

**Guidance on information requirements and chemical safety assessment**

**Appendix R10-2 Recommendations for nanomaterials applicable to Chapter R.10 Characterisation of dose [concentration] - response for environment**



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**European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

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# Appendix R10-2: Recommendations for nanomaterials

## 1. INTRODUCTION

This appendix has been developed in order to provide advice to registrants preparing their registration dossiers for nanomaterials. The content of the appendix implements the advice provided by the REACH Implementation Project on Nanomaterials 3 (RIP-oN 3) on exposure assessment and risk characterization.

The final report of the project contains a large amount of information including applicability of the methods, research gaps etc. This appendix implements only the agreed outputs (i.e. the recommendations for guidance update).

For further information (e.g. research & development requirements or reasoning under the advice provided for guidance, reader can refer to the final report of RIP-oN3. (<http://ec.europa.eu/environment/chemicals/nanotech/index.htm>).

## **2. RECOMMENDATIONS ON CHARACTERISATION OF DOSE/CONCENTRATION-RESPONSE FOR ENVIRONMENT ARISING FROM RIP-oN 3 for NANOMATERIALS**

### **2.1 Specific advice for the guidance document**

#### **2.1.1 Extrapolation methods**

Section R10.2.4 deals with extrapolation methods to calculate the PNEC, including the use of assessment factor methods.

The general principle of these assessment factor methods is that the result from a laboratory test is divided by an appropriate assessment factor. The sparser the available data, the higher is the assessment factor which is applied. PNECs are estimated by division of the lowest relevant value for the toxicity with the assessment factor corresponding to the amount and type of data. Tables R.10-4, R.10-5, R.10-6, R.10-7, R.10-8, R.10-9, R.10-10 and R10-13 present assessment factors that under certain circumstances should be considered as general factors. These factors can sometimes be changed if properly justified. One of the plausible justifications is when evidence established by read-across from closely related compounds can demonstrate the use of a higher or lower factor. However, in relation to nanomaterials where there is uncertainty due to the absence of available data, the use of read-across from available data on bulk or other forms of the material in place of specific data for the nanomaterials being assessed must be scientifically justified and may be associated with additional uncertainty.

#### **2.1.2 Calculation of PNEC using equilibrium partitioning**

Sections R10.5.2.1, R10.5.3.1 and R.10.6.1 explain the use of the equilibrium partitioning methods to calculate the PNEC for freshwater sediment, marine sediment and soil respectively.

In this respect, it should be noted that for some nanomaterials the Equilibrium Partitioning Method may not be applied provisionally for the calculation of PNEC for freshwater sediment, marine sediment or soil as the method has limited applicability for very adsorptive compounds which do not enter equilibrium.

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EUROPEAN CHEMICALS AGENCY  
ANNANKATU 18, P.O. BOX 400,  
FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU