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

Opinion on the results of the Risk Assessment of:

**MONOCHLOROACETIC ACID (MCCA)
ENVIRONMENTAL PART**

CAS N° : 79-11-8

EINECS N° : 201-178-4

**Carried out in the framework of Council Regulation (EEC) 793/93 on
the evaluation and control of the risks of existing substances¹**

**Adopted by the CSTEE during the 39th plenary meeting
of 10 September 2003**

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.

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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.

GENERAL COMMENTS

The environmental part of the document is in general of good quality. The RAR has been mostly based on previous reports produced by the Swedish authority, the German authority and an industry organisation (ECETOC). The document clearly indicates that the data described in those reports have not been re-evaluated by the rapporteur. These reports have not been submitted to the CSTEE and therefore the committee cannot produce an opinion on the quality and the transparency of the data. The Swedish document was part of the OECD HPVC programme, which is assumed to be equivalent to the initial phase of the EU risk assessment process. The criteria for data validation of the German and the ECETOC reports are unknown. The data are essential for setting the environmental risk of MCAA. The CSTEE considers that the use of data taken directly from previous reports including those produced by industry organisations without a re-evaluation of the original reports by the rapporteur reduce the transparency of the risk assessment as the validation criteria selected by the authors are unknown.

The RAR presents information on the acid MCAA and the sodium salt, SMCA. Considering the low pKa (2.86) of MCAA it is assumed that under environmental conditions both the acid and the salt will appear as the anion form and therefore a single assessment can be done. This assumption is supported by the CSTEE.

The formation of MCAA in the environment due to emission of other chemicals not related with the life cycle of MCAA and even the possibility of a natural formation. Therefore a natural background remains as a critical gap in the risk assessment and further information is requested. The CSTEE agrees with this need. In addition, the CSTEE considers that additional information should be requested on the effect assessment of MCAA, considering higher tier tests for the effect

assessment of aquatic communities (studies have been already conducted) and continuous exposure via atmospheric wet deposition for the terrestrial compartment.

Conclusion (iii) for the local assessment of some production/processing sites is also supported by the CSTEE, where the PEC/PNEC ratios are very high, while in other cases, with PEC/PNEC ratios close to 1, the refinement of the PNEC should be conducted before reaching this conclusion. As the studies have already been conducted, no new studies are required, but the evaluation of existing data.

SPECIFIC COMMENTS

Exposure assessment

The RAR focuses on the uses of MCAA and the sodium salt as chemical intermediates. This part is well presented and the estimations of the local emissions produced during the production and use of these chemicals by industrial facilities are acceptable. The use of site-specific data for the assessment is also supported. The removal rates in the WWTP and the dilution factors are key elements in the risk assessment of MCAA and its sodium salt. The CSTEE agrees with the assumption of ready biodegradation. However, in the opinion of the Committee, the rapporteur should present an assessment on the quality and quantity of the available information for supporting the industry proposal of WWTP removal rates up to 99.99%, and in particular, if these rates are maintained through the whole year and under all conditions.

The main problem for the exposure assessment appears when considering the contribution of emissions from the life-cycle of MCAA (described in the RAR as emissions from intentional MCAA producers) and those corresponding to the production of MCAA in the environment or associated to other human activities. Several examples of production of MCCA in the technosphere (e.g. during drinking water chlorination) and in the atmosphere are described in the report, and even the possibility for a natural production of non-anthropogenic origin.

The contribution of emissions for intentional MCAA producers has been assumed as negligible by some authors but the RAR indicates that the estimated regional PECs are within the range of measured concentrations in the monitoring studies. The need for additional information in order to clarify this issue is supported by the CSTEE. Two key routes should be investigated, formation of MCAA in the atmosphere followed by wet deposition, and the possible contribution of domestic effluents, including the possible presence of MCAA residues in products for consumers, and other sources including chlorination of drinking water.

Effects assessment

Aquatic organisms

The sodium salt of MCAA is a herbicide and as expected algae is the most sensitive taxonomic group. The RAR summarises the information, including some essential data collected from previous reports (produced by national authorities and industry organisations) and establishes the conclusions on these data without a re-evaluation. In the opinion of the CSTEE this approach reduces the confidence and transparency of the report, and at least the critical studies should be re-evaluated by the rapporteur as the quality assessment can be different among different programmes.

The information provided in the RAR on the long-term fish study is very poor, only lethality data are provided and it is not clear if relevant sublethal endpoints were considered. However, algae

and plants are expected to be much more sensitive than fish and no additional fish studies are needed.

