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REGULATORY SCRUTINY BOARD OPINION

Revision of list of pollutants affecting surface and groundwaters

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Brussels, RSB

Opinion

Title: Impact assessment / Revision of list of pollutants affecting surface and groundwaters

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The sustainable management of the EU's surface water and groundwater bodies is regulated by three Directives. This legislation lists a number of polluting substances and their threshold values, also in combination, as well as monitoring and reporting arrangements for these substances. A recent fitness check of EU water legislation identified areas of improvement in relation to tackling chemical pollution.

This initiative aims to address the legal obligation to review the lists of water pollutants and their corresponding standards. At the same time, it follows up on the findings of the water fitness check regarding implementation shortcomings, aiming to improve the regulatory response to emerging environmental and health risks.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

- (1) The design of the options is overly complex and does not bring out clearly the key policy choices.
- (2) The impacts on SMEs and on citizens are not analysed sufficiently. The report does not assess how individual Member States may be affected.
- (3) The report is not clear about the order of magnitude of the expected impacts. It does not critically assess the validity of the illustrative benefit and cost estimates and their relevance to this initiative. The comparison of options is not based on their effectiveness, efficiency and coherence.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The design of options should allow the identification of impacts, separately for each option or their combination. The options and their presentation should be simplified, and purely technical elements moved to the Annexes. The report should provide more aggregated and more relevant options and sub-options. Options linked to administrative simplification and burden reduction should be grouped together.

(2) The analysis of the impacts on SMEs and citizens should be further developed. The report should elaborate on the impacts on SMEs, including in terms of the compliance costs and administrative burden, and present the results of the application of the proportionate SME test. The impacts on consumers should also be further analysed (indicatively, in relation to pharmaceuticals, personal care products, consumers' health, cost of water services) and the evidence should be clearly presented for the conclusions reached. The report should be more explicit on the implementation deficits in the problem analysis and examine the different possible impacts across Member States. It should map out the respective efforts required from different Member States to meet the targets set.

(3) The report should critically examine the validity of the benefit and cost estimates presented as the examples of the potential impacts, provide more detail on the scope and methods used and indicate how relevant the examples are to this initiative. It should strengthen a summary of the results of the cost benefit analysis, taking into account all qualitative and quantitative evidence and indicating the overall order of magnitude of the expected impacts of the preferred option. Given the link with many existing and ongoing initiatives, the report should discuss the relevance and attribution of costs and benefits to this initiative. Annex 3 should be simplified to integrate in a concise manner the qualitative and quantitative evidence. The analysis should reflect any changes to the options' structure.

(4) The report should clarify the costs and cost savings in scope of the One In, One Out approach. The dedicated section and Annex 3 seem incomplete. All costs and benefits related to the One In, One Out approach should be identified and clearly presented.

(5) The report should systematically integrate the criteria of effectiveness, efficiency and coherence in the comparison of options.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Revision of the lists of pollutants affecting surface and
	groundwaters and the corresponding regulatory standards in the
	Environmental Quality Standards, Groundwater and Water
	Framework Directives

Reference number	PLAN/2020/8554
Submitted to RSB on	25 May 2022
Date of RSB meeting	22 June 2022

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option							
Description	Amount	Comments					
Direct benefits							
Improved surface water quality	 Additions: total benefits not quantified for EU27, but: Avoided/reduced environmental impacts and potential toxic effects on aquatic species. E.g. Carbamazepine has population effects for aquatic species through impacts on fertility and reproduction (particularly crustaceans). Ibuprofen exhibits potential toxic effects for some aquatic species including fertility effects (hormone levels) in fish while nicosulfuron has aquatic toxicity (particularly to flora) and concerns over carcinogenicity as a secondar poisoning issue. Diclofenac is one of the highest concern pharmaceuticals for environmental impacts with potential toxic effects on avian population via surface water species. Estrone E1, 17- Beta estradiol (E2), Ethinyl estradiol (E22) are associated with chronic ecosystem level impacts from exposure to hormones and EDC. PFAS has a widespread and very long-lasting environmental effects while Bisphenol A causes population level effect as an endocrine disrupting chemical for aquatic organisms. Triclosan is toxic for aquatic organisms particularly larvae and fish eggs with effect identified on a range of aquatic species including amphibians. Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin Deltamethrin Esfenvalerate and Permethrin are associated with toxic aquatic environments given the very high usage rates and risks for loss t water, including non-target aquatic fora. Avoided/reduced human health impacts (Glyphosate, Triclosan, PFAS, Bisphenol A via reduced exposure through drinking water) including from specific exposure to Neonicotinoids (Acetamiprid, Clothianidin, Imidacloprid, Thiamethoxam), EDC (Bifenthrin, Deltamethrin Esfenvalerate, Permethrin) and (potential) carcinogenic effects (Ethinyl estradiol (EE2), Nicosulfuron). E.g. Annual costs related to endocrine disruptor exposure were estimated to be €163 billion (above €22 billion with a 95% probability and above €196 billion with a 25% probability (>9). This is due t th	g y s s s s t t t o n s s s s					

