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Priority Substances in Water – review proposal

Frequently Asked Questions on priority substances in water and pharmaceuticals – MEP briefing

COM proposal for a Directive as regards priority substances in the field of water policy, COM(2011)876

"Bringing our rivers, lakes and wetlands to ecological health"

What is in the current proposal for the revised Priority Substances Directive from the European Commission?

Our rivers, lakes and wetlands remain at risk from hazardous chemicals with long lasting negative effects on our environment, economy and society according to various research studies. The European Environment Agency (EEA) recently warned that more needs to be done to address the water pollution in European ecosystems, including controlling pollution at source. The EEA report also highlighted significant negative impacts on freshwater and marine ecosystems caused by substances with endocrine disrupting properties and other emerging pollutants. It can therefore be concluded that the EU needs to step up its efforts to meet the objectives of international agreements such as the OSPAR Convention that include the binding target to stop discharges, emissions and losses of hazardous chemicals by 2020.

The European Commission proposal adds 15 chemicals to the existing list of 33 Priority Substances and establishes new EQS (Environmental Quality Standards) values for these 15 substances.

Member States will then need to:

i) Monitor their presence in water and for some substances in sediment and/or biota; and
ii) Where their concentration exceeds safe limits set by the environmental quality standard (EQS), bring their concentrations within agreed standards using a cost-effective combination of measures as part of the second cycle of River Basin Management Plans under the Water Framework Directive (2015-2021).

Six of the proposed new substances are identified as Priority Hazardous Substances and are thus subject to the phase out obligation within 20 years from adoption of this revised Directive. The 3 pharmaceuticals that are at the center of the debate in the European Parliament are not identified as priority hazardous substances and are not subject to phase out.

The proposal also revises EQS values for 7 of the existing 33 substances based on most recent science and monitoring results.

Is there enough scientific evidence for action at the EU level?

All 15 proposed substances are backed by a solid body of research, and for many of them national standards already exist in different Member States. Experts from Member States and stakeholders have been closely involved throughout the prioritization process and the evidence was considered sufficient to designate them as priority substances – based essentially on their hazard and their presence in the aquatic environment.

The technical work for the review of the priority substances to regulate at EU level was led by European Commission (DG ENVI) and the Joint Research Centre, with participation of the national experts from all member states and experts from industry, agriculture associations and NGOs. The proposed standards were also submitted and reviewed by the independent Scientific Committee on Health and Environmental Risks (SCHER). As part of this prioritisation more than 2000 substances, all of which pose a risk to aquatic ecosystems, were screened but, mainly because of lack of monitoring data across EU Member States, only 15 substances were prioritized for action at EU level.

Many of the 15 substances are persistent and/or bioaccumulative as well as toxic (e.g. dioxins, PFOS) and are therefore likely to remain in the environment for decades and affect birds and mammals including humans via secondary poisoning. Others are characterized by acute toxicity (e.g. cypermethrine, dichlorvos), show evidence of carcinogenicity in humans (e.g. dioxins, dicofol), or are known endocrine disruptors (e.g. heptachlor, the estradiols).

Is there enough scientific evidence in the case of the three proposed pharmaceuticals?

As with the other 12 new substances proposed, and contrary to claims by certain industries, there's a solid body of evidence underpinning the proposal for 3 pharmaceuticals to be included as Priority Substances. They have been included in the list following the full technical consideration of monitoring results and research studies reviewed by the experts, which demonstrate that pharmaceuticals pose a significant risk to the aquatic environment in the concentrations observed.

In particular, the European Environment Agency report from 2011 provides a summary of numerous studies that document a range of detrimental impacts of pharmaceuticals upon freshwater ecosystems. For example, introducing synthetic oestrogen at concerntrations found in polluted environments (5-6 ng/l) in a Canadian Experimental Lake resulted in feminization of the of male fathead minnows and within 7 years the fish species was almost extinct from the lake, clearly demonstrating that endocrine distruptors can threaten the sustainability of wild fish populations. This is supported by a report from the German Environment Agency which identifies 24 pharmaceuticals for urgent action as they pose significant risk to the health of freshwater ecosystems. (See annex for further information).

It is of high importance that these pharmaceuticals are included in the revised list, so that they can be properly monitored and, where necessary, a cost-effective combination of measures can be developed to meet safe limits for water and human health.

The logic of the process and of the Water Framework Directive is that Member States set environmental objectives based on scientific assessment, thus listing substances as priority substances needs to be based on factual scientific assessment. The important considerations of costs involved, need to be considered as part of the trade-offs mechanisms

provided by the Water Framework Directive, for example application of exemptions due to the technical infeasibility or disproportionality of the costs of reaching scientifically sound environmental objectives.

The study that the pharmaceutical industry has widely distributed to MEPs was neither presented to the experts during the prioritization exercise nor has it been peer reviewed.

