As indicated above, formulators of PPPs are not necessarily restricted to the MS where they are used or authorised. The data obtained did not allow the degree of correlation to be determined. However, for the above four PPPs, the information obtained showed that the number of products containing these substances was higher in FR than in other MS, and since all four substances are in the preferred package, FR could be more affected than some other MS. The picture is less clear for many of the MS partly because, despite the widespread authorisation of these substances, few MS provided monitoring data, and the prioritisation of two of the substances was based primarily on modelling (taking account of use). Even in MS like FR, the effects would be limited, however, since only one substance is proposed as a PHS, most of the costs (e.g. of implementing buffer strips) are likely to be in the baseline, and larger farming and PPP (formulation and use) sectors are likely to be able to handle any need to decrease or cease emissions.
- In relation to the inclusion of pharmaceuticals, the effects on authorities (monitoring obligation initially); and in due course also on patients and medical professionals (in relation to take-back schemes and prescription practice) could be greater in some MS than others, depending upon their per capita consumption of the pharmaceuticals. For example, DE would likely be more affected than ES, because per capita consumption of Diclofenac is several-fold higher. Likewise, effects in MS with lower per capita consumption of the contraceptive pill (e.g. EL, PL) would be less.
- Impacts in relation to certain substances could be more noticeable in MS with extensive coastlines, and significant dockyards, that have not already restricted the use of Cybutryne, and possibly in MS with more aquaculture (specifically salmon farming, i.e. in IE, UK, (NO) if using Cypermethrin).
- Impacts related to substances present significantly in urban waste water discharges (e.g. BDE, DEHP, HBCDD, Ni, PFOS, pharmaceuticals), would be likely to be felt mainly in MS with higher population density and lower water resources (smaller water courses) (especially UK, NL and parts of DE); these substances are distributed throughout the substance options.
- Sub-regional impacts might be seen in relation to Nickel (as a result of effects of local conditions on bioavailability), E2 (because of differences in the extent and intensity of livestock farming as well as conurbations) and PAHs (according to the influence of natural sources and conditions).
- The positive impact of the option to flexibly present the results of monitoring ubiquitous PBTs should by definition benefit all MS. The other preferred non-substance options should also benefit all MS though those with a tradition of monitoring only in water could face more adaptation costs. All MS would benefit from the possibility provided by the watch list to improve the prioritisation process and thus ensure that long-term EU-wide obligations are introduced only for substances most relevant at that level.

In conclusion, the preferred options do not appear to have significant unfair distributional impacts when the baseline is taken into account.

5.8.4. Approach to translating the options into a legislative proposal

The options above would be implemented by amending the EQSD 2008/105/EC and WFD Annex X.

6. MONITORING AND EVALUATION

The WFD contains built-in monitoring and evaluation processes. Regular monitoring of the environmental concentrations of the PS and PHS is foreseen in the Directive. MS report every six years (as part of the River Basin Management Plan) on chemical status and their programmes of measures. In addition, MS report monitoring data annually to the EEA as part of the State of the Environment reporting.

In addition, the implementation of the WFD in accordance with the Common Implementation Strategy, involving as it does working groups such as the WG E on Chemical Aspects, allows the Commission to obtain informal oral and written feedback from MS on the implementation and effectiveness of the Directive and of any relevant measures. Feedback can also be obtained from other stakeholder groups on the wider impacts of the legislation, and this would be done during the course of the next review due in four years.

ANNEX I: Glossary / List of acronyms

AA-EQS	Annual Average EQS
BDE	Brominated Diphenylether
CIS	Common Implementation Strategy for the Water Framework Directive
CMEP	Chemical Monitoring and Emerging Pollutants Sub-group of WGE
COMMPS	Combined Monitoring and Modelling-based Prioritisation
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DEHP	Bis(2-ethylhexyl)phthalate
DL-PCB	Dioxin-like Polychlorinated biphenyl
DOC	Dissolved Organic Carbon
E2	17 beta-estradiol
EE2	17 alpha-ethinylestradiol
EEA	European Environment Agency
EFPIA	European Federation of Pharmaceutical Industries and Associations
EQS	Environmental Quality Standard, i.e. the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment (WFD Article 2.35)
EQSD	Environmental Quality Standards Directive (Directive 2008/105/EC of the European Parliament and the Council on environmental quality standards in the field of water policy)
GAC	Granular Activated Carbon (tertiary water treatment)
HBCDD	Hexabromocyclododecane
HELCOM	Helsinki Convention for the protection of the Baltic Sea
HRT	Hormone Replacement Therapy
ICPDR	International Convention for the Protection of the Danube River
IPPC	Integrated Pollution Prevention and Control Directive (Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control)
JRC	Joint Research Centre of the European Commission

MAC-EQS	Maximum Allowable Concentration EQS
MS	Member State(s)
NAP	National Action Plan
NSAID	Non-steroidal Anti-inflammatory Drug
OSPAR	Oslo-Paris Convention for the protection of the North Sea
PBT	Persistent Bioaccumulative and Toxic
PCB	Polychlorinated biphenyl
PHS	Priority Hazardous Substance under the Water Framework Directive
Poly-BDE	Poly-Brominated Diphenyl Ethers
POP	Persistent Organic Pollutants under the Stockholm Convention
PPP	Plant Protection Product
PS	Priority Substance under the Water Framework Directive
RAR	Risk Assessment Report
RBD	River Basin District
RBMP	River Basin Management Plan under the Water Framework Directive
RBSP	River Basin Specific Pollutant
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
SCTEE	= CSTEE
SME	Small and medium-sized enterprises
SVHC	Substance of Very High Concern
TGD-EQS	Technical Guidance Document for deriving EQS (European Commission, 2011b)
UWWTD	Urban Waste Water Treatment Directive (Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment)
UWWTP	Urban Waste Water Treatment Plant
WFD	Water Framework Directive (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)

WG E	Working Group E on Chemical Aspects (under the Strategic Coordination Group for the Common Implementation Strategy of the WFD)
WISE	Water Information System for Europe (http://water.europa.eu)

ANNEX II: Summary of the prioritisation process and the establishment of EQS

This annex summarises the main criteria for the identification of priority substances (PS) and the results of the technical work done to review existing PS (EQS and PHS status), to identify new P(H)S and to set EQS for them.

Criteria for the identification of PS

According to WFD Article 16(2) PS should be identified among those causing a risk to or via the aquatic environment, by means of

a. Risk assessment carried out under the chemicals, PPP and biocides legislation (Regulation (EEC) No.793/93, Directive 91/414/EEC and Directive 98/8/EC respectively)

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

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

i. Evidence regarding the intrinsic hazard of the substances,
ii. Evidence from monitoring of widespread contamination
iii. Other factors that may indicate widespread contamination such as production volumes and use patterns

Some of the above points make particularly clear the importance of considering the route of exposure, i.e. substances identified as PS/PHS must be relevant to or via the aquatic environment, not other environmental compartments alone.

Summary of the prioritisation exercise and its results

The first list of 33 PS was established by Decision 2455/2001[38] in 2001 (effectively Annex X of the WFD).

At the time the first list was identified, very few risk assessment were available under the chemicals, PPP and biocides legislation. The COMMPS procedure[39] was developed as a simplified risk-based assessment that combined the available information on the intrinsic hazard of substances (point c.(i) above) with estimates of exposure based on monitoring information (point c.(ii) above) and modelling information derived from production volumes and use patterns (point c.(iii) above).

In view of the large number of potentially harmful substances, it was necessary in the current review, as for the first list, to conduct a prioritisation process to identify those most likely to cause harm to or via the aquatic environment. The prioritisation process was based on the criteria set out in the WFD Article 16(2) (see above), taking account of the experience gained with the COMMPS procedure used to establish the first list. An opinion[40] on that procedure

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38 OJ L3331, p 1, 15.12.2001

39 Combined monitoring-based and modelling-based priority setting, developed for the first prioritisation exercise: http://ec.europa.eu/environment/water/water-dangersub/lib_pri_substances.htm

40 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

from the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), and discussions among Commission services, MS and stakeholder experts, were considered in the development by WG E of an improved methodology.

A combination of different approaches was considered best to identify candidates for the list. Each of the approaches in WFD Article 16(2) was pursued in parallel. The simplified risk-based assessment used outputs from extensive monitoring and modelling exercises. In the context of considering assessments under other legislation, attention was also given to Substances of Very High Concern (SVHCs) under REACH, and substances of concern under the Convention on Persistent Organic Pollutants (POPs). Substances of concern at MS level were also examined, as well as the substances identified in Annex III of the EQS Directive.

The parallel prioritisation processes, which were subject to expert review in the Sub-Group on Review, 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. 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 prioritisation processes and the short-listing procedure were followed by further shortlisting on the basis of detailed dossiers prepared by the Commission and MS experts.

Because the implementation of the legislation on chemicals, PPP and biocides has progressed substantially since the previous prioritisation, it was possible to refer to many more risk assessments under those other pieces of legislation, including some in draft stage and others prepared on a voluntary basis.

Particular attention was paid to the risk ratio for each substance, i.e. the measured environmental concentration divided by the predicted no-effect concentration, and to evidence of persistence or bioaccumulation. The status of the substances was considered on the basis of information relating to the criteria for substances of very high concern in Article 57 of the REACH Regulation, for example the PBT and very Persistent very Bioaccumulative (vPvB) criteria, in association with information on exposure of and via the aquatic environment.

Existing substances (EQS and PHS status) were reviewed on the basis of revised or finalised risk assessment reports and decisions made under other legislation. Consideration was given to observations from MS regarding analytical difficulties.

In setting the EQS, use was made of the revised Technical Guidance Document on the Derivation of Environmental Quality Standards, which provided improved scope for considering the setting of standards in biota and/or sediment where relevant, as compared with the 2005 version that was used for the setting of the EQS for the first list of PS.

Further details of the technical process are provided in Commission Staff Working Paper SEC(2011)1544 (European Commission 2011).

The conclusions of the prioritisation process were that the substances listed in the table below pose a risk to or via the aquatic environment for the reasons indicated, and that there are

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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

therefore technical grounds for regulating them under the WFD. (See also Annex V for more information on the substances.)

CAS#	Substance	Main reasons for prioritisation as PS (or PHS)
57-63-6	17 alpha-ethinylestradiol	Endocrine disruptive; risk ratio >1
50-28-2	17 beta-estradiol	Endocrine disruptive; risk ratio >1
74070-46-5	Aclonifen	Ranked high in modelling based prioritisation; bioaccumulative and toxic (and some evidence of persistence); risk ratio >1
42576-02-3	Bifenox	Ranked high in modelling based prioritisation, very toxic, risk ratio >1
28159-98-0	Cybutryne (Irgarol®)	Substance of concern in MS, toxic, risk ratio >1; degrades only slowly; main degradation product (M1) also toxic; persists in sediments.
52315-07-8	Cypermethrin	Ranked very high in monitoring-based prioritisation and high in modelling-based prioritisation; very toxic; risk ratio >1
62-73-7	Dichlorvos	Ranked very high in monitoring-based prioritisation, medium in modelling-based prioritisation, risk ratio >1; possibly carcinogenic to humans (IARC 2B, Carc. Cat. 3 probable under Dangerous Substances Directive); potential for local mutagenicity.
15307-79-6	Diclofenac	Toxic; risk ratio >1
115-32-2	Dicofol	Annex III substance; ranked high in monitoring and in modelling based prioritisation, risk ratio >1; recommended for designation as POP (Stockholm Convention); possibly carcinogenic to humans, possibly endocrine disruptive; organochlorine PPP, similar to DDT.
1746-01-6	Dioxins (and dioxin-like PCBs)	Annex III substances. POPs (Stockholm Convention and CLRTAP). PBT properties. Ranked very high in monitoring-based prioritisation; some congeners probably carcinogenic to humans, possibly endocrine disruptive.
3194-55-6 / 25637-99-4	HBCDD	Ranked high in modelling-based prioritisation; PBT, SVHC under REACH, recommended POP, EU RAR conclusion of risk to aquatic environment.
76-44-8/ 1024-57-3	Heptachlor/Heptachlor epoxide	Ranked very high in monitoring -based prioritisation; POP (Stockholm Convention); very toxic to aquatic organisms; risk ratio >1; possibly/probably carcinogenic to humans, possibly endocrine disruptive.
1763-23-1	PFOS	Annex III substance, PBT, POP, risk ratio >1
124495-18-7	Quinoxyfen	PBT and vPvB properties
886-50-0	Terbutryn	Ranked high in modelling based prioritisation, medium in monitoring-based prioritisation, toxic, risk ratio >1

The conclusions of the assessment of new technical information regarding existing PS are presented in the table below. (See also Annex V for more information on the substances.) For other existing substances, there was either no new risk assessment report or no grounds within such a report to make a (significant) change to the EQS or a change to the status of the substance.

PS n°#	Substance	Rationale for review/nature of change
2	Anthracene	Review of the EQSs prompted by revised RAR for pitch. Conclusion that high acute toxicity justifies setting MAC equal to AA-EQS.

PS n°#	Substance	Rationale for review/nature of change
5	Poly (including octa) BDE	Modelling-based prioritisation identified octa BDE (BDE-197) as a priority. EQS for the group of BDEs (hitherto for penta BDE (CAS 32534-81-9)) therefore reviewed to cover octabromo BDE (CAS 32536-52-0) and take account of new information. However, proposed EQS (more stringent than before) based on BDE 99 (penta derivative). Extension of PHS status to octa BDE on grounds of PBT properties
12	DEHP	Reprotoxic Cat 1B (Reg (EC) No 1272/2008), in Annex XIV of REACH (since 2011), EU RAR (2008) 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). Change status to PHS.
15	Fluoranthene	Review of the EQSs prompted by revised RAR for pitch. Conclusion that biota EQS is critical EQS. Corresponding water EQS much more stringent than existing EQS. MAC also more stringent.
20	Lead	EU VRAR 2008, SCHER review of VRAR 2009, first draft of Chemical Safety Report for REACH registration, and need to consider bioavailability. Review of EQS promised at time of 2006 Commission proposal. EQS $_{bioavailable}$ now proposed.
22	Naphthalene	Review of the EQSs prompted by revised RAR for pitch. Conclusion that need slightly more stringent EQS for freshwater and introduction of MAC.
23	Nickel	New information (EU RAR 2008, SCHER review of RAR 2009, additional industry studies related to REACH registration), and need to consider bioavailability. Review of EQS promised at time of 2006 Commission proposal. EQS $_{bioavailable}$ now proposed.
28	PAHs Benzo(a)pyrene Benzo(b)fluoranthene Benzo(k)fluoranthene Indeno(1,2,3-cd)pyrene Benzo(g,h,i)perylene	Review of the EQSs prompted by revised RAR for pitch. Conclusions: Biota EQS is critical EQS for all but Benzo(g,h,i)perylene. Corresponding water EQS more stringent than existing EQS. Introduction of MAC for three PAHs; slightly changed MAC for Benzo(a)pyrene. Revised EQS for Benzo(g,h,i)perylene slightly less stringent in freshwater, more stringent in saltwater.
33	Trifluralin	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.)

The revision and derivation of EQS

EQS for the first list of PS were set in the Environmental Quality Standards Directive (2008/105/EC) [41] in 2008. The rationale for the EQS Directive is well explained in the Commission Communication (COM (2006) 397 final) that accompanied the Commission proposal[42].

A guidance document was used to set standards for the first list of PS[43]. Standards were set only in water, except for three substances (mercury and its compounds, hexachlorobenzene and hexachlorobutadiene) for which they were set in biota, with the proviso that if MS chose to use a water standard it should be equally protective. According to Article 3(2) of the EQS Directive, MS may opt to apply EQS for sediment and/or biota instead of the water standards

41 OJ L348, p.84-97, 24.12.2008

42 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52006DC0398:EN:NOT

43 Lepper, 2005.

in the Directive but they too should offer at least the same level of protection as the prescribed water standards.

The 2005 guidance has been revised[44] and substantially expanded to update to the latest scientific and technical knowledge. The new guidance, which received a generally favourable opinion from the SCHER in 2010 has been used to update EQS for existing substances, derive EQS for other matrices than water, and derive EQS for the newly identified substances. The following tables present the updated and derived standards for existing and new substances.

