



EUROPEAN COMMISSION

Brussels, 19.10.2012
C(2012) 7021 final

Dear Presidents,

The Commission would like to thank you for the Opinion of the Spanish Parliament on the Commission Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards Priority Substances in the Field of Water Policy {COM(2011) 876 final} and apologises for the delay in replying.

The Commission welcomes the Spanish Parliament's acknowledgement that the proposal conforms with the principle of subsidiarity. The Commission takes note of the comments made regarding the inclusion of pharmaceuticals and metabolites in the list of priority substances, including the suggestion that the substances be included in the watch list instead.

Whilst we appreciate the need to ensure that the listing of substances is properly justified, we emphasise that the prioritisation of substances for listing was based on a thorough scientific review of the evidence, both the evidence of intrinsic hazard and that of exposure. The pharmaceuticals (one of them also being a metabolite) were subjected to the same considerations as the other substances as regards potential risk. Because they are not yet regulated, most Member States do not routinely monitor them, and therefore only a few provided monitoring data for the database that was compiled specifically for the priority substances review. However, that database was not the only source of monitoring information. The Impact Assessment refers to other sources showing that the Environmental Quality Standards (EQS) for these substances are exceeded in several Member States. The presence and effect of pharmaceuticals in the aquatic environment has also been documented extensively in the scientific literature in recent years. The Water Framework Directive Article 16(2) in any case allows the use of other information such as use patterns that may indicate widespread contamination, and exceedances in other Member States can be predicted on this basis.

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The watch list would be for substances for which it has not yet been possible to establish a significant risk at EU level. It would therefore not be appropriate to include the three pharmaceuticals, for which a risk has already been established.

I hope that these clarifications address the comments raised in the opinion submitted by the Spanish Parliament and I look forward to continuing our constructive political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*