Does setting EQS for the pharmaceuticals mean they will be banned in the EU?

The proposal does not provide any ban or phase-out obligation on pharmaceuticals. It simply requires Member States to monitor these substances in their waters and ensure that their concentration does not exceed the established safe limits which do not pose a risk to aquatic environment will not be crossed.

In water bodies where these safe limits are exceeded, Member States will need to develop a combination of cost-effective measures to reduce their concentrations, which will be part of the WFD river basin management planning (2015-2021 period). These plans foresee active public participation, cost-benefit analysis, as well as possible extension of deadlines to meet these standards until 2027 or even lower the standards if the costs of reaching them are considered disproportionately expensive compared to the benefits. Member States have already made extensive use of these provisions of the WFD in their existing river basin management plans.

What would happen if substances are not listed as "priority substances"?

The status quo would be maintained – so nothing would happen. There would be almost no monitoring of these substances in the aquatic environment and thus ongoing negative impacts with little possibility to take action under WFD or related EU legislation. This means, that in future reviews of the priority list, the lack of monitoring data for these substances across EU Member States would still be an issue.

What are the costs involved? Can costs and benefits be estimated?

The monitoring costs to Member States of adding new substances are minimal as they already undertake monitoring for the existing 33 substances. The Commission estimates additional monitoring costs of adding pharmaceuticals to the list of priority substances at €15-38 million per year for the whole of the EU. The Commission states it was not possible to estimate the costs of the measures across the EU as it will very much depend on local conditions and on the choices made when preparing and implementing 100+ river basin management plans.

The UK study indicating costs of €18 per person per year was derived from a model using a worst case scenario: assuming an EQS much stricter than the level actually proposed by the Commission (2,7 $^{10-4}$ mg/l instead of 4.0 $^{10-4}$ mg/l) and solely focused on the end of the pipe solution of upgrading waste water treatment which assumes no control measures taken at source.

We have criticized the cost-benefit methodology used by the Commission for the impact assessment, as it did not take into account important cost effective measures at EU level to address the pollution at source. We agree with the European Commission that cost-benefits

of specific measures to reduce concentrations are best considered as part of the river basin management planning, making full use of WFD provisions for cost effectiveness of the combination of measures and, when justified, extending the deadline or lowering the standard related to technical feasibility or disproportionality of the costs.

What other measures could be taken to reduce the concentration of pharmaceutical residues in water?

The cost-benefit methodology used by the Commission, which has also been at the center of much debate, focused solely on end-of-pipe solutions with the proposal not considering upstream solutions for reducing concentration of pharmaceutical residues in water. It is true that upgrading wastewater treatment plants with advanced techniques that would remove not only pharmaceuticals but also other micropollutants can be costly.

There are however also simple low cost measures both “end of the pipe” and “upstream”:

- tertiary sand filtration which can remove estrogens from water.
- “take back schemes” for unused pharmaceuticals that EU legislation already requires MS to implement, however, the level of implementation and efficiency of these collection schemes varies amongst Member States leaving room for improvement, as there is no requirement for pharmaceuticals to be incinerated at high temperature, once they are safely collected
- encouraging design of green pharmaceuticals that are fully metabolized in the body and rapidly biodegrade in the environment into harmless compounds;
- educating healthcare professionals to optimise medicines prescription behaviour so that only the right amount of pharmaceuticals needed is prescribed, giving priority to the least environmentally hazardous medicines.

These upstream measures are being discussed in the context of the revision of EU legislation on pharmaceuticals. The inclusion of pharmaceuticals in this proposal should act as a catalyst for these discussions.

In addition, even though, the proposal does not require substitution of the pharmaceutichals, alternatives may be considered to reduce the costs. For example, several Non-Steroidal Anti-Inflammatory Drugs exist that could be used instead of diclofenac, with similar therapeutic efficacy but allowing easier removal in conventional waste water treatment plants.

Do all Member States/other European Commission services support inclusion of the pharmaceuticals as priority substances?

All relevant Commission services were involved in the development of the DG ENVI led proposal. No Member State expert objected to the inclusion of the pharmaceuticals as priority substances in the Working Group charged with the task of the technical prioritisation. There are differences of opinion at political level between Member States in the Council working group and these continue to be debated.

BACKGROUND:

What are the "priority substances"?
Priority (Hazardous) Substances are chemical pollutants that pose a significant risk to (or via) the aquatic environment across the EU. There are currently 33 of these Priority Substances listed in the Water Framework Directive (WFD) and Environmental Quality Standards (EQS) Directive. Member States have to monitor their concentrations in surface, groundwater and coastal waters and take measures at national or local level to meet the set EQS for the substances listed in the WFD by 2015. Member Stats can justify conditions that allow them to apply exemptions for lower standards or extend the deadline provided the conditions set in the WFD are met. Of the list of current 33 Priority Substances (PS), 15 because of their dangerous are classified as Priority Hazardous Substances (PHS), and are targeted for cessation or phase out by 2020.

