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ITT: Comparing marine and freshwater toxicity for fish, crustacean and algae in order to inform the potential future use of REACH toxicity data in HMCS

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1. Introduction

For some time, there has been the recognition that the Harmonised Mandatory Control System (HMCS) that manages the use and discharge of oilfield chemicals in the region of the North-East Atlantic that falls under the Oslo-Paris commission (OSPAR) would need to harmonise with European chemical legislation such as Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) & the Biocidal Products Regulation (BPR). Consequently, over the last decade there have been several amendments to the HMCS processes to harmonise aspects for the HMCS with REACH and the BPR, e.g. some pre-screening aspects, PLONOR¹ chemicals and REACH Annex IV & V substances along with substances Restricted or Authorised under REACH. Other changes are being discussed like the harmonisation of assessment factors for the derivation of predicted no-effect concentrations (PNECs).

Currently, mainly marine toxicity data is requested from chemical suppliers through the submission of a HOCNF. If harmonization with REACH assessment factors would occur also toxicity data requirements will change, opening-up for the use of freshwater data under HMCS. While harmonization of assessment factors is being discussed, it is therefore also key to determine the optimum set of toxicity testing/data requirements for HMCS aligned with REACH requirements. Testing requirements for HMCS should be defined based on, among other, the REACH marine assessment factors, REACH data and testing requirements, animal welfare considerations, and minimization of testing efforts and test duplication.

This Invite to Tender outlines the scope of work anticipated for the work required.

2. Background

At the 2019 OIC meeting an Intersessional Correspondence Group was established (ICG-REACH) to progress the OSPAR objective of harmonising HMCS and REACH. So far discussions within ICG-REACH have mainly focussed on scope determination. At the June 2020 ICG-REACH meeting some initial ideas were presented outlining a "REACH plus" system/concept in which HMCS is aligned with REACH, but with additional measures to address those areas covered only under HMCS.

One of the consequences of the harmonization of assessment factors between HMCS and REACH would be the acceptance of freshwater toxicity data for fish, crustacean and algae under HMCS. It is recognised, however, that uncertainty might exist on the representativeness of freshwater data for the marine environment. Although the REACH marine assessment factors partly address this uncertainty, it would be valuable to quantify this uncertainty by reviewing and collating existing information on the comparison of marine and freshwater toxicity for fish, crustacean and algae to

¹ PLONOR substances are those that are believed to "Pose Little Or NO Risk" to the marine environment

inform on the potential future use of available marine and freshwater toxicity data from e.g. REACH and BPR in HMCS.

With the application of an additional assessment factor of 10 for deriving a marine PNEC, REACH does acknowledge that there might be a difference in sensitivity of marine and freshwater species but that this difference can be mainly attributed to a wider taxonomic diversity in marine ecosystems. Only when toxicity data for specific marine taxonomic groups are provided (in addition to data for fish, crustacean and algae) the uncertainty in the PNEC estimation can be reduced by lowering the assessment factor.

To feed the discussion on the acceptance of freshwater data (for algae, crustacean and fish) under HMCS, EOSCA would like to execute the project described in this document.

3. Scope of Work

EOSCA is seeking contractor support to execute the work described herein. The following main headings outline the key activities that would need to be executed.

3.1 Literature search and study data collection

Over the last couple of decades, several studies focussed on the comparison of freshwater and marine toxicity data (e.g. Hutchinson *et al.* 1998; Klok *et al.* 2012; Leung *et al.* 2001; Wheeler *et al.* 2001 and 2002, Yanagihara *et al.* 2022). These and other studies that compare sensitivity of freshwater and marine species (with focus on fish, crustacean and algae) should be collected through a literature search. Especially of interest would be studies that include OSPAR recommended test protocols in their evaluations (table 1).

Table 1; Marine toxicity testing requirements (water) for completing HOCNF.

