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Directorate C - Public Health and Risk Assessment
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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

Risk Assessment Report on

Hexachlorocyclopentadiene (HCCP)

Environmental Part

CAS No.: 77-47-4

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Adopted by the SCHER
during the 11th plenary of 4 May 2006

TABLE OF CONTENTS

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 in general of acceptable quality; but there are several aspects requiring an in-depth evaluation. HCCP is not produced in Europe but imported for the production of other chemicals. The larger quantity is imported for the production of endosulfan; thus, the figures presented in the RAR should be reconsidered due to the decision 2005/864/EC: Commission Decision of 2 December 2005 concerning the non-inclusion of endosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (notified under document number C (2005) 4611).

The report proposes conclusion (ii)[1] for all compartments; the SCHER must express concerns on the methodology employed for assessing the risk of HCCP as impurity in pesticide formulations. Nevertheless, the decision for withdrawal endosulfan formulations from the market will solve this concern. In addition, the SCHER disagrees with the proposal of HCCP as a non-PBT chemical due to lack of bioaccumulation potential. The measured BCFs of HCCP are low when expressed as measured HCCP but they are relatively high when expressed as total radioactivity. The RAR indicates a 95% clearance times for ^{14}C of 211 days, and a BCF for total radioactivity

[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.

higher than 1000. Two potential explanations are suggested: either a rapid metabolism of HCCP in fish or a degradation of HCCP by photolysis in water. In both cases the metabolites would be much more bioaccumulable than HCCP. These phenomena have not been properly considered, the SCHER recommends a proper assessment of the metabolites before concluding a low bioaccumulation potential.

3.2 Specific Comments

3.2.1 Exposure assessment

According to the RAR, HCCP is not produced in Europe but imported for the synthesis of the pesticide endosulfan, HET-acid and as a minor use, for coating materials. The RAR considers that the main environmental emissions are related to the formulation and the presence of HCCP as impurity in the final products.

HCCP is a rapidly degraded by photolysis but it is not ready biodegradable, is volatile, and has a low solubility in water.

The report uses as much as possible site-specific information for the assessment and includes the names of the companies, WWTP flows, dilution factors, etc. The SCHER welcomes this approach for giving transparency to the RAR.

The emissions and PEC estimations related to the industrial uses of HCCP are acceptable. Nevertheless, it should be considered that the figures are supported by site-specific data where risk mitigation alternatives are already implemented.

The RAR includes a scenario covering the risks related to the presence of HCCP as impurity of endosulfan formulations to be used as pesticide in the Mediterranean region. Surprisingly, instead of the agreed European scenarios adopted under Directive 91/414 the RAR has employed a Dutch model “adjusted” to the Mediterranean situation. The model is not harmonized with the EU protocols and presents several deficiencies. The RAR recognised that the model was developed specifically for The Netherlands and reflects the typical Dutch situation regarding environmental characteristics and agricultural situations at the local scale. Nevertheless, the RAR authors apply this model to citrus and tomato in the Mediterranean area, assuming that the only needs for the adjustment are the modifications in the temperature, volume of water in soil, the fraction of organic carbon in soil, concentration of suspended matter in water and fraction of organic carbon in sediment. This assumption indicates a poor knowledge of agricultural conditions in the Mediterranean region. The assessment is not acceptable and the SCHER recommends the use of the harmonized scenarios under directive 91/414, or simply, a comparative assessment of HPPC and endosulfan in the formulation for assessing if HCCP may under some circumstances represent a higher risk than that related to the pesticide.

The bioaccumulation potential of HCCP is described on the basis of several studies. The available information suggests a BCF of 11 for HCCP due to rapid metabolisms, but a relatively high BCF, with values up to 1297, measured as total radioactivity. Additional data demonstrate that biotransformation in invertebrates is 2.7 to 13 times lower than in fish. For algae, the reported BCF was 1090 in a 24h experiment using static exposure conditions. The combination of the bioaccumulation potential of HCCP in the lower levels of the trophic chain and the rapid dissipation of the chemical from water in some circumstances suggest a potential relevance of secondary poisoning for invertebrates and fish which should be considered. The RAR suggests that the accumulation of radioactive metabolites could be related to the biotransformation of HCCP and/or the photolytic degradation of HCCP in water producing bioaccumulable degradation products. It should be considered that if the observed bioaccumulation is related to photolytical products present at very low concentrations in water the BCFs of these degradation products could be above the trigger for bioaccumulation in the PBT assessment. A further assessment of available information is required for getting a clear picture of the bioaccumulation potential of HCCP metabolites.

The PECs have been calculated with EUSES and the calculations are included as an addendum.

3.2.2 Effect assessment

The effect assessment includes toxicity data on several freshwater and marine organisms. Due to the physical-chemical properties of HCCP data other than measured values obtained in flow-through experiments should be considered with care. There are two chronic reproductive NOECs on aquatic invertebrates. One on the freshwater species *Daphnia magna* and one on the marine species *Mysidopsis bahia*. The *Daphnia magna* study has limitations as it is based on nominal concentrations. The acute toxicity data covers several marine fish and invertebrate species, and suggests a particular sensitivity of the mysid species, but no of marine organisms in general. The mysid value is properly used for the derivation of the PNEC freshwater. However, the RAR considers as valid a 30d fish NOEC based on survival. This value is just one half of the acute 96h LC50 obtained in the same study. Data on other organisms do not confirm this very low acute to chronic ratio. The $PNEC_{aquatic\ organisms}$ is calculated by applying a factor of 10 to a valid chronic NOEC for the mysid. The SCHER consider that the PNEC should be recalculated, using an assessment factor of 50, as no proper fish chronic NOECs are available. Therefore, the Committee suggests a PNEC of 0.006 ug/l for freshwater and marine compartments.

No data on sediment organisms are available and a PNEC for sediments is calculated by the equilibrium partition method. The approach is considered acceptable in this case, but the PNEC should be recalculated using the proposed $PNEC_{aquatic\ organisms}$.

A $PNEC_{microorganisms}$ is calculated from a suitable test, the toxicity value and the PNEC should be considered with care as they are orders of magnitude above the solubility limit.

For the soil compartment, a limited data set, covering plants and micro-organism is available. The RAR properly estimates the PNEC using the assessment factor and the equilibrium partitioning methods and select the second one as it produces the lowest value; the value, must be recalculated using the proposed $PNEC_{aquatic\ organisms}$.

The PNEC for secondary poisoning is estimated from a LOAEL which represents the lowest tested concentration. The ecological relevance of the selected endpoint is not presented.

3.2.3 Risk characterisation

The PEC/PNEC ratios are orders of magnitude below 1 in all cases except for the scenario based on the presence of HCCP as impurity in endosulfan formulations. Although the SCHER recommends a recalculation of the PNEC values, the PEC/PNEC values obtained from the proposed PNECs should still be well below 1 for all compartments, and therefore the SCHER agrees with conclusion (ii) for industrial processing.

As the PECs presented for the application of endosulfan are not acceptable, the Committee cannot agree with conclusion (ii) for this scenario, and suggests a revision based on the European harmonised scenarios for the application of plant protection products.

The PBT assessment concludes that HCCP is persistent and toxic but not bioaccumulable. The committee considers that the assessment of the bioaccumulation potential requires an in-depth analysis covering the potential for the production of bioaccumulable chlorinated metabolites.

4. List of Abbreviations

BCF	Bioconcentration factor
EUSES	European Union System for the Evaluation of Substances
HET-acid	Chlorendic acid
LOAEL	Lowest Observed Adverse Effect Levels
NOEC	No Observed Effect Concentration
PBT	Persistence-Bioaccumulation-Toxicity
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
WWTP	Wastewater Treatment Plant

5. Acknowledgements

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