

ECHA Provides Clarification on PNEC/ DNEL Derivation and Risk Assessments

Case 1:

- A non-classified substance according to CLP
- Showing effects in human health endpoints (without classification)
- Not a PBT/vPvB

Question to ECHA	Answer from ECHA
<ul style="list-style-type: none"> - Are DNELs to be derived? - Are all DNELs or only those for the respective exposure route to be derived? - Are risk assessments necessary? - Are PNECs to be derived and risk assessments to be conducted, in case a DNEL has been derived? 	<ul style="list-style-type: none"> - DNELs need to be derived, if effects have been observed in the required studies (and no-effect-level can be derived), independent of whether the effects qualify for triggering a classification. <ul style="list-style-type: none"> ○ For long-term systemic effects, all routes should be addressed (except oral for occupational assessment) , route-to-route extrapolation may be applied. ○ If the effects observed are of local nature only, it is enough to address the corresponding exposure route only. - PNECs are to be derived if effects were observed in the required ecotoxicological studies, since there is no direct relationship between DNEL to PNEC derivation. - Exposure assessment and risk characterisation are not required as the substance is not classified as hazardous or considered a PBT/ vPvB (REACH Art 14(4)).

Case 2:

- Substance classified for human health endpoints
- No classification for environmental endpoints
- Showing no effects in ecotox studies
- Not a PBT/vPvB

Question to ECHA	Answer from ECHA
<ul style="list-style-type: none"> - Are DNELs to be derived? - Are all DNELs or only those for the respective exposure route to be derived? - Are risk assessments necessary? - Are PNECs to be derived and risk assessments to be conducted, in case a DNEL has been derived? 	<ul style="list-style-type: none"> - DNELs and PNECs – see Case 1. - If no PNECs and DNELs have been derived, qualitative exposure assessment and risk characterisation are not required in the CSR (despite the classification) provided. Still qualitative assessment might be needed. - If no PNECs have been derived, but a long-term inhalation or oral DNEL has been derived for general population, exposure assessment and risk characterisation may still be required for humans via the environment, depending on tonnage band and specific hazard classes.

Case 3:

- A non-classified substance
- Not a PBT/vPvB
- Showing no effects in the aquatic ecotox studies
- Exhibiting slight effects in the microorganisms studies (STP)

Question to ECHA	Answer from ECHA
- Is it possible to derive a PNEC STP (one compartment) only, skipping PNECs for other compartments as no hazard up to the limit dose has been observed?	- It is possible to derive a PNEC STP only.

Case 4:

- A non-classified substance
- With derived PNECs and DNELs

Question to ECHA	Answer from ECHA
- Is the exposure assessment necessary? - Or can the CSR be waived instead due to the fact that the substance is not classified?	- Exposure assessment and risk characterisation are not required in the CSR as the substance is not classified as hazardous or considered a PBT/vPvB (REACH Art. 14(4)). - A CSR with sections 1-8 is still requested.