¹ Based on an exchange rate of 1 EUR = 1.09 USD

This opinion concerns a draft impact assessment which may differ from the final version.

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	enefits (total for all provisions) – Preferred Option	~
Description	Amount	Comments
	Esfenvalerate, Permethrin). E.g. across Europe, crop pollination by insects accounted for approximately €14.6 billion annually (72).	
	- Avoided costs of water treatment for drinking water, agriculture and industry (Acetamiprid, Clothianidin, Imidacloprid, Thiacloprid, Thiamethoxan	
	Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, glyphosate, triclosan, bisphenol A, PFAS) (in the case of source control and pathway disruption	n
	measures). E.g. in 2015, approximately €0.5 billion was spent annually to remove pesticides in wastewater treatment plants (WWTP) in Europe (73).	
	- Economic benefits for aquaculture from improved food quality (Estrone E1, 17- Beta estradiol (E2), Ethinyl estradiol (EE2), Acetamiprid, Clothianidir	
	Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, Diclofenac, Carbamazepine, ibuprofen, Nicosulfuron triclosan, PFAS, bisphenol A)	1,
	- Innovation for development of alternative chemicals and technologies (e.g. Bisphenol A)	
	Amendments: total benefits not quantified for EU27, but:	
	- Updated EQS based on new science and re-appraisal of risk would provide more appropriate protections (all substances)	
	- Improved protections for human health particularly in relation of POP substances, issues around bioaccumulation (dioxins and furans, chlorpyrifos	
	hexachlorobutadiene, HBCDD), EDC (diuron, chlorpyrifos), exposure to chronic pollutants (mercury, nickel). E.g. chlorpyrifos and PBDE as endocrin	
	disruptors were associated with attention deficit hyperactivity disorder (ADHD) and with other cognitive deficiencies. The productivity loss caused by	
	these disorders is estimated to be €124 billion annually in EU. Additionally, prenatal exposure to chlorpyrifos across the EU would cost an additional	
	€21.4 billion in social costs. The neurotoxicity of chlorpyrifos is estimated to be 70 to 100% according to the epidemiological and toxicologica	al
	evidence, which corresponds to a social cost of €46.8 billion and €195 billion annually in the EU (69). It was also estimated that the cognitive deficit	s
	caused by chlorpyrifos and methylmercury would cost the EU €177 billion and €9.89 billion, respectively	
	- Reduced environmental concentrations, improved environmental protections for ecosystem services (cypermethrin, nonylphenols, PAHs)	
	- Avoided health costs for aquaculture (cypermethrin, tributyltin, mercury, nickel)	
	- Cost savings and efficiencies: the proposed EQS is less stringent for heptachlor/heptachlor oxide, hexachlorobenzene, PBDEs and fluoranthene	е,
	meaning resources can be reallocated and costs saved from measures no longer needed.	
	- Potential innovation opportunity to remove use as an intermediate in manufacture of rubber products (diuron)	-
	Other eight pollutants: total benefits not quantified for EU27, but:	
	- Three of the four cyclodiene pesticides (aldrin, dieldrin, endrin; isodrin is an isomer of aldrin) are listed as POPs under the Stockholm Convention and	a
	have been banned in the EU for many years. The rate of EQS exceedance suggests environmental risk is low, and benefits of continued monitoring may be limited. However, monitoring data are needed anyway under the POPs Regulation and could inform decontamination measures.	У
	- DDT is also a recognised POP. Use in EU has long since ceased and rate of EQS exceedance is extremely low. Maintaining the monitoring time-serie	
	would support the tracking of DDT in the environment, and link with monitoring of, e.g. imported foods.	.5
	- While tetrachloroethylene and trichloroethylene are still in use, and health concerns well founded, the monitoring data shows exceedances in only 6 and	d
	3 surface water bodies out of 97,000 suggesting a very low environmental risk at present. However, these substances are still of concern in groundwate	
	and drinking water, and in marine waters, and the links between surface and groundwater bodies mean that for the moment it is prudent to continu	
	monitoring them in surface waters.	
	Deselection: total benefits not quantified for EU27, but	
	• Deselection of substances that no longer represent an EU-wide risk could free up resources for reallocation by Competent Authorities to the monitoring	g
	and/or management of emerging pollutants, including watch-list substances and the new priority substances.	
	• The pesticides alachlor, simazine and chlorfenvinphos are clearly hazardous but no longer approved for use; the risk of exposure is very low and would	d
	be expected to remain so.	
	Carbon tetrachloride and trichlorobenzenes are still in use. However, the rate of exceedance of the EQS is very low. Deselection of trichlorobenzenes i	is
	questionable compared to other substances given that its risk quotient RQ and MSFD relevance.	