What is the relationship between the renewal of the list of priority substances and the EU Water Framework Directive and why is the renewal urgent?

The Water Framework Directive requires the European Commission to review the list of priority substances at least every 4 years to take in account new scientific evidence and monitoring data. These reviews are an integral part of the river basin management set by the WFD, and Member States need to implement measures to reach "good chemical status", within legal deadlines of the WFD. Member States would have to ensure that the additional substances are monitored, and that the EQS are met by 2021. There are a set of options available for Member States that allow them to apply exemptions from this obligation, provided certain conditions such as technical feasibility or disproportionality of the costs are met. Thus, it is crucial that the renewed list of priority substances is adopted in 2012 (early 2013) in order for Member States to properly integrate the new standards in elaboration of the river basin management plans due to be adopted by the end of 2015.

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ANNEX: Studies demonstrating risks of pharmaceuticals in water

(Extract EEA report p. 31-32)

“Numerous studies across Europe document the occurrence of sexual disruption of freshwater fish found in the proximity of effluent discharges from wastewater treatment plants. Jobling et al. (2006), for example, report that intersex in roach in the UK was significantly correlated with predicted concentrations of oestrogens in river reaches receiving treated sewage effluents. In the Netherlands, elevated concentrations of vitellogenin were observed together with an increased prevalence of intersex in wild male bream in a small river receiving treated sewage (Vethaak et al.,2005). Both in situ and laboratory bioassays showed oestrogenic hormones to be primarily responsible for these effects. In Spain, vitellogenin was found to be increased in male carp downstream of a sewage treatment plant (Petrovic et al., 2002) whilst in Italy, 50 % of barbel sampled below a polluted tributary of the River Po showed intersex gonads (Viganò et al., 2001). Endocrine disruption of male fish has also been recorded in the Czech Republic, both in a polluted stretch of the River Elbe downstream of three major chemical plants (Randak et al., 2009) and downstream of the city of Brno (Blahová et al., 2010).

Additionally, laboratory studies have shown that the combined effects of EDCs can be additive, whereby such chemicals at levels, individually, below which any effects can be detected, result in observable detrimental effects when combined (Brian et al., 2005). EDCs have been observed to cause effects in other freshwater biota, including mudsnails exposed via sediments (Duft et al., 2003), and identified as a potential factor in the global decline in amphibians (Hayes et al., 2002). If too long for a quote, this part could go out

Endocrine disruption in estuarine and marine environments has also been documented. Elevated blood vitellogenin concentrations were observed in male dab (Scott et al., 2007) and cod (Scott et al., 2006) caught in open waters of the North Sea. In both studies, the fish were far out to sea away from any direct sources of pollution. Larger fish were found more likely to have elevated vitellogenin levels, suggesting a gradual accumulation, via feeding, of oestrogenic compounds in the marine food chain. Endocrine disruption has also been detected in tuna and swordfish in the Mediterranean (Fossi et al., 2002), with the latter being linked to PCB concentrations in the fish (Fossi et al., 2004). In the United Kingdom, investigative programmes in several estuaries have found endocrine disruption in flounder, a bottom-dwelling flatfish particularly exposed to any contamination of sediment (Thomas et al., 2004). The UK research showed that male flounder caught in industrialised estuaries, receiving effluent from sewage treatment works and industry, had elevated concentrations of vitellogenin, with cases of intersex and testicular abnormalities also recorded (Allen et al., 1999). Also of note, however, is evidence of a lessening in the degree of endocrine disruption over time in some UK estuaries, a finding in line with improvements to the treatment of wastewater (Kirby et al., 2004; Kleinkauf et al., 2004). Improvements have also been noted elsewhere, with a declining trend in imposex being observed, for example, in whelks netted in Danish coastal waters of the Belt Sea (Strand, 2007).

In some cases oestrogenic effects are known to be irreversible (Rodgers-Gray et al., 2001), and in severely feminised fish, fertility is reduced, raising implications for population survival (Jobling et al., 2002). An illuminating example is the experiment by Kidd et al. (2007), where a synthetic oestrogen was introduced to a whole lake in the Canadian Experimental Lake Area for seven years, at concentrations found in polluted environments (5–6 ng/l). Male fathead minnows showed clear signs of feminisation (vitellogenin and intersex), while altered egg development was observed in females. Strikingly, within seven years, fathead minnows were almost extinct from the lake, clearly illustrating that endocrine disrupters can threaten the sustainability of wild fish populations.

In addition, a report from the German Environment Agency listed 24 pharmaceuticals as priorities based on high risk (including diclofenac , EE2 and EE).
