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EXECUTIVE SUMMARY OF THE 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**

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Disclaimer: This executive summary 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.

1. PROBLEM DEFINITION

1.1. Background

The Water Framework Directive 2000/60/EC (WFD) establishes a comprehensive framework for the protection of surface and groundwater, setting environmental objectives including the achievement of good chemical and ecological status and the prevention of deterioration.. To meet good chemical status, water bodies must meet the Environmental Quality Standards (EQS) set for certain chemicals – the Priority Substances (PS) - identified under the WFD as posing a risk to or via the aquatic environment at EU level. Some PS are identified as Priority Hazardous Substances (PHS) because of their persistence, bioaccumulation and/or toxicity or equivalent level of concern. In addition to the objective of good chemical status, the WFD requires the adoption of control measures aimed at the progressive reduction of PS and at the cessation or phasing out of discharges, emissions and losses of PHS to the aquatic environment. Currently, control measures are taken at MS level; at EU level, measures are reliant on other legislation (such as REACH, plant protection products, biocides). The WFD also allows for exemption from meeting good chemical status in specific water bodies on the grounds of technical unfeasibility, disproportionate costs or natural conditions.

The WFD (Article 16(4)) requires the Commission to review the list of PS at least every four years, and the EQS Directive 2008/105/EC (EQSD) (Article 8) requires the Commission to report the outcome of its first review to the European Parliament and the Council 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 as appropriate, and to review the existing PS. The proposed new substances and changes to existing substances are expected to have an impact in the 2015 updated RBMPs¹ and programmes of measures.

The required review was carried out with the assistance of the Working Group E on Chemical Aspects (WG E) under the WFD Common Implementation Strategy², including participation of all MS and a wide range of stakeholders³. It was a scientific/technical exercise involving the identification of risks from chemicals to the aquatic environment and the setting of EQS for them. The methodology for setting the EQS, and the EQS derived, were submitted to the Scientific Committee on Health and Environmental Risks (SCHER⁴) for its opinion. The impact assessment takes as given the results of the scientific/technical work.

In the course of reviewing the PS list, possible improvements in the functioning of the EQSD 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.

¹ River Basin Management Plans

² <http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy.pdf>

³ <http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=371>, under "Sub-groups", "Priority Substances".

⁴ 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

1.2. What is the issue requiring action?

Three main issues require action:

(i) the availability of new information about risks caused by existing PS and new chemicals. New chemicals are being developed all the time, so not all will have been considered during the first prioritisation and for those that were, new information may have become available.

(ii) the fact that some of the most harmful chemicals already on the PS list or proposed for addition⁵ are ubiquitous persistent, bioaccumulative and toxic (PBT) substances. The measures already taken on those have reduced emissions very significantly. However, because of their intrinsic properties, widespread use and common potential for long-range transport, some of them are still found in the aquatic environment, mostly in sediment and/or biota, at concentrations above the EQS, therefore entailing widespread failures of the objective of good chemical status. Three sub-problems need to be considered, as follows:

- Presentational issue: the widespread exceedances of the EQS by ubiquitous PBTs will hide the improvements made in relation to other substances because the chemical status of water bodies under the WFD has to be reported on the basis of all the PS.
- Choice of monitoring matrix between water, sediment or biota: the EQSD currently allows MS to choose the matrix for each PS. PBTs tend to accumulate in sediment and/or biota and may be hardly detectable in water even with state of the art analytical techniques. MS which apply a water EQS might inappropriately categorise water bodies as having "good chemical status" even when the sediment and/or biota contain PS at levels that still pose a risk.
- Reduced monitoring effort for ubiquitous PBTs: Any changes in the environmental concentrations of ubiquitous PBTs are likely to occur only over the long term and a lower monitoring frequency and lower number of monitoring sites than normal under the WFD would seem justified.

(iii) the fact that there is a paucity of fit-for-purpose monitoring data on which to base assessment of exposure and thus the prioritisation of new PS in future reviews. A very large monitoring database was compiled for the current prioritisation, but more could be done to overcome the vicious circle that unless a substance is already regulated, it is unlikely to be widely monitored, but that if it is not monitored and the environmental concentrations cannot be reliably modelled either, estimation of the risk posed at EU level may not be robust enough to justify regulation.

2. ANALYSIS OF SUBSIDIARITY

Water pollution has a very important transboundary character. 60% of the EU territory lies in shared river basins (EC, 2007). The Union's policy for controlling the pollution of surface waters is set out in Article 16 of the WFD which, together with Article 8 of the EQSD, provides the basis for the PS list and its review. The related issues addressed in the options concern the functioning of the legislation.

3. OBJECTIVES

⁵ PBTs included in the PS list are by definition PHS.

The following table presents the general and specific objectives in relation to the problems, sub-problems and options:

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 latest scientific knowledge Improve knowledge (of risks and effectiveness of measures taken to reduce or eliminate emissions) through monitoring	A2
	Proposed substances		Identify new substances that cause risks and set EQS for them Improve knowledge (as above) through monitoring	A3a-A3c
Specific difficulties with ubiquitous PBTs	Presentational issues	Improve the functioning of the EQSD	Improve communication of progress in water quality within the WFD implementation	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 monitoring ubiquitous PBTs while maintaining the effectiveness of the monitoring	B4a-B4b
Knowledge base	-	Provide adequate tools to improve the future identification of substances of concern to or via the aquatic environment at EU level.	Provide a mechanism to improve the knowledge base and make future identification of PS more effective	C2-C3

4. POLICY OPTIONS

4.1. Policy options in relation to the substances

The first set of policy options refers to the inclusion of substances in Annex X of the WFD, the (re)determination of their status (PS or PHS) and the revision or establishment of EU-wide EQS for them. The options are fully based on the outcome of the expert technical work. They are cumulative on the basis of theoretically increasing impacts, with pharmaceuticals being included last because they have not hitherto been regulated under the WFD. Option A1 represents no change to the current list.

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	N	N
	Poly-BDE	Y*	Y	N
	DEHP	N	N	Y
	Lead	Y	N	N
	Naphthalene	Y	N	N
	Nickel	Y*	N	N
	Polyaromatic hydrocarbons (PAHs)			
	Benzo(a)pyrene	Y*	Y	N
	Benzo(b)fluoranthene	Y*		
	Benzo(k)fluoranthene	Y*		
	Indeno(1,2,3-cd)pyrene	Y*		

Option	Substance	Change or establishment of EQS in water?	Biota EQS proposed?	Change from PS or identified as PHS?
	Benzo(g,h,i)perylene	Y*	N	
	Fluoranthene	Y*	Y	N
	Trifluralin	N	N	Y
Option A3a: Existing-PS changes plus (selected) Annex III substances	Dicofol	Y	Y	Y
	PFOS	Y	Y	Y
	Quinoxifen	Y	N	Y
	Dioxins and DL-PCBs	N	Y	Y
Option A3b: Existing-PS changes plus (selected) 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
Option A3c: Existing-PS changes plus (selected) Annex III substances plus other new substances including pharmaceuticals	Terbutryn	Y	N	N
	17 alpha-ethinylestradiol (EE2)	Y	N	N
	17 beta-estradiol (E2)	Y	N	N
	Diclofenac	Y	N	N

For existing PS, Y* implies a change in EQS greater than one order of magnitude. Other EQS changes for existing PS (marked only Y) are minor.

4.2. Policy options in relation to ubiquitous PBTs and the knowledge base

The three sub-problems associated with ubiquitous PBTs are addressed by sub-options B2a and b, B3a and b, B4a and b. These sub-options, the substance options A2-A3c, and the knowledge-base options C2-C3, are independent. Options B3a and B3b could apply to any PS, not only ubiquitous PBTs.

Option	Description
B1: No change	No change to current functioning of EQSD and WFD
B2a: Allow separate presentation of ubiquitous PBTs	Allow MS to present the ubiquitous PBTs separately from the rest of the PS/PHS in their RBMP assessments, whilst still including them in the chemical and overall assessment.
B2b: Take ubiquitous PBTs out of chemical status	Take ubiquitous PBTs out of chemical status altogether, whilst maintaining the obligation to monitor and report trends. Good status could be met on the basis of satisfying the EQS for the other PS.
B3a: Choice of matrix linked to analytical sensitivity	MS would be able to choose the matrix except where the available analytical technique fulfils the performance criteria ⁶ 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 the others, and there is an EQS available at EU level for at least the 'best performing' matrix.
B3b: Fixedmatrix	The choice of matrix for monitoring and compliance checking would be fixed at EU level for each substance.

⁶ Commission Directive 2009/90/EC requires MS to use analytical techniques that meet certain minimum quality requirements in relation to the EQS. In the absence of techniques that meet such minimum criteria, the best available techniques not entailing excessive costs should be used.

