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(Agreed at SEAC 37)

SEA-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO

1. Background

Two Substances of Very High Concern (SVHC) with endocrine disrupting (ED) properties for the environment were recently added to Annex XIV of REACH (OPnEO[1] and NPnEO[2]). These are the first two SVHCs added to Annex XIV on the basis of these properties.

In August 2017, ECHA hosted a workshop in Brussels on 'Applications for Authorisation for Environmental Endocrine Disrupters' to have an open exchange of views between interested stakeholders on the available scientific evidence relating to the hazard and risk assessment of NPnEO and OPnEO. As a follow-up to that workshop, CEFIC and Eurometaux jointly hosted a workshop at their premises in Brussels on 4 October 2017 to discuss the applications for authorisation system for these substances. The agenda included a session specifically focussed on appropriate socioeconomic analysis for substances where reference values (PNEC values or dose-response relationships) were not available.

The outcomes of the workshops were discussed during RAC-42 and RAC-43 meetings, and a Question and Answer paper addressing key risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO, was agreed at RAC-43 and available on the ECHA website[3].

RAC note that where an applicant assumes that OPnEO or NPnEO are non-threshold substances and no dose-response is proposed, or is not supported by RAC after evaluation, RAC will evaluate the application on the same basis as an application for a PBT/vPvB substance and focus their evaluation on the reliability and representativeness of the description of releases to the different environmental compartments and on the appropriateness and effectiveness of the operational conditions and risk management measures.

A non-threshold approach to risk assessment also has implications for appropriate socio-economic analysis in applications for authorisation. Therefore, building on the work of RAC, SEA-related considerations were discussed during SEAC-37, and this document outlines one possible approach for an SEA in an application for authorisation for a substance with endocrine disrupting properties for the environment. However, an applicant may choose to use a different approach to justify its authorisation.

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[1] Entry 42: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [4-tert-octylphenol, ethoxylated; 4-tert-OPnEO]
[2] Entry 43: 4-nonylphenol, branched and linear, ethoxylated [4-NPnEO]
[3] *Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO* is available at https://echa.europa.eu/documents/10162/13637/npneo_and_opneo_for_agreement_final_en.pdf/026cbafc-6580-1726-27f3-476d05fbeef0

2. Starting point

An authorisation may be granted for the use of a substance if the applicant can demonstrate that the socio-economic benefits outweigh the risk arising from the use and there are no suitable alternatives (Article 60(4)). Full quantification of both benefits and risk is not required by REACH, and the possibility for qualitative and semi-quantitative approaches for SEA is clearly recognised in the relevant guidance documents. These approaches can also be used to justify that benefits of a use outweigh risks. The approach to be chosen depends on the complexity and the impact of the specific case. A straightforward qualitative assessment may be sufficient in certain cases (e.g. where the benefits for society from the continued use are evidently considerable and the emissions to environment are properly controlled), whilst in other cases more in-depth analysis may be required.

3. Possible approach for SEA

In terms of assessing the benefits of continued use, applications for authorisation for substances with endocrine disrupting properties for the environment do not differ from any other application. The benefits assessment is based on the non-use scenario, where the substance is no longer available for the applicant to use. Although there may be costs related to additional risk management measures (i.e. the cost of further risk management measure that could be implemented in addition to those that are currently in place) these are not relevant for the assessment of the benefits of continued use. However, these costs may be used to justify that releases are minimised as far as technically and practically possible.

The environmental risk or impacts from the use of these substances are not possible to quantify when thresholds or dose-response relationships cannot be defined. In the event that a dose-response relationship was available, it would not necessarily be possible to link the observed effects with an outcome that would have a clear welfare consequence. Furthermore, the monetisation of these outcomes would not be necessarily possible. In these cases, the applicant may decide to approach the SEA on a similar basis as an application for a PBT/vPvB substance[4]. In these applications, monetised benefits of continued use and quantified release estimates, complemented with qualitative information, form the basis of a semi-quantitative approach to justifying that the benefits of continued use outweigh risks. When appropriate, this information can be complemented with more detailed qualitative or quantitative information to further justify the case.

For the applicant to conclude that the benefits of continued use outweigh the risk, it seems necessary to provide as part of the assessment:

- a monetised estimate of the benefits of continued use
- quantified release estimates accompanied with a qualitative description of where the releases occur (e.g. dilution capacity of a river and number of release sources and their temporal and geographical distribution)
- a qualitative description of the potential impacts (e.g. on fish populations)

[4] SEAC approach for evaluating PBT and vPvB cases is available at https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

This information should, in principle, always be available for the applicant, and may be sufficient to conclude, based on a qualitative comparison, that the benefits of a use outweigh the risk. If this is not the case, the applicant may provide further contextual information on the likelihood and significance of potential impacts (e.g. the margin of safety between predicted or measured environmental concentrations and relevant thresholds of exposure/adverse effect in biota or quality standards from other legislation) or illustrative quantitative assessments (e.g. based on worst case scenarios or a break-even analysis) to support the case.

Finally, the applicant needs to perform a qualitative comparison of the benefits and risk of the continued use and explain why they consider that from a societal perspective it is better to continue to use the substance. As mentioned above, the level of effort and detail required will depend on the complexity and the impact of the specific case.

The information provided in the application for authorisation will be assessed on a case-by-case basis by SEAC. Any benchmarks (e.g. € of reducing kg of release) above which an authorisation would always be granted cannot be set. Some information on the order of magnitude of such a benchmark has been reported for PBT/vPvB substances in a study referred to in the SEAC PBT approach[5]. However, it should be noted that this information is not directly applicable to substances with endocrine disrupting properties for the environment.

[5] Oosterhuis F. and Brouwer R. (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances available at http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf