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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				
	roundwaters 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. Over view of Delic	fits (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 specie through impacts on fertility and reproduction (particularly crustaceans). Ibuprofen exhibits potential toxic effects for some aquatic species includin 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 (EE2) are associated with chronic ecosystem level impacts fro 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, Permethrin being highly toxic to the aquatic environmental concerns for terrestrial pollinators (with Bifenthrin, Deltamethrin Esfenvalerate, Permethrin being highly toxic to the aquatic environment even at low concentrations). Glyphosate is associated with potential harm to aquatic environments given the very high usage rates and risks for loss to water, including non-target aquatic flora. 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, Thiacloprid, Thiamethoxam), EDC (Bifenthrin, Deltamethrin Esfenvalerate, Permethrin) and (potential) carcinogenic effects (Ethinyl estradiol (EE2), Nicosulfuron). E.g. An	ag ry ns m tts tts nn, eer nnt tto m in rs to on tts is

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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Description	Amount	Comments
escription	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, Thiamethoxa Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, glyphosate, triclosan, bisphenol A, PFAS) (in the case of source control and pathway disruptic 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, Clothianidi Imidacloprid, Thiacloprid, Thiamethoxam Bifenthrin, Deltamethrin Esfenvalerate, Permethrin, Diclofenac, Carbamazepine, ibuprofen, Nicosulfuro triclosan, PFAS, bisphenol A) - 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, chlorpyrifo 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 be these disorders is estimated to be €124 billion annually in EU. Additionally, prenatal exposure to chlorpyrifos across the EU would cost an addition €21.4 billion in social costs. The neurotoxicity of chlorpyrifos is estimated to be 70 to 100% according to the epidemiological and toxicologic	m n, n, ns, ne by 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 defici 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 fluoranthen 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 are 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. 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-series would support the tracking of DDT in the environment, and link with monitoring of, e.g. imported foods. While tetrachloroethylene and trichloroethylene are still in use, and health concerns well founded, the monitoring data shows exceedances in only 6 are 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 continue monitoring them in surface waters. 	ay es nd er
	 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 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 wou 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 questionable compared to other substances given that its risk quotient RQ and MSFD relevance. 	ld

I. Overview of Benefits (total for all provisions) – Preferred Option Comments Description Amount 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 on 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 €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 million population): Improved availability of clean raw groundwater for abstraction and lower production and maintenance costs (for drinking water, irrigation, livestock watering) 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 industry (GAC treatment costs € millions per site) in the case of source control and pathway disruption measures 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 of €1.5 billion to the EU) 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 pathway disruption measures) Improved efficiency - specific risks to groundwater are investigated and dealt with locally rather than through EU wide schemes which may be too high level to be effective 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

Increased knowledge and understanding of the risks of metabolites of pesticides posed to the water environment.

control and pathway disruption measures).

plus reduced impacts on groundwater biota

I. Overview of Bene	fits (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 bette understanding of risks. 	r
	 Improved knowledge and better data for use during pesticide parent authorisation process. 	
Indirect benefits		
Digitalisation, administrative	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.	
streamlining and bet		
risk management options	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	savings 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).	1
(direct/indirect)	Described of existing 1.5. C.3.6 million - C.11.7 million per year (monitoring of 3 substances).	
	The deselection of substances is likely to bring cost savings from no longer needing to monitor the deselected substances.	

Coat tring		Citizens / Consumers		Businesses		Administrations	
Cost type		One-off Recurrent		One-off	Recurrent	One-off	Recurrent
Surface vater	Direct adjustment costs	Not applicable - €0	Not applicable - €0	end of pipe treatment measures. E.g. the pharmaceuticals in France is €10 million the proposed restriction of PFASs in fire	with proposed EQS for Ethinyl estradiol opprid, Thiamethoxam, Bifenthrin, Glyphosate, Triclosan, PFAS and ource control, pathway disruption, targeted cost of a take-back scheme for unused a. The 2022 Annex XV restriction report for efighting foams estimates that the ban is er a 30-year period or €390 million per year		Not quantified

	Citizens / Consumers		Businesses		Administrations	
Cost type	One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	One-off	Recurrent	year for pharmaceuticals; for pesticides to clothianidin and imidacloprid to €285 mirange is €10- €32 per population equivalent. Moderate/Small costs to ensure complia (E2), Diclofenac, Carbamazepine, Azitha Acetamiprid, Thiacloprid, Nicosulfuron of source control and pathway disruption forthcoming revision of the UWWTD on costs of pathway disruption measures (e. €1.6 million for acetamiprid to €12.8 mill treatment cost range is €10- €20 per populate dependent). Amendments: Not quantified for EU27, but: Significant costs to ensure compliance for PAHs, Mercury, Nickel implementing a disruption, targeted end of pipe treatment which would ensure that granules or mull are not placed on the market for use or us pitches or similar applications if they coreight indicator-PAHs would cost €45m (additional controls and treatment for farm m². Wastewater treatment (Mercury, Nicper population equivalent, per annum (te Mine drainage (Mercury) - €100,000 -€1 operating costs. Moderate/Small costs to ensure complia Hexachlorobutadiene, Nonyl Phenol, Tri	hese range from €162 million for llion for glyphosate. Wastewater treatment ent, per annum (technology dependent). ance for Estrone E1, 17- Beta estradiol romycin, Clarithromycin, Erythromycin, due to small distance to target, availability a measures and/or positive impact of a quaternary end of pipe treatment. E.g. g. buffer strips) for pesticides range from lion for nicosulfuron. Wastewater alation equivalent, per annum (technology to cypermethrin, Chlorpyrifos, Diuron, range of source control, pathway to measures. E.g. the restriction proposal ches (in particular from end-of-life tyres) sed as infill material in synthetic turf attain more than 20 mg/kg in total of the 74) over a 10-year period. Costs of med animal use of cypermethrin are €27.6 kel, PAH, Cypermethrin) - €1.17- €26.2 chnology dependent). 0,000,000 per plant and €0.4 per dm³	One-off	Recurrent

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

Cost type		Citizens / C	Consumers	Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
				cost the EU €3.2m per annum for surface water (74). No additional costs for Dicofol, I Hexachlorobenzene, Fluoranthene	e, PBDEs. , but minor additional compliance costs		
Surface water	Direct administrative costs	Not applicable - €0	Not applicable - €0	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 vater	Direct enforcement costs	Not applicable -€0	Not applicable - €0	Not quantified	Not quantified	Not quantified	Additions: Not quantified for EU but additional analytic costs range from €11-100 per sample for all substances except for PFAS. For PFAS analytical costs are up €250 per sample. Amendments: Not quantified, but amendments for Chlorpyrifos and Dioxins and furans co lead to additional analytical costs (due to the proposed EQS beiconsiderably lower that the existing one)

II. Overview of	costs – Preferre	ed option					
G 44		Citizens / C	Consumers	Bus	sinesses	Admi	nistrations
Cost type		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
							Other 8 pollutants: Not quantified, but cyclodiene pesticides, DDT, tetrachloroethylene and trichloroethylene have ar EQS that warrants monitoring and analysis by MS.
Surface water	Indirect costs	loss of use (c HRT, hormone Ethinyl estract restricted/banne Societal impacts/restricted use Carbamazepine, controls impincreased costs medicine (inclusionly medication Possible food soloss 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 liol (EE2) is d s from loss of use of Diclofenac, Ibuprofen if elemented and for other types of ding prescription s) security issues if out chemical/non- natives in place Deltamethrin ermethrin) s for domestic pet of Imidalcoprid is s of goods and result of source		Not quantified	Not applicable - €0	Not applicable - €0
Groundwater	Direct adjustment	Not applicable - €0	Not applicable - €0	PFAS: Not quantified for EU27, but:	30-year period or €390 million per year (22)	PFAS: Not quantified for	Not quantified

G		Citizens /	Consumers	Businesses		Administrations	
Cost type		One-off Recurrent		One-off Recurrent		One-off	Recurrent
	costs			biosolids Paper manufacturing: €77 million/y temperature incineration of paper mil Pharmaceuticals: Not quantified for Returns program / Green Pharmacy million per MS) nrMs: Not quantified for EU27, but:	r high temperature incineration of 10% of all r (landfilling) to €192 -€288 million/yr high l wastes EU27, but: initiatives in a small number of MS (<€1-10 coss of approved substances, costs of produc	soil remediation: €5 million (10) sites) - €760 million (20 sites) Cost of legacy pollution from landfill sites - average of €690,000 up to €77 million per	
Froundwater	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	lead to: - Possible from loss pharmaceut use could and well-be animals w	societal impacts	- additional costs associated availability of alternatives (p but unlikely for Carbamazep nrMs: - Restrictions on use impact pesticides are available and that permitted parent pesticides. - Un-intentional impacts for	I with substitution of pharmaceuticals and product substitution viable for Sulfathemoxazole ine) on farming sector and crop yields. Substitute can be cheaper or up to 100 times more costly		Not applicable - €0

G		Citizens / Consumers		Businesses		Administrations	
Cost type		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Digitalisation, administrative streamlining and better risk management options		Not applicable - Not applicable -	agricultural fields over winter Increased data requirements could make gaining authorisation of new products more challenging. Not quantified for EU27, but: Option 2 (Guidelines on the monitoring of groups/ mixtures of pollutants): Costs due to monitoring of estrogen are low, but possible measure to be taken due to monitoring results may be substantial. Option 8 (Repository of standards of EQSs for the RBSPs): agreeing on RBSPs EQS would likely lead to substantial costs for MS for implementation of substantive measures where necessary. 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: Option 2 (Guidelines on the monitoring of groups/mixtures of pollutants): Limited cost to develop the guidance	Not quantified for EU27 but: Option 6 (An obligatory groundwater watchlist): Additional cost for	
	Direct administrative costs Direct regulatory	Not applicable -	€0	Not quantified	Not quantified		Not quantified
and better risk	fees and charges	Not applicable - €0	€0	Not quantified	Not quantified	NA	NA
management options	Direct enforcement costs	Not applicable - €0	Not applicable - €0	Not quantified	Not quantified		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 reporting

Continue		Citizens / Consumers			Businesses		Administrations	
Cost type		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 RBS EQSs)	
				Costs related to the 'one in	one out' approach			
	Direct adjustment costs	NA	NA	NA	NA	NA	NA	
Γotal	Indirect adjustment costs	NA	NA	NA	NA	NA	NA	
	Administrative costs (for offsetting)	NA	NA	NA	NA	NA	NA	