Proposed changes to EQS and status for existing PS:

#	Substance	Proposed AA-QS $_{water}$ µg/l (Existing)	Proposed MAC-QS $_{water}$ µg/l (Existing)	Proposed Biota EQS µg/kg ww	Change to PHS?
2	**Anthracene**		0.1 (0.4)		
5	**Poly (including octa) BDE**	F 4.9 10^{-8} (0.0005) S 2.4 10^{-9} (0.0002)	F 0.14 (na) S 0.014 (na)	0.0085	
12	**DEHP**				Yes
15	**Fluoranthene**	6.3 10^{-3} (0.1)	0.12 (1.0)	30	
20	**Lead**	F 1.2 $_{bioavailable}$ (7.2) S 1.3 $_{bioavailable}$ (7.2)	F 14.25 (na) S 14.25 (na)		
22	**Naphthalene**	F 2.0 (2.4) S 2.0 (1.2)	130 (na) 130 (na)		
23	**Nickel**	F 4 $_{bioavailable}$ (20) S 8.6 $_{bioavailable}$ (20)	F 34 S 34		
28	**PAHs**				
	Benzo(a)pyrene	1.7 10^{-4} (0.05)	F 0.27 (0.1) S 0.027 (0.1)	Benzo(a)pyrene as marker 2 for fish 5 for crustaceans and cephalopods 10 for molluscs	
	Benzo(b)fluoranthene	1.7 10^{-4} (0.03*)	F 0.017 (na) S 0.017 (na)		
	Benzo(k)fluoranthene	1.7 10^{-4} (0.03*)	F 0.017 (na) S 0.017 (na)		
	Indeno(1,2,3-cd)pyrene	1.7 10^{-4} (0.002**)			
	Benzo(g,h,i)perylene	F 8.2 10^{-3} S 8.2 10^{-4} (0.002**)	F 8.2 10^{-3} (na) S 8.2 10^{-4} (na)		
33	**Trifluralin**				Yes

Notes to the table:

- PHS means priority hazardous substance
- F means freshwater
- S means other surface waters
- Eco means the standard is set for protection of ecology
- If not specified the standards apply to both freshwater and other surface waters.
- (na) means not available
- If left blank means no standard or no change to standard or status proposed
- The existing standards for the two PAH marked with (*) and the two marked as (**) are given in Directive 2008/105/EC as the sum of the two compounds.
- For the PAHs, the AA-QS water of 1.7 10^{-4} µg/l corresponds to the biota EQS and benzo(a)pyrene can similarly apply as a marker for all five PAHs.

Proposed EQS and PHS status for newly identified substances:

[44] European Commission, 2011b

Substance	Proposed AA-QS $_{water}$ µg/l	Proposed MAC-QS $_{water}$ µg/l	Proposed Biota EQS µg/kg ww	PHS?
Dicofol	F $1.3\ 10^{-3}$ S $3.2\ 10^{-5}$		33	Yes
PFOS	F 0.00065 S 0.00013	F 36 S 7.2	9.1	Yes
Quinoxyfen (tbc)	F 0.15 S 0.015	F 2.7 S 0.54		Yes
Dioxin			Sum of PCDD+PCDF+PCB-DL $8.0\ 10^{-3}$ µg.kg^{-1} TEQ	Yes
Aclonifen	F 0.12 S 0.012	F 0.12 S 0.012		No
Bifenox	F $1.25\ 10^{-2}$ S $1.25\ 10^{-3}$	F 0.04 S 0.004		No
Cybutryne	0.0025	0.016		No
Cypermethrin	F $8.2\ 10^{-5}$ S $8.2\ 10^{-6}$	F $5.8\ 10^{-4}$ S $5.8\ 10^{-5}$		No
Dichlorvos	F $6\ 10^{-4}$ S $6\ 10^{-5}$	F $7\ 10^{-4}$ S $7\ 10^{-5}$		No
HBCDD	F $1.6\ 10^{-3}$ S $0.8\ 10^{-3}$	F 0.52 S 0.052	167	Yes
Heptachlor/ heptachlor epoxide	F $2.1\ 10^{-7}$ S $1.0\ 10^{-8}$	F $3\ 10^{-4}$ S $3\ 10^{-5}$	$6.7\ 10^{-3}$	Yes
Terbutryn	F 0.065 S 0.0065	F 0.34 S 0.034		No
17alpha-ethinylestradiol	F $3.5\ 10^{-5}$ S $7\ 10^{-6}$			No
17beta-estradiol	F $4\ 10^{-4}$ S $8\ 10^{-5}$			No
Diclofenac	F 0.10 S 0.01			No

- If left blank means no standard proposed
- TEQ means toxic equivalents

ANNEX III: Background and details regarding ubiquitous PBTs and knowledge base (watch list) options

Ubiquitous PBTs

Presentational issues

Many measures have already been taken to reduce or eliminate emissions of these substances, and there is little more, if anything, that can be done from the water management perspective to improve the situation, other than plug outstanding implementation gaps or attempt remediation (if technically and economically feasible) of highly contaminated "hotspots". For some substances, additional measures might still be possible in other policy areas, e.g. those dealing with diffuse or air emissions, but the persistence of the substances means that it may take many years – thus well beyond a RBMP cycle - for any of the measures (other than remediation) to have an impact on the levels in the aquatic environment, which in many cases are a legacy of past use or the unintended consequences of human activities.

The WFD (Article 4) and the EQSD (Article 6) contain exemption mechanisms that could be used by MS to justify not meeting the EQS, i.e. on the grounds that doing so would not be technically feasible or would entail disproportionate costs, that the achievement of the objectives will take longer than the WFD timelines due to natural conditions, or that the pollution has a transboundary origin. However, these exemptions would need to be used widely, and the improvements made in relation to other substances would be hidden. Indeed, waters are assessed in the WFD for their overall chemical status against all the EQS and therefore a bad situation for some chemicals (in this case PBTs) could blur even a rather positive situation for other substances. The "maps" used for reporting of chemical status would then be dominated by failures.

Since the outcome of the current review could add several ubiquitous PBTs to the PS list, and since some of those already identified in 2001 could be subject to more stringent EQS, it is likely that the failure rate would increase. Theoretically, given that the possible new PS referred to here are ubiquitous and often present in concentrations higher than the no-effect levels, MS should have identified them as RBSPs under the WFD and an EQS should have been set at national level. However, this has happened only rarely (see table in Annex V) and, as a consequence, listing these substances as PS could indeed have a significant impact on the chemical status.

Choice of monitoring matrix

The EQSD, in its final form as agreed by the legislator, includes the flexibility for MS to choose the matrix to monitor the PS. EQS for water are given in Annex I of the EQSD, but MS can choose to develop and use sediment and/or biota standards that offer at least the same level of protection as those provided for water. The exception to this is the case of three substances (Mercury, Hexachlorobenzene and Hexachlorobutadiene), for which EQS for biota are given in the EQSD[45] that MS have to use unless they develop and apply a water standard

[45] These substances are hydrophobic and bioaccumulative and therefore the preferred matrix for monitoring is biota; their concentrations in water are so low that are rarely measurable using state of the art analytical techniques. The main exposure route causing risk is secondary poisoning, i.e. risks to human health via ingestion of contaminated fish or shellfish.

that offers the same level of protection as the biota standard (hence the water standards in Annex I are never used for these three substances).

Knowledge and methodologies to develop EQS for sediment and biota have evolved significantly, and it is now possible to derive standards for these matrices (SCHER, 2010). However, this expertise is not available in all MS. For example, the Sub-Group on Review (which worked on the prioritisation and EQS derivation) received significant input from around one third of the EU MS, all from the EU15. The information in the first RBMP shows that, except in a few Member States, the number of national or river basin standards set by Member States is very limited, demonstrating the limited experience of many MS at deriving EQS. In addition, from a MS survey done in 2011, only 5 MS have indicated they might use the flexibility in the EQSD to derive their own standards for sediment and/or biota for substances other than the three for which such standards are provided at EU level. The biota standards for these three, though, are used by almost all MS (19 out of the 20 who responded). This demonstrates a preference for using the EU standard, probably because it is seen as robust but also because its provision eliminates the need for MS to derive a national (equally protective) water standard.

Most of the ubiquitous PBTs are very hydrophobic. It is therefore difficult to monitor them in water. The analytical techniques available are rarely sensitive enough to reliably detect concentrations of the order of the EQS, as the EQS is itself very close to (or below) the limit of determination. This means that where the results of an analysis are below the limit of determination, the concentration in the sample may still be higher than the EQS. Commission Directive 2009/90/EC requires MS to use analytical techniques that meet certain minimum quality requirements in relation to the EQS, but it also establishes that if the analytical techniques don't meet those minimum criteria, the best available techniques not entailing excessive costs should be used. Because of this clause, some MS are applying water standards for certain substances even though they are not able to monitor at the level of that EQS. The fact that PBTs tend to accumulate in sediment and biota means that their concentrations are likely to be higher in those matrices than in water. The analytical methods are therefore more likely to be adequate, and more likely to demonstrate exceedance of the EQS established for those matrices. MS which apply a water EQS set at a level below the limit of determination of the analytical technique might therefore conclude that "there is no problem", even though the application of a sediment or biota standard might reveal extensive failure. Although legally possible within the current legislative set-up, it is clearly unacceptable that water bodies are categorised as having "good chemical status" while they contain elevated values in sediment and/or biota that pose a risk to or via the aquatic environment.

The assessments of chemical status reported by MS in their first RBMPs illustrate the problem. For example, in one MS using the biota standard for Mercury, 100% of surface water bodies fail to achieve good chemical status. A neighbouring country, which suffers the same problem of widespread Mercury pollution by atmospheric deposition, monitors in water and reports a failure rate of only 0.4%. Although it is not clear whether the latter country's EQS is equally protective, the fact is that a very similar environmental situation is assessed and reported in a very different way due to the choice of matrix. Another MS that had orally indicated widespread failure of the Mercury standard in biota has reported in the RBMPs a failure rate based on a water standard of only 8.4%.

Monitoring effort

An additional issue that has been raised by MS in relation to these substances is the monitoring requirements. The WFD (Annex V) sets minimum monitoring requirements which are adapted to the RBMP cycle. They aim at:

- providing a general assessment of the status of waters in the basin (surveillance monitoring - monthly frequency during one year within the 6-year cycle),
- establishing the status of the water bodies with a sufficient level of confidence and measuring the improvements resulting from the programmes of measures (operational monitoring (guideline) - monthly frequency throughout the cycle as a guideline).

The EQSD prescribes a minimum frequency for compliance monitoring of sediment and/or biota of once every year and for trend assessment once every three years. The WFD and the EQSD allow for reduced frequency if justified on the basis of technical knowledge and expert judgement. For ubiquitous PBTs, any change in environmental concentrations that might occur as a result of measures is likely to occur over the long term (unless remediation is carried out) and therefore a lower monitoring frequency would seem justified. A reduction in the number of monitoring sites might also be reasonable. If MS choose to use a sediment or biota standard, the default monitoring frequency is already lower (annually rather than monthly). The issue is how, for ubiquitous PBTs, the monitoring frequency can be optimised to minimise the administrative burden while still yielding sufficient information.

Knowledge base

Emerging pollutants

The NORMAN network[46] defines emerging pollutants as: "pollutants that are currently not included in routine monitoring programmes at the European level and which may be candidates for future regulation, depending on research on their (eco)toxicity, potential health effects and public perception and on monitoring data regarding their occurrence in the various environmental compartments". In addition, there are many unregulated "emerging substances" which have been detected in the environment but whose fate, behaviour and effects are not yet well enough understood for them to be necessarily regarded as pollutants. The NORMAN database of these emerging pollutants and emerging substances numbers some 750 substances.

Watch list technical details and structural support

The technical elements of the proposed watch list would be as follows:

- Selection of the substances to monitor (around 20±5) in accordance with the following criteria:
  - (Emerging) pollutants for which there is evidence from the information available (e.g. from research and MS monitoring or studies, and taking into account use patterns and available monitoring and ecotoxicological data) that they may pose a risk to or via the aquatic environment at EU level, but for which there are insufficient data or insufficiently high-quality data to assess the risk

[46] The NORMAN network started its activities in September 2005 with the financial support of the European Commission (NORMAN project - 6th Framework Programme) and it is now established as a permanent self-sustaining network of more than 50 reference laboratories, research centres and related organisations for the monitoring and biomonitoring of emerging environmental substances. http://www.norman-network.net/

- Development of guidelines (substance-specific, if appropriate) on:
  - selecting representative stations (250-300 across the EU) (to be selected by MS)
  - sampling methods and/or periods
  - the monitoring matrix/matrices (water, sediment and/or biota)
  - the minimum number of samples (1-5, average of 2, per year per station)
  - the analytical methods and/or minimum performance criteria
  - any other technical needs to deliver a high quality dataset.

Existing structures would be used for the technical work and for data collection. In particular, the technical work would be done using the existing informal structures of the WFD Common Implementation Strategy (CIS), in particular the WG E and its sub-group on Chemical Monitoring and Emerging Pollutants (CMEP), co-chaired by the JRC. Experts from MS, stakeholders and the Commission are represented and they have the experience and the expertise for this task. Other options such as establishing a new group have been considered but seemed superfluous and inefficient in comparison. Data collection would be done using the Water Information System for Europe (WISE) managed by the EEA - an already a well-established EU system for collecting water data. Alternative options considered (e.g. establishing an ad-hoc system for reporting) would likely be more expensive and less effective.

The additional monitoring involved, which would be done by MS, would be limited. Current water-related monitoring requirements are already quite substantial across the EU, not only for the WFD PS (estimated cost ca. 69 million Euros annually, see Annex IV) but also for other WFD obligations (ecological status), other Water Directives (Bathing Water, Nitrates, Urban Waste Water) and other water-related international commitments (OSPAR, HELCOM, Barcelona Convention, Rhine Commission, ICPDR, etc). The proposal for the watch list to have 20±5 substances monitored at 250-300 stations is considered reasonable noting that:

- For each substance on the watch list a minimum of information would need to be gathered (available monitoring data, ecotoxicological information, use patterns, etc). This would imply additional work for the WG E and the CMEP sub-group. The proposal is consistent with the amount of work that the existing groups can handle without increasing significantly the administrative costs.
- There is a pragmatic limit on how many substances can be considered in detail for prioritisation in each of the regular reviews of the PS list. In the current review, the prioritisation process arrived at a short-list of 41 substances for detailed consideration, and in 15 substances being proposed for addition to the list (the subject of options A3a-A3c above). This has been used as a guideline: a watch list of 20 substances renewed on average every two years would provide monitoring data on about 40 substances every 4 years. This would provide substantial and probably sufficient input for the objective of the regular review of the PS., especially in view of the other possible sources of information including the data on RBSPs.
- There are 110 RBDs in the EU, 176 if each national part is considered separately. The figure of 250-300 stations would provide for at least one station per RBD and more in the case of large RBDs. This would provide an EU-wide picture.

To ensure that the watch list served its purpose and was as cost-effective as possible, it would be updated regularly and the results subjected to expert scrutiny. If one year of monitoring showed that there was no significant risk at EU level, the relevant substance could be removed. There would be annual electronic reporting to WISE, and the data would be analysed by the experts of the WG E/CMEP sub-group. If the information were not

conclusive after a year, the substance would be kept on the watch list. If the information were considered sufficient for risk assessment purposes, the substance would be replaced by another. It is estimated that on average the substances would remain on the list for 2 years.

ANNEX IV: Approach to the assessment of impacts

Assessment of impacts arising from regulation of the substances

According to the provisions of the WFD and EQSD, the review addressed the following issues:

(i) Determine whether additional substances should be identified as PS or PHS and if so, to establish the appropriate EQS for each substance in water, sediment and/or biota.
(ii) In relation to existing PS and PHS and considering any new technical/scientific information:
  – review the existing EQS
  – establish, if appropriate, EQS for sediment and/or biota
  – review the PHS classification
(iii) Consider the need for control measures for both existing and newly identified PS and PHS (according to Article 16(6) of the WFD and Article 7 of EQSD).

In relation to (i) and (ii) above, the choice of matrix (i.e. water, sediment and/or biota), and the determination of the EQS, are largely scientific/technical decisions that take account of the behaviour of a particular substance in the environment and the availability of relevant scientific information. There are also established criteria for identifying PS as PHS (set out in the WFD, and closely linked with REACH, as indicated in Recital 28 of the EQSD). These are described in the Commission Staff Working Paper SEC(2011)1544 (European Commission 2011).

To support the imact assessment, a study was conducted by the consultancy Entec. A 'bottom-up' approach was developed that allowed the assessment of impacts substance by substance, allowing aggregation of impacts in the different options. The methodology is described in detail in the report by Entec (Entec, 2011b). The individual substance reports from Entec are also available (Entec, 2011) . The fact sheets in Annex V of this report summarise the main results of the assessment of impacts for each of the substances.

The main elements of the methodology were the following:

– The approach to undertaking the impact assessment was based around a case study approach for individual substances in order to assess the impacts of the possible outcomes of the review, using the best available information. In this approach, a number of case studies (generally two or three per substance) were carried out at a MS level. The intention was to allow the impacts within the MS to be assessed in more detail than would be possible at the EU-level, due to the lesser amount of data collection and consultation required. This approach is also more feasible where data availability is limited. Multiple case studies were deemed necessary for each substance to ensure that the range of potential impacts (e.g. in different MS and impacts on different sectors) was covered. Assumptions were applied because of data gaps. An assessment (predominantly qualitative) was then made of the applicability of the case study findings at the EU level.

– The primary selection criterion for the initial case study (or studies) was monitoring data. In particular, MS where the monitoring data showed failure of the current or likely EQS were selected, to ensure that at least one case study was undertaken on a MS where impacts were likely to be identified.

– The impact of applying control measures for one substance on other substances was considered (since the application of measures for control of one substance may also imply control of other substances to a greater or lesser extent).

– A largely qualitative approach was taken to the assessment of impacts. The scope for quantifying the benefits, especially the environmental and social benefits (cf economic) was particularly limited. Although it was possible to put a figure on some costs (e.g. for advanced UWWT) and benefits (e.g. for recreational angling) it was not always possible to extrapolate. Section 5.2.1.1 presents the main benefits that were considered in dealing with substances. More information can be found in section 2.6.7 of the methodology report (Entec, 2011b).

Assessment of additional monitoring costs for the substances

Calculations were done using bottom-up (starting from unit costs for analysis) and top-down (starting from overall figures on expenditure by MS) approaches to estimate the costs of adding substances to the PS list.

A questionnaire was circulated to MS in 2010 to gather information on the costs of monitoring the existing PS. 22 MS replied and 16 gave information on monitoring costs, i.e. unit costs for sampling and analysis in the different matrices and overall current costs of monitoring of WFD PS.

Two complementary methodological approaches were applied to these data to calculate monitoring costs. They are explained below.

Bottom-up approach

Some data treatment was carried out on the unit costs, i.e. removal of outliers and calculation of average unit values for sampling and analysis in water (total and dissolved), sediment and biota. The results were as follows (EU average):

Unit costs	Euros	
Sample water	128	Average of total and dissolved (112 and 145)
Sample sediment	228	
Sample biota	422	
Analysis water	133	Average of total and dissolved (105 and 162)
Analysis sediment	128	
Analysis biota	151	

The proportions of sampling in water, sediment and biota were extracted as a starting point from the monitoring database compiled for the review. They were: 93% in water, 6% in sediment, 1% in biota.

A weighted average of the sampling and analytical costs using these percentages resulted in the following unit costs:

Sample weighted average	137 Euros
Analysis weighted average	133 Euros

The Commission implementation report on the WFD Monitoring programmes of 2009[47] identified 18535 sampling stations in 23 MS where PS are being monitored, including operational and surveillance monitoring. Extrapolation on the basis of population gives around 21500 stations in the EU27 in which PS are monitored.

The minimum frequency of monitoring depends on the type of monitoring: monthly during one year out of six in the case of surveillance monitoring and monthly for operational monitoring. But there are flexibilities to reduce the frequency on the basis of technical knowledge and expert judgement. For monitoring in biota or sediment, the minimum frequency is once per year (Article 3(2)c of EQSD); a reduced frequency is also possible on the basis of technical knowledge and expert judgement. Trend analysis in sediment and biota for a number of PS as per Article 3(3) of the EQSD is once every 3 years. Overall, a value of 2 samples per year will be used.

It was necessary to take into account that only substances discharged into water bodies are monitored in them. Moreover, each sampling point is adequate to monitor the presence of a certain group of substances: pesticides, industrial chemicals, metals, substances linked to consumer products/conurbations/UWWTPs, etc.. It was assumed for the cost calculation that an average of between 20% and 40% of the substances (8 to 16) are monitored per sample per station.

On the basis of the above assumptions, the total estimated cost of current monitoring of existing PS in the EU27 was calculated to lie within the range 51 to 97 million €.

The unit costs are assumed to be robust since they are based on data from a good balance of MS (geographically and socio-economically). Still, the basis of some assumptions could change. For example, the proportion of sediment and biota sampling is likely to increase as the EQSD is more fully implemented (Article 3(2)) and additional MS develop expertise in this. Water samples would still form the highest proportion as the frequency of monitoring is much higher. Changing from the current figures of 93, 6 and 1% respectively to 80, 15 and 5% would result in an increase of 1 million € per year[48], so a small percentage of the overall cost range calculated above.

Top-down approach

In response to the questionnaire referred to above, 11 MS provided the overall costs of monitoring existing PS. Extrapolation to the whole of the EU27 on the basis of population leads to an estimate of the total costs of monitoring for existing PS of 57 million €.

A sensitivity analysis was done to consider the influence of particular MS data on the estimate, since of the 11 MS, 4 were from the EU15 and 7 from the EU12, and costs and expenditure tend to be higher in the former. Extrapolating separately resulted in 41 million (if only EU12 data were used) and 94 million (if only EU15 data were used). This confirms that the estimate of 57 million is towards the lower end of the range.

[47] Main report: http://ec.europa.eu/environment/water/water-framework/implrep2007/pdf/sec_2009_415_en.pdf, Annex: http://ec.europa.eu/environment/water/water-framework/implrep2007/pdf/sec_2009_415_2_en.pdf

[48] Assumes the average frequency of monitoring of 2 samples per year.

Conclusions

Feedback from MS confirms the robustness of the assumptions and results.

There are a number of sources of uncertainty:

– Flexibility provided by the WFD for MS to tailor monitoring programmes to the local situation and to select the matrix for monitoring. A good overview was obtained from the reporting in 2007 (Article 8 of WFD) and the Monitoring report of 2009[47], although programmes may have been adapted later on at the RBMP stage.

– Data on unit costs were obtained from only 16 MS. However, they covered a good geographical and socioeconomic range, and the plausibility of the results was confirmed by several MS and the JRC.

– Data on the overall costs of monitoring of existing PS were obtained from only 11 MS, of which only 4 were from the EU15.

– Monitoring of new substances may need some development costs that are not reflected in the unit costs, which relate to routine monitoring of existing PS.

– New substances (either newly proposed PS or substances added to the watch list) are not the same as the existing PS. However, the types of substances are similar, the analytical techniques are frequently the same, and there is no reason to believe that costs will differ substantially.

– For a few substances the analytical costs may be higher if very low determination limits are required.

Resulting estimates for costs of monitoring for the EU (for the overall costs the lowest and the highest of the two calculations based on the two independent approaches is given):

Million €	Average	Low	High
Unit costs sampling (weighted average for all matrices)	128	-	-
Unit costs analysis (weighted average for all matrices)	133	-	-
Overall costs of monitoring of existing PS	69	41	97
Unit costs per PS based on overall monitoring	1.7	1	2.4

Cost estimate for the watch list (relevant to options C2 and C3)

Estimated annual monitoring costs for the watch list are in the following table using the unit costs derived above for sampling and analysis and the range in number of stations, substances and the average frequency of 2 samples per year, as presented in section 4.4.2:

Million €	15 substances	25 substances

250 stations	2.0	3.3
300 stations	2.4	4.0

These costs are calculated considering one sample per analysis. This substantially overestimates the costs, as some of the substances will be of the same type and therefore will be analysed in the same sample. If indeed only one sample were needed for all the substances, the costs would be halved.

However, there is also an important source of underestimation. The analytical costs that were reported by MS refer to routine analysis of existing PS. There is a need to consider development and adaptation costs for the substances in the watch list, as they may not be analysed on a routine basis in the MS. This could result in higher costs per analysis. Increasing the unit costs of analysis by 50% would result in an increased annual cost for the watch list of 25%, resulting in a total of 2.5 to 5 million € for the whole EU.

It is estimated that the above sources of overestimation and underestimation would partially cancel each other out. The range of the cost estimate (2 to 4 million €) is considered robust, as confirmed by consultation with MS, and represents between 3 and 6% of the current average overall costs of monitoring of PS (69 million, average of the range 41-97 million €).

ANNEX V: Substance factsheets

Contents

These substance factsheets are essentially based on the information in Entec (2011) and technical documents (EQS dossiers, source-screening and measures sheets) produced during the review process.

17-alpha-ethinylestradiol (EE2) factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	Fresh 3.5 10^{-5} Salt 7 10^{-6}
Rationale:	
Endocrine disruptive; risk ratio >1	
Main sources (production, use etc):	
Synthetic steroid most commonly used as the oestrogen component of combined oral contraceptives; also in the treatment of menopausal and post-menopausal symptoms and for other medicinal purposes. No data on production in the EU, though indications of production in DE. Approx 32 million women use EE2-based oral contraceptives in the EU. Consumption varies widely, from 52% of women between 15 and 49 years old in DE to 3.4% in PL. EE2 is excreted by people that consume it (57-85% is excreted unchanged) and enters the environment primarily through the sewerage wastewater system.	
BASELINE	
Monitoring and predictions show exceedances of the EQS in water (see "Uncertainties"). Emissions may be reduced due to improvement in waste water treatment driven by the general good status objective of the WFD. Public awareness of take-back schemes for unused or expired pharmaceuticals very variable (73% Swedish know, 77% British do not). Data on success of take-back schemes generally lacking but also very variable.	
IMPACTS	
Costs:	
Some potential measures identified but effectiveness very difficult to estimate as no experience of reducing environmental impact of pharmaceuticals in use. Current EU legislation does not provide the mechanisms to take most of these measures at EU level. Most feasible measures (e.g. improvement of take-back schemes, information to patients, doctors and pharmacists to influence prescription and achieve partial replacement by alternative contraceptives, etc) would be expected to reduce consumption of EE2 over the long term and increase that of alternatives, e.g. the progestogen-only pill, whose active hormone undergoes higher removal rates in UWWTPs. Long-term economic impacts on pharmaceutical companies producing EE2-based contraceptive pills due to reduced sales (current sales in EU are estimated at several hundred million €) unless they can move into the market for alternatives. Admin costs: Monitoring costs for MS. Depending on the design of the take-back schemes and awareness raising programmes, there might be additional costs incurred by public bodies.	
Benefits:	
Better knowledge of water quality and therefore better possibilities for targeting measures. Environmental benefits of decreasing environmental concentrations below no-effect levels, in particular for fish, possible increase in sustainability of fish stocks through reduced negative impacts on fish reproduction. Benefits for wider biodiversity related to increased fish stocks. Potential economic and social benefits related to commercial fisheries and recreational uses (angling). Economic benefits for pharmaceutical companies selling alternatives to EE2. Lower risk of endocrine–disrupting substances in drinking water, hence potential savings in drinking water treatment.	
Special points:	
Sectors (most relevant): Fisheries, medical, pharmaceuticals. Geographical impacts: Widely used across the EU, but higher usage in DE, PT, BE, FR, NL and HU.	
Uncertainties:	
Extent of monitoring of this "emerging pollutant" limited (3 countries in database, plus literature). Usefulness of monitoring information also limited because limits of detection usually 2 orders of magnitude higher than the EQS. No information on production in the EU. Uncertainties regarding effectiveness of measures due to the lack of experience in reducing the environmental impact of pharmaceuticals in use.	

17-beta-estradiol (E2) factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	Fresh 4 10^{-4} Salt 8 10^{-5}
Rationale:	
Endocrine disruptive; risk ratio >1	
Main sources (production, use etc):	
Naturally-occurring steroidal oestrogen produced by humans, livestock and wild animals. Also used to manufacture synthetic oestrogenic and hormonal products. Natural excretion of E2 by humans and animals accounts for around 90% of emissions to surface waters. Excretion from livestock is 10 times higher than from humans (estimated in the EU at 1000 kg/day for livestock vs 100 kg/day for humans) but human discharge is fully to water, cf. only a fraction of the livestock excretion. Therefore human and livestock emissions to water estimated to be of the same order of magnitude. Pharmaceutical uses of E2 account for less than 10% of total emissions, of which 90% due to hormone replacement therapies (HRT) (800 to 2200 kg/year) the rest to use in oral contraceptives.	
BASELINE	
Monitoring and predictions show exceedances of EQS in water (see "Uncertainties"). Emissions to surface water from human excretions may be reduced due to improvement in waste water treatment driven by general good status objective of the WFD. Emissions from livestock likely to be reduced due to increased protection of water courses at farm level driven by WFD, Nitrates Directive and the Directive on the Sustainable Use of Pesticides, through the implementation of buffer strips.	
IMPACTS	
Costs:	
Some potential measures have been identified but effectiveness very difficult to estimate. Measures should focus on reducing emission due to human and livestock excretion (e.g. improvements to UWWTPs and protection of water courses from livestock). Emissions from pharmaceutical uses would be reduced at the same time by improved UWWTPs. Difficult to estimate the need for additional measures to reduce emissions to water from livestock beyond the baseline. Cost of fencing to avoid livestock access to water courses is estimated at 2 to 12 €/ha/year. Estimated costs to upgrade UWWTPs to remove E2: For England and Wales: 18 € per inhabitant per year based on a stricter EQS than that proposed; For CH: 11-18 € per inhabitant per year depending upon the number of plants to be upgraded. These costs assume no source control and, if entailed, would likely be passed through in full or in part to consumers, within proportionate limits (exemptions could be applied on grounds of disproportionality or non-feasibility). Significant increase in energy use due to increased treatment (equivalent to 1 million tons of CO_2 in England and Wales). Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality and therefore better possibilities for targeting measures. Environmental benefits of decreasing environmental concentrations below no-effect levels, in particular for fish, possible increase in sustainability of fish stocks through reduced negative impacts on fish reproduction. Benefits for wider biodiversity related to increased fish stocks. Potential economic and social benefits related to commercial fisheries and recreational uses (angling). Increased waste water treatment will reduce discharge of many other pollutants. Lower risk of endocrine-disrupting substances in drinking water, hence potential savings in drinking water treatment.	
Special points:	
Sectors (most relevant): Fisheries, livestock farming, pharmaceuticals, sewerage/water. Geographical impacts: Highest emissions estimated for FR, DE, UK, IT, ES, PL, IE and NL.	
Uncertainties:	
Uncertainties regarding the proportion of E2 from livestock that reaches surface waters. Uncertainties about the effectiveness of the WFD measures included in the baseline to limit human and livestock E2 emissions to water. Limited monitoring information available for this "emerging pollutant" (2 countries in database, plus literature) and its usefulness is reduced because llimits of determination often higher than the EQS).	

Aclonifen factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	0.12 µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Ranked high in modelling based prioritisation; bioaccumulative and toxic (and some evidence of persistence); risk ratio >1	
Main sources (production, use etc):	
Herbicide manufacture and use (over 1000 tonnes/yr). Use as pre-emergence herbicide on a range of arable crops, especially potatoes, peas, maize, sunflowers. Also in forestry (tree nurseries). Losses to water by way of spray-drift, run-off, spills.	
BASELINE	
Monitoring data from 3 MS; exceedances of EQS in FR (which has the highest use and the most substantial monitoring dataset). Losses to water likely to decrease as a result of recently introduced requirement under Directive 91/414/EEC for buffer strips next to water courses. Likely to be aided by implementation of the Directive on Sustainable Use of Pesticides.	
IMPACTS	
Costs:	
Buffer strips already obligatory, but wider strips and/or additional measures might be locally required in response to monitoring results. Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; feedback to the PPP authorisation process. Possible additional benefits to biodiversity if measures improved. Reduced risk of failure of individual and total pesticides standards in drinking water.	
Special points:	
Note: Many benefits expected to be achieved under the baseline, but could be accelerated if improved knowledge of concentrations leads to better management, e.g. wider buffer strips, better timing of application, more widespread restrictions on spray-equipment cleaning methods. Sectors (most relevant): Agriculture (arable). Geographical impacts: Widely used in EU (18 MS in 2008) but 70% in FR. 7 formulators in FR, 1 in SE (the case-study MS); no data for other MS. Active substance produced in FR by DE-based company.	
Uncertainties:	
Extent of failure of EQS following recent introduction of buffer zones under Directive 91/414/EEC and adoption of the Directive on the Sustainable Use of Pesticides. Uncertainty regarding peak concentrations following application.	

Anthracene factsheet	
Proposal: More stringent MAC for existing substance.	**Proposed status:** Unchanged (PHS due to PBT properties)
Proposed critical EQS: QS $_{\text{freshwater, eco}}$	Unchanged
Proposed corresponding EQS in freshwater:	Not relevant
Proposed MAC:	0.1 µg/l (cf 0.4 µg/l)
Rationale:	
Review of the QSs prompted by revised RAR for pitch. Conclusion that high acute toxicity justifies setting MAC equal to AA-EQS.	
Main sources (production, use etc):	
Aromatic hydrocarbon. Occurs naturally in fossil fuels/derivatives and is produced during combustion; is therefore emitted from many industrial processes using fossil fuels or involving combustion. Pure anthracene (approx 1000 tonnes per annum in EU) manufactured from coal tar pitch for limited range of uses (e.g. pyrotechnics 0.2 tonnes). Produced in larger quantities (estimated 27000 tonnes per annum) in coal-tar distillation products. Coal tar pitch can be considered main use; in binding agents for e.g. electrodes, road construction, roofing. Total emissions highest from coke production, aluminium production, creosote and wood preservation (restricted conditions since 2003), domestic fuel combustion, vehicle engines, tyres (production and use), agricultural burning and forest fires, though half-life in air short, therefore atmospheric deposition relatively low cf some other PAHs, though still significant. Emissions to water (approx 9 tonnes in E-PRTR 2008) highest from metals production.	
BASELINE	
4 MS report current failure of existing AA-EQS. Monitoring database reports some concentrations higher than proposed MAC. Regulation (EC) No 850/2004 on POPs imposes release reduction provisions; REACH Annex XVII restrictions. possible inclusion in Annex XIV; IPPC Directive/IED; Directive 2004/107 on concentrations in air; Directive 98/70/EC on PAH content of diesel; Various BATs and BREFs, e.g. for aluminium production; Regulation (EC) No 1881/2006 on food standards for PAHs; inclusion in Annex I of Directive 98/8/EC effective from May 2013..	
IMPACTS	
Costs:	
Mostly in baseline, since existing AA-EQS already 0.1 µg/l and existing MAC only four-fold less stringent, and emissions to water should be phased out anyway. Possibly additional measures directed at (industrial) point source emissions (more relevant to MAC than diffuse sources). Admin costs: None beyond baseline, except possibly additional permitting administration and additional targeted monitoring in the short term.	
Benefits:	
Mostly in baseline, but possible acceleration of local improvements in water quality and ecosystem health.	
Special points:	
Note: Although accumulation in biota is relevant (secondary poisoning), critical EQS remains direct toxicity. Sectors (most relevant): Coal tar distillation; energy, metals production. Geographical impacts: Relevant industries (point sources) more prevalent in some MS than others.	
Uncertainties:	
Extent of failure of current MAC in all MS; inclusion or not in REACH Annex XIV.	

Bifenox factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	1.25 10^{-2} µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Ranked high in modelling based prioritisation, very toxic, risk ratio >1	
Main sources (production, use etc):	
Herbicide manufacture and use (over 200 tonnes/yr). Use as post-emergence herbicide predominantly on winter cereal crops, also on some grasslands. Losses to water by way of spray-drift, run-off, spills.	
BASELINE	
Monitoring data from 3 MS; exceedances of EQS in FR (which has the highest use and the most substantial monitoring dataset). Losses to water likely to decrease as a result of Directive on Sustainable Use of Pesticides.	
IMPACTS	
Costs:	
If buffer strips already obligatory (as in some MS), no additional cost to farmers; additional measures might be locally required in response to monitoring results. Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; feedback to the PPP authorisation process. Possible additional benefits to biodiversity. Reduced risk of failure of individual and total pesticides standards in drinking water.	
Special points:	
Note: Many benefits expected to be achieved under the baseline, but could be accelerated if improved knowledge of concentrations leads to better management, e.g. (wider) buffer strips, better timing of application, more widespread restrictions on spray-equipment cleaning methods. Sectors (most relevant): Agriculture (arable). Geographical impacts: Widely authorised in EU (19 MS) but most use in FR. Marketed by 3 companies in FR and 3-4 in UK (the case-study MS); no data for other MS, but production of active substance likely to be in Israel (head office of producer based there).	
Uncertainties:	
Extent of failure of EQS following recent adoption of the Directive on the Sustainable Use of Pesticides. Uncertainty regarding peak concentrations following application.	

Cybutryne factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	0.0025 µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Substance of concern in MS, toxic, risk ratio >1; degrades only slowly; main degradation product (M1) also toxic; persists in sediments.	
Main sources (production, use etc):	
Biocidal (algicidal) use - approx 10 tonnes/yr in EU (incomplete data) - especially as antifouling agent in coatings for boat hulls (commercial, recreational) and on marine equipment/constructions, but also in coatings on buildings. Losses to water mainly by leaching from coated surfaces; some losses during application. Leaching losses in NL continental shelf sea estimated at 850 kg in 2007.	
BASELINE	
Monitoring database contains data from 3 MS and CH showing exceedance or near-exceedance of proposed EQS in 2 MS and CH); data in literature confirm potential for exceedance. Some national bans on use for small vessels have recently come into force. Uses as antifouling agent and film/masonry preservative currently being reviewed under the Biocidal Products Directive 98/8/EC; outcome could affect baseline.	
IMPACTS	
Costs:	
Any additional material costs for substitutes. Labour costs if use more frequent mechanical cleaning/maintenance. Increased shipping fuel costs/CO_2 etc emissions if alternatives less effective. Costs might be passed on to consumers/passengers. Admin costs: Monitoring costs for MS. Possibly sediment remediation costs.	
Benefits:	
Better knowledge of water quality; feedback to the biocidal products authorisation process; information to support remediation. Possible benefits to biodiversity, and to fisheries and angling. Stimulation of innovation to find additional alternatives. Employment opportunities if more frequent mechanical cleaning/maintenance.	
Special points:	
Note: Some benefits likely to be achieved under the baseline, but not all MS have national bans in place and only small vessels are covered. Sectors (most relevant): Coatings, Construction, Fisheries, Leisure (angling, boating), Transport (shipping) Geographical impacts: Produced by BASF (DE-based), possibly in CH. MS with coastlines likely to benefit most, especially if (partial) ban not already in place (as in DK, SE, UK). Benefits to third countries if EU boats use less harmful antifouling agent.	
Uncertainties:	
Extent of failure of EQS following introduction in some MS of national bans. Extent of use on buildings.	

Cypermethrin factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	8.2 10^{-5} µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Ranked very high in monitoring-based prioritisation and high in modelling-based prioritisation; very toxic; risk ratio >1	
Main sources (production, use etc):	
Insecticidal PPP and biocide: approx up to 100 tonnes/yr used in EU. Used as PPP on arable crops, in orchards and forestry, and as biocide in wood preservatives and for veterinary use (sheep dipping, salmon farming). Secondary release from textile factories using wool.	
BASELINE	
Monitoring database contains data from 5 MS showing exceedance of proposed EQS in 3 MS, in particular UK. National ban on use in sheep dipping now in force in UK. Biocidal uses currently being reviewed under the Biocidal Products Directive 98/8/EC; outcome could affect baseline. Use in salmon farming apparently declining but could be temporary due to practice of rotating chemical treatments to cope with resistance development.	
IMPACTS	
Costs:	
Costs to arable farmers of implementing buffer zones. Costs to sheep farmers of measures to reduce entry of cypermethrin into water (possibly of the order of 10 million Euros per MS based on estimates by the UK). Costs to textile factories of effluent treatment. Costs to salmon farmers of using management measures to ensure compliance with EQS. In Scotland, a quality standard was introduced several years ago but salmon farmers have been able to continue using Cypermethrin with appropriate management If cypermethrin use could not continue (despite no proposal to designate it as a PHS), possible cost of finding substitutes to maintain portfolio of treatments for rotation, although alternative treatment using hydrogen peroxide (less harmful to environment) already being developed. Additional material costs for substitutes, if relevant. In horticulture and cereal cropping, alternatives generally available, plus possibility of controlling certain pests by irrigation management. Loss of cypermethrin (though not foreseen in the options) would have only a minor impact, except in the context of vine weevil control, where in the UK at least there could be some costs (ADAS 2010, HGCA 2009). Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; feedback to the PPP and biocidal products authorisation processes. Possible benefits to biodiversity and to fisheries and angling.	
Special points:	
Note: Some benefits likely to be achieved under the baseline where ban on use in sheep dipping already introduced. Sectors (most relevant): Aquaculture, Agriculture, Pesticides (Biocides, Plant Protection Products). Geographical impacts: Formulations manufactured by 5 companies in EU, location not known; active substance produced at least partly outside EU. Authorised in most MS. Impacts less severe where ban on use in sheep dipping already in place. Salmon farming only an issue for DK, IE, UK.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method. Extent of failure in UK following ban on use in sheep dipping in UK. Extent to which used for sheep dipping in other MS (ES, FR, IT, RO have high numbers of sheep). Likely trend in use in agriculture and forestry. Outcome of Biocidal Products Directive review.	

DEHP factsheet	
Proposal: New status for existing substance	**Proposed status:** PHS
Proposed critical EQS: Unchanged **Proposed corresponding EQS in freshwater:**	As in existing EQS Directive
Rationale:	
Reprotoxic Cat 1B (Reg (EC) No 1272/2008), SVHC under REACH and listed in Annex XIV of REACH, EU RAR (2008) 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).	
Main sources (production, use etc):	
Industrial chemical, used as plasticiser in polymers, mainly in flexible PVC (for roofing, piping, tubing, flooring, furniture, clothing etc) and, to a limited extent in some non-polymer products. Emissions to environment during production, formulation, use and disposal – highest from disposal (consisting mainly of emissions from non-managed disposal, i.e. waste remaining in the environment from use), but also significant through run-off, washing/abrasion etc during use, especially from outdoor polymer use to soil and from indoor use to water. E-PRTR reports 21 tonnes emitted through UWWTPs in 2008 (approx 97% of total to water), 10 tonnes from chemical industry to air, but these emissions may not cover many of the emissions from use.	
BASELINE	
Failures of EQS currently in at least four MS (data not complete). REACH Annex XIV authorisation required from Feb 2015; temporary authorisation for some uses likely – possible derogations for some uses. Eventual substitution, therefore decrease in emissions from new use, expected in due course. (Substitutes exist for DEHP and final product type. DEHP was 18% of plasticiser use in 2009.) But emissions from existing use likely to continue for some time. Legislation on industrial emissions contains measures relevant to DEHP and PVC. Directives on incineration and landfill of waste contain generic requirements.	
IMPACTS	
Costs:	
Mostly in baseline. Impacts on DEHP producers and companies processing flexible PVC (approx 800 in EU), including impacts on employment (though could shift to alternative substances/products), and additional cost of substitutes, estimated at 9 to 21% in 2008 (could be passed to consumers, but could decrease with increased use). Additional water treatment (waste water, storm water run-off, landfill leachate) including cost of SUDs and energy costs, CO_2 emissions. To cease all emissions, replacement of many PVC fixtures/fittings/products; costs of correct disposal. However, such water treatment or product replacement before natural "end-of-life" would be subject to assessment of costs, including environmental costs, and exemptions on the basis of disproportionate costs and non-feasibility could be applied. Admin costs: Possibly remediation costs (MS and/or industry). Possibly costs of scheme(s) to remove products from use (though such schemes unlikely).	
Benefits:	
Mostly in baseline. Better water quality and reduced build-up of DEHP in sediments; potential for better human health. Knock-on benefits of measures such as SUDs.	
Special points:	
Note: PHS designation consistent with approach under REACH. Many benefits expected to be achieved under the baseline, but could be accelerated/enhanced. Sectors (most relevant): Construction, electrical, footwear, medical, plastics/polymers, textiles, water/sewerage. Geographical impacts: Production in fewer than 10 MS (possibly only 7 sites remaining); considerable variation in reported releases (E-PRTR) to water and air.	
Uncertainties:	
Extent of failure of EQS in some MS. Exact number of DEHP producers. Data on human health and environmental impacts of some alternatives. Outcome of REACH authorisation process. In addition to REACH,	

separate consideration being given to banning use in electrical equipment and PVC – outcome not certain. Impacts on import.

Dichlorvos factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-QS $_{\text{freshwater, eco}}$	$6\ 10^{-4}$ µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Ranked very high in monitoring-based prioritisation, medium in modelling-based prioritisation, risk ratio >1; possibly carcinogenic to humans (IARC 2B, Carc. Cat. 3 probable under Dangerous Substances Directive); potential for local mutagenicity.	
Main sources (production, use etc):	
Use as organophosphorus insecticide. Residual non-authorised use as PPP. Possible losses from biocidal use, e.g. from indoor use on grain/nut stores, use of insecticidal sprays etc (largely indoor but also outdoor, including domestic use). Leaching from disposal of unused products.	
BASELINE	
Monitoring shows evidence of failure of EQS in 7 MS, possibly others. Losses to water should decrease since no longer in Annex I of Directive 91/414/EEC (effective as of 2008).	
IMPACTS	
Costs:	
Possibly additional water treatment costs. Possible costs to current producers if consumption decreases, e.g. if certain product types no longer authorised (though impacts most likely in baseline). Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; potential for better water quality and ecosystem health; therefore potential for better aquaculture/fisheries/angling.	
Special points:	
Note: Most use apparently indoors, but some outdoor use (e.g. on mosquitoes) still authorised, and disposal could pose a risk. Exposure in humans largely by inhalation. Sectors (most relevant): Biocidal product manufacturers, Consumers. Geographical impacts: Possible impacts on India (producer) depending upon outcome of Biocidal Products review, and on one or more EU product formulators. Authorisation already withdrawn in DK, SE, UK. Reported use seems highest in IT.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method. Outcome of Biocidal Products Directive review.	

Diclofenac factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	0.1 µg/l (freshwater), 0.01 µg/l (saltwater)
Proposed: MAC-EQS $_{freshwater,eco}$	75 µg/l (freshwater), 7.5 µg/l (saltwater)
Rationale:	
Toxic; risk ratio >1	
Main sources (production, use etc):	
Non-steroidal anti-inflammatory drug (NSAID), suitable for human and veterinary use, first introduced in the UK in 1979. Diclofenac has anti-inflammatory, antipyretic and analgesic action. Four producers in the EU according to ESIS. Average consumption of 0.46 g per person per year but varies widely (0.05 to 0.89 based on data from 9 MS). Emissions via excretion and discard of unused medicines in sink/toilet or domestic waste.	
BASELINE	
Monitoring and predictions show exceedances of the EQS in water (DE, FR, IT, UK, SE, AT, PL). Consumption of NSAIDs has shown an upward trend over recent years in Central and Eastern European countries (Inotai A et al ,2010). Public awareness of take-back schemes for unused or expired pharmaceuticals very variable (73% Swedish know, 77% British do not). Data on success of take-back schemes generally lacking but also very variable.	
IMPACTS	
Costs:	
A wide range of measures could be implemented but effectiveness very difficult to estimate as no experience of reducing environmental impact of pharmaceuticals in use. Current EU legislation does not provide the mechanisms to take most of these measures at EU level. Most feasible measures (e.g. improvement of take-back schemes, influence of prescription, information to patients, doctors and pharmacists, etc) are expected to have a long-term effect to reduce consumption of diclofenac and increase other alternative anti-inflammatory drugs. Long-term economic impacts on pharmaceutical companies producing diclofenac due to reduced sales, unless they can move into the market for alternatives. Admin costs: Monitoring costs for MS. Depending on the design of the take-back schemes and awareness-raising programmes, there might be additional costs incurred by public bodies.	
Benefits:	
Better knowledge of water quality and therefore better possibilities for targeting measures. Environmental benefits to decrease environmental concentrations below no-effect levels, in particular for fish. Economic benefits for pharmaceutical companies selling alternatives to diclofenac.	
Special points:	
Sectors (most relevant): Medical, pharmaceutical. Geographical impacts: Widely used across the EU, but higher usage per inhabitant in DE, EE, PL, SE and UK. Production in the EU located in DE and IT.	
Uncertainties:	
Limited information about levels in the aquatic environment in large parts of the EU. Important uncertainties as regards the effectiveness of the measures due to the lack of experience in reducing the environmental impact of pharmaceuticals in use.	