I. Overview of Benefit	ts (total for all provisions) – Preferred Option	
Description	Amount	Comments
Improved	PFAS: total benefits not quantified for EU27, but	
groundwater quality	 Lower risk of (irreversible) damage to natural resources such as groundwater and connected surface waters and ecosystems (i.e. reduced impact or sensitive water bodies such as wetlands and rivers, and fish); Avoided illness / death through low level exposure through drinking water / food to PFAS: estimated the annual health expenditure due to kidney cancer. 	r
	€12.7 to €41.4 million in the EEA countries; hypertension in the EEA countries estimated at €10.7 to 35 billion per year (based on 207.8 millio population);	
	 Improved availability of clean raw groundwater for abstraction and lower production and maintenance costs (for drinking water, irrigation, livestoc watering) 	k
	Benefits to sectors requiring a high quality of groundwater such as bottled water and other water uses (angling, swimming, etc).	
	• Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for drinking water supply, agriculture and industr (GAC treatment costs € millions per site) in the case of source control and pathway disruption measures	y
	Reduced energy costs and related process costs for wastewater treatment to tackle PFAS (in the case of source control and pathway disruption measures)
	 Increased knowledge and understanding of the risks of PFAS posed to the water environment. 	
	 Consistent approach to data collection at EU level and improved knowledge (more data collected) on the impact of PFAS. 	
	Pharmaceuticals: total benefits not quantified for EU27, but	
	Reduced pollution of groundwater and connected aquatic ecosystems with reduced impact on sensitive habitats.	
	• Increased reuse and recovery of pharmaceutical-free materials (e.g. use of sludge, treated wastewater).	
	 Reduction in AMR likely to be small (mainly covered by baseline measures) - Reduction in AMR through control of anti-biotic use (costs avoided c €1.5 billion to the EU) 	ſ
	Small increase in well-being from reduced risk of chronic ingestion in drinking water / improved ecosystem health.	
	 Positive impact on shellfish and fisheries where groundwater inputs to rivers and estuaries is significant 	
	Reduced energy, carbon emissions and chemicals use associated with reduced treatment of drinking water (in the case of source control and pathwa disruption measures)	
	• Improved efficiency - specific risks to groundwater are investigated and dealt with locally rather than through EU wide schemes which may be too hig level to be effective	h
	• Consistent approach to data collection at EU level and improved knowledge (more data collected) on the impact of these two pharmaceuticals. nrMs: total benefits not quantified for EU27, but	
	 Reduced risk of damage to natural resources such as groundwater and connected ecosystems 	
	 Benefits to sectors requiring a high quality of groundwater such as bottled water or aquaculture and other water uses (angling, swimming, etc.). Increased availability of clean raw groundwater for abstraction (for drinking water, irrigation, livestock watering) 	
	Avoided costs of (pre)treatment as a result of improved quality for potable water and process water for agriculture and industry	
	 Increased ecosystems services from groundwater biota not impacted by nrMs and cocktail effects 	
	 Climate change impacts through reduced energy use (e.g. due to changes to wastewater and drinking water treatment processes) (in the case of source control and pathway disruption measures). 	e
	 Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment. 	
	plus reduced impacts on groundwater biota	

