



**EUROPEAN COMMISSION**  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate C - Public Health and Risk Assessment  
**C7 - Risk assessment**

**SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS**

**SCHER**

**Opinion on**

**“Risk Assessment Report on Nitrobenzene  
Environmental Part”**

**CAS No.: 98-95-3**

**EINECS No.: 202-716-0**

Adopted by the SCHER  
during the 7<sup>th</sup> plenary of 23 September 2005

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## 1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

## 2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

- (1) Does the SCHER agree with the conclusions of the Risk Assessment Report?
- (2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.
- (3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

## 3. GENERAL COMMENTS

The environmental part of the RAR is of very good scientific quality and follows the principles recommended by the TGD. The available information is properly used and supports the proposed conclusions. The local exposure assessment is based on specific data for the production and processing facilities. The SCHER agrees with the proposal of Conclusion ii<sup>1</sup>) for all environmental compartments. However, as the Human Health part is not included in the current version of the RAR, no information on mammalian toxicity, through the oral and inhalation routes, is presented. The committee suggests a re-evaluation of the potential risks for mammals, including the inhalation route, after the validation of the mammalian toxicological profile of nitrobenzene.

## 4. SPECIFIC COMMENTS

### 4.1. Exposure assessment

Nitrobenzene is water soluble and relatively persistent in the environment. It is stable to hydrolysis and non-ready biodegradable. A significant biodegradation by adapted inoculums has

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<sup>1</sup> According to the *Technical Guidance Document on Risk Assessment – European Communities 2003*:

- conclusion i): *There is a need for further information and/or testing;*
- conclusion ii): *There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;*
- conclusion iii): *There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*

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been observed in some experimental designs, but not consistently. The potential for bioaccumulation is low, as indicated by the low Kow and confirmed in experimental BCF measurements. The low Koc indicates high mobility in soil and low potential for adsorption on WWTP sludge.

The use of the TGD default values for local PECs estimation would suggest high concentrations. However, site specific information is available and has been used in the report. Site specific release factors are presented but the information on the employed dilution factors is restricted to the TGD requirement for non using values higher than 1000. The inclusion of the employed dilution factors in Table 3.7 would be beneficial for increase transparency.

The RAR includes a significant amount of monitoring data, which in general agrees with the model estimations.

## **4.2. Effect assessment**

### *4.2.1. Aquatic organisms*

The information covers acute toxicity data, and chronic NOECs on invertebrate and algae. According to the TGD, the PNEC is derived by applying a factor of 50 to the lowest valid NOEC value. The published very low chronic NOECs on fish and amphibians are considered invalid and, therefore, excluded from the assessment. The rationale for excluding these data is clearly presented, and the SCHER agrees with the proposal. No toxicological information on sediment dwelling organisms is available. The equilibrium partitioning method is employed in the RAR. Considering the physical-chemical properties and the ecotoxicological profile of nitrobenzene this approach is considered valid.

Two PNEC micro-organisms are derived considering the specific information on the WWTP of each facility. The approach is acceptable.

### *4.2.2. Terrestrial organisms*

The toxicity of nitrobenzene to soil organisms is limited. Standard tests are available only for earthworms. The RAR presents two alternative ways for setting the PNEC soil, the use on a assessment factor based on the earthworm acute LC<sub>50</sub> and the equilibrium partitioning method; the second method is selected as a lower value is obtained. The available toxicity tests on plans cover exposure through a nutrient medium and atmosphere. These non standard tests have been properly used for supporting the risk assessment.

The RAR does not include the Human Health assessment and, therefore, no information on the toxicity of nitrobenzene to mammals is presented.

A low potential for bioaccumulation is expected.

## **4.3. Risk characterisation**

The PEC/PNEC ratios based on site specific assessments are below 1 suggesting a low risk for all compartments. The RAR also includes the comparison of atmospheric levels and toxicity data on plans exposed via air. The SCHER welcomes this approach.

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The committee also recommends re-evaluating the risk for mammals after the validation of the oral and inhalation mammalian toxicity studies.

## **5. LIST OF ACRONYMS AND ABBREVIATIONS**

BCF	Bio concentration factor
LC <sub>50</sub>	median Lethal Concentration
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
WWTP	Waste Water Treatment Plant

## **6. ACKNOWLEDGEMENTS**

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