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DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION  
Directorate C - Scientific Opinions  
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**Scientific Committee on Toxicity, Ecotoxicity and the Environment**

Brussels,  
C2/JCD/csteop/**TetrachloroethyleneEnv22022002/D(02)**

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND  
THE ENVIRONMENT (CSTEE)**

**Opinion on the results of the Risk Assessment of:**

**TETRACHLOROETHYLENE**

**Environmental Part**

**CAS No.: 127-18-4**

**EINECS No.: 204-825-9**

**REPORT VERSION:  
Final report of August 2001**

**Carried out in the framework of Council Regulation (EEC) 793/93 on  
the evaluation and control of the risks of existing substances<sup>1</sup>**

**Opinion expressed at the 30th CSTEE plenary meeting**

**Brussels, 22 February 2002**

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<sup>1</sup> Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of those substances if they are produced or imported into the Community in volumes above 10 tonnes per year. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC) 1488/94, which is supported by a technical guidance document.

## Terms of reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTE is invited to examine the following issues:

1. Does the CSTE agree with the conclusions of the Risk Assessment Report
2. If the CSTE disagrees with such conclusions, the CSTE is invited to elaborate on the reasons for this divergence of opinion.

## GENERAL COMMENTS

The environmental part of the document is in general of very good quality. The RAR identifies atmosphere as the mainly exposed compartment. The CSTE particularly recognises the efforts to develop quantitative risk assessment proposals for atmospheric exposures in the absence of recommendations in the TGD.

The CSTE agrees with the proposed conclusions with two exceptions.

- The PEC/PNEC ratio for terrestrial plants exposed through air in the metal cleaning scenario is almost 1 and the uncertainty around this assessment is obviously high. Considering also that measured air levels in different areas above the PNEC have been identified, and that there is no information on the industrial activities located in the vicinity of these areas, a monitoring programme should be considered before assuming a low risk for this particular use.
- The risk for secondary poisoning has not been assessed on the basis of the Kow and the BCF in fish. The CSTE supports this conclusion for bioaccumulation through aquatic food chains. However, the RAR identifies an additional route: exposure of herbivorous animals consuming terrestrial plants exposed through air. The mammalian toxicity data validated in the human health part should be used to assess this particular risk.

The RAR presents an open question regarding the risk of the degradation product trichloroacetic acid in some areas. The RAR suggests two options, risk reduction or need for further information. The CSTE considers that further information should be required for producing a proper assessment.

## SPECIFIC COMMENTS

### Exposure assessment

The report presents a detailed description of the available information for production sites, as well as ad-hoc scenarios for releases related to the main uses: dry cleaning and metal cleaning. It is particularly relevant the comparison between the estimated PECs and the measured concentrations in different environmental compartments. A good agreement (excluding a specific site in Italy) is observed for surface waters and air. For municipal

wastewaters, data show several cases with concentrations clearly higher than the estimated PEC (assuming a single dry cleaning unit), suggesting that the selected scenario is not necessarily a realistic worst case situation. However, the expected concentrations will be in any case, lower than those estimated for industrial effluents, and therefore, this aspect will not affect the final conclusions. Similarly, measured concentrations in groundwaters are frequently higher than the PEC<sub>local</sub>.

The lack of bioaccumulation potential is confirmed from the measured levels in biota. However, relatively high concentrations have been detected in plants, even at 10 km from the industrial site. The amount of information is reduced to two figures for spruce needles and a range for fruit and vegetables. However, the concentrations are three orders of magnitude higher than the values estimated by EUSES. The report assumes that these levels are likely related to atmospheric deposition and water absorption. The explanation can be accepted, but the environmental relevance (exposure of herbivorous vertebrates and invertebrates) has not been considered in the report.

Atmosphere is properly described as the most relevant environmental compartment, due to both direct emissions and volatilisation from aquatic systems. Due to its high density, tetrachloroethylene may accumulate at the ground level. The potential for precipitation dissolved in rainwater has been also identified. The possibility of cycles of volatilisation-precipitation is not considered in the RAR but cannot be disregarded.

