COUNCIL OF THE EUROPEAN UNION

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COVER NOTE

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Subject:	Report from the Commission to the European Parliament and the Council on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy

Delegations will find attached Commission document COM(2011) 875 final.

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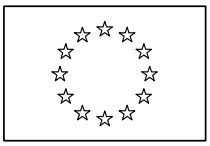

EUROPEAN COMMISSION

Brussels, 31.1.2012
COM(2011) 875 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy

(Text with EEA relevance)

{SEC(2011) 1544 final}

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1. LEGAL BACKGROUND

Article 16(4) of the Water Framework Directive (WFD, 2000/60/EC)[1] requires the Commission to review regularly its Annex X which contains the list of priority substances in the field of water policy, identified among those posing a significant risk to or via the aquatic environment. Article 16(2) sets out the criteria for the identification of priority substances. In addition, Article 16(3) requires the Commission to identify priority hazardous substances, a subset of priority substances characterised by their persistence, bioaccumulation and toxicity or equivalent level of concern.

Article 16(6) requires the Commission to put forward proposals of controls for the progressive reduction of discharges, emissions and losses of priority substances and for the cessation or phase-out of emissions, discharges and losses of priority hazardous substances. It also sets out a time limit of 20 years to achieve the cessation or phase-out, from the date of adoption of the controls.

The existing list of 33 priority substances was established by Decision No 2455/2001/EC[2], and amended by Directive 2008/105/EC[3] (EQSD). The latter also established environmental quality standards (EQS) for all the 33 priority substances and for 8 other pollutants that were already regulated at EU level under existing legislation.

Article 8 of EQSD requires the Commission to consider, within the framework of the review of WFD Annex X, inter alia the substances set out in Annex III to that Directive for possible identification as priority substances or priority hazardous substances. The Commission should report the outcome of its review to the European Parliament and to the Council by 2011 and accompany the report, if appropriate, with relevant proposals, in particular proposals to identify new priority substances or priority hazardous substances or to identify certain priority substances as priority hazardous substances and to set corresponding EQS for surface water, sediment or biota, as appropriate.

This report is the Commission report required by Article 8 of the EQSD. It is accompanied by a Commission proposal for a Directive amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

2. SUMMARY OF THE TECHNICAL PROCESS AND CONSULTATION

The technical work for the review was led by DG ENV and the JRC and carried out by a range of experts. These included members of the Chemical Aspects Working Group E (WG E) under the WFD Common Implementation Strategy (CIS)[4], and consultants contracted by the Commission. The membership of WG E consists of Commission DGs, Member States and

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1 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [OJ L327 of 22.12.2000]. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02000L0060-20090113:EN:NOT

2 Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy. OJ L 331, 15.12.2001, p. 1. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:331:0001:0005:EN:PDF

3 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy. OJ L 348, 24.12.2008, p. 84.

4 http://ec.europa.eu/environment/water/water-framework/objectives/implementation_en.htm

stakeholder organisations including a range of European industry associations, NGOs and intergovernmental organisations.

WG E contributed significantly to the review by supporting the collection of data (including monitoring and hazard data), the prioritisation process for identifying new substances, the update of the Technical Guidance Document on EQS setting, and the derivation of EQS. It also supported the review of the existing priority substances (EQS and priority hazardous status).

The draft EQS were submitted to the Scientific Committee on Health and Environmental Risks (SCHER)[5] for its opinion.

The review was completed with an impact assessment supported by an Impact Assessment Steering Group made up of Commission services and by a consultancy contract. The contractors drafted individual substance impacts reports taking into account the conclusions of the technical work and additional inputs from WG E and other stakeholders not represented in that WG.

The Impact Assessment Board discussed the Impact Assessment report at its meeting on 22 June 2011. The comments made by the Board have been addressed in the final Impact Assessment report SEC(2011)1545.

3. SUMMARY OF THE OUTCOME OF THE REVIEW

3.1. Introduction

The review of Annex X to Directive 2000/60/EC has been undertaken in accordance with the requirements of the WFD. The technical details of the review are explained in the accompanying Commission Staff Working Paper SEC(2011)1544.

3.2. Review of existing priority substances

As a consequence of the technical review and taking into account newly available information, the following changes are proposed to existing EQS:

- the water EQS of the following existing priority substances are proposed for update: Anthracene, Fluoranthene, Naphthalene, Polyaromatic hydrocarbons, Polybrominated diphenyl ethers, Lead and Nickel.

- biota EQS have been developed and are proposed for Fluoranthene, Polyaromatic hydrocarbons and Polybrominated diphenyl ethers, because due to their properties these substances are more easily and reliably measurable in this matrix.

- existing biota EQS for Hexachlorobenzene, Hexachlorobutadiene and Mercury are maintained, but the water EQS and footnote 9 in Part A of Annex I to Directive 2008/105/EC are deleted because those EQS do not afford adequate protection.

[5] 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

The updated EQS represent, according to the latest scientific knowledge, an adequate level of protection of the aquatic environment and of human health via the aquatic environment.

As regards the status of existing substances, and according to the latest information, the substances Di-(2-ethylhexyl)-phthalate (DEHP) and Trifluralin are proposed to be classified as priority hazardous substances.

3.3. Identification of new priority substances

Based on the outcome of the technical process, it is proposed to identify the following substances as priority substances: Aclonifen, Bifenox, Cybutryne, Cypermethrin, Dichlorvos, Terbutryn, 17alpha-ethinylestradiol, 17beta-estradiol and Diclofenac, and the following as priority hazardous substances: Dicofol, Perfluorooctane sulfonic acid and its derivatives (PFOS), Quinoxyfen, Dioxins and dioxin-like compounds, Hexabromocyclododecane (HBCDD) and Heptachlor/heptachlor epoxide.

Water EQS are being proposed for all the new substances except for Dioxins and dioxin-like compounds. Biota EQS are proposed for Dicofol, PFOS, Dioxins and dioxin-like compounds, HBCDD and Heptachlor/heptachlor epoxide.

3.4. Review of substances in Annex III to Directive 2008/105/EC

Four substances/groups of substances listed in Annex III to Directive 2008/105/EC are being proposed for inclusion in the priority substances list: Dicofol, Dioxins and dioxin-like compounds, PFOS and Quinoxyfen. The inclusion of a fifth, the Dioxin-like PCBs, is covered by the inclusion of Dioxins and dioxin-like compounds. The toxicity data for non-dioxin-like PCBs are not sufficient to derive a reliable EQS and therefore these PCBs are not proposed for inclusion.

For the other substances in Annex III to Directive 2008/105/EC, the review concluded that there was not enough evidence of significant risk to or via the aquatic environment at EU level to include them at this stage in the list of priority substances. In the context of future reviews of Annex X to Directive 2000/60/EC, the Commission will re-assess the information available and make proposals for inclusion in the priority substances list if appropriate.

More details about the outcome of the review can be found in the accompanying Commission Staff Working Paper SEC(2011)1544.

3.5. Identification of control measures at EU level

At the time of the Commission proposal in 2006, a review of the existing control measures concluded that numerous acts had been adopted at EU level since 2000 that constituted control measures in the sense of Article 16 of the WFD. Additional measures at EU level were not deemed necessary to achieve the objectives of the WFD. It was considered that, if additional measures were necessary at local level, Member States could include them in their river basin management plans (see recitals 7 and 8 of the EQSD).

Since then, the legislation to control the authorisation and placing on the market of chemicals has been substantially expanded and improved, in particular with the adoption of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH)[6] and of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market[7]. This and other existing EU legislation (e.g. biocides and veterinary medicines legislation) contains mechanisms suited to controlling the uses and emissions of most of the priority substances at EU level (e.g. evaluation, restriction, authorisation). These existing mechanisms should therefore be applied before others are developed and should in principle be sufficient to achieve the objectives of the WFD.

More information can be found in the Impact Assessment report SEC(2011)1547.

3.6. Other outcomes

The technical work and the consultation process in the context of the review of the priority substances provided the opportunity to look at other aspects of the implementation of the EQSD.

One important achievement has been the update of the Technical Guidance for deriving Environmental Quality Standards, which contains expanded and updated sections on sediment and biota standards. This has allowed the derivation of standards for biota for those substances that, due to their intrinsic properties and their fate in the aquatic environment, are best regulated in that matrix. This will significantly improve the protection offered by the EQSD.

Another important aspect has been the identification of problematic substances that, due to their persistent, bioaccumulative and toxic behaviour, will continue to cause exceedances of the EQS for a long time, even though very stringent measures to limit emissions have already been taken. Because of their characteristics, they merit separate treatment in terms of their monitoring and the presentation of their impact on chemical status.

Finally, the review has identified the need for a mechanism to improve the collection of targeted and high-quality monitoring data from across the EU to support future prioritisation exercises. The impact assessment demonstrates the benefits of establishing such a mechanism.

4. OUTLOOK FOR FUTURE REVIEWS OF ANNEX X TO DIRECTIVE 2000/60/EC

The review of the priority substances list was undertaken at the same time REACH implementation began and the European Chemicals Agency (ECHA) was being set up. Future prioritisation exercises will take advantage of the wealth of information provided by the REACH registration process, whose first deadline was in November 2010. Also, the expertise on risk assessment at EU level is being concentrated in ECHA and other agencies that deal with risk assessment of other chemicals, such as the European Food Safety Authority (EFSA) for pesticides and the European Medicines Agency (EMA) for pharmaceuticals. For future reviews of the priority substances list, the Commission will explore the possibilities to exploit in a more efficient way the expertise on risk assessment existing at EU level. This initiative should also ensure that there continues to be a high degree of coherence and consistency between the WFD and related policies such as chemicals, biocides, pesticides and pharmaceuticals.

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[6] OJ L 396, 30.12.2006, p. 1-849.
[7] OJ L 309, 24.11.2009, p. 1-50.