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**Scientific Committee on Toxicity, Ecotoxicity and the Environment**

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

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

# 3,4-DICHLOROANILINE

**CAS No.: 95-76-1**

**EINECS No.: 202-448-4**

**REPORT VERSION (Environment)**

**Draft – 18 July 2001**

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

**Opinion expressed at the 29th CSTEE plenary meeting**

**Brussels, 09 January 2002**

[1] 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 CSTEE is invited to examine the following issues:

1. Does the CSTEE agree with the conclusions of the Risk Assessment Report?

2. If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion

### INTRODUCTION

3,4-dichloroaniline (3,4-DCA) is produced in the EU at two production sites. Production volume is 13500 to 15500 t/a (1996-1998). 3,4-DCA is exclusively used as intermediate in chemical industry, in particular for the production of phenylurea herbicides.

It is worth to note that one of the major sources of 3,4-DCA emission in the environment is the degradation of phenylurea compounds, used as herbicides and antifouling agents, and that therefore, it must be considered as a major metabolite in the risk assessment of these compounds (diuron, linuron, propanil, etc.) in the framework of Council Directives 91/414/EEC on plant protection products and 98/8/EC on biocides.

## GENERAL COMMENTS

The report is of good quality and the conclusions are based on a suitable amount on information both on exposure (at least for production and processing emissions) and on effects.

The CSTEE agrees with conclusion iii) for the aquatic environment (water and sediments) and for secondary pollution through the food chain.

The CSTEE also agrees with conclusion I) for an improvement of PNEC values for sediment dwelling organisms.

The CSTEE does not agree with conclusion ii) for the terrestrial compartment due to the release of 3,4-DCA as a metabolite of sulfonylurea compounds. There is a need for an improved exposure assessment due to this exposure route, both for the terrestrial and aquatic compartment. Anyway, the CSTEE recognises that this assessment should be made under Council Directives 91/414/EEC on plant protection products and 98/8/EC on biocides. Control measures, if needed, should be taken on the use of individual parent compounds.

The exposure to the impurities and breakdown products TCAB and TCAOB is assessed in the RAR. However, the effects of these substances are not reviewed, which is surprising as they are quite potent.

# SPECIFIC COMMENTS

## Exposure assessment

Emissions of 3,4-DCA are assessed in relation to releases during production and processing. Emissions due to degradation of phenylurea compounds used as plant protection products or biocides are not adequately quantified in the report.

3,4-DCA is not readily biodegradable, or hydrolisable. In anaerobic conditions, slow degradation occurs to more resistant monochloroanilines.

The major degradation route is photodegradation.

Therefore, 3,4-DCA is relatively persistent in water, sediments and soil, while it is rapidly degraded in the atmosphere.

Due to its physico-chemical properties and emission patterns, the main compartments exposed are water and soil.

PEClocal are properly calculated for production and processing emissions.

A more precise exposure assessment is needed for emissions due to the use of phenylureas as plant protection products or antifouling agents. This would be better done under Directives 91/414/EEC and 98/8/EC.

Monitoring data are available for German and Dutch rivers.

## Effects assessment

***Aquatic organisms***

Toxicological information on 3,4-DCA for the aquatic compartment is quite abundant.

Several short term and long term toxicity data are available on various species of fish, invertebrates and algae. Life cycle test results are available for fish, as well as data on endocrine effects.

On the basis of this information a PNECaqua= 0.2 μg/L is calculated by applying a factor of 10 to a NOEC of 2 μg/L.

From data on micro-organisms (bacteria and activated sludge) A PNECwwtp= 0.44 mg/L is calculated.

The CSTEE agrees with the proposed PNECs for water and wwtp.

Short and long term toxicity data are also available for various species of sediment dwelling invertebrates. Nevertheless, very low NOEC figures obtained from a long term *Chironomus* test are questionable, because no statistically significant dose related response was found. Therefore, a tentative PNECsediment = 0.05 mg/kg is calculated by applying a factor of 100 to a NOEC of 5 mg/kg obtained with a *Lumbriculus* 14 days test. This figure is in reasonably good agreement with the PNECsediment calculated using the equilibrium partitioning method (0.039 mg/kg), applied to the lowest NOEC for the water compartment (2 µg/L for life cycle test).

The CSTEE agrees with the proposed tentative PNEC and with the need for a repeated *Chironomus* test.

***Terrestrial organisms***

Short and long term toxicity data are available for soil micro-organisms, invertebrates and vascular plants. A PNECsoil = 10 mg/kg is properly calculated by applying a factor of 10 to the NOEC of 100 mg/kg.

No data are available for exposure through the atmospheric compartment. Nevertheless, taking into account the low environmental exposure due to low volatilisation and rapid photodegradation, the assumption of a low relevance of this information can be accepted.

***Secondary poisoning***

3,4-DCA has a log Kow of 2.7 and a moderate bioconcentration potential from water. Nevertheless, due to its resistance to biodegradation and metabolism, biomagnification starting from sediment/soil dwelling organisms to birds and mammals is likely to occur.

A PNECoral = 0.3 mg/kg is calculated by applying a factor of 1000 to a NOAEL of 300 mg/kg obtained in a 28 d repeated dose study on rats. No data are available on birds.

The CSTEE agrees with the proposed PNECoral for secondary poisoning.

## Risk characterisation

***Aquatic environment***

Very high PEC/PNEC ratios were calculated for production and processing, for the water and sediment compartments, either using the generic or the site specific scenarios.

Moreover, PEC/PNEC>1 were also obtained in some cases using monitoring data for European rivers.

Therefore the CSTEE agrees with conclusion iii) for the aquatic environment.

The CSTEE also agrees with conclusion i) for sediments, due to the need for refining the PNEC through a confirmation of some long term data on sediment dwelling species.

***Terrestrial environment***

The CSTEE agrees with conclusion ii) for the atmospheric compartment and with conclusion iii) for secondary poisoning through the food chain.

For the soil compartment, the CSTEE does not agree with conclusion ii). There is a need for a more refined exposure assessment due to the use of phenylurea compounds as plant protection products and biocides.

This assessment should be done under Directives 91/414/EEC on plant protection products and 98/8/EU on biocides. Measures for limiting the risk, if needed, should be taken on the use of individual parent compounds.