Dicofol factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{biota, sec\ pois}$	33 µg/kg biota ww
Proposed corresponding EQS in freshwater:	1.3 10^{-3} µg/l
Rationale:	
Annex III substance; ranked high in monitoring and in modelling based prioritisation, risk ratio >1; recommended for designation as POP (Stockholm Convention); possibly carcinogenic to humans, possibly endocrine disruptive; organochlorine PPP, similar to DDT.	
Main sources (production, use etc):	
Possibly residual (non-authorised) use as PPP, predominantly against mites and ticks on fruits, vegetables and ornamentals, thence losses to water by way of spray-drift, run-off, spills. Otherwise secondary release, e.g. by leaching, from contaminated soils and sediments.	
BASELINE	
Monitoring shows evidence of failure of EQS in ES and FR, with uncertainty regarding other MS. Losses to water should decrease since no longer in Annex I of Directive 91/414/EEC (effective as of March 2010).	
IMPACTS	
Costs:	
Admin costs: Monitoring costs for MS. Possibly sediment remediation costs.	
Benefits:	
Better knowledge of water quality; remediation if necessary, with potential for better water quality and better biota and human health; potential for better aquaculture/fisheries/angling.	
Special points:	
Note: Most benefits expected to be achieved under the baseline, but could be accelerated if monitoring results lead to remediation. Sectors (most relevant): None particularly beyond baseline (assuming no longer manufactured in EU). Geographical impacts: Impacts on ES, IT and non-EU producers already in baseline (assuming not manufactured in EU only for export). Dicofol was authorised in 11 MS, many of which withdrew authorisation in the 1990s. ES, FR and IT known to have been users until 2010 - might have more need for remediation.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method. Extent of failure of EQS following exclusion from Annex I of Directive 91/414/EEC.	

Dioxins and Dioxin-like-PCBs factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{biota, sec\ pois}$ **Proposed corresponding EQS in freshwater:**	8 10^{-3} µg TEQ/kg biota wwNone calculated.
Rationale:	
Annex III substances. POPs (Stockholm Convention and CLRTAP). PBT properties. Ranked very high in monitoring-based prioritisation; some congeners probably carcinogenic to humans, possibly endocrine disruptive.	
Main sources (production, use etc):	
Dioxins are unintentional by-products of thermal processes involving organic matter, e.g. during power station combustion, non-ferrous metals production and other industrial manufacturing, waste incineration, forest fires. Atmospheric deposition widespread. Direct emissions to water from organic chemicals production, pig-iron and steel production, chlorine-based industries, e.g. paper production, textile washing/bleaching. PCBs are chlorinated organic compounds formerly produced and used in EU in manufacturing electrical and hydraulic equipment and lubricants etc; 12 congeners are dioxin-like. Combustion of waste may produce some DL-PCBs. Atmospheric deposition occurs. Most direct emissions to water are from urban wastewater treatment plants, probably from ongoing use of PCB-based flooring, sealants and paints. Secondary emissions of dioxins and DL-PCBs possible, e.g. leaching from landfills and contaminated soils, release from sediments.	
BASELINE	
Monitoring shows evidence of failure of tentative water and/or sediment EQS in several MS, and some exceedances of draft biota EQS. Emissions have decreased because of action under international and EU POPs, waste and industrial emissions legislation, including ELVs on emissions of dioxin from waste incineration, BREFs on emissions from industrial processes, requirements for the disposal of PBC-containing waste and restrictions on transboundary movements of hazardous waste. PCBs banned for use in open applications since 1976 (Directive 76/403/EEC) and closed applications since 1985 (Directive 85/467/EEC), though remain in flooring, sealants, paints etc. Food standards exist.	
IMPACTS	
Costs:	
Most costs in baseline. Possibly additional water-treatment costs, including energy/CO_2 emissions. Possibly accelerated measures to reduce the likelihood of dioxins formation in industrial/domestic combustion processes (e.g. optimal combustion conditions, fuel switching), to capture dioxins from emitted gases, and to reduce the likelihood of accidental fires. Possibly 5-10% reduced efficiency of blast furnace operation with optimised emissions. Possible earlier investment in measures (e.g. insulation) to reduce fuel consumption. Possible costs to replace PCB-containing materials and items in buildings (and dispose of PCB-containing items correctly). Possible passing on of costs from industry to consumers, especially energy costs. Admin costs: Monitoring costs for MS. Possibly sediment remediation costs.	
Benefits:	
Most benefits in baseline. Better knowledge of water quality; avoidance of environmental accumulation (by accelerated measures); remediation if necessary; potential for better water quality and better biota and human health; potential for better aquaculture/fisheries/angling; improved consumer confidence (though could be lower in the short term); reduced likelihood of exceeding food standard and WHO Tolerable Daily Intake. Possible stimulation of innovation; benefits to producers of abatement/cleaner technologies. Possible employment in remediation work.	
Special points:	
Note: Most costs and benefits expected to be realised under the baseline, but could be accelerated. Sectors (most relevant): None particularly beyond baseline. Geographical impacts: Most impacts already in baseline; could be higher remediation costs in some MS due to concentration of certain industries.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method.	

Fluoranthene factsheet	
Proposal: Biota EQS as critical EQS. Corresponding water EQS much more stringent than existing EQS. MAC also more stringent.	**Proposed status:** Unchanged (PS)
Proposed critical EQS: QS $_{biota, hh}$	30 µg/kg biota ww (freshwater and marine)
Proposed corresponding EQS in freshwater:	6.3 10^{-3} µg/l (cf 0.1 µg/l) (freshwater and marine)
Proposed MAC:	0.12 µg/l (cf 1.0) (freshwater and marine)
Rationale:	
Review of the QSs prompted by revised RAR for pitch.	
Main sources (production, use etc):	
Aromatic hydrocarbon. Occurs naturally in fossil fuels/derivatives and is produced during combustion; is therefore emitted from industrial processes using fossil fuels or involving combustion. Not produced or used in pure form. Used through use of coal tar pitch, high temperature (CTPHT); production approx 800000 tonnes in 2004 in EU, small amount imported, more than one third exported. Main use in binding agents for e.g. electrodes, furnace lining materials (refractories), road construction, roofing. Also present in creosote, tar paints, tyres etc.. Reported emissions to water approx 8.5 tonnes in E-PRTR 2008, highest from the energy sector (mainly from refining and combustion) and metals production (particularly aluminium, though 2009 emissions from one major contributor are much lower). Other emissions to water from production of basic organic chemicals, and from wood treatment with creosote etc. Emissions from incomplete combustion (including from vehicles, domestic fuel and agricultural burning, and wildfires) may lead to atmospheric deposition.	
BASELINE	
8 Member States report current failure of existing AA-EQS in at least one water body. INERIS monitoring database reports some concentrations higher than proposed EQS and MAC. Regulation (EC) No 850/2004 on POPs imposes release reduction provisions; REACH Annex XVII restrictions. possible inclusion in Annex XIV; IPPC Directive; Directive 2004/107 on concentrations in air; Directive 98/70/EC on PAH content of diesel. Various BATs and BREFs, e.g. for aluminium production; Regulation (EC) No 1881/2006 on food standards for PAHs, inclusion in Annex I of Directive 98/8/EC effective from May 2013.	
IMPACTS	
Costs:	
Possibly additional measures directed at (industrial) point source emissions. Possible additional waste water treatment. Admin costs: Possible change in monitoring costs due to shift to biota standard. Possibly remediation costs (MS and/or industry).	
Benefits:	
Better knowledge of water quality (due to switch to biota monitoring). Improvement in water quality; decreased scope for accumulation in the environment (fluoranthene binds to particles), potential for better biota health and better aquaculture/fisheries/angling (including reduced wastage); potential for better human health (though carcinogenicity not confirmed).	
Special points:	
Sectors (most relevant): Chemicals, energy, metals production. Geographical impacts: Relevant industries (point sources) more prevalent in some MS than others. Possible greater impact on ES aluminium producers if still using the Söderberg technique.	
Uncertainties:	
Extent of failure of proposed EQS and MAC in some MS.inclusion or not in REACH Annex XIV	

HBCDD factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{biota, sec\ pois}$	167 µg/kg biota ww
Proposed corresponding EQS in freshwater:	1.6 10^{-3} µg/l
Rationale:	
Ranked high in modelling-based prioritisation; PBT, SVHC under REACH and included in Annex XIV of REACH, recommended POP, EU RAR conclusion of risk to aquatic environment.	
Main sources (production, use etc):	
Industrial chemical, used as flame retardant in polymers: insulation boards (Expanded PolyStyrene, eXtruded PolyStyrene), electronic equipment (High Impact PolyStyrene), textile coatings (for furniture etc.). Produced in NL, approx 6000 tonnes in 2005. Emissions to environment from all phases of life cycle. Approx half of total emissions are to wastewater from formulation. Estimated to be in 200 million homes.	
BASELINE	
Monitoring shows some exceedances of water and biota EQS. REACH Annex XIV authorisation required from August 2015; temporary authorisation for some uses likely. Eventual substitution, therefore decrease in emissions from new use, expected. Possible POP designation (Stockholm Convention, CLRTAP) would also reduce emissions from new use. But emissions from old uses likely to continue, including from disposal of building materials in landfills, and HBCDD will persist in the environment.	
IMPACTS	
Costs:	
Mostly in baseline. Enhanced effluent treatment at production sites. Enhanced waste water treatment costs and CO_2 emissions. In the absence of alternative substance for use in EPS/XPS, possible additional cost of alternative insulation materials. Possible safety issues if not equally fire retardant. HIPS alternative could mean + €4-5 per TV. Costs to current producer and at least 50 formulators, including effects on employment (up to 30 000 EPS/XPS jobs). Possible costs to users (at least 600) and consumers. Admin costs: Monitoring costs for MS, possibly remediation costs (MS and/or industry).	
Benefits:	
Mostly in baseline. Better knowledge of water quality; remediation if necessary, resulting in better water quality and ecosystem health; decreased scope for bioaccumulation, therefore potential for better biota health; potential for better aquaculture/fisheries/angling; improved consumer confidence (though could be lower confidence in the short term); potential for better human health; stimulation of innovation; benefits to producers of alternatives including potential employment; employment in remediation work.	
Special points:	
Note: PHS designation consistent with approach under REACH. Most costs and benefits expected to be realised under the baseline – dependent upon REACH Annex XIV authorisations; could be accelerated. Sectors (most relevant): Chemicals production, construction, electronic equipment, textiles. Geographical impacts: One production site in EU (NL), but products produced at 50 sites throughout EU. Use lower in Scandinavia due to different national fire regulations. Benefits likely beyond the EU.	
Uncertainties:	
Possible authorised uses under Annex XIV of REACH; timeline for availability of alternatives (none yet for EPS/XPS, though in pipeline); environmental and health impacts of chosen alternatives; impacts of waste disposal route (incineration cf landfill).	

Heptachlor factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{biota, hh}$	6.7 10^{-3} µg/kg biota ww
Proposed corresponding EQS in freshwater:	2.1 10^{-7} µg/l
Rationale:	
Ranked very high in monitoring -based prioritisation; POP (Stockholm Convention); very toxic to aquatic organisms; risk ratio >1; possibly/probably carcinogenic to humans, possibly endocrine disruptive.	
Main sources (production, use etc):	
Organochlorine insecticide. Possibly (unlikely) residual (non-authorised) use. Otherwise secondary release, e.g. by leaching from contaminated soils and sediments.	
BASELINE	
Monitoring shows evidence of failure of biota EQS in 3 MS and corresponding water EQS in at least 6 MS. Losses to water should decrease since no longer in Annex I of Directive 91/414/EEC and use prohibited by Regulation (EC) No 850/2004.	
IMPACTS	
Costs:	
Possibly additional water-treatment costs (to remove leached heptachlor), including energy/CO_2 emissions. Admin costs: Monitoring costs for MS. Possibly sediment remediation costs.	
Benefits:	
Better knowledge of water quality; remediation if necessary, with potential for better water quality and better biota and human health; potential for better aquaculture/fisheries/angling.	
Special points:	
Note: Most benefits expected to be achieved under the baseline, but could be accelerated if monitoring results lead to remediation. Sectors (most relevant): None particularly beyond baseline. Geographical impacts: Most impacts already in baseline; could be higher remediation costs in MS with heavier previous use.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of sufficiently sensitive analytical method.	

Lead factsheet	
Proposal: Revised EQS taking account of bioavailability, for existing substance,	**Proposed status:** Unchanged (PS)
Proposed critical EQS: QS $_{freshwater, eco}$	1.2(fresh), 1.3(salt) (bioavailable) µg/l (cf 7.2 µg/l)
Proposed corresponding EQS in freshwater:	Not applicable
Proposed MAC:	14.25 µg/l
Rationale:	
New information (EU VRAR 2008, SCHER review of VRAR 2009, first draft of Chemical Safety Report for REACH registration), and need to consider bioavailability.	
Main sources (production, use etc):	
Production approx 1.5 million tonnes per annum in EU, consumption slightly higher, value approx 3 billion Euros. At least 8 primary (from ore) production sites in at least 5 MS, approx 30 secondary (recycling) production sites in at least 12 MS. Production associated with mining/extraction of other metals, especially zinc. Main uses: in batteries/accumulators, also in shot, boat keels, weights, building materials (roofing), cable sheathing, glass, solder material, chemical compounds, some paints. Value of use in EU: another 3 billion Euros/annum. Emissions to water highest from battery production, primary and secondary lead and sheet lead production (including mining), pulp/paper production, ferrous and non-ferrous metal processing, power generation, lead crystal glass production, plastic treatment, lead piping, waste disposal including landfill and incineration. Also from diffuse sources: hunting/fishing, road run-off (tyres, vehicle exhausts), roof run-off, soil erosion; and indirectly via atmospheric deposition (vehicular and industrial emissions to air, wildfires) (all of which may also enter surface water via UWWTPs). E-PRTR 2008 reports total EU emissions of lead to water of 135 tonnes from 586 facilities.	
BASELINE	
Eight MS report failure of current EQS in up to 2.8% of freshwater bodies. Proposed EQS (bioavailable) effectively slightly more stringent than existing; compliance likely to be similar (i.e. at approx 6 cf 7.2 µg/l total lead), though could be poorer where dissolved organic carbon (DOC) low. Subject to control under several Directives and Regulations, including REACH, IPPC/IED, Drinking Water Directive, Groundwater Directive, WEEE Directive, Batteries Directive.	
IMPACTS	
Costs:	
Mostly in baseline. Possible increase in need for control measures (e.g. SUDs for run-off) and/or remediation at/near historic mining sites and/or other contaminated areas where DOC levels are low. Admin costs: Possible slight increase in monitoring costs for some MS, i.e. those not already monitoring the parameters required to run biotic ligand models.	
Benefits:	
Many in baseline. Better water quality and ecosystem health (lead is bioaccumulative and toxic); potential for improved aquaculture/fishing; potential for better human health/IQ; employment in control/remediation work. Focus on bioavailability likely to lead to better monitoring information, therefore also better targeting of control measures/remediation.	
Special points:	
Note: Lead is classified as Reprotoxic 1A, i.e. could be considered a PHS on the grounds of an equivalent level of concern. However, exposure of humans via surface waters is relatively low compared with exposure via other routes. Sectors (most relevant): Construction, mining, energy, sewerage/water. Geographical impacts: Possibly greater costs in MS reporting failure of existing EQS. Possibly greater costs in MS with high number of facilities reporting high total emissions to water, esp. FR, PL, UK, and/or in MS with higher percentage of lead communication pipes, e.g. FR, IE, UK (estimated cost of replacement in UK approx £8-10 billion in 2005.)	
Uncertainties:	
Extent of failure of current EQS, and extent of variation in DOC (thus bioavailability of lead) across the EU. Effectiveness of lower lead standard in drinking water (10 µg/l) at reducing lead in domestic effluent.	

Effectiveness of existing and possible additional measures at contributing to meeting the EQS.

Naphthalene factsheet	
Proposal: Slightly more stringent EQS for freshwater, introduction of MAC for existing substance.	**Proposed status:** Unchanged (PS)
Proposed critical EQS: QS $_{\text{freshwater, eco}}$	2.0 µg/l (cf 2.4 µg/l) (same for marine cf 1.2)
Proposed corresponding EQS in freshwater:	Not relevant
Proposed MAC:	130 µg/l (cf none)
Rationale:	
Review of the QSs prompted by revised RAR for pitch.	
Main sources (production, use etc):	
Aromatic hydrocarbon. Occurs naturally in fossil fuels/derivatives and is produced during combustion; is therefore emitted from industrial processes using fossil fuels or involving combustion. Production (approx 200000 tonnes per annum in EU) from coal tar and petroleum for use as a chemical intermediate (in the production of plasticiser intermediates, pesticides and dyestuffs) mothballs, grinding wheels and pyrotechnics. Approx 25% exported. Also present in creosote, tar paints etc.. Reported emissions to air and water (approx 192 and 190 tonnes respectively in E-PRTR 2008) highest from the energy sector (especially to water, mainly from oil drilling/refining) and metals (including aluminium) production. Other emissions to water from wood treatment with creosote etc. Emissions from incomplete combustion (including from vehicles, domestic fuel and agricultural burning, and wildfires) could lead to atmospheric deposition, but half-life in air short.	
BASELINE	
2 MS (RO, UK) report current failure of existing AA-EQS in at least one water body. INERIS monitoring database reports no concentrations higher than proposed EQS or MAC. EU RAR calculates PECs that could locally exceed AA-EQS or MACs close to industrial point sources. Regulation (EC) No 850/2004 on POPs imposes release reduction provisions; REACH Annex XVII restrictions. possible inclusion in Annex XIV; IPPC Directive; Directive 2004/107 on concentrations in air; Directive 98/70/EC on PAH content of diesel; Directive 98/8/EC – restrictions on biocidal use; Directive 91/414/EEC excludes naphthalene-based PPPs. Various BATs and BREFs, e.g. for aluminium production; Regulation (EC) No 1881/2006 on food standards for PAHs; inclusion in Annex I of Directive 98/8/EC effective from May 2013.	
IMPACTS	
Costs:	
Mostly in baseline, since little change in AA-EQS and no reported exceedance of proposed MAC. Possibly additional measures directed at (industrial) point source emissions if MAC exceeded. Admin costs: None beyond baseline, except possibly additional permitting administration and additional targeted monitoring in the short term in relation to the MAC.	
Benefits:	
Mostly in baseline, but possible acceleration of local improvements in water quality and ecosystem health.	
Special points:	
Sectors (most relevant): Chemicals, energy, metals production. Geographical impacts: Producers located in AT, BE, DE, DK, ES, FR, IT, NL, UK. Could be more affected than other MS by any need for additional point-source controls in view of introduction of MAC.	
Uncertainties:	
Extent of failure of proposed EQS and MAC in some MS. Inclusion or not in REACH Annex XIV	

Nickel factsheet	
Proposal: Revised EQS taking account of bioavailability, for existing substance,	**Proposed status:** Unchanged (PS)
Proposed critical EQS: QS $_{freshwater, eco}$	2 or 4 (fresh), 8.6 (salt) (bioavailable) µg/l (cf 20 µg/l)
Proposed corresponding EQS in freshwater:	Not applicable
Proposed MAC:	34 µg/l

Rationale:

New information (EU RAR 2008, SCHER review of RAR 2009, additional industry studies related to REACH registration), and need to consider bioavailability.

Main sources (production, use etc):

Production (from ore) approx 80000 tonnes per annum in EU (500 million Euros). Mined in 21 European countries. Used mainly (85% of "new" nickel) in alloys, also in metal plating, batteries, pigments, other chemicals, steel production (especially stainless). Products (wide range, e.g. vehicles, domestic appliances and fittings, chemical plants, medical equipment) valued at 40 billion Euros/annum in EU.

Emissions to water (467 tonnes reported in E-PRTR for 2008) highest from industrial processes (including pulp and paper processing, electrolytic and chemical processes), steel products in contact with water (including heating elements), waste disposal, mining. Significant flow through UWWTPs. Emissions to air (350 tonnes in E-PRTR for 2008) from combustion, some of which reaches water by atmospheric deposition (directly and via soil). Inputs also from manure use in agriculture. Some diffuse sources, e.g. urban road run-off, pass through UWWTPs.

BASELINE

9 MS report failure of current EQS in up to 3.7% of rivers. EQS (bioavailable) of 2 µg/l or 4 µg/l effectively more stringent than existing (i.e. at approx 5.6 or 11.2 cf 20 µg/l total dissolved Nickel, assuming standard dissolved organic carbon (DOC), pH and hardness), therefore failures more likely, particularly in areas with low DOC. Estimated failure – up to approx 50% of monitoring sites in some MS at 2 µg/l . Nickel subject to control under several Directives and Regulations, including REACH, IPPC/IED, Drinking Water Directive, Groundwater Directive, WEEE Directive, Batteries Directive, but probably not sufficient to achieve revised EQS..

IMPACTS

Costs:

Possible increase in need for control measures to reduce industrial Nickel emissions to UWWTPs especially where DOC levels are low (e.g. improved BAT; precipitation/reverse osmosis to treat effluent at source – 65% removal possible, capital cost per reverse osmosis unit 30,000 €, plus running costs). Reduced Nickel usage in vehicle parts (tyres etc) and road surfaces. Possible replacement of domestic appliances. Possible additional treatment of landfill leachate (25-40% removal; cost per plant 90,000-180,000 €, plus annual running costs around 35-100 €; additional water treatment at UWWTPs (£335 million per annum in UK for sand filtration and GAC), measures to reduce atmospheric emissions (low-sulphur fuels, desulphurisation - £100-1000 million/tonne decrease), lime dosing of abandoned mines (£3.5 million capital cost, £1 million/annum to run).

Admin costs: Possible slight increase in monitoring costs for some MS, i.e. those not already monitoring the parameters required to run biotic ligand models.

Benefits:

Some in baseline, but stricter EQS likely to lead to better water quality and ecosystem health (nickel is toxic and can accumulate in soils/sediments), therefore potential for improved aquaculture/fishing. Focus on bioavailability likely to lead to better monitoring information, therefore also better targeting of control measures/remediation. Benefits to human health mainly if measures lead to decreased atmospheric emissions.

Special points:

Sectors (most relevant): Chemicals, domestic appliances, metal alloys, mining, energy, sewerage/water.

Geographical impacts: Possibly greater costs in MS reporting failure of existing EQS. Possibly greater costs in MS with high number of facilities reporting high total emissions to water, esp. FR, DE, IE, IT, UK.

Uncertainties:

Extent of failure of current EQS, and extent of variation in DOC, pH (thus bioavailability of nickel) across the EU. Effectiveness of existing and possible additional measures at contributing to meeting the EQS.

PAHs factsheet	
Proposal: Biota EQS as critical EQS for all but Benzo(g,h,i)perylene. Corresponding water EQS more stringent than existing EQS. MAC introduced for three PAHs; slightly changed for Benzo(a)pyrene. Revised EQS for Benzo(g,h,i)perylene slightly less stringent in freshwater, more stringent in saltwater.	**Proposed status:** Unchanged (PHS)
Proposed critical EQS: QS $_{biota, hh}$ **Proposed corresponding EQS in freshwater:** **Proposed MAC:**	2 or 5 or 10 µg/kg biota ww (fish, crustaceans & cephalopods, molluscs, respectively, in fresh and marine water); Benzo(a)pyrene as marker. 1.7 10^{-4} ug/l
Rationale:	
Review of the QSs prompted by revised RAR for pitch.	
Main sources (production, use etc):	
Aromatic hydrocarbon. Occurs naturally in fossil fuels/derivatives and is produced during combustion; is therefore emitted from industrial processes using fossil fuels or involving combustion. Not produced or used in pure form. Used through use of coal tar pitch, high temperature (CTPHT); production approx 800000 tonnes in 2004 in EU, small amount imported, more than one third exported. Main use in binding agents for e.g. electrodes, furnace lining materials (refractories), road construction, roofing. Also present in creosote, tar paints, tyres etc.. Reported emissions to water approx 10 tonnes in E-PRTR 2008, highest from metals production (particularly aluminium) and the energy sector (mainly from refining and combustion). Other emissions to water from production of basic organic chemicals, animal and vegetable products from food/beverage industry, wood treatment with creosote etc. Emissions from incomplete combustion (including from vehicles, domestic fuel and agricultural burning, and wildfires) may lead to atmospheric deposition.	
BASELINE	
6 to 10 MS report current failure of existing AA-EQS for some PAHs (most commonly Indeno(1.2.3-cd)pyrene and Benzo(g,h,i)perylene, in one or more water bodies. Calculated PECs in EU-RAR indicate that concentrations could be higher than proposed EQS and MAC. Regulation (EC) No 850/2004 on POPs imposes release reduction provisions; REACH Annex XVII restrictions. possible inclusion in Annex XIV; IPPC Directive; Directive 2004/107 on concentrations in air; Directive 98/70/EC on PAH content of diesel. Various BATs and BREFs, e.g. for aluminium production; Regulation (EC) No 1881/2006 on food standards for PAHs; inclusion in Annex I of Directive 98/8/EC effective from May 2013.	
IMPACTS	
Costs:	
Possibly additional measures directed at (industrial) point source emissions. Possible additional waste water treatment. Possible costs related to changes in domestic fuel use. Admin costs: Possible change in monitoring costs due to shift to biota standards. Possibly remediation costs (MS and/or industry).	
Benefits:	
Better knowledge of water quality (due to switch to biota monitoring). Improvement in water quality; decreased scope for accumulation in the environment (binds to particles), potential for better biota health and better aquaculture/fisheries/angling (including reduced wastage); potential for better human health (most PAHs are carcinogenic), though existing food standards should already be met and protective.	
Special points:	
Sectors (most relevant): Chemicals, energy, metals production. Geographical impacts: Relevant industries (point sources) more prevalent in some MS than others. Possible greater impact on ES aluminium producers if still using the Söderberg technique.	
Uncertainties:	
Extent of failure of proposed EQS and MAC in some MS. Inclusion or not in REACH Annex XIV	

PBDE factsheet	
Proposal: Biota EQS (and correspondingly more stringent water EQS) for existing substance, intended to cover additionally commercial octa BDE (BDE-197).	**Proposed status:** PHS for tetra, penta, hexa and hepta BDEs
Proposed critical EQS: QS $_{biota, hh}$ **Proposed corresponding EQS in freshwater:**	8.5 10^{-3} µg/kg biota ww 4.9 10^{-8} µg/l
Rationale:	
Modelling-based prioritisation identified octa BDE (BDE-197) as a priority. EQS for the group of BDEs (hitherto for penta BDE (CAS 32534-81-9)) therefore reviewed to cover octaBDE (CAS 32536-52-0) and take account of new information. However, proposed EQS based on BDE 99 (penta derivative). Biota recognised as most appropriate matrix.	
Main sources (production, use etc):	
Industrial chemicals, used as flame retardants. Only deca BDE still used in EU – mainly as flame retardant for textiles (drapery, upholstery) and in non-electrical-equipment-related polymers. Not chemically bound. Emissions to environment (air, water, soil) from all phases of life cycle, therefore from formulation and new use of deca BDE products, and from use and disposal of existing products, including furniture, upholstery, carpets, drapery, computers, televisions, automotive parts (penta BDE particularly from flexible polyurethane foam, octa BDE and deca BDE from housings for electrical and electronic products). Commercial deca BDE contains deca and nona BDE and a trace of the octa BDE derivative, and can debrominate. E-PRTR emissions to water mainly from textile factories and UWWTPs.	
BASELINE	
Five MS report current failure of existing standards. Penta and octa BDE subject to restricted use under Regulation (EC) No 552/2009 – use effectively banned in EU since 2004. POP designation (Regulation (EC) No 850/2004) for tetra, penta, hexa, and hepta derivatives since 2010. Deca BDE banned in electrical and electronic equipment since 2008 (Directive 2002/96/EC); other uses continue; not produced in EU, but imported (60k tonnes produced worldwide in 2007). Alternatives exist. Disposal controlled by WEEE directive. Limits in waste being proposed. Voluntary control (VECAP) for industrial emissions. Possible inclusion of penta and octa BDEs in Rotterdam Convention.	
IMPACTS	
Costs:	
Mostly in baseline. Possibly enhanced waste water treatment costs and CO_2 emissions to meet lower EQS. More stringent treatment of landfill leachate. Admin costs: Possible slight change to monitoring costs (shift from water to biota monitoring) for MS; possibly increased identification of sites for remediation. Possibly costs of scheme(s) to remove products from use (though such schemes unlikely).	
Benefits:	
Most in baseline. Better water quality and ecosystem health; decreased scope for bioaccumulation, therefore potential for better biota health; potential for better aquaculture/fisheries/angling; improved consumer confidence; potential for better human health; employment in remediation work. Biota monitoring could improve quality of monitoring information, therefore also the targeting of remediation.	
Special points:	
Note: PHS designation of penta BDE (technical/commercial mixture) consistent with approach under Stockholm convention. Most costs and benefits expected to be realised under the baseline. Sectors (most relevant): Textiles, sewerage/water. Geographical impacts: Possible impacts on producers outside EU if need to meet lower EQS for lower brominated congeners leads to restrictions on use of deca BDE. Benefits likely beyond the EU.	
Uncertainties:	
Extent of failure of EQS in MS due to inadequate analytical sensitivity.	

PFOS factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{biota,\ sec\ pois}$	9.1 µg/kg biota ww
Proposed corresponding EQS in freshwater:	6.5 10^{-3} µg/l
Rationale:	
Annex III substance, PBT, POP, risk ratio >1	
Main sources (production, use etc):	
Industrial chemical, not produced in EU. Used in fire-fighting foams (residual use due to end 2011), coatings in photography and photolithography (semi-conductors), wetting agents in electroplating (until 2015), mist suppressants in chromium plating, and hydraulic aviation fluids. Possible emissions from use/disposal of old products (carpets, textiles), and from soils/sewage sludge/sediments.	
BASELINE	
Monitoring database contains data from 3 MS and NO, all showing exceedances of proposed EQS. REACH (Annex XVII) derogations for some uses. However, gradual substitution, therefore decrease in emissions from new use, expected. POP designation (Stockholm Convention) should also reduce emissions from new use. But emissions from old uses likely to continue, and PFOS will persist in the environment.	
IMPACTS	
Costs:	
Remediation of soil/sediment and/or enhanced waste water treatment costs and CO_2 emissions. Possible earlier development costs for alternatives in photography, photolithography, aviation. In the absence of alternatives, cost of phasing out emissions to water could be disproportionate. Admin costs: Monitoring costs for MS, possibly remediation costs (MS and/or industry).	
Benefits:	
Better knowledge of water quality; remediation if necessary, resulting in better water quality and ecosystem health; decreased scope for bioaccumulation, therefore potential for better biota health; potential for better aquaculture/fisheries/angling; improved consumer confidence; potential for better human health (workers, consumers); stimulation of innovation; potential employment in remediation work.	
Special points:	
Note: PHS designation consistent with approach under REACH. Many benefits expected to be achieved under the baseline, but could be accelerated. Sectors (most relevant): Aviation industry. Semi-conductor industry. Geographical impacts: Probably no differences in EU. Possible impact on China (only producer).	
Uncertainties:	
Spatial distribution of PFOS in environment; extent of failure of EQS; timeline for availability of alternatives.	

