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

Opinion on the results of the Risk Assessment of:

BENZENE

Environment

CAS N° : 71-43-2

EINECS N° : 200-753-7

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

Adopted by the CSTEE during the 36th plenary meeting of 6 February 2003

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[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

It is opinion of the CSTEE that more conservative PNEC for water and for the soil compartment must be assumed.

Moreover, no data are available for assessing a PNEC for terrestrial organisms through atmospheric exposure and this is unacceptable for a high volatile chemical such as benzene, for which atmosphere is the most exposed compartment.

The CSTEE agrees with conclusion iii) applied to waste water treatment plants and to the aquatic environment. Even assuming the less conservative PNEC proposed in the RAR (considered as non-acceptable by the CSTEE) a PEC/PNEC > 1 was calculated for some local sites. Therefore there is the need for limiting the risk in surface water.

The CSTEE considers that the relevance and reliability of the data provided by Black et al. must be carefully evaluated. The decision for excluding these data for the PNEC derivation must be substantiated on scientific evidence and presented in the report in a transparent way. If not enough scientific evidence becomes available, the data should be included for the PNEC derivation or, alternatively, conclusion i), requesting information which could clarify the real sensitivity of aquatic vertebrates, should be considered.

The CSTEE agrees with conclusion ii) applied to secondary poisoning through the food chain.

The CSTEE does not agree with conclusion ii) applied to the atmosphere and to the terrestrial compartment. Information on the effects on living organisms through atmospheric exposure must be provided. Moreover more information is needed for a better assessment of PNEC for the soil compartment.

Finally, the RAR statements on risk due to ozone formation are controversial. Conclusion iii) is proposed, but in the same time specific in-depth evaluation is recommended. The CSTEE agrees on the need for more precise quantitative information on this item.

SPECIFIC COMMENTS

1. EXPOSURE ASSESSMENT

World benzene demand is estimated as higher than 32 million tonnes per year. To assess European production, data for some companies were not available and have been estimated. Therefore, the reliability of production data should be taken with some care.

Benzene is a highly volatile chemical (about 100 hPa) and major emissions are in air. Therefore, the atmosphere must be assumed as the compartment of major concern. Degradation in air mainly occurs by reaction with hydroxyl radicals. At the most frequent OH concentrations, half-life may range from 4 to 20 days.

Due to the high vapour pressure volatilisation losses from water occur; nevertheless benzene is also water soluble (1.8 g/L), therefore concentrations of concern in water are likely.

As for aerobic biodegradation, benzene is considered as readily biodegradable while, in anaerobic conditions, degradation is negligible.

In the RAR, regional and continental concentrations in the different environmental compartments are calculated using the SimpleBox model. The results are the following:

Compartments	PEC regional	PEC continental
Air	1.54 µg/m^3	0.73 µg/m^3
Water	0.275 µg/L	0.03 µg/L
Sediment	1.35 µg/kg	0.158 µg/kg
Natural soil	0.02 µg/kg	0.009 µg/kg
Agricultural soil	0.017 µg/kg	0.008 µg/kg
Groundwater	7 ng/L	3 ng/L

For air, surface and groundwater and sediments, predicted data are in reasonable agreement with available monitoring data. Experimental data for soil are not reported in the RAR.

Local PECs are calculated for several production and processing sites according to the TGD.

For surface water, PEClocal ranges between a minimum of 0.3 and a maximum of 4700 µg/L.

For sediments, PEClocal has been calculated using the partitioning equilibrium method, according to the TGD, applied to three representative water concentrations (lowest monitored value, monitored value from polluted water, maximum calculated PEClocal water). Calculated values range from 0.37 to 17,500 µg/kg.

Calculated concentrations in effluents from local sites are between 1 and 101,700 µg/L. Thesd values are in good agreement with monitoring data of benzene in effluents of industrial waste water treatment plants which are between 0.2 and 78,000 µg/L.

Air PEClocal, calculated according to the TGD, ranges from 1.48 to 4084 µg/m^3.

Benzene in air can be responsible of the increase of tropospheric ozone.

PECsoil calculated according to the TGD ranges from 1.2 to 142 54 µg/kg.

Soil concentrations are calculated assuming only wet and dry deposition as emissions onto soil. No direct application on benzene in local contaminated sites has been taken into account. This may lead to an underestimation of local PECsoil. No reliable experimental data are available to confirm calculated values.

Even if highly volatile, benzene in soil can be washed-out in the pore water and, due to its low Koc, can be leached in groundwater. Close to petrol storage facilities, values as high as 1.3 mg/L have been measured. In the Danish monitoring programme maximum values of more than 5 µg/L have been measured. Therefore the value of 0.05 µg/L, indicated in the RAR as typical European groundwater value, can be frequently overcome and must be taken with some care.

2. EFFECTS ASSESSMENT

Aquatic organisms

Several data are available on aquatic organisms, nevertheless, due to the high volatility of the substance, most of them are performed with unsuitable methodology (static rests, nominal concentrations, etc.). Therefore a careful check of the reliability is needed.