Option	Description
B4a: Conditional decrease in monitoring for ubiquitous PBTs	Reduce monitoring obligations for ubiquitous PBTs if certain specified conditions are met: enough information on the presence of the substance in water bodies (in particular in sediment and/or biota), i.e. a robust monitoring baseline.
B4b: Unconditional decrease in monitoring for ubiquitous PBTs	Reduced monitoring requirements for ubiquitous PBTs would be specified in the EQSD without conditions.
C2: Knowledge base: watch list without legal obligation	Establish a voluntary mechanism for monitoring substances posing a possible risk to or via the aquatic environment at EU level using a "dynamic" list (with substances being regularly added and removed) to ensure the provision of high-quality EU-wide monitoring data for the prioritisation process. Around 20 substances to be on the list at any one time, monitored by MS at 250-300 representative sites across the EU according to agreed technical guidelines.
C3: Knowledge base: watch list with legal obligation	Establish a mechanism as in C2 but with a legal obligation for MS to monitor.

5. ASSESSMENT OF IMPACTS

5.1. Impacts of options related to the substances

Option	Positive impacts	Negative impacts
A2	Better and more robust knowledge of the extent of the risks, coherence with the latest scientific progress, allowing MS and other policies to take the necessary measures to reduce the risks caused by these substances. Improved protection of human health and aquatic biodiversity.	Potential significant costs to upgrade some industrial and UWWTPs (for Nickel) to meet AA-EQS of 2 µg/l, depending on local conditions. (UK estimate of approximately €2 billion whole-life investment plus attendant additional running costs.). Lower costs if AA-EQS set to 4 µg/l.
A3a	As above plus: Additional information about the risk posed by the additional substances and about the effectiveness of related measures. Valuable data and information for decision making in the context of the plant protection product, chemicals, industrial emissions and waste policy. Additional protection of human health and aquatic biodiversity.	Depending on local conditions, potential significant costs to upgrade some industrial and UWWTPs (for Nickel). Additional monitoring costs of 4-9.6 million € per year for the whole EU. Substitution costs for Quinoxifen, if not in baseline.
A3b	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.	Additional cumulative monitoring costs (over and above Option A2) of 12-28.8 million € per year for the whole EU. In addition to non-monitoring costs of option A3a: potential costs of substitution (if necessary for Cybutryne and Terbutryn, possibly Cypermethrin in salmon farming).
A3c	As above plus: Improved information on the extent of pollution by pharmaceuticals, and EU-wide EQS as benchmarks for deciding possible measures at MS level. Additional protection of human health and aquatic biodiversity.	Additional cumulative monitoring costs (over and above Option A2) of 15-36 million € per year for the whole EU. In addition to non-monitoring costs of option A3b: Possible costs of additional UWWTP upgrades to remove E2 if locally required and not sufficient from option A2 and to reduce E2 emissions from livestock to water.

Monitoring costs are likely overestimated for the options that include more substances as, for example, sampling costs increase less steeply as the number of substances increases.

5.2. Impacts of options related to ubiquitous PBTs and knowledge base

Option	Positive impacts	Negative impacts
B2a	Easier demonstration by MS of reduced pollution by other PS despite failures for ubiquitous PBTs. Legal certainty maintained by no change in definition of chemical status.	No significant negative impacts identified though there could be discrepancies between the approaches taken by different MS.
B2b	Very straightforward way of allowing MS to demonstrate progress in reducing pollution by other PS.	Reduced environmental protection because there would be no EU EQS and no driver for taking measures. Legal uncertainty.
B3a	Improved harmonisation of the assessment of chemical status; better picture of the extent of the problem. Flexibility to quickly adapt monitoring strategies to new analytical techniques.	Possible limited adaptation costs for some MS without experience in monitoring and analysis in certain matrices. Lack of legal clarity if there are no standardised analytical methods for certain substances.
B3b	High level of harmonisation of the assessment of chemical status and a good picture of the extent of the problem. Legal clarity.	Possible adaptation costs for some MS without experience in monitoring and analysis in certain matrices. Impossible to adapt quickly to new analytical techniques.
B4a	Cost savings of 0.8 to 2.9 million € per annum in EU.	No significant negative impacts identified.
B4b	Cost savings of 0.8 to 2.9 million € per annum in EU.	Certain undesirable trends or hotspots could be overlooked.
C2	Objective of fit-for-purpose EU-wide monitoring data to support prioritisation likely to be met at least partially.	Monitoring costs: 2 to 4 million € per year for the EU. Costs to develop technical specifications for monitoring (less than 0.2 million € per year for the whole EU).
C3	Legal obligation would make the outcome more certain to meet the objective (without it, MS would prioritise (other) legal obligations in their budgets).	As above for option C2, plus minor additional administrative costs in the European Commission..