Quinoxyfen factsheet	
Proposal: New priority substance	**Proposed status:** PHS
Proposed critical EQS: QS $_{\text{freshwater, eco}}$	0.15 µg/l
Proposed corresponding EQS in freshwater:	-
Rationale:	
Annex III substance; PBT properties.	
Main sources (production, use etc):	
Use as PPP (fungicide), predominantly on cereals and grape vines, thence losses to water by way of spray-drift, run-off, spills. Otherwise secondary release, e.g. by leaching, from contaminated soils and sediments. EU sales 68 000 kg/yr.	
BASELINE	
Limited monitoring data (2 MS) shows isolated exceedance of EQS in FR, but authorised in 17 MS, therefore uncertainty regarding other MS. Losses to water could decrease with introduction of National Action Plans for PPPs under the Sustainable Use of Pesticides Directive; current authorisation under Directive 91/414/EEC acknowledges need to limit risk to aquatic environment; exclusion from Annex I of that Directive would be expected to follow after review of authorisation in 2014 given position in Regulation (EC) No. 1107/2009 on not authorising PBTs, if PBT properties confirmed.	
IMPACTS	
Costs:	
Costs to one (major agrochemical) producer and formulators/retailers unless can provide substitute products. Costs to users if substitutes more expensive. Possible concern regarding resistance of powdery mildew to alternatives, although several alternatives are authorised (Entec 2011, ADAS 2010, HGCA 2009). Fewer of them may be suitable for hops than for other crops. Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; potential for better water quality and biodiversity, better biota and human health, aquaculture/fisheries/angling.	
Special points:	
Sectors (most relevant): Agrochemicals, Arable farming. Geographical impacts: Impacts particularly on farmers in DE, ES, FR, IT (highest sales in these MS); possibly on employment if production localised; US-based company but location of production of active substance not known.; at least 6 formulators/marketers in FR, 3 in UK. (case-study MS); no data for other MS.	
Uncertainties:	
Extent of failure of proposed EQS in several MS in absence of widespread monitoring. Possibility of decrease in use under baseline because of resistance.	

Terbutryn factsheet	
Proposal: New priority substance	**Proposed status:** PS
Proposed critical EQS: AA-EQS $_{freshwater,eco}$	0.065 µg/l
Proposed corresponding EQS in freshwater:	Not relevant
Rationale:	
Ranked high in modelling based prioritisation, medium in monitoring-based prioritisation, toxic, risk ratio >1	
Main sources (production, use etc):	
Biocidal (algicidal) use - approx 200 tonnes/yr in EU - especially in coatings on buildings, from which run-off occurs.	
BASELINE	
Monitoring data from 9 countries shows exceedances of EQS in 4 MS and CH. Losses to water could be lower in coming years because no longer in Annex I of Directive 91/414/EEC (2003 and 2007 staged withdrawal of herbicidal use authorisation in different MS). Uses as preservative for film, wood, masonry currently being reviewed under the Biocidal Products Directive 98/8/EC; outcome could affect baseline.	
IMPACTS	
Costs:	
Installation and maintenance of sustainable urban drainage systems (SUDs) (variable depending upon type). Possible enhanced waste water treatment. Admin costs: Monitoring costs for MS.	
Benefits:	
Better knowledge of water quality; feedback to the biocidal products authorisation process. Possible benefits to biodiversity, and to angling. Reduced risk of failure of drinking water standards. SUDs could have shared benefits, e.g. flood control, energy saving. Stimulation of innovation in construction to minimise need for biocidal coatings.	
Special points:	
Note: Some benefits expected to be achieved under the baseline, but not all MS have SUDs in place to capture run-off in urban areas, and this could lead to improvements, as could changes in pattern of use. Sectors (most relevant): Construction, Coatings Geographical impacts: Marketed by two companies in EU. Products formulated in various MS, including LV; active substance produced at least partly outside EU.	
Uncertainties:	
Extent of failure of EQS now that no longer used as herbicide. Availability of substitutes.	

Trifluralin factsheet	
Proposal: New status for existing substance	**Proposed status:** PHS
Proposed critical EQS: Unchanged **Proposed corresponding EQS in freshwater:**	As in existing EQS Directive
Rationale:	
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. 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).	
Main sources (production, use etc):	
Possibly residual (non-authorised) use as PPP (herbicide), thence losses to water by way of spray-drift, run-off, spills. Possible isolated emissions via UWWTPs due to recovery/disposal of hazardous waste (data for ES and IT in E-PRTR 2007, 2008). However, no longer authorised for use in EU. Possible emissions from production (for export) in HU, though none reported in E-PRTR. Possible secondary release, e.g. by leaching from contaminated soils and sediments.	
BASELINE	
Current failure of EQS in CY, ES, HU, IT, NL, RO, SK. No further primary emissions from use expected at present (authorisation under Directive 91/414/EEC withdrawn in 2009). Any emissions from production in HU would have to cease if POP designation agreed. Possibly secondary emissions from disturbed sediments.	
IMPACTS	
Costs:	
Possible cost to producer in HU if production for export had to cease, with possible loss of jobs unless redeployment possible – though these costs would be in baseline if designated as POP. Admin costs: Possibly remediation costs (MS and/or landowners).	
Benefits:	
Remediation if necessary, with potential for better water quality and better biota and human health; potential for better fisheries/aquaculture/angling.	
Special points:	
Note: PHS designation consistent with latest scientific information and approach under PPP legislation. Some impacts would be in baseline if POP designation agreed. Sectors (most relevant): Agrochemicals, Arable farming Geographical impacts: Possible impact in HU if production causes emissions, as production would have to cease. Impacts otherwise greatest in MS where use was greatest and/or exceedance of EQS is observed, if remediation proves necessary.	
Uncertainties:	
Extent of contamination of soils/sediments and secondary emissions. POP designation.	

ANNEX VI: Description of the main policies affecting the baseline and interactions with the WFD

Implementation of the WFD: measures in river basin management plans (RBMPs)

The 13 existing substances that have been assessed are already included as PS or PHS in Annex X of the WFD, with EQSs listed in Annex I of the EQS Directive. For these substances, measures should already have been identified and their implementation be underway or planned where failures of the EQS occur. The approach to achieving phase-out of emissions of PHS should also be under consideration.

For all existing substances there are existing EU measures. Measures sheets have been compiled for all of them. See factsheets in Annex V for summary information.

One of the difficulties involved in assessing the impacts of a change to an existing substance is to understand the extent to which MS intend to undertake measures, the detail of those measures, and their likely effectiveness. The WFD requires MS to adopt and publish RBMPs and programmes of measures in December 2009. 20 MS have adopted plans and programmes at the time of writing this impact assessment report. Another 3 are expected to adopt them in 2011. The remaining 4 are expected to have longer delays.

Once the plans and programmes are adopted, the WFD gives MS until December 2012 at the latest to make operational the measures. This means the details about implementation of the measures are being developed at the moment. This leads to considerable uncertainty in assessing the ultimate effectiveness of measures.

In addition to substance-specific measures, another source of uncertainty stems from a number of generic measures that are included in the programmes of measures that aim to improve water quality and/or reduce concentrations of certain types of pollutants in the environment. These are relevant to both existing and proposed substances. For example, the study by EcoLogic and ACTeon (2010) which reviewed agricultural measures in WFD draft programmes across Europe identifies some of these measures. This provided information relevant to proposed substances including general information on PPP policies and trends, and information on diffuse nutrient pollution that could contribute towards addressing substances such as 17 beta-estradiol (e.g. measures to reduce nutrient input to rivers, such as preventing cattle reaching river banks).

There are also a range of measures to address water quality that are not specific to a substance and will provide overall improvements, while at the same time contributing towards compliance of specific substances (i.e. including the existing and proposed substances assessed here). Such measures include:

- Improved wastewater treatment;
- Addressing urban runoff (both water quality and flood risk) through use of Sustainable Urban Drainage Systems (SUDS);
- Measures to address morphology pressure, including improving riparian habitats;

- Measures to address rural diffuse pollution (particularly reductions in nitrogen and phosphorus inputs), for example by controls on manure spreading, preventing cattle reaching river banks, general PPP measures.

While not necessarily targeted at particular existing or proposed substances, over time these measures have the potential to contribute towards achieving the EQSs of a range of substances.

Some of the proposed substances are explicitly considered by some MS, where they are defined as Specific Pollutants. This means that the relevant MS are already committed to monitoring the substance and addressing any failures of the (existing) EQS. However as the EQS is self-defined by the MS, it may still be necessary for the MS to undertake further work if the substance were to be defined as a PS/PHS, potentially with a more stringent EQS. Information collected from WG E representatives to the Commission (note that not all MS provided information) indicates that 10 of the 15 proposed substances are already included as specific pollutants in at least one MS. Heptachlor, PCBs, and Dioxins are the most commonly monitored, probably as a result of obligations under the Stockholm Convention.

Substance	MS including the substance as specific pollutant	Number of MS
Aclonifen	SE (0.2 µg/l; 0.1 mg/kg sediment)	1
Cybutryne	SE (0.003 µg/l in marine water; 0.0002-0.0008 mg/kg dw)	1
Cypermethrin	DK (1 µg/kg in river or lake sediment)	2
	UK (0.1 ng/l annual mean; 0.4 ng/l 95th percentile)	
Dichlorvos	BE (0.0007 µg/l average, 0.007 µg/l MAC), IT (0.01 µg/l), NL (0.0006 µg/l), IE (monitored but no EQS), DE (0.0006 µg/l)	5
Dioxins (and DL-PCBs)	DK (between 0.00005-0.0001 µg/kg WW in marine bivalves; between 0.1-0.2 µg/kg WW in marine sediment; between 0.0002-0.0004 µg/kg WW in marine fish),	4
	IT (sum T.E. PCDD, PCDF and PCB dioxin-like): 0.002 µg/kg dw	
	SE (0.9 ng TEQ fish/kg; 8 pg TEQ mammals/g)	
	IE (monitored but no EQS)	
HBCDD	DK (0.2 µg/kg WW marine fish)	2
	SE (0.3 µg/l in freshwater, 0.03 µg/l in marine water; 0.9 mg/kg sediment; 1.5 mg/kg biota)	
Heptachlor	AT (0.004 µg/l), BE (0.009 µg/l average; 0.09 µg/l MAC), IT (0.005 µg/l), RO (0.0002 µg/l), CY (monitored but no EQS), IE (monitored but no EQS), NL (0.0005 µg/l), DE (0.1 µg/l)	8
PFOS	DK (0.2 µg/kg WW marine fish)	3
	CZ 25 µg/l	
	SE (30 µg/l in freshwater; 3 µg/l in marine water; 0.006 mg/kg biota)	
Terbutryn	CZ (0.1 µg/l), BG (0.01 µg/l)	2

Based on WISE electronic submission from 19 MS (AT, BE, BG, CZ, DE, EE, FI, FR, HU, IE, IT, LT, LV, NL, PL, RO, SE, SK and UK) plus data from ENTEC (2011) for DK and CY

In summary, there is considerable uncertainty regarding the impact that the WFD programmes of measures will have in reducing the emissions of existing and proposed PS, and ultimately in reducing their presence in the environment.

Plant Protection Products

Active substances may only be included in PPPs in the EU if they are authorised by inclusion on Annex I of Directive 91/414/EEC (regarding placement of PPPs on the market). Individual active substances can be added to Annex I by individual directives which, in some cases, include requirements or restrictions on use of the substance (for example requirements to leave a buffer zone around surface water bodies).

Directive 91/414/EEC will be replaced by Regulation (EC) No 1107/2009 in June 2011 which maintains the authorisation of active substances at EU level.

Directive 2009/128/EC, establishing a framework for community action to achieve the sustainable use of pesticides, will be implemented from 2011. The directive includes measures to:

- Include instructions on safety, storage and disposal of pesticides with sales;
- Improve public awareness of possible risks from the use of pesticides;
- Promote research programmes aimed at determining the impacts of pesticide use on human health and the environment;
- Provide systems for regular inspection of pesticide application equipment. These must commence by 2016 and be carried out at least once every five years, and a certification programme put in place;
- Generally prohibit the use of aerial spraying (from a plane or helicopter) of pesticides (although derogations are possible);
- Take measures to avoid pollution of the aquatic environment, such as using the most efficient application techniques, establishing buffer strips, planting hedges along waterbodies, and reducing or eliminating use in areas with a high likelihood of runoff of surface water or sewers (e.g. roads and railways);
- Promote low-pesticide pest management methods (including integrated pest management and organic farming);
- Minimising or prohibiting use of pesticides in sensitive areas including Natura 2000 sites and public spaces (such as parts or sports grounds).

All of these measures must be implemented in National Action Plans, which are to be communicated to the Commission by 14 December 2012. As the plans have not been produced yet, there is some uncertainty about the exact measures that will be put into place, but the directive clearly has the potential to reduce concentrations of PPPs in water.

The Directive complements well the action under the WFD but does not replace it. The EQS under the WFD provide a benchmark for assessing whether measures are effective, and the WFD focuses on PPPs that have been identified as posing a risk to the aquatic environment.

The substances that are included in the policy options and that are concerned by the PPP legislation are Trifluralin, Dicofol, Quinoxyfen, Aclonifen, Bifenox, Cypermethrin, Dichlorvos, Heptachlor and Terbutryn.

Biocides

Directive 98/8/EC on the placing on the market of biocidal products aims to:

- Harmonise the European market for biocidal products and their active substances;
- Provide a high level of protection for people, animals and the environment through risk assessment;
- Ensure products are sufficiently effective against the target species.

Active substances that are authorised for use are placed on to Annex I of the directive. However the review programme, i.e. the approval for placing on Annex I, is still ongoing. The review covers 23 different product types including, for example, disinfectants, preservation products, non-agricultural pesticides, and anti-fouling products. It does not include PPPs, which are covered under Directive 91/414/EEC.

A Commission proposal (COM(2009) 267) to replace Directive 98/8/EC is currently under negotiation. The regulation aims to improve the functioning of the internal market in biocidal products while maintaining the high level of the environmental and human health protection. As under Directive 98/8/EC there would be a two-tiered authorisation process: inclusion of the active substance in Annex I, followed by authorisation of the biocidal product.

The substances that are included in the policy options and that are concerned by the biocides legislation are Cybutryne, Cypermethrin, Dichlorvos and Terbutryn.

Persistent organic pollutants

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Stockholm Convention was adopted in 2001 and entered into force in 2004. It required parties to take measures to eliminate or reduce the release of POPs into the environment. There were twelve original POPs, including pesticides, industrial chemicals and by-products. In 2009, nine additional chemicals were added to the annexes of the Stockholm Convention. There are three classifications:

- Annex A (elimination): parties must take measures to eliminate the production and use of the chemicals listed under Annex A. In some cases, specific exemptions for ongoing use or production may be made;
- Annex B (restriction): parties must take measures to restrict the production and use of the chemicals listed under Annex B in light of any applicable acceptable purposes and/or specific exemptions listed in the Annex;
- Annex C (unintentional production): parties must take measures to reduce the unintentional releases of chemicals listed under Annex C with the goal of continuing minimisation and, where feasible, ultimate elimination.

The convention is implemented in the EU through Regulation (EC) No 850/2004. The regulation complements earlier Community legislation on POPs and aligns it with the provisions of the international agreement. The regulation contains provisions regarding

production, placing on the market and use of chemicals, management of stockpiles and wastes, and measures to reduce unintentional releases of POPs. Furthermore, MS must set up emission inventories for unintentionally produced POPs, national implementation plans (NIPs) and monitoring and information exchange mechanisms.

The WFD mechanism can ensure monitoring of these substances in the aquatic environment and facilitate progress towards the cessation/phase-out objective. It has been recognised that under the Stockholm and UNECE LRTAP Conventions "there is a general lack of coordinated monitoring or regional surveys that focus on POPs in the freshwater environment"[49].

The following substances relevant to this assessment are included under the Stockholm Convention: Heptachlor, Dioxins, PCBs, some polyBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE) and PFOS.

REACH

Regulation (EC) No 1907/2006 deals with the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH). It entered into force in June 2007. The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. The regulation required manufacturers and importers to gather information on the properties of their chemical substances, and to register the information in a central database.

The elements in REACH include:

- All substances are covered by the REACH regulation unless they are explicitly exempted;
- Registration requires manufacturers and importers of chemicals (1 tonne or above per year) to obtain relevant information on their substances and to use those data to identify and apply the appropriate risk management measures. Substances not included include those that are regulated elsewhere (e.g. PPPs, biocides and medicinal products), those present at very low risk, or those occurring in nature that have not been chemically modified (e.g. minerals, ores);
- Substances of very high concern may be included in the Candidate List and may be made subject to authorisation (inclusion in Annex XIV). For these substances to continue to be used, applicants will have to demonstrate that risks associated with uses of each substance are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternative substances or technologies.

[49] Global Monitoring Plan for Persistent Organic Pollutants under the Stockholm Convention Article 16 on effectiveness evaluation. First regional monitoring report Western Europe and other groups Region (2008). http://chm.pops.int/Portals/0/Repository/GMP/UNEP-POPS-GMP-RMR-WEOG.English.PDF and UN-ECE Convention on Long-Range Transboundary Air Pollution. Working Group on Effects. POPs in the Freshwater environment: Effects of long-range transboundary air pollution. EB.AIR/WG.1/2005/6 (2005). http://www.unece.org/env/documents/2005/eb/wg1/EB.AIR.WG.1.2005.6.e.pdf

- Restrictions can be placed on the manufacture, marketing or use of particular substances.

DEHP and HBCDD have been added to REACH Annex XIV for authorisation (February 2011).

Other substances included in this assessment are being considered for authorisation. This includes Anthracene (and related oils, pastes) and coal tar pitch high temperature (relevant to PAHs, Anthracene, Fluoranthene, Naphthalene). If these substances are indeed added to Annex XIV, then, depending on the outcome of the authorisation process, the baseline for these substances could change substantially. In any case the WFD will monitor the concentrations of these substances in the aquatic environment and, in the case of PAHs and Anthracene, progress towards the cessation/phase-out objective.

The substances that are included in the policy options and that are concerned by REACH are Anthracene, BDE, DEHP, Lead, Naphthalene, Nickel, PAH, Fluoranthene, PFOS and HBCDD.

Industrial emissions

The Directive on Industrial Emissions (Directive 2010/75/EC) recasts seven existing Directives relating to industrial emissions into a single coherent legislative instrument. The recast covers the Integrated Pollution Prevention Control (IPPC) Directive, the Large Combustion Plants Directive, the Waste Incineration Directive, the Solvents Emissions Directive, and three Directives on Titanium Dioxide. The directive has been developed to: improve implementation of BAT; reduce limitations of compliance enforcement and environmental improvements; reduce unnecessary administrative burden; improve scope and provision to achieve Thematic Strategy objectives of air, waste and soil.

The Directive uses the concept of Best Available Techniques (BAT). Emission limits and operating conditions contained in the IPPC authorisation permits are based on BAT, taking into account the technical characteristics of an installation, its geographic location and the local environmental conditions. BAT reference documents (BREFs) are produced by the European IPPC-Bureau for each sector.

Potentially all substances are concerned by the industrial emissions directive, although those that are not produced or are only formulated in the EU may not be concerned.

Pharmaceutical legislation

The approval process for medicinal products for human use is described in Directive 2001/83/EC (Directive of the European Parliament and of the Council on the Community code relating to medicinal products for human use) and further amendments. In this directive, the basic parameter for approval is a positive risk/benefit evaluation of the product, which includes a safety and efficacy assessment. As a further parameter, the "potential environmental risk posed by the medicinal product" should be assessed "and, on a case-by-case basis, specific arrangements to limit it shall be envisaged."(EU Directive 2004/27, Article 8 (3b)). In any event, environmental impact cannot constitute a criterion for refusing marketing authorisation for a human medicinal product. However, it is a criterion for veterinary medicinal products.

For existing pharmaceutical products for human use there is no obvious mechanism to revise marketing authorisations on the basis of the environmental impacts.

There is a commitment by the Commission to look at the environmental impact of pharmaceuticals. A study will be launched in 2011 which will build on a large range of studies and information available[50]. Impact of this Commission initiative in the longer term is uncertain at the moment.

The substances that are included in the policy options and that are concerned by the pharmaceuticals legislation are EE2, E2 and Diclofenac.

Waste legislation

Waste legislation covers a large share of the entire EU environmental acquis and includes thirteen main legislative acts adopted by the European Parliament and the Council and a large number of related decisions adopted through comitology procedures. The overall scope of this legislation is the prevention or reduction of waste production, the re-use, the recycling, other types of recovery than recycling and the disposal of different categories of waste; permitting and control of disposal operations, mainly landfills; and shipments of waste within the EU as well as to and from third countries.

The basic requirements are laid down by the Waste Framework Directive 2008/98/EC which is complemented by specific legislation addressing particular environmental threats associated with waste. This specific legislation includes harmonised rules on waste management practices, including strict emission limits and operating requirements for the incineration and landfill of waste; harmonised rules on shipments of waste; and product specific legislation setting targets for collection, re-use, recovery and recycling and introducing producer responsibility principles for specific waste streams derived from consumer goods, in particular packaging waste, end of life vehicles, waste electrical and electronic equipment, mining waste and batteries.

The latest Commission implementation report COM(2009)633 recognises progress on the implementation of the waste legislation but also important implementation gaps. Further progress in the coming years may have an important influence on the baseline for some of the substances identified under the review, as important emissions to water may be generated by waste handling and/or disposal.

Interactions of main upstream policies with the WFD

Existing policies at EU level, at least for industrial chemicals, PPPs and biocides, include appropriate mechanisms that can be used to develop process and product controls to address the risks identified by the WFD.

- Emission controls are best suited to reducing, where necessary, the emissions of PS. However, they may also be appropriate to control the emissions to water of PHS of natural origin or those produced unintentionally, which it may not be possible to eliminate completely. In the context of the 2006 proposal the Commission stated that there were already a number of pieces of EU legislation that set emission controls for

[50] Roig B, 2010; EEA, 2010; SRU, 2007; Swedish Medical Products Agency, 2009; Apoteket, 2006; CGEDD, 2010.

point sources (notably the Urban Waste Water Treatment Directive and the IPPC) and concluded that additional emission controls were best developed and implemented at MS level. This conclusion is still valid.

- Product controls, such as limits on production or use, appear to be best suited to the cessation and phase-out objective for PHS although they may also be useful to reduce emissions from a particular use, e.g. by restriction. A range of tools is already available in the EU legislation:
    - Under REACH, the evaluation, restriction and authorisation processes
    - Under the PPP legislation, the evaluation, restriction and authorisation processes and periodic review
    - Under the biocides legislation, the evaluation, restriction and authorisation processes and periodic review
    - Under the pharmaceuticals legislation, the authorisation and review processes for veterinary medicines.

One of the main objectives of these EU legislative instruments is to prevent the placing in the market of substances that may cause unacceptable risks. PPPs and biocides require risk assessment prior to authorisation. Industrial chemicals need to be registered under REACH, including a chemical safety assessment. If the latter shows the need to limit the risks, the registrant is required to take and recommend adequate risk management measures. Where registration alone is not sufficient to manage the risks, restriction or authorisation may be used.

The WFD identifies PS by assessing the risks to the aquatic environment, largely relying on monitoring information. The WFD prioritisation process acts as a safety net to ensure that the assumptions and results of the risk assessments carried out for placing in the market of certain substances under other legislation, including any mitigation measures that are applied, are actually delivering adequate protection of water resources and of human health via the aquatic environment. The WFD can also identify substances posing a risk that have been in use for many years, in some cases without having been subjected to a proper risk assessment. The WFD can then feed back to these upstream policies the information gathered that demonstrates unacceptable risks, for these policies to act according to their established procedures.

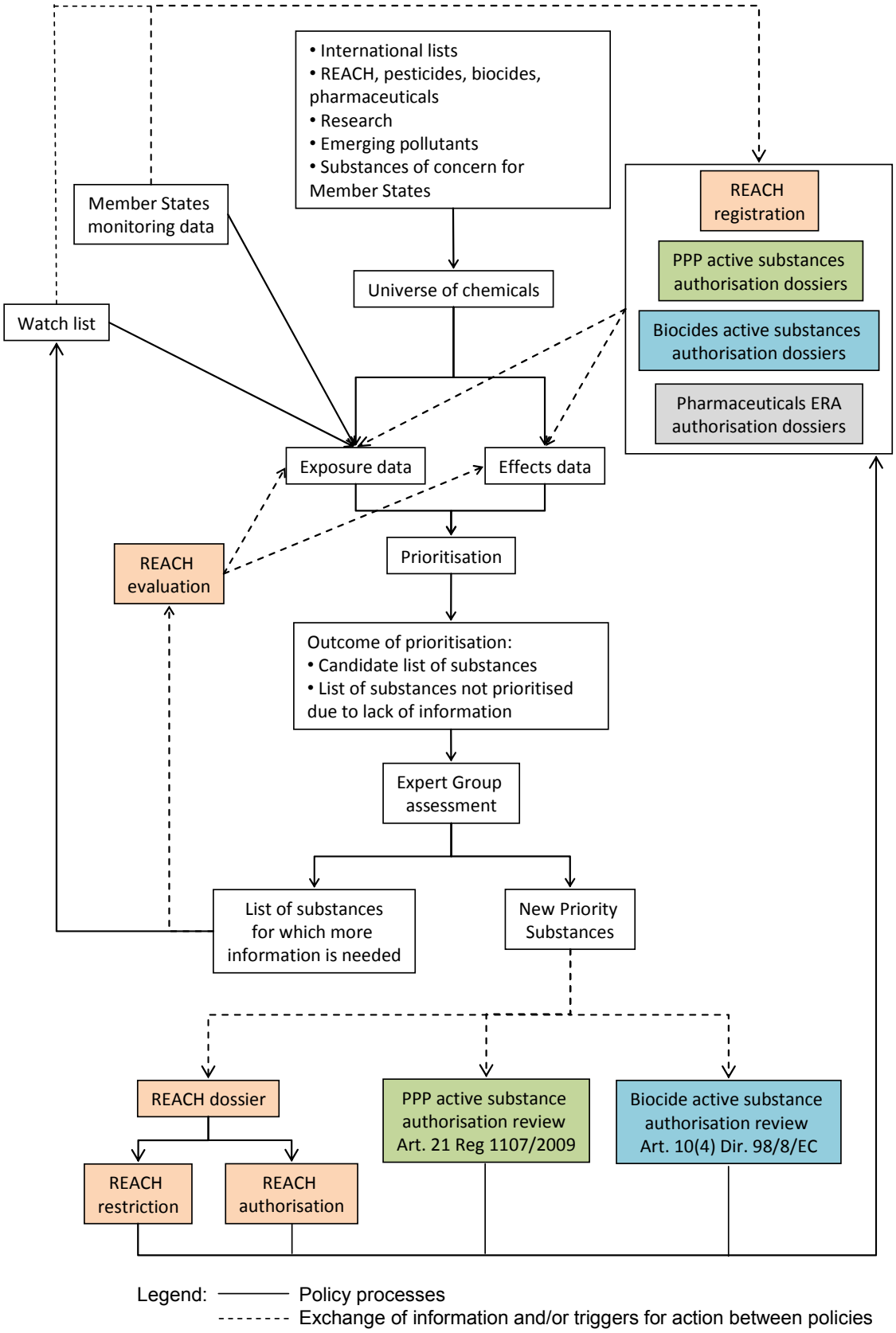
As regards the pharmaceutical legislation, since 2004 it requires applications for the authorisation of new products to be accompanied by an Environmental Risk Assessment. However, the results of this assessment are not considered in the risk-benefit balance that is the basis of the authorisation for human medicines, though it is for veterinary medicines. As regards human pharmaceuticals authorised before 2004, there is no mechanism in the legislation to address environmental impacts.

The diagram on the following page illustrates the interaction of some of the main upstream policies regulating the use and placing on the market of substances (i.e. REACH, PPPs, biocides, pharmaceuticals) with the WFD priority substances process. The white boxes indicate WFD processes. The potential role of the watch list as per options C in the text is also included.

The central vertical process describes the main steps of the WFD prioritisation exercise, including a risk assessment step that uses data on substances exposure and effects. Upstream

policies constitute an important source of data for the WFD prioritisation exercise and on the other hand they also benefit from the monitoring data gathered under the WFD.

Interactions with other policies (waste, industrial emissions) are not included in the diagram.


• International lists
• REACH, pesticides, biocides, pharmaceuticals
• Research
• Emerging pollutants
• Substances of concern for Member States
Member States monitoring data
Universe of chemicals
Watch list
REACH registration
PPP active substances authorisation dossiers
Biocides active substances authorisation dossiers
Pharmaceuticals ERA authorisation dossiers
Exposure data
Effects data
REACH evaluation
Prioritisation
Outcome of prioritisation:
• Candidate list of substances
• List of substances not prioritised due to lack of information
Expert Group assessment
List of substances for which more information is needed
New Priority Substances
REACH dossier
PPP active substance authorisation review Art. 21 Reg 1107/2009
Biocide active substance authorisation review Art. 10(4) Dir. 98/8/EC
REACH restriction
REACH authorisation
Legend:
Policy processes
Exchange of information and/or triggers for action between policies

ANNEX VII: List of stakeholders involved in the consultation

List of stakeholders members of the Working Group E on Chemical Aspects

Organisation	Sector
ECPA (European Crop Protection Association)	Pesticides
Business Europe	Business organisation
AESGP (Association of the European Self-Medication Industry)	Pharmaceuticals
AISE (International Association for Soaps, Detergents and Maintenance Products)	Detergents
CEPI (Confederation of European Paper Industry)	Pulp and paper
CONCAWE (European Oil Companies' Association for Environment, Health and Safety in Refining and Distribution)	Oil
EFPIA (European Federation of pharmaceuticals Industries and Associations)	Pharmaceuticals
EUCETSA (European Committee of Environmental Technology Suppliers Association)	Equipment suppliers
EUDA (European Dredging Association)	Dredgers
Greenpeace	Environmental NGO
Commission OSPAR	International Convention Secretariat
COPA-COGECA (Committee of Agricultural Organisations in the European Union - General Committee for Agricultural Co-operation)	Agriculture
EEB (European Environmental Bureau)	Environmental NGO
EUREAU (European Union of National Associations of Water Suppliers)	Water utilities
EURELECTRIC (The Union of the Electricity Industry)	Energy
WWF (World Wild Fund)	Environmental NGO
CEFIC (European Chemical Industry Council)	Chemical
EUROMETAUX	Metals
EUROFER	Metals
EUROMINES	Mining

The list is also available on the Register of Commission Expert Groups[51].

List of stakeholders addressed in the targeted consultation

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

Organisation	Sector
FEAP (Federation of European Aquaculture Producers)*	Aquaculture
EMPA/AEPM (European Mollusc Producers Association)*	Aquaculture
Europêche*	Fisheries
European Anglers' Alliance	Angling
ETF (European Transport Workers' Federation)	Transport
EAPO (European Association of Fish Producer Organisations)	Fisheries
CESA (Community of European Shipyards Associations)	Shipping
COCERAL	Grain producers
EGA (European Generic Medicines Association)	Pharmaceuticals
CPME (Standing Committee of European Doctors)	Public Health
PGEU (Pharmaceutical Group of the European Union)	Public Health
European Patients' Forum	Public Health
EPHA (European Public Health Alliance)	Public Health
HAI Europe (Stichting Health Action International Europe)	Public Health
HEAL (Health & Environment Alliance)	Public Health
BEUC (The European Consumers' Organisation)	Consumers

* These three organisations are represented on the Strategic Coordination Group under which WG E operates, but do not have members in WG E itself; they were targeted because of the particular relevance to them of the substances under review.

ANNEX VIII: References

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