# PEC PNEC approach

The EU Technical Guidance Document (EU-TGD) on risk assessment ([EC 2003](#_ENREF_2)) defines the PNEC as the concentration below which unacceptable effects on organisms will most likely not occur. The ratio between the Predicted Environmental Concentration (PEC) and the PNEC can then be used as an indication of the likelihood of adverse effects to occur.

Certain assumptions are made concerning the aquatic environment, which allow an extrapolation to be made from single-species short-term toxicity values to ecosystem effects, expressed as the Predicted No Effect Concentration (PNEC). It is assumed that:

* ecosystem sensitivity depends on the most sensitive species, and;
* protecting ecosystem structure protects community function as well.

These two assumptions have important consequences. By establishing which species is the most sensitive to the toxic effects of a chemical in the laboratory, extrapolation can subsequently be based on the data from that species. Furthermore, the functioning of any ecosystem in which that species exists is protected provided the structure is not distorted to such a degree that it causes an imbalance.

It is generally accepted that protection of the most sensitive species should protect structure, and hence function. For most substances, the pool of data from which to predict ecosystem effects is very limited as, in general, only short-term toxicity data are available. In these circumstances, it is recognized that, while not having a strong scientific validity, empirically derived assessment factors must be used. Assessment factors have also been proposed by the US-EPA and the OECD.

In applying such factors, the intention is to take into account the uncertainties in the information to predict a concentration below which an unacceptable effect will most likely not occur. It is not guaranteed to be a level below which the chemical is considered to be safe. However, it is likely that an unacceptable effect will not occur ([EC 2003](#_ENREF_2)).

The PNEC can be derived from laboratory NOEC (No Observable Effect Concentration) and/or L(E)C50 (50% Lethal or Effect Concentration) values by applying an assessment factor. The magnitude of the assessment factor depends on the amount of suitable toxicity data. The highest assessment factor (10,000) is applied when only a limited set of acute toxicity values is available. The lowest assessment factor (10) is applied when chronic NOECs are available for three trophic levels (usually algae, crustaceans and fish) and at least two additional marine taxonomic groups ([EC 2003](#_ENREF_2)). The assessment factors applicable on taxonomic groups of fresh water organisms ([EC 1996](#_ENREF_1)) are a factor 10 lower than the marine assessment factors and are less refined ([EC 2003](#_ENREF_2)). The EU TGD is a widely accepted document and has for instance been adopted in REACH guidelines for chemical safety analysis ([ECHA 2008](#_ENREF_3)).

The PEC PNEC ratio is also known as the Risk Characterisation Ratio ‘RCR’. Ratio values above 1 indicate potential risk from the compound towards the environment. The scale of the risk can be crudely measured by considering this ratio – a figure of 1 to 10 is of lower concern, between 10-100 additional data are needed. Over 100 is of major concern, and action to reduce the risk to the environment should be required (EC, 2003).

## References

EC (1996) Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances, Vol. Office for Official Publications of the European Communities

EC (2003) Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances Commission Regulation (EC) No 1488/94 on Risk Assessment of existing substance Directive 98/8/EC of the European Parliament and Council concerning the placing of biocidal products on the market. In. European Commission Joint Research Centre

ECHA (2008) Chapter R.10: Characterisation of dose [concentration]-respons for environment. In: Guidance on information requirements and chemical safety assessment