The RAR includes the description of several studies on the biodegradation. Anaerobic degradation by a process of reductive dechlorination is proved, while aerobic degradation cannot be demonstrated. As a worst-case assumption, no aerobic biodegradation is considered. The CSTEE supports this conclusion.

The RAR also includes specific concerns for some degradation products, such as TCA and vinyl chloride. However, degradation of tetrachloroethylene is not the only source for these metabolites. Further information is required to quantify the contribution of the tetrachloroethylene breakdown in the overall presence of these metabolites in different environmental compartments.

## **Effects assessment**

### **Aquatic organisms**

A large number of acute and chronic toxicity data on aquatic organisms behaving to different trophic levels is available, nevertheless, due to the volatility of the substance, their reliability must be evaluated carefully. Static tests based on nominal concentration must be taken with care. This situation was properly considered in the RAR. On this basis, acceptable NOEC on two species (fish and invertebrates) are available, including the most sensitive group. Moreover, a 72 hour EC<sub>10</sub> on algae was assumed as a long term NOEC. A PNEC<sub>water</sub> = 51 µg/L, calculated by applying a factor of 10 to the long term NOEC on daphnia can be accepted.

For sediments, the partition method is adequate and properly applied for estimating the PNEC. A PNEC<sub>sediment</sub> of 277 mg/kg is proposed in the RAR and the CSTEE agrees with this value.

Calculation of PNECmicro-organisms, done by applying a factor of 10 to the lowest valid EC50 figure, is acceptable.

### **Terrestrial organisms**

The terrestrial assessment presented in the RAR is of very high quality. Data are adequately presented, several options are discussed and a final conclusion is clearly presented.

The CSTEE particularly recognises the effect assessment for terrestrial plants exposed through the atmosphere. In the absence of recommendations for this assessment in the TGD, the report presents a clear overview of the available data, presents three different possibilities for the PNEC derivation, and after demonstrating that all approaches produce similar values, selects the lower value for the definitive assessment. The approaches are clearly presented and scientifically valid, and therefore, the CSTEE support the proposed PNECs for the terrestrial assessment.

Unfortunately, this innovative approach has not been followed for the assessment of secondary poisoning. The standard evaluation, based on the Kow and the BCF in fish has been followed to conclude that the assessment of secondary poisoning is not required. However, the RAR had previously identified the potential accumulation in plants exposed through air. Concentrations in leaves are similar to those reported/estimated for fish, but due to the larger ingestion of plant material by herbivorous animals compared to fish by ictivorous vertebrates, the dose for herbivorous is expected to be significantly higher, and therefore, an assessment of secondary poisoning by this route should be included.

### **Risk characterisation**

For the aquatic compartment including sediments the RAR indicates that all PEC/PNEC ratios are below 1. Conclusion ii) is supported by the CSTEE.

For the terrestrial (soil) compartment the RAR concludes that tetrachloroethylene itself has a low risk, with all PEC/PNEC ratios below 1. The CSTEE supports this conclusion. A potential risk is identified for the degradation product trichloroacetic acid in some areas. The RAR suggests two options, risk reduction or need for further information. The CSTEE agrees with the rationale of the *rapporteur* for choosing the second option. Further information should be produced for reducing the uncertainty of this assessment.

A potential risk for the atmosphere has been identified for production and processing. The PEC/PNEC ratio for the metal industry is quite close to 1, and the risk for precipitation-volatilisation cycles has not been considered. Monitoring data indicate concentrations higher than the PNEC value in several areas of Europe, without clear identification of the sources. Therefore, a monitoring programme on metal cleaning sites should be considered before concluding that tetrachloroethylene does not represent a significant risk.

The RAR does not include the assessment of groundwater pollution. Most detected values are below the PNEC, as well as the estimated PEC, therefore the ecological risk is expected to be

low. However, the assessment for drinking water production and for the protection of the resource should be considered.

The RAR does not include the assessment of potential for secondary poisoning on the basis of the low Kow and BCF in fish. The assessment for the accumulation of tetrachloroethylene in terrestrial plants exposed through air and the subsequent exposure of herbivorous animals should be included.