EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on CHLOROFORM Environmental Part

CAS-No.: 67-66-3
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Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCHER adopted this opinion at its 19th plenary on 20 September 2007

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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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. OPINION

3.1 General comments

The RAR is of good quality and presents the assessment in a transparent way. The available information on local emissions are presented and compared with the TGD default values. Data gaps are covered by sound assessments of related information. Exposure estimations are compared with monitoring data.

The effect assessment is well done except for the terrestrial (soil) compartment. The RAR follows the TGD and in absence of relevant toxicity data, the PNEC is derived by the equilibrium partitioning method from the PNEC aquatic organisms. However, the SCHER considers that this approach is not suitable for chloroform, as the derivation from the PNEC aquatic organisms is not protective, as observed for the sediment. In addition, the specific toxicity for microbial processes is not covered from the PNEC aquatic organisms. Thus, the SCHER considers that the PNECsoil should be recalculated.

Nevertheless, the committee supports the RAR conclusions, including conclusion ii)[1] for the soil compartment, as the revised PNEC would remain above the PEC soil. It must be noticed that the low local risk related to chloroform production and its use for HCFC production is mostly due to the implementation of control measures and the large dilution factors.

3.2 Specific comments

3.2.1 Exposure assessment

Chloroform is mostly used for the production of hydrochlorofluorocarbon-22 (HCFC 22); this use is expected to be reduced due to the regulation of HCFC as an ozone depleting substance. Additional applications include its use as solvent. The RAR also presents different sources of unintentional production of chloroform.

[1] *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

Chloroform is considered as a volatile compound, it is not biodegradable and volatilization represents the main dissipation route from WWTP. Its potential for bioaccumulation is low.

The RAR includes the TGD default estimations for transparency, but use as much as possible the information provided by the industry for producing a refined assessment. PECs are also compared with a significant amount of monitoring data, which in general are in agreement with the predictions.

3.2.2 Effect assessment

The properties of chloroform increase the complexity of the effect assessment as the amount of information is relatively high but in general of low reliability. The RAR justifies the adopted decisions.

The PNECs for aquatic organisms and WWTP micro-organisms are based on a relatively large amount of information. It is important to notice that the PNEC for micro-organisms is lower than the PNEC for aquatic organisms. The information for sediment dwelling organism is limited and the RAR, following the TGD, compares the PNEC derived from the toxicity data and that obtained through the application of the equilibrium partitioning method. The first approach is selected as it produces a more conservative approach. In fact, the equilibrium partitioning method estimates a PNEC very close to the reported NOEC for chironomids and the EC10 for sediment metanogenic bacteria.

The information for soil dwelling organisms is limited to a contact filter paper test. The RAR proposes the development of the PNEC soil organisms following the equilibrium partitioning method and the PNEC aquatic organisms as suggested by the TGD. However, in the opinion of the SCHER the in-depth evaluation of the information available for aquatic organisms, micro-organisms and sediment dwelling organisms clearly indicates that this approach is not suitable for chloroform. Micro-organisms, relevant taxa for the soil compartment, are particularly sensitive to chloroform. Therefore, the committee suggests using the PNEC micro-organisms instead of the PNEC aquatic organisms for the derivation of the PNEC soil organisms when using the equilibrium partitioning method. In addition, as the derivation of the PNEC micro-organism is based on very short tests (hours), relevant for the WWTP assessment but not for the soil compartment and additional factor of 10 should be used. These recommendations would produce a tentative PNEC of 16 µg/kg soil (ww).

The PNEC aquatic organisms has also been used for emissions to the marine environment, instead of applying an additional factor of 10 to the freshwater PNEC. The information does not indicate that marine organisms could be expected to be more sensitive than freshwater organism, and therefore, the SCHER supports this value and the application of case-by-case assessments instead of the automatic TGD procedure.

Because of the low BCF, no assessment for secondary poisoning is conducted.

3.2.3 Risk characterisation

PEC/PNEC values for the use of chloroform as solvent are higher than 1, and the RAR indicates conclusion iii). A risk for WWTP is also observed; conclusion (iii) applies to several production sites, to all uses and unintended releases related to losses of chloroform as a byproduct during chemical manufacturing.

Conclusion ii) applies to all other cases including the soil compartment. For this compartment, all PEC/PNEC ratios would remain below 1 even if the PNEC soil organisms proposed by the RAR is substituted by the SCHER recommendation. Thus, the Committee, although recommends the revision of the PNEC, supports the conclusions presented in the RAR. When considering the extrapolation of these data to facilities in other countries, it must be noticed that the low local risk related to chloroform production

and its use for HCFC production is mostly due to the implementation of control measures and the large dilution factors.

No PBT assessment is included; this assessment is not needed due to the low bioaccumulation potential.

4. LIST OF ABBREVIATIONS

EC10	10% Effect Concentration
HCFC	chlorodifluoromethane
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulable, Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
ww	wet weight
WWTP	Waste Water Treatment Plants