

**Eurometaux Position Paper on the Water Framework Directive Priority Substance list following the 4th of February 2011 sub-group review meeting - agenda item 5 “Status of selected proposed and existing priority substances”**

With the support of EUROFER, Euromines, Concawe and Cefic

**A priori**

This document is Eurometaux's generic input for the upcoming discussion at Working Group E (15-16 March) on the status proposed and existing priority substances.

**Background**

At the 4 February 2011 meeting of the European Commission's Priority Substance sub-group to review the Water Framework Directive's list of Priority Substances (PS), the background for assigning the hazardous status, i.e. Priority Hazardous Substances (PHS), was explained. This paper sets out the position of Eurometaux regarding the issues discussed at the meeting and may be considered generic input for the upcoming discussion at Working Group E (15-16 March).

**Reference documents on priority hazardous status as presented at the 4<sup>th</sup> of February meeting**

- “Identification of PHS – Modified procedure in accordance with Article 16(3) of the WFD” Working document ENV/191000/01 final, January 2001
  - [http://ec.europa.eu/environment/water/water-dangersub/pdf/wd\\_env\\_191000\\_01\\_final.pdf](http://ec.europa.eu/environment/water/water-dangersub/pdf/wd_env_191000_01_final.pdf)
- “Identification of PHS” Informal background document related to COM proposal on PS, August 2005
  - [http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework\\_directive/thematic\\_documents/priority\\_substances/supporting\\_background/identificationpdf/EN\\_1.0\\_&a=d](http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_background/identificationpdf/EN_1.0_&a=d)
- REACH Regulation (especially Article 57 and Annex XIII)
  - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF>

In the 2005 document, the following optional criteria were mentioned for a substance representing an ‘equivalent level of concern’:

- a) Very Persistent, Very Bioaccumulative (vPvB)- criteria;
- b) Persistent Organic Pollutants (POP) (cf. Stockholm Convention) ;
- c) Carcinogenic, Mutagenic and toxic for reproduction( CMR)<sup>1</sup> ;
- d) Very Persistent, Very Toxic (vPvT) for substances with a high mobility;
- e) Targeted risk assessments showing a particular risk for parts of the aquatic environment (in particular marine and groundwater);

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<sup>1</sup> i.e. applicable only to CMR 1a and 1b under the new CLP regulation.

The 2005 document further acknowledged more work was to be done: “Following the discussion in the Expert Advisory Forum, a common understanding was reached that “some criteria for determining ‘equivalent level of concern’ need further development and others may be subject to different interpretation.” Further work will be necessary in the future in order to develop **Community-wide agreed criteria and thresholds** to assess the ‘equivalent level of concern’ in the context of the Water Framework Directive.”

### **The prioritization review process**

**The prioritization process is almost in the final stage, with the Commission aiming to adopt a proposal by June 2011.** The development of Community-wide agreed criteria and thresholds, as announced in the 2005 document, is still a challenge. However up until 4 February no significant stakeholder consultation had been undertaken regarding the criteria to be used for assessing PHS status.

At the 4 February sub-group meeting a discussion took place regarding a possible alignment of the criteria for identifying PHS substances with those used for the prioritisation of substances under Article 57 of the REACH Regulation, specifically the identification of candidate substances for authorisation.

**Whilst in principle consistency between the Water Framework Directive and REACH is desirable, it is also necessary to carefully consider the implications of applying individual components of the REACH Regulation to other regulatory regimes.** Specifically in the case of WFD PHS criteria, it is important to recognise that there are significant differences between the objectives and implications of prioritisation under the authorisation component of REACH and under the Water Framework Directive.

It must be recognised that the authorisation component of the REACH Regulation consists of multiple stages:

1. Intrinsic hazardous properties according to Article 57 are used to assess whether the substance can be placed on the candidate list for authorisation (i.e. substances of very high concern).
2. Additional considerations are used to evaluate whether a substance should be added to Annex XIV of the REACH Regulation, i.e. become subject to authorisation. These include an evaluation of whether uses of the substances are sufficiently controlled by existing community legislation, resulting in the assessment that they do not need an authorisation.
3. Authorisations may be granted if risks are adequately controlled or if the socio-economic benefits outweigh the risks and there are no suitable alternatives available.

**Under the Water Framework Directive, identification of a substance as PHS is followed by a process to determine measures required to achieve the control of these substances. There is hence a need for careful consideration of how these processes can be aligned, recognising that the implementation of REACH authorisation is still at an early stage.**

Importantly, the protection goals associated with the Water Framework Directive are limited to those related to EU surface waters and groundwaters, whereas the protection goals of REACH extend much further to consider other non-aquatic environmental matrices. It is therefore critical that **when considering the use of REACH criteria for WFD purposes, any application is strictly limited to scenarios relevant to EU surface waters in the present context. This includes considering the relevancy and importance of routes of exposure.**

As well as relevancy of exposure routes, **other factors must be considered in any alignment of criteria. These include a demonstration that the substances present a significant risk to or via the aquatic environment, a first condition to be selected as a priority substance, and the relevancy of other existing legislation.**

Eurometaux feels strongly that given the potentially significant implications of fixing criteria for PHS identification, it is necessary that a full review be undertaken, considering both the issues raised in this document and those of other stakeholders. **A consultation should be held on a specific proposal for PHS criteria revision. Once the criteria have been agreed, a dossier should be prepared for each substance under review. Such a dossier should identify high quality data, and then, from an agreed dataset, assess whether the revised PHS criteria are met. Such a dossier should also undergo stakeholder consultation. Considering that the REACH implementation is only in an early stage of authorisation, such process should be undertaken in a later phase, after the project proposal, to allow sufficient return of experience of REACH implementation.**

Eurometaux is very concerned that **the limited time available before a Commission proposal is to be adopted may make it impossible to complete the abovementioned process in a robust way.** Regarding any PHS criteria revision, industry is concerned that **the lack of full consideration and consultation could result in an unmanageable PHS list which is not necessarily relevant to surface waters, delivers little added value over and above other legislation (including REACH) and is in fact not well aligned with REACH authorisation mechanisms and objectives.**

Finally, it is important to recognise that any consideration of classifying a substance as a PHS must be accompanied by an impact assessment that quantitatively compares impacts of the potential measures, and the costs and benefits associated with these measures taken within the WFD context, taking into consideration the analytical limits.

### **Conclusions**

Eurometaux feels strongly that given the potentially significant implications of a change in criteria for PHS identification, it is necessary that a full review and consultation should be undertaken. The undersigned industries remain very concerned that the limited time available before a Commission proposal is to be adopted may make it impossible to complete the abovementioned process in a way that ensures that WFD PHS criteria are directly relevant to the environmental protection objectives of the Water Framework Directive, and to the maximum extent aligned with REACH.

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