I. Overview of Benefits (total for all provisions) – Preferred Option									
Description	Amount	Comments							
	Consistent approach to data collection at EU level and improved knowledge (more data collected) on nrMs in groundwater leading to better understanding of risks.								
	Improved knowledge and better data for use during pesticide parent authorisation process.								
Indirect benefits									
Digitalisation, administrative streamlining and better	Option 2 (Guidelines on the monitoring of groups/mixtures of pollutants): not quantified for EU27, but the guidance document itself has limited impact, however a provision for monitoring estorgens with EBM could have substantial positive impacts.								
risk management	Option 6 (An obligatory groundwater watchlist): not quantified for EU27, but positive impacts due to better decision-making processes regarding substances posing risks and better comparability of data.								
	Option 8 (Repository of standards of EQSs for the RBSPs): not quantified for EU27, but positive impact through harmonization of EU-wide standards allowing more effective measures. Positive impacts for social well-being and health, providing equal standard of water resource across EU	;							
	Option 9 (Allowing flexible adaptation to scientific progress and knowledge by updating the lists of pollutants and their EQS (under both SWD and GWD) by way of delegated acts): not quantified for EU27, but positive impact due to quicker actions to address new substances. Positive impacts as innovation and research will lead to possible employment opportunities								
Administrative cost say	vings related to the 'one in, one out' approach*								
(direct/indirect)	Deselection of existing PS: €3.8 million - €11.7 million per year (monitoring of 5 substances).								
	The deselection of substances is likely to bring cost savings from no longer needing to monitor the deselected substances.								

II. Overview of costs – Preferred option									
Cost type		Citizens / C	Consumers	Bus	inesses	Administrations			
Cost type	One-off Recurrent One-off Recurrent		Recurrent	One-off	Recurrent				
Surface water	Direct adjustment costs	Not applicable - €0	Not applicable - €0				Not quantified		

—	Citizens /	Consumers	Busin	esses	Admir	nistrations
Cost type	One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Cost type			One-off year for pharmaceuticals; for pesticides the clothianidin and imidacloprid to €285 mintrange is €10- €32 per population equivaled Moderate/Small costs to ensure compliai (E2), Diclofenac, Carbamazepine, Azithr	Recurrent hese range from $\in 162$ million for llion for glyphosate. Wastewater treatment ent, per annum (technology dependent). nce for Estrone E1, 17- Beta estradiol omycin, Clarithromycin, Erythromycin, lue to small distance to target, availability measures and/or positive impact of quaternary end of pipe treatment. E.g. g. buffer strips) for pesticides range from lion for nicosulfuron. Wastewater lation equivalent, per annum (technology or Cypermethrin, Chlorpyrifos, Diuron, ange of source control, pathway measures. E.g. the restriction proposal ches (in particular from end-of-life tyres) ed as infill material in synthetic turf tain more than 20 mg/kg in total of the V4) over a 10-year period. Costs of ned animal use of cypermethrin are $\in 27.6$ cel, PAH, Cypermethrin) - $\notin 1.17- \notin 26.2$ chnology dependent).		
			Moderate/Small costs to ensure complia Hexachlorobutadiene, Nonyl Phenol, Tril and/or limited scope for additional measu	putyltin due to small distance to target		

² Cost calculation is based on the average cost of dip pens and containment areas to allow drying \in 1,120 as a one-off cost multiplied by the number of sheep farms in Eurostat (24,600) rounded to three significant figures.

C		Citizens / Consumers		Businesses		Administrations	
Cost type		One-off	Recurrent	One-off	Recurrent	One-off Recurre	
				 cost the EU €3.2m per annum for a surface water (74). No additional costs for Dicofol, F Hexachlorobenzene, Fluoranthene Other 8 pollutants: Not quantified, (extremely low current exceedance) 	, PBDEs. but minor additional compliance costs es).		
Surface water	Direct administrative costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Not quantified
Surface water	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not applicable - €0	Not applicable - €0
Surface water	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Additions:Not quantified for EUbut additional analyticosts range from €11-100 per sample for alsubstances except forPFAS. For PFASanalytical costs are up€250 per sample.Amendments:Not quantified, butamendments forChlorpyrifos andDioxins and furans colead to additionalanalytical costs (due tothe proposed EQS beconsiderably lower ththe existing one)

