

# EUROPEAN COMMISSION DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION Directorate C - Scientific Opinions

Unit C2 – Management of Scientific Committees; scientific co-operation and networks

Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels, C2/JCD/csteeop/NaphthalaeneHH22022002/D(02)

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

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

**NAPHTHALENE** 

CAS N°: 91-20-3 EINECS N°: 202-049-5

REPORT VERSION (Environment): Final report, October 2001

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

Opinion expressed at the 30th CSTEE plenary meeting

**Brussels, 22 February 2002** 

<sup>&</sup>lt;sup>1</sup> 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.

#### **GENERAL COMMENTS**

The major problem related to an environmental risk assessment of naphthalene, is due to the complexity of emission patterns. Major responsible for naphthalene environmental exposure are indirect emissions, mainly deriving from combustions, anthropogenic as well as natural.

If one strictly considers only emission patterns due to production and direct uses of naphthalene, the RAR is reasonably good and based on a large amount of information, at least for the aquatic environment.

On these bases, the CSTEE can agree on most of the conclusions of the report. Reasons of disagreement are the need for more information on toxicity on terrestrial organisms and the unacceptable justification for not performing risk characterisation for the atmosphere and secondary poisoning. Major details are given in specific comments.

Nevertheless, the relevance of additional emission sources is clearly demonstrated by the large amount of information on experimental monitoring data, mentioned in the risk characterisation but not used for conclusions, indicating that PNEC values are frequently and largely exceeded in all environmental compartments, and indicating that naphthalene must be considered a chemical of high environmental concern.

Therefore the CSTEE strongly recommends that a risk assessment on naphthalene be performed taking into account emissions other than production and direct uses, in order to assess the need and the technical likelihood of more stringent control measures to protect environment and human health.

#### **SPECIFIC COMMENTS**

### General information on exposure

Among the products containing naphthalene, the assessor has not taken "lower grade naphthalene oil" into consideration. The reason for that should be stated.

#### **Exposure assessment**

The estimated emission factors to air during production in the EU (0.001 - 0.026 kg/tonne) are very different from the factor estimate in the USA (0.239 kg/tonne). The latter is based on the particulate

organic matter emissions, while the European estimate is based on site-specific information. It is not clear if there is a difference in the basis for the estimates.

From abiotic degradation experiments, a half-life of about 23 days was calculated for photolysis of naphthalene in surface water. In the atmosphere, a half-life of 16 hours has been assessed. Abiotic degradation patterns are not significant for the soil compartment.

Standard tests indicate that naphthalene is nor readily neither inherently biodegradable. Nevertheless, numerous experimental data indicate half-life values consistent with the default values suggested by EUSES for inherent biodegradation (t/2 = 150 d for surface water and 300 d for soil and sediments). Therefore, these values can be taken as acceptable for risk assessment. In anaerobic conditions naphthalene is resistant to degradation.

Due to its physical-chemical properties, naphthalene is expected to adsorb to soil and sediments and to volatilise.

Bioaccumulation potential is relatively high. Nevertheless, naphthalene can be metabolised by vertebrates and invertebrates and therefore this will reduce biomagnification in the food web.

Local, regional and continental PEC for surface water, sediments soil and air have been calculated according to the TGD.

Monitoring data are available for a relevant number of European surface water systems. As usual, the meaning of monitoring data is difficult to evaluate without a precise knowledge of the sampled sites; nevertheless, it is worthy of note that levels measured in European rivers are often higher than local PECs calculated for surface water, with the exception of the extremely high value (294  $\mu$ g/L) referred to grinding wheels manufacture. Many values referred to non polluted areas are more or less consistent (at least as order of magnitude) with PECregional, but are at least one or two orders of magnitude higher than PECcontinental.

Very high concentrations of naphthalene have been measured in groundwater close to contaminated sites. These values are often higher than the calculated PEC for soil pore water. It must be remembered that PECporewater is considered an extremely conservative worst case indicator of groundwater contamination. A level for "uncontaminated" groundwater is indicated as less than  $0.03 \, \mu g/L$  (equal to PECregional for surface water).

For sediment too, measured data are frequently substantially higher than calculated PEClocal and practically always higher than the PECregional. Measured values for sediments in the open sea in the Western Mediterranean, are reported in the range 0.5 to 11  $\mu$ g/kg, where calculated PECregional and PEC continental are 1 and 0.1  $\mu$ g/kg respectively.

The same holds true for soil and air. The average of monitoring data from "uncontaminated" soils is substantially higher in comparison to most calculated PEClocal.

The bulk of information on monitoring data in all environmental compartments, clearly indicate that naphthalene contamination depends, in large amount, from emission sources other than those considered in the report.

In spite of the relatively high log Kow and high experimental BCFs, exposure through secondary poisoning has not been assessed. In the RAR, this is justified not on the basis of properties of the

substance but because naphthalene does not carry specific risk phrases. This justification cannot be accepted by the CSTEE.

#### Effects assessment

#### **Aquatic organisms**

Acute toxicity data on naphthalene are available for several fish species (freshwater and marine). If low reliable data (too old, static test, nominal concentrations) are excluded, 96h LC50 values range from 1.8 to 7.8 mg/L. Comparable results were obtained with other vertebrates (amphibians).

From chronic toxicity tests, a precise NOEL is not clearly determined. A NOEC of 0.12 mg/L was observed in a 40 days test on juvenile pink salmon, but 50% mortality at 0.11 mg/L was calculated for trout fry exposed during hatching.

Several data are also available for invertebrates, showing 48h EC50 values ranging from 2.1 to 24 mg/L. Also in this case, higher figures must be taken with care due to nominal concentrations.

Chronic data on freshwater invertebrates are methodologically unclear or questionable.

On algae too, data available are obtained with hardly comparable methodological approaches. 50% photosynthesis reduction was observed at 2.8 mg/L in 4 hours experiments.

QSAR predictions using equations for narcosis give results consistent with experimental short-term data on fish daphnia and algae.

A PNECwater=2.4  $\mu$ g/L is calculated by applying an application factor of 50 to the 0.12 mg/L NOEC on pink salmon. Reasons for excluding lower figures obtained on trout fry exposed during hatching are not acceptable. Extrapolating a NOEC from these data would lead to a PNEC lower than 2  $\mu$ g/L. Even if the difference is small, it will change some borderline statements in the risk characterisation.

On the basis of available data on microorganisms, the calculated PNEC for WWTPs is acceptable.

For sediments, the equilibrium-partitioning method is used for calculating PNEC. The equation applied is slightly different from those proposed by the TGD, using suspended matter/water instead of sediment/water partition coefficient.

There is no mention on the value used for Kp in the calculation and on how it is justified. Moreover, the equilibrium-partitioning method is not appropriate for naphthalene (see below), nevertheless, risk for the aquatic environment is unlikely to occur, with the exception of a few emission patterns, thus the approach can be accepted for sediments as a first approximation.

#### **Terrestrial organisms**

A PNEC for soil of  $53.3 \mu g/kg$  was calculated with equilibrium-partitioning method due to the limited information on toxicity for terrestrial organisms. The CSTEE considers that the equilibrium-partitioning method is not appropriate for naphthalene, considering the physical-chemical characteristics which suggest exposure is not only related to pore water but to air in soil networks and the toxicological profile of this molecule which has been used as a biocide, therefore

specific mechanisms for some taxinomic groups could be expected. Tests on soil organisms should be conducted.

The report states that it was not possible to calculate a PNEC for the atmosphere, although NOEC for inhalation toxicity are available. Reasons to justify this statement are not reported. Atmosphere is an important compartment for a volatile chemical such as naphthalene. Therefore the lack of risk characterisation for the atmosphere is not acceptable.

#### **Risk characterisation**

If risk characterisation is strictly related to the emission patterns considered in the report, the CSTEE opinion can be resumed as follows.

- For the water and sediment compartments, the CSTEE agrees with conclusion iii) applied to the use of naphthalene as a pore former in the production of grinding wheels. This conclusion must be extended to the use as intermediate in pyrotechnic manufacture, because a slightly lower PNEC should be applied. The CSTEE agrees with conclusion ii) for other emission patterns.
- For micro-organisms in STP, the CSTEE agrees with conclusion iii) applied to the use of naphthalene as a pore former in the production of grinding wheels. The CSTEE agrees with conclusion ii) for other emission patterns.
- For the soil compartment, the CSTEE agrees with conclusion iii) applied to the use of naphthalene as a pore former in the production of grinding wheels. The CSTEE does not agree with conclusion ii) for other emission patterns. There is the need for more information on toxicity on terrestrial organisms.
- Justifications for not performing risk characterisation on the atmospheric compartment and on secondary poisoning cannot be accepted by the CSTEE.

Nevertheless, it is clear from monitoring data that naphthalene is a chemical of concern. Measured concentrations in all environmental compartments are frequently substantially higher than calculated PNECs.

Naphthalene emissions from production and use patterns considered in the report, may often add to relatively high background levels, deriving from other emission sources, giving rise to levels harmful for man and the environment.

Therefore the CSTEE strongly recommends that a wider risk assessment on naphthalene is performed, including additional direct or indirect emission sources, in order to evaluate if measures to reduce total emissions are really needed and technologically possible.