6. COMPARISON OF OPTIONS

6.1. Comparison of the options related to the substances

As regards effectiveness at achieving the objectives, the broadest option (A3c) takes greatest account of the latest scientific information included in the review, significantly improves knowledge of the risks posed by all the newly identified substances, and optimises protection against them. No additional measures are proposed at EU level. Any necessary measures would most likely be taken at local level, although actions at EU level under other legislation could in due course be prompted if the monitoring information made this necessary. The baseline takes account of existing measures and expected decisions under other EU legislation.

No disproportionate costs at EU level are identified. If disproportionate costs were incurred locally, the exemptions under the WFD could be used for particular water bodies if the conditions set out in the WFD are fulfilled.

6.2. Comparison of the options related to ubiquitous PBTs and knowledge base

Option	Effectiveness	Efficiency	Consistency	Overall mark
B1	0	0	0	0
<i>Options on presentation</i>				

B2a	++ Avoids presentational issue although formally chemical status would still be affected by the ubiquitous PBTs.	++ No major costs involved and reduced administrative burden for MS.	+ Coherent with WFD, providing more flexibility in terms of presentation	+++++
B2b	+ Avoids presentational issue completely but undermines the objective of reducing the risks posed by certain substances.	++ No major costs involved and reduced administrative burden for MS.	-- Incoherent with WFD and chemicals policy.	+
<i>Options on monitoring matrix</i>				
B3a	++ 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	++ Strong driver for using the most appropriate matrix. Contributes to improved knowledge of the risks of substances and effectiveness of measures. 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 progress in analytical techniques. Could hinder progress in analytical techniques for other matrices.	+
<i>Options on reduced monitoring</i>				
B4a	+ 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	+ 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.	≈	+
C2	+ 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 decreased by the likelihood of data gaps.	NA	++
C3	++ Increased knowledge and likely to cover all or most of the EU countries in a harmonised way	++ Provides targeted high-quality EU datasets, fit for purpose for PS prioritisation.	NA	++++

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): ++ strongly positive; + positive; -- strongly negative; - negative; ≈ marginal/neutral; NA not applicable

6.3. Summary of preferred options and impacts

The preferred options are:

A3c - all substances;

B2a - flexible presentation for ubiquitous PBTs;

B3a - choice of matrix linked to analytical sensitivity;

B4a - conditional reduced monitoring for ubiquitous PBTs;
 C3 - watch list with legal obligation.

These would be implemented by amending the EQSD 2008/105/EC and WFD Annex X. The benefits, costs and distributional effects relative to the baseline are summarised in the following table, taking account of the interactions between the options.

<p>Benefits</p> <ul style="list-style-type: none"> • 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 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;
<p>Costs</p> <ul style="list-style-type: none"> • Additional monitoring costs to public authorities; • 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; • The possible costs, unknown but not likely to be significant, of substituting Quinoxifen, if authorisation not anyway withdrawn under the plant protection products legislation; these could fall on the producers, formulators, farmers and/or consumers depending upon the substitute; • Costs to operate the watch-list.
<p>Main distributional effects</p> <p>The most significant distributional effects are summarised here, except generic environmental and health benefits. Most relate to the preferred substance option (A3c) rather than the options addressing the other general objectives. There is uncertainty about how many would be in the baseline.</p> <p>Sectoral effects</p> <ul style="list-style-type: none"> • could occur in agriculture and plant protection products, due to the inclusion of four currently used plant protection products in the preferred package; however, most of the measures that might be needed would be expected in the baseline; • could also occur in the water industry, resulting from the need to meet a more stringent EQS for Nickel, and an

EQS for E2;

- would occur in the public sector as a result of having to monitor additional substances, and possibly also to cover investments in UWWTPs (a cost that would likely be passed on to consumers);
- could occur in other sectors such as aquaculture, construction the metals industry, transport and waste handling, but would not be expected to be significant.

Producer and user-specific effects

- could arise for the producers and formulators of the pesticides and biocides, again depending upon the baseline;
- could affect the export of certain substances still produced in the EU for export, including HBCDD and Trifluralin, although this export could stop anyway under the baseline.

MS and region-specific effects

- could include minor effects on trade in relation to exported and imported substances, but these would be largely in the baseline;
- could occur in relation to plant protection products, since some MS use more and have a larger number of products on the market;
- could include effects relating to relative pharmaceutical consumption, extent of coastline, prevalence and density of urban conurbations, intensity of livestock farming, and natural conditions affecting bioavailability

Overall, the preferred options would achieve the most objectives with the greatest efficiency while ensuring coherence with the existing legislation and avoiding significant unfair distributional effects.

7. 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.