~		Citizens / C	Consumers	Businesses		Adm	inistrations
Cost type		One-off Recurrent		One-off	One-off Recurrent		Recurrent
							Other 8 pollutants: Not quantified, but cyclodiene pesticides, DDT, tetrachloroethylene and trichloroethylene have a EQS that warrants monitoring and analysis by MS.
Surface water	Indirect costs	loss of use (c HRT, hormon Ethinyl estrac restricted/banne Societal impacts /restricted use Carbamazepine, controls imp increased costs medicine (inclu only medication Possible food loss of use with chemical altern (Bifenthrin, Esfenvalerate, P Societal impacts owners if use of restricted Increased price	could lead to: al impacts from ontraceptive pill, e treatments if diol (EE2) is d s from loss of use of Diclofenac, , Ibuprofen if blemented and for other types of uding prescription as) security issues if out chemical/non- natives in place Deltamethrin Permethrin) s for domestic pet of Imidalcoprid is es of goods and result of source		Not quantified	Not applicable - €0	Not applicable - €0
Groundwater	Direct adjustment	Not applicable	Not applicable -€0		30-year period or €390 million per year	PFAS: Not (22) quantified for	Not quantified

		Citizens / (Consumers	Ru	sinesses	Admi	nistrations
Cost type		One-off Recurrent		One-off			Recurrent
	costs			per substitute use. Management of contaminated bios (landfilling) to €503-€755 million/yr biosolids Paper manufacturing: €77 million/yr temperature incineration of paper mill Pharmaceuticals: Not quantified for I Returns program / Green Pharmacy i million per MS) nrMs: Not quantified for EU27, but:	solids (water industry): €201 million/y high temperature incineration of 10% of al (landfilling) to €192 -€288 million/yr high wastes EU27, but: nitiatives in a small number of MS (<€1-10 ss of approved substances, costs of produc	soil remediation:	
Groundwater	Direct administrative costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified		Not quantified but no significant additional costs for risk / status assessments
	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Not applicable - €0	Not applicable - €0
	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified		Additional analytical costs for EU27: PFAS: €45-48 million Pharma: €2 million nrMs: €4-5 million
	Indirect costs	Not quantified but proposals could Not quantified but proposals could lead to: lead to: - - Possible societal impacts from loss of use of pharmaceuticals - Restricting use could impact on health and well-being of people and nrMs: - animals where alternatives have side effects / different efficacy. - Restrictions on use impact on farming sector and crop yie pesticides are available and can be cheaper or up to 100 tim that permitted parent pesticides - Un-intentional impacts for example glyphosate is used to crops, which are used to mitigate nutrients in run-off /			with substitution of pharmaceuticals and oduct substitution viable for Sulfathemoxazole ne) n farming sector and crop yields. Substitute an be cheaper or up to 100 times more costly s xample glyphosate is used to destroy cover		Not applicable - €0

		Citizens / Consumers		B	Businesses		nistrations
Cost type		One-off	Recurrent	One-off	One-off Recurrent		Recurrent
Digitalisation, administrative streamlining and better risk management options		Not applicable - €0	Not applicable - €0	products more challenging. Not quantified for EU27, but: Option 2 (Guidelines on the monitoring to monitoring of estrogen are low, but results may be substantial. Option 8 (Repository of standards of E would likely lead to substantial costs for measures where necessary. Option 9 (Allowing flexible adaptation	r s could make gaining authorisation of new g of groups/ mixtures of pollutants): Costs due possible measure to be taken due to monitoring QSs for the RBSPs): agreeing on RBSPs EQSs or MS for implementation of substantive to scientific progress and knowledge by r EQS (under both SWD and GWD) by way of	Not quantified for EU27, but: Option 2 (Guidelines on the monitoring of groups/mixtures of pollutants): Limited cost to develop the guidance	Not quantified for EU2 but: Option 6 (An obligatory groundwater watchlist): Additional cost for monitoring and reportin
Digitalisation, administrative streamlining	administrative costs	Not applicable - €0	Not applicable - €0			Not quantified	Not quantified
and better risk	Direct regulatory fees and charges	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	NA	NA
management options	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified	Mon	Not quantified for EU27 but: Option 2 (Guidelines on the monitoring of groups/ mixtures of pollutants): Minor monitoring costs of estrogens. Option 6 (An obligatory groundwater watchlist): Additional cost for monitoring and reportin

II. Overvie	w of costs – Preferre	d option					
Cost type		Citizens / Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Indirect costs	Substitution Prices				NA	Option 8 (Repository of standards of EQSs for the RBSPs): substantial costs for MS for implementation of monitoring (following the agreement on RBSF EQSs) NA
			1	Costs related to the 'one in, on	e out' approach		I
Total	Direct adjustment costs	NA	NA	NA	NA	NA	NA
	Indirect adjustment costs	NA	NA	NA	NA	NA	NA
	Administrative costs (for offsetting)	NA	NA	NA	NA	NA	NA