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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

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

Opinion on the results of the Risk Assessment of:

PIPERAZINE

Environmental part

CAS N°: 110-85-0

EINECS N°: 203-808-3

**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 43rd plenary meeting
of 28 May 2004**

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.

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.*

General comments

The environmental part of the draft RAR is of good quality and the CSTEE agrees with most of the outcomes of the report. Nevertheless some conclusions could be probably revised.

In particular, for the aquatic environment, the results of the risk characterisation indicate $PEC/PNEC > 1$ and the possibility of a risk for the aquatic environment in many production, formulation and use sites. Regional $PEC/PNEC$ is lower than 1. Therefore the RAR indicates **Conclusion iii** for some local sites only. Nevertheless, it should be noted (as underlined in the RAR) that in most cases exposure was calculated using worst-case TGD default assumptions, therefore local PECs could be overestimated.

If a refined exposure assessment could be possible (by getting more precise information on site specific emissions and dilutions, as well as by getting monitoring data), **Conclusion i** would be more suitable. If it would be impossible or too difficult to obtain this kind of information, **Conclusion iii** would be acceptable.

For the terrestrial compartment the CSTEE does not agree with the proposed **Conclusion ii**; toxicity tests on terrestrial organisms should be requested (**Conclusion i**).

The CSTEE agrees with **Conclusion ii** for atmosphere and secondary poisoning.

Some information, particularly on exposure, is reported in Annexes that were not provided.

Specific comments

Exposure

In general, exposure assessment is properly performed.

PEC regional and continental for the aquatic compartment are correctly calculated according to the TGD. For the local PECs, as mentioned before, in many cases site-specific data were not available and TGD default assumptions were used. Reliable monitoring data were not available.

For the terrestrial compartment, a particular case is exposure due to the use of animal manure from stocks treated with veterinary products containing piperazine. Exposure was calculated according to data provided by Spaepen et al (1997). It must be remembered that a detailed scenario suitable for assessing this type of exposure has been developed by working groups established within the EFSA (formerly working groups established within the SCAN). The scenario allows calculating PEC in soil, groundwater and surface water deriving from chemicals used as feed additives for animals. Some weak points were found in the Spaepen paper. In particular the worst case for nitrogen application (600 kg N/ha y in Italy) was assumed as unreliable (it derives from unconfirmed personal communications) and a most reliable worst case of 350 kg N/ha y was used.

In the present case, the EFSA scenario would not produce different conclusions, but it is opinion of the CSTEE that the procedure proposed by EFSA should be used in general for this kind of exposure.

The regional assessment should consider the application of animal manure in agricultural soils

Effects assessment

Piperazine is practically no toxic on algae and fish and moderately toxic on Daphnia.

The procedure for calculating a PNEC for water based on a long term test on the most sensitive organism is acceptable.

No effect data are available for the atmospheric environment, as well as for soil dwelling organisms. In this last case, the partitioning approach has been used.

Piperazine is a biologically active chemical used as anti-parasitic drug. Therefore specific mechanisms of action on target organisms must be considered. The use of the equilibrium partitioning approach for this kind of chemicals is not appropriate. The CSTEE considers that toxicity tests on soil dwelling organisms, covering specific taxonomic groups related to the biological activity of piperazine, should be requested.

Risk characterisation

For the aquatic compartment, a $PEC/PNEC > 1$ has been found for many local production and use sites. A $PEC/PNEC < 1$ was calculated at regional level.

It is opinion of the CSTEE that a more precise exposure assessment would be useful, by getting some more information on site-specific local conditions. Moreover, monitoring data in local emission sites would be also needed.

Even if no data on effects in the atmospheric compartment are available, environmental exposure through air is low, due to the very short half life of piperazine. Therefore a risk for the atmosphere is unlikely to occur. The CSTEE considers acceptable **Conclusion ii**.

For the terrestrial compartment, $PEC/PNEC$ values, calculated with the partitioning approach, are lower than 1. In this case too, exposure to piperazine is relatively low. Nevertheless, for reasons previously mentioned, the CSTEE suggests **Conclusion i**.

The CSTEE agrees with **Conclusion ii** for secondary poisoning due to the negligible accumulation potential of piperazine.