Taxonomic group	Species	Protocol
Algae	<i>Skeletonema costatum</i> or <i>Phaeodactylum tricorutum</i>	ISO/DIS protocol 10253
Crustacea	<i>Acartia tonsa</i> or <i>Tisbe battaglia</i>	ISO protocol TC 147/SC5/WG2
Fish (juveniles)	<i>Scophthalmus maximus</i> or <i>Cyprinodon variegatus</i>	Part B of the OSPAR Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry (published by OSPAR in 1995, available from www.ospar.org)

In addition to collecting existing studies that compare marine and freshwater toxicity, information should be extracted from a selection of REACH dossiers that contain both results of the above listed marine studies and their freshwater counterparts. This would allow for pairwise comparison of results for a selection of substances (preferably > 30). EOSCA members should be approached to identify any additional studies that might be available in the grey literature. The result of this activity will be a literature database containing information of the collected studies, e.g., type of publication, title, and authors and an excel spreadsheet with collected toxicity information from REACH dossiers.

3.2 Review, data collation and analysis.

The objective of this study is to determine whether, a systematic difference exists between marine and freshwater toxicity test results for algae, crustacean and fish. Results and conclusions from the collected studies that compare marine and freshwater toxicity data should be reviewed and summarized, together with any other information collected. Any evidence, or the absence of evidence, for a systematic difference in sensitivity should be registered.

Statistical analysis including one-to-one comparisons of species' sensitivity, focussing on the data collected from REACH dossiers on HOCNF required test species and their freshwater counterparts should also be conducted.

3.3 Summary conclusions, study recommendations and outlook

Harmonization of CHARM assessment factors and REACH R10 marine assessment factors would also require harmonization of data requirements. Under REACH there is greater acceptance of freshwater data and in some cases, there may be chronic data available. Analysis of collected data should provide quantitative information on the uncertainty associated with the acceptance of freshwater toxicity data.

Based on the outcome of the study further suggestions for defining an optimum set of toxicity testing/data requirements for HMCS aligned with REACH should be developed. These requirements should be defined based on, among other, the outcome of the above-described analysis, REACH marine assessment factors, REACH data and testing requirements, animal welfare considerations, and minimization of testing efforts and test duplication.

4. Deliverables

After an initial kick-off meeting it would be expected that the contactor would progress the work through contacts at EOSCA to complete the assessment. A small Steering Committee would meet periodically to review progress.

The final deliverable will be a written report, and where suitable it would be planned that the work and findings be presented to EOSCA and the ICG-REACH or other suitable forum.

The timeline for conducting this work is still to be determined. For now, the most likely period for conducting this work is Q4-2024 – Q1-2025.

5. Tender requirements

Successful tenderers will provide the following in their project offers:

- Overview of experience with both HMCS and European chemical legislative systems.
- Description of planned activities
- Breakdown of activities with associated timelines and cost estimates
- CVs of key contributors
- Project management structure

Only proposals that are received before 30th November 2024 will be evaluated.

Tender documents should be sent by email to:

EOSCA: Nik Robinson, secretary@eosca.eu

Questions related to this tender can also be addressed to the person mentioned above.

6. References

Hutchinson T, Scholz N, Guhl W. 1998. Analysis of the ECETOC aquatic toxicity (EAT) database - IV - Comparative toxicity of chemical substances to freshwater versus saltwater organisms. *Chemosphere* 36(1):143-153.

Klok, C., de Vries, P., Jongbloed, R., & Tamis, J. 2012. Literature review on the sensitivity and exposure of marine and estuarine organisms to pesticides in comparison to corresponding freshwater species. *EFSA Supporting Publications*, 9(11), Article 357. <https://doi.org/10.2903/sp.efsa.2012.en-357>

Leung KM, Morritt D, Wheeler JR, Whitehouse P, Sorokin N, Toy R, Holt M, Crane M. 2001. Can saltwater toxicity be predicted from freshwater data? *Mar Pollut Bull* 42(11):1007-1013.

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