

Workshop on applications for authorisation for environmental endocrine disruptors

22nd of August, 2017

10:00 to 16:00 – CCAB 1B

The purpose of the workshop is to have an open exchange of views between stakeholders and ECHA on the available scientific evidence relating to the hazard and risk assessment of NPnEO and OPnEO. In particular, the workshop will consider whether it is possible to derive thresholds or dose-response relationships for these substances.

09:30 Registration

10:00 **Welcome and Introduction** – Tim Bowmer (ECHA, Chairman of RAC)

10:20 **Conclusion from the Commission's report on the granting of authorisations for substances with endocrine disrupting properties**
Enrique Garcia-John (European Commission)

10:30 **ECHA's Endocrine Disruption Expert Group and the identification of OPnEO and NPnEO as SVHC**
Conor Clenaghan (ECHA)

10:50 **Thresholds for Endocrine Disruptors and Related Uncertainties – Summary of a JRC report**
Frauke Stock (UBA)

11:10 **Ecotoxicological Hazard and Risk Assessment Approaches for Endocrine-Active Substances – Summary of a SETAC Pellston Workshop**
Annegaaiké Leopold (Calidris Environment bv)

11:30 **Environmental Quality Standards (EQS) NP and OP under the Water Framework Directive**
Helen Clayton (DG Environment)

11:50 **Summary of the RAC evaluation and opinion on the proposal for a restriction on the use of nonylphenol ethoxylates in textiles**
Peter Simpson (ECHA)

12:15 Lunch

13:30 **Development of a rationale for a risk-based approach to applications for authorisation for OPnEO**
Tomas Sendor (Ramboll Environ)

13:50 **World café discussions** key issues relevant to preparing applications

15:00 **Coffee**

15:20 **Reporting by Rapporteurs**

15:50 **Summing up**

16:00 **Close**

World café discussions

A group will spend 15 mins discussing each question, then moves to the next group. All participants will therefore be able to contribute to all of the four questions.

Q1– What hazard information and analysis would need to be presented for NPnEO or OPnEO to robustly demonstrate 'adequate control' (RCR<1)?

- What compartments are relevant (freshwater, seawater, sediments, terrestrial)
- Is it appropriate to consider 'minimum requirements' for datasets in terms of, for example, taxonomic diversity, sensitive life-stages (including delayed effects) and multi-generational effects; from where could these requirements be taken?
- How to take account of previous evaluations by ECHA's committees (SVHC identification and RAC restriction opinion)?
- Are mixture effects in the environment relevant?
- What are the inherent 'advantages and disadvantages' of an application for these substances via the 'adequate control' route?

Q2 – What kind of hazard information and analysis could be presented in an Application for Authorisation for NPnEO or OPnEO under the 'socio-economic route', for example if no threshold can be demonstrated?

- Can the ED effects of these substances be translated into a dose-response relationship that could be used in a socio-economic impact assessment (e.g. response can be valued)? Is such a dose-response necessary or could a cost-effectiveness approach be used (as currently used for PBT/vPvB substances)?
- How could the appropriateness and effectiveness of operational conditions and risk management measures be demonstrated?
- What are the inherent 'advantages and disadvantages' of an application for these substances via the socio-economic route?

Q3 – What kind of environmental exposure/release data could be presented in an application for authorisation for NPnEO or OPnEO?

- How critical is exposure data when demonstrating 'adequate control'?
- Which environmental compartments are relevant (freshwater, seawater, sediments, terrestrial environment (via sludge))?
- Can releases and environmental concentrations of NPnEO, OPnEO and relevant degradation products be estimated with confidence?
- What could be the role of measured 'exposure data' in Applications for Authorisation, particularly any that seek to demonstrate 'adequate control'?

Q4 – What could be the 'next steps' for stakeholders in relation to Applications for Authorisation for these substances?

Map and descriptions

See next page for a map with the following descriptions.



Albert Borschette Congress Center (CCAB)

The meeting room for this workshop is CCAB 1B.



Sandwich shops

A selection of sandwich shops close to the conference centre.

- Paul (Rue Froissart 72)
- Exki shop (Rue Froissart 94)
- Shop & Go Froissart (Rue Froissart 123)
- Exki shop (Rue de la Loi 232, near Berlaymont)



Place Jourdan – Restaurants

A selection of restaurants only 2 minutes' walk from the conference centre.



Parc Leopold – For good weather

Parc Léopold or Leopoldspark is a public park located right next to the conference centre, and could be a nice choice for a sandwich lunch if the weather is nice.