From the available database, an LC50 of 5.3 mg/L on rainbow trout is a reliable figure.

The lowest long term NOEC is 3.5 µg/L, result of a 27 day embrio-larval test on rainbow trout.

A NOEC of 0.8 mg/L was found on early life stages of *Pimephales promelas*.

Short-term data on crustaceans are relatively homogeneous, ranging between 10 and 48 mg/L. The lowest figure is a 48h EC50 of 10 mg/L.

Other invertebrates shows a short term acute toxicity ranging from 12 and 320 mg/L:

A 7 day NOEC of 3 mg/L was found on *Ceriodaphnia dubia*

On algae, a 72h EC50 of 29 mg/L and an EC10 of 8.3 mg/L are reliable figures.

Additional data are available on amphibian larvae, showing a NOEC of 3.5 µg/L.

For the derivation of a PNEC for water, in the RAR a factor of 10 is applied to the 0.8 mg/L NOEC on *Pimephales promelas*, giving a PNECwater = 0.08 mg/L.

The lowest figures obtained on rainbow trout and on amphibian larvae were not used for the calculation of the PNEC. All these low figures are reported in a paper of Black et al. (1982) where very low figures are also reported for other comparable chemicals (e.g. toluene). No plausible explanation was found for the large discrepancies between these data and other available information. On the other hand, no plausible reasons were found for the inconsistency of the data of Black et al. (1982).

Even if these NOEC values seem very low in comparison with other toxicity data, it is the opinion of the CSTEE that the reasons for excluding them are insufficiently justified. Therefore, in absence of more sound reasons for excluding them, a factor of 10 should be applied to the NOEC of 3.5 µg/L, giving a PNEC water = 0.35 µg/L.

Microorganisms

A PNECmicroorganisms = 1.3 mg/L is properly calculated by applying as factor of 10 to the lowest value available on nitrifying bacteria.

Terrestrial organisms

Very few data are available on benzene effects through air exposure. Some experiments were performed on vascular plants, indicating no significant effects at high concentrations in air. The experiments are very old and methodologically controversial. They are not considered suitable for the assessment of a PNEC.

No other data are reported by the RAR on toxicology by inhalation in animals. It is reasonable to suppose that at least inhalation data for mammals is provided in the human health section. Anyway, no information is provided for the assessment of effects on the environment through atmospheric exposure. This is not acceptable for a highly volatile substance such as benzene.

Two 14 day growth tests on higher plants and one 28 day mortality test on earthworms seem to indicate no effect at the higher concentration tested (1,000 mg/kg). Nevertheless, these tests are performed on nominal concentrations, without analytical control, and must be considered as not entirely reliable.

Some experiments were performed on heartworm by contact on filter paper, showing a 48 h EC50 between 0.1 and 1 mg/cm^2.

These data are considered unsuitable for assessing a PNEC in soil and are not used for the risk assessment.

In absence of suitable data on soil organisms, a PNECsoil of 0.2 mg/kg has been calculated using the equilibrium partitioning procedure.

Even if the procedure is, in principle, acceptable, it was based on the PNECwater of 0.08 mg/L, which has been assumed as unacceptable.

If a PNECwater of 0.35 µg/L is assumed, it derives a PNECsoil of 0.001 mg/kg

Secondary poisoning

Due to the low lypophylicity of the substance, a risk for secondary poisoning can be assumed as negligible.

3. RISK CHARACTERISATION

Waste water treatment plants

The ratio Clocal eff/PNECmicroorganisms is >1 in 23 out of 48 local sites, indicating a risk for microorganisms in waste water treatment plants.

Surface water

Assuming the PNECwater of 80 µg/L proposed by the RAR, a PEC/PNEC>1 is calculated in 2 out of 48 sites. If the more conservative value of 0.35 µg/L is assumed, a PEC/PNEC>1 is calculated for 35 out of 48 sites.

Therefore, even if, in order to better define a PNEC, more reliable long-term data are strongly recommended, these data clearly indicate a risk for the aquatic environment.

Atmosphere

Due to the lack of data on effects of benzene trough atmospheric exposure, risk characterisation is not possible. It is the opinion of the CSTEE that for a highly volatile chemical such as benzene this is unacceptable. Toxicity data on terrestrial organisms through air exposure must be provided.

It is underlined in the RAR the possibility of a risk due to ozone formation. Nevertheless, a quantitative assessment cannot be performed.

Terrestrial compartment

Using the more conservative PNEC of 0.001 mg/kg, and the maximum calculated PEC of 0.142 mg/kg it results a PEC/PNEC of 142. Therefore a risk for the soil compartment is possible.

More information is needed on toxicity for soil organisms to refine PNEC and on monitoring data on soil to confirm the PEC.

Non compartment specific effects relevant to the food chain

Due to the low bioaccumulation potential, the CSTEE agrees with the assumption that a risk characterisation is not required.