The PNEC is derived following the standard TGD approach, applying a factor of 10 to the lowest chronic laboratory data.

A higher-tier study is mentioned, but finally not used in the assessment. Results of additional higher tier studies on MCAA have been recently published in the open literature (Hanson et al. 2002; Hanson and Solomon, 2002). The experience with other herbicides demonstrates that higher tier studies offer a much better approximation to the ecologically relevant effects of herbicides than single species laboratory tests (Brock et al., 2000). Both, the higher tier studies reported in the RAR and those published recently suggest no relevant effects at concentrations much higher than the proposed PNEC. Therefore, these studies should be considered and a refined PNEC should be established.

The derivation of a PNEC for sediment dwelling organisms based on the equilibrium partitioning method creates large uncertainties. As water is expected to be the only significant exposure route, the assessment of the water column organisms is expected to cover sediment dwelling organisms.

No information on the toxicity of aquatic vascular plants is presented in the RAR, however toxicity on plant species is available from the publications mentioned above. The assessment of this group is considered essential for a chemical with known herbicidal activity, and therefore should be included in the refinement of the PNEC.

The derivation of the PNEC microorganisms is based on the use of assessment factor of 10 for the NOEC observed at the larger exposure period seems to be too conservative.

Terrestrial organisms

The effect assessment uses not only the generic TGD proposals but also the available information on the herbicidal activity. This approach is welcomed. However, in the opinion of the CSTEE there are too many gaps for a sound assessment and further information should be required.

Considering the rapid degradation of MCAA in soil, the authors offer an alternative estimation of the NOEC based on estimated time averaged concentrations, but there are several uncertainties in this proposal. The OECD test on seedling emergence should be further described. These tests are usually conducted on artificial soil, and if this is the case (this point should be clarified), the use of soil degradation DT50 values for artificial soil is not acceptable. All soil studies are conducted as static tests due to obvious reasons, and therefore it should be assumed that the TGD proposals are based on initial concentrations. Any correction, such as the use of time-weighted averages should be use consistently. As the industrial scenario corresponds to an application of WWTP sludge as fertiliser, which is a non-continuous process, the CSTEE considers that the comparison of initial PEC soil with the PNEC obtained from the NOEC based on initial concentrations in the toxicity study represents a better alternative than the use of time weighted averages obtained with very large uncertainties.

A special case for MCAA is the exposure due to atmospheric wet deposition. This exposure pattern, joint to the known action of MCAA as contact herbicide, requires a specific assessment. The RAR includes directly a risk assessment based on the recommended herbicidal application rate. In the opinion of the CSTEE, additional information should be requested, considering either the efficacy and selectivity studies conducted to determine the herbicidal activity of the chemical or

new tests using this exposure route. A PNEC for plants exposed via wet atmospheric deposition should be established.

The identification of this herbicide as toxic to bees also requires a specific assessment of the potential risk of foliar dwelling invertebrates exposed via atmospheric wet deposition.

Although the TGD does not offer guidance on this evaluation, there is enough scientific information for extrapolating laboratory data on bees to relevant effects under field situations (e.g. from the comparisons conducted for supporting the risk assessment of Plant Protection Products).

Risk characterisation

The risk characterisation for aquatic organisms should be revisited after the refinement of the PNEC aquatic organisms on the basis of the higher tier studies. In any case as the PEC/PNEC for site I-C is over 5000, a risk for this site is expected even after refinement and conclusion iii) for this site is supported by the CSTEE.

The low risk for terrestrial plants is not supported by the CSTEE. The conclusion is based on the assumption that a "safety margin" of 100,000 between the recommended application rate as herbicide and the exposure level is enough. This large safety factor gives an apparent impression of low risk which is not supported by data. Extrapolation from the dose demonstrated to be effective to control all target plants and long-term effects on vegetation (structure and function) associated to atmospheric wet deposition cannot be substantiated on scientific grounds. The original studies conducted for supporting this herbicidal dose (efficacy, selectivity, phytotoxicity on crop and non-target plants, etc.) should be studied for identifying relevant toxicity parameters (including the slope of the dose/response curves and interspecies variability). Alternatively, specific studies on terrestrial plants exposed via atmospheric deposition should be conducted.

The potential for bioaccumulation is low, as supported by the toxicokinetic information, and low risk of secondary poisoning is expected.

REFERENCES

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