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EPA Proposed Test Rule, Standards for 1,1-Dichloroethylene under TSCA

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Brussels, 6 October 1986.

BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

COMMENTS OF THE

EUROPEAN CHEMICAL INDUSTRY ECOLOGY AND TOXICOLOGY CENTRE

(E C E T O C)

ON

EPA PROPOSED TEST RULE, STANDARDS

FOR 1,1-DICHLOROETHYLENE UNDER TSCA

(51 FR 28840, August 12, 1986)

D.A. Stringer
Director

Dear Sirs,

1,1-DICHLOROETHYLENE - EPA PROPOSED TEST RULE
(51 FR 28840, Aug. 12, 1986)

We would like to take this opportunity to submit to you, by way of written comment on this proposed Test Rule, the enclosed ECETOC Review "Joint Assessment of Commodity Chemicals, No.5 - Vinylidene Chloride", published in August 1985. We would also like to draw your attention to the existence of a UK Health and Safety Executive Toxicity Review on Vinylidene Chloride (No.13, published in 1985). We believe these publications contain facts and arguments germane to the issues addressed in the above Test Rule, and in particular we would like to make the following points :

i. We submit that the existing data base on 1,1-dichloroethylene is adequate to assess the risks of exposure to this substance, both in occupational and non-occupational contexts.

ii. While prokaryotic test systems show evidence of genotoxic potential, this potential does not appear to be generally expressed in higher test systems or in animals.

iii. The data on mutagenicity suggest that non-genotoxic mechanisms may play an important role in the expression of carcinogenic activity.

iv. The only carcinogenic effect seen has been in one of 18 studies, in which tumours were seen in the male mouse kidney at a dose level which also produced significant nephrotoxicity. The male mouse kidney is also the most sensitive target for the acute and chronic toxic effects of 1,1-dichloroethylene. It seems likely that toxicity and carcinogenicity are related, with a specific combination of circumstances being prequisites to result in the expression of genotoxic potential in this particular species, strain, sex and organ. Carcinogenic effects have not been seen in the many other studies and the male mouse kidney findings are thus probably not relevant to humans.

It is difficult to see what relevant information the proposed test programme will contribute to the data base on which decisions about levels of risk have to be made. The Distribution, Excretion and Metabolism work may or may not show differences between Swiss and B6C3F1 mice adequate to explain why a response was not seen in the B6C3F1 mouse kidney in the NTP study, but it will not alter the findings of the Maltoni study nor the substantial data base currently available indicating that the male mouse kidney is a particularly sensitive target. A further inhalation carcinogenicity study in the Swiss mouse will probably merely serve to confirm the findings of the Maltoni study and may explain the findings in animals but will not improve risk assessment for man. Despite possible deficiencies in the Maltoni study, the overall evaluation is accepted as demonstrating a carcinogenic potential. In such a case a repetition of a two year study is redundant.

In summary, we submit that adequate information is currently available to assess carcinogenicity risks from 1,1-dichloroethylene, that humans are unlikely to be at risk at currently prevailing exposure levels and that the proposed testing is unlikely to contribute information having a substantial bearing on the above issues.

D. A. Stringer

6th October, 1986