MEMO/12/59

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Proposal for a revised directive of the European Parliament and of the Council on Priority Substances in the field of water quality

What are Priority Substances?

Priority Substances are chemical pollutants that pose a significant risk to (or via) the aquatic environment at EU level. There are currently 33 of these Priority Substances listed in Annex X of the Water Framework Directive (WFD). Member States have to monitor their concentrations in surface waters and meet the Environmental Quality Standards (EQS) set for them within a certain timeline, unless they meet conditions that allow them to apply exemptions.

One of the environmental objectives of the Water Framework Directive is to achieve "good chemical status" for EU waters. In practice this means achieving the EQS for priority substances and for eight "other pollutants" already regulated under earlier legislation.

What are Priority Hazardous Substances?

Priority Hazardous Substances are a subset of Priority Substances, of which they are the most dangerous. They are characterised by their persistence, bioaccumulation and toxicity, or by an equivalent level of concern. Because of these dangerous properties, the WFD requires their emissions to the aquatic environment to be phased out within 20 years of their designation as "priority hazardous".

How were the additional substances in the proposal selected?

The selection was made on the basis of a science-based prioritisation procedure in line with the principles set out in Article 16(2) of the WFD.

Substances identified under other legislation (such as chemicals, plant protection products, and biocides) as being of potential concern to the aquatic environment were shortlisted for further consideration. In addition, the outputs of two prioritisation processes, based on monitoring and modelling data for some two thousand substances, were used to identify other substances posing a risk. The substances in Annex III of the Environmental Quality Standards Directive (EQSD), if not already shortlisted, were added, along with substances of particular concern to Member States. The combined outputs were reviewed by experts from the Commission, Member States and stakeholders to identify the substances for which the evidence was considered sufficient to designate them as Priority Substances – based essentially on their hazardousness and their presence in the aquatic environment.

More details about this process can be found in the Commission Staff Working Paper accompanying the report to the European Parliament and the Council.

What are the additional substances used for and why are they of concern?

The following table provides more information on the proposed new Priority Substances:

Substance	Type/Use	Concern
17 alpha-ethinylestradiol (EE2)	Pharmaceutical; synthetic steroid hormone used mainly in oral contraceptives.	Endocrine disruptive; prolonged exposure to low concentrations of EE2 has been shown to cause sex changes, alterations in reproductive capacity, and ultimately population collapse in fish
17 beta-estradiol (E2)	Steroid hormone: excreted naturally (approx 90%) in human and livestock urine but also (<10%) as a result of pharmaceutical use (of which 90% from Hormone Replacement Therapy).	Endocrine disruptive; chronic studies show effects on sexual development and fecundity in fish.
Aclonifen	Herbicide, used on a range of arable crops.	Toxic to a range of aquatic organisms.
Bifenox	Herbicide, used to kill broadleaf weeds in cereal crops and grassland.	Toxic to a range of aquatic organisms.
Cybutryne (Irgarol®)	Biocide used as antifouling agent in coatings for boat hulls etc.	Toxic; degrades only slowly and main degradation product also toxic; persists in sediments.
Cypermethrin	Insecticidal pyrethroid plant protection product and biocide, used in arable farming, salmon farming, sheep dipping and wood preservation.	Toxic to a range of aquatic organisms. Binds to sediment. Use in the marine environment is authorised in a few countries of the world but prohibited in Canada where suspicion exists regarding a possible link with the death of lobsters.
Dichlorvos	Organophosphorus insecticide and biocide, used in grain/nut stores, insecticidal sprays/strips. Use – a few kg to a few tonnes/yr in different Member States; probably closer to lower figure since 2008 when decision on non-authorisation as a plant protection product took effect.	Toxic particularly to aquatic invertebrates and fish; possibly carcinogenic to humans.

Diclofenac	Pharmaceutical, used as Non-Steroidal Anti-Inflammatory Drug (NSAID).	Toxic, directly (e.g. chronic studies show effects on fish), and via secondary poisoning, e.g. vultures in India affected by veterinary use in cattle.
Dicofol	Organochlorine former plant protection product and biocide, until recently authorised for use on fruit and vegetable crops. Possibly residual use.	Toxic; similar to DDT, recommended for designation as POP (Persistent Organic Pollutant under the Stockholm Convention); possibly carcinogenic to humans, possibly endocrine disruptive.
Dioxins (and dioxin-like PCBs)	Dioxins: by-products of thermal combustion PCBs: chlorinated organic compounds formerly used to manufacture electrical equipment etc.; some also produced by combustion.	PBTs (persistent, bioaccumulative and toxic substances), POPs (Stockholm Convention and CLRTAP). Some forms probably carcinogenic to humans; other possible effects include endocrine disruption, impairment of immune system, nervous system, reproduction. Limits already set for presence in feed and food.
HBCDD	Industrial chemical, used as flame retardant, especially in polystyrene, including insulation boards.	PBT, SVHC under REACH, recommended POP. Possibly toxic to reproduction in humans.
Heptachlor/ Heptachlor epoxide	Organochlorine insecticide, no longer authorised but secondary emissions possible.	POP; very toxic to aquatic organisms; possibly/probably carcinogenic to humans, possibly endocrine disruptive.
PFOS	Industrial chemical, used in hydraulic aviation fluids, photography, electroplating. Present in many existing products, especially textiles.	PBT, POP. Toxic to animals especially mammals. Possible carcinogen in humans; possible effects on thyroid function.
Quinoxyfen	Fungicide, used mainly on cereals, grape vines.	PBT and vPvB properties. Accumulates particularly in sediments.
Terbutryn	Biocide, used especially in coatings for buildings, as preservative.	Toxic especially to algae and aquatic plants.

What action would have to be taken as a result of the proposal?

Member States would have to take it into account in preparing and implementing their second River Basin Management Plans under the WFD, which are due to be adopted in 2015. They would have to ensure that the additional substances are monitored, and that the Environmental Quality Standards are met by 2021. This could mean taking measures at national or local level.

No measures are included in the proposal itself. Existing EU and/or international legislation – on chemicals, plant protection products etc - is expected to reduce the emissions of many of the substances. Inclusion of the substances in the Priority Substances list means that monitoring data would be obtained to provide feedback on the effectiveness of existing legislation.

If additional measures taken at local or national level proved insufficient to meet the EQS, additional EU measures might need to be considered, as required by Article 16(6) of the WFD.

What would be the expected impacts?

An impact assessment was conducted to support the proposal. The conclusion was that the expected benefits would outweigh the costs.

Benefits

There would be positive impacts in terms of the quality of surface waters and thus potential for positive effects on the health of the environment, wildlife and human beings. Our knowledge about pollution levels and the effectiveness of measures taken by water and other policies to reduce emissions to the environment would be improved.

Costs

No specific measures at EU level are proposed. Member States can select the most cost-effective measures that best fit their national/local situation. Nevertheless, the impact assessment considered a range of potential measures that Member States might take, including those related to the improvement of urban waste water treatment in certain areas (especially with a high population), measures to reduce emissions at source and so forth.

Since most of the substances would not be designated Priority Hazardous Substances, there would be no need to find substitutes for them. The substances that would be designated as Priority Hazardous Substances are already, or will probably soon become, subject to controls under other legislation, and in most cases substitutes are available or are likely to be developed within the 20-year timeframe for phasing out emissions. The inclusion of a substance in the WFD list provides valuable information about the effectiveness of the measures taken by other policies to reduce emissions.

Some monitoring costs would be incurred for the additional substances, but they would be minor in relation to the existing overall monitoring costs. The Commission proposal contains additional flexibility to allow Member States to reduce the monitoring of certain substances (that due to their characteristics do not need frequent monitoring), and therefore partially offset the new monitoring costs.

Would the Commission proposal give rise to disproportionate costs in the Member States?

The impact assessment concluded that costs would not be disproportionate.

Where local conditions would give rise to disproportionate costs or it is technically not feasible to reach the objectives, Article 4 of the Water Framework Directive allows Member States to apply exemptions from meeting good chemical status, provided all relevant conditions in the Directive are met.

What would be the implications of including pharmaceuticals?

As is required for all priority substances, Member States would have to meet the usual monitoring requirements. Analysis of the data gathered should help them to identify any necessary action to meet the respective Environmental Quality Standards. No measures are proposed at EU level.

There should be no impact on the freedom of doctors to prescribe or of patients to choose and obtain the listed pharmaceuticals. Nor does the proposal question their medicinal value.

The proposal is consistent with the Commission's commitment to strengthen pharmacovigilance and with the greater knowledge now available of the risks posed to the aquatic environment by some pharmaceutical substances.

What would be the difference between the Watch List and the Priority Substances List?

EU waters currently contain thousands of chemicals about which there is very little information regarding levels and occurrence. They may or may not pose risks to the environment or human health, but in the absence of regulation they are not routinely monitored. The proposal includes a mechanism to allow monitoring data to be gathered EU-wide for substances of possible concern over approximately one or two years, to support decision-making on the risks posed by those substances. No EU standards or phase-out obligations would apply to the substances on the Watch List, nor would they have to be monitored as widely as the Priority Substances. The information obtained would feed into the subsequent review of the Priority Substances list.

What are the substances "behaving as ubiquitous PBTs" that are mentioned in the proposal and subject to special provisions? Why are those provisions needed?

Several substances that are persistent, bioaccumulative and toxic occur very widely in the aquatic environment. This is largely due to past use, as the use of most such substances is no longer allowed or severely restricted. Some such substances may still be authorised however, for specific uses for which an appropriate substitute is not yet available. Moreover, some of the substances are being emitted from products that are still in use and were manufactured before the substances were regulated, or from those that are disposed of as waste. Others can potentially be transported by long-range atmospheric transport from outside the EU, or may be included in products imported from third countries.

Despite the current restrictions, their characteristics mean that these substances could remain at concentrations above the standards set for them for long periods, especially if they have accumulated in sediment and/or living organisms in the aquatic environment. The concentrations of these substances are slowly decreasing due to current measures (e.g. substitution by other substances and hence elimination of emissions). In most cases there is little that Member States can do to speed up the reduction of the concentrations, on top of the measures that have already been taken (in many cases at EU level).

The Commission proposal would allow Member States to:

- Reduce the monitoring effort for these substances. As their concentrations are likely to change only very slowly over time, it is enough to monitor them less frequently and less intensively than other substances. Member States would be allowed to reduce monitoring only if they already have a robust information base about the extent of pollution by these substances.
- Allow separate presentation by Member States of the concentrations of substances behaving as ubiquitous PBTs. This is important because the slow improvement seen for these substances should not hide improvements achieved for other substances, for which the measures that would be taken would relatively quickly achieve the standards set. The improvements would be hidden because the Water Framework Directive definition of good chemical status requires all standards to be met, therefore if one fails, the status is not met.

What happens next?

The proposal is being forwarded to the EU Council of Ministers and the European Parliament for their consideration (discussion and adoption).

For more information, Europe website:

http://ec.europa.eu/environment/water/water-dangersub/pri_substances.htm

See also IP/12/88