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Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels, C2/AST/csteeop/**Bisph A ENV27062002/D(02)**

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

Opinion on the results of the Risk Assessment of:

**BISPHENOL A
ENVIRONMENTAL PART**

**CAS NO: 80- 05- 7
EINECS NO: 201-245- 8**

**Carried out in the framework of Council Regulation (EEC) 793/93 on
the evaluation and control of the risks of existing substances¹**

Opinion expressed at the 32nd CSTEE plenary meeting

Brussels, 27 June 2002

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.

**CSTEE COMMENTS ON:
RISK ASSESSMENT REPORT ON:**

**BISPHENOL-A
Environmental Part**

CAS No.: 80-05-7

EINECS No.: 201-245-8

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:

Introduction

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 environmental part of the document is in general of very good quality. The complexity of the exposure assessment is very large, considering the number of uses, and the rapporteur summarises the available data. The decisions for using real emission/exposure data when available and for including generic scenarios when required are well documented and supported by the CSTEE.

The environmental effect assessment of bisphenol-A is also problematic due to the identification of a potential for endocrine disruption for this chemical. The RAR includes a separate subchapter for addressing the endocrine disruption potential and this decision increases the transparency of the report. In this discussion, a significant fact has not been considered, in the fish multigenerational studies, the NOECs are decreasing for the successive generations by factor of 5 to 10. Similar results, although briefly presented in the RAR, have also been observed for sediment dwelling organisms. This issue, (F1 more sensitive than F0; F2 more sensitive than F1) has not been addressed, while the CSTEE considers that it is critical, particularly when comparing the laboratory NOEC values with the measured concentrations.

Therefore, conclusions (i) and (iii), need for further information and for risk reduction measures, are fully supported by the CSTEE, while the decision of conclusion (ii) for some uses based on “negligible emissions” should not be accepted until clarification of the effect assessment has been achieved. In the opinion of the CSTEE the consideration of negligible should not be based exclusively on the expected level of emission, but related to the concentrations that could cause effects. The argument of “negligible” should be used when the expected exposure level is so low, in relation to the PNEC or the effect level, that a quantitative assessment is not required. For chemicals where the effect level may be in the range of the limit of detection achieved by standard methodologies, at least a qualitative comparison between exposure and effects should be required before deciding a negligible exposure.

Although, bioconcentration in fish is relatively low, this is expected to be related to rapid metabolism/elimination in vertebrates, therefore, additional studies on algae and invertebrates should be considered.

The request for additional information to clarify ecologically relevant effects should consider the overall profile of this molecule. A mesocosm study, covering water and sediment compartments and several species representing different taxonomic groups and reproductive strategies should be considered. The effect refinement should consider a tiered approach covering essential needs, such as the high sensitivity of some taxonomic groups (including molluscs, which are particularly relevant in the marine environment), and the need for addressing multi-generation evaluations. The advantages and disadvantages of the available possibilities, from single species to mesocosms studies, must be considered. In any case, and in concordance with the CSTE activities in the field of EDC, the committee will be glad to comment on the testing strategy if consulted.

The presence of bisphenol-A in sludge from municipal plants and animal slurry indicates that contamination of agricultural soils is a real issue, the use of the equilibrium partitioning method is not acceptable for bisphenol-A, and acute tests are not suitable for EDCs, therefore, chronic tests on soil dwelling organisms are also required.

SPECIFIC COMMENTS

Exposure assessment

The RAR presents a good and comprehensive overview of the available information on potential emissions of bisphenol-A. The available information covers in some cases 100% or close to 100% of the production/use tonnage and therefore, site-specific scenarios are presented in the RAR. In other cases, the rapporteur includes an expert judgement on the representativeness of the available information, and presents generic scenarios when conclusions suggest that the available information does not cover the total European production/use conditions, the rationale for the decisions is transparent and well documented.

The emissions of bisphenol-A are mainly to water and mostly coming from thermal paper recycling and the use as an inhibitor in PVC production. Industry claim that the latter use should be phased out by the end of 2001, which should leave the recycling of thermal paper as the dominant release source. It would thus be useful to estimate the present and future use volumes of these papers.

Some contradictory data on the biodegradation potential of bisphenol-A are presented and the overall conclusion of ready biodegradation is finally adopted. This conclusion is perfectly acceptable for the Waste-Water Treatment Plants, but not necessarily for the environmental compartments. Concentrations in surface water, and particularly in sediments, in some areas where no specific emissions are reported, are relatively high, and can only be related to a widely dispersed distribution of the local emission points, covering large areas of the EU, or a lower biodegradation than expected. In any case, these points should be further investigated.

The potential for bioaccumulation in fish is low, however, this low bioaccumulation potential can be mostly related to the rapid metabolism/elimination in fish due to glucuronidation as observed in one fish study and confirmed from mammalian toxicokinetic studies. Therefore, considering the very high toxicity of the chemical and the sensitivity of taxonomic groups with high filtration rate and metabolism expected to be slower than fish, further information on the bioconcentration factor, covering algae and invertebrates, should be required.

The estimated PEC values are supported. However, the CSTEE is concerned about the levels observed in both surface water and sediments. Levels in surface water in areas where no specific releases have been identified are in the same range than the regional PEC, and measured levels in sediments in different areas are much higher than the regional value.

Effect assessment

Aquatic organisms

The RAR considers independently the standard toxicity endpoints and those related to endocrine disruption. Different PNEC values are obtained and the so-called “conservative-PNEC” derived from specific assays addressing long-term reproduction endpoints and effects related to estrogenic activity is finally used.

The CSTEE is particularly concerned by the observed reduction in the NOEC value from one generation to the next one in the multi-generation studies. For fish, the NOEC for egg production is 640 µg/l for F0 and 160 for F1. For eggs hatchability the NOEC is 160 µg /l for F1 and 16 µg /l for F2. Additional suggestions on this increase in the sensitivity are briefly presented for chironomids. The RAR does not address this issue, that could or could not be related to experimental design conditions, but that in any case is critical for the PNEC derivation.

Terrestrial organisms

No information on toxicity to terrestrial (soil) organisms is available. The use of the equilibrium partitioning method, using fish data for assessing the effects on soil dwelling organisms, is not acceptable considering the toxicological profile of Bisphenol A and in particular the large differences in the sensitivity of different taxonomic groups.

Secondary poisoning

Avian data are presented but the RAR concludes that the data are not suitable for the risk assessment due to their experimental design. The CSTEE supports this conclusion. The proposed PNEC_{coral} is in agreement with the TGD recommendations. A revision of the value should be considered if additional information on the interpretation of developmental data becomes available.

Risk characterisation

Aquatic compartment: The need for additional information is supported by the CSTEE, this conclusion should be extended to those uses for which “negligible exposure” has been used to propose conclusion (ii).

Atmosphere: There is a lack of information other than mammalian inhalation studies but the physical-chemical properties suggest that this compartment is of low relevance. Therefore conclusion (ii) can be accepted.

Soil: The CSTEE considers that no proper PNEC value can be established, therefore, conclusion (i) should be considered for all exposure scenarios.

Secondary poisoning: The CSTEE agrees with the low risk for bioaccumulation in vertebrates. However, the potential accumulation in algae and invertebrates should be considered.

COMMENTS ARISING FROM THE REPORT EVALUATION WHICH ARE RELEVANT FOR OTHER CHEMICALS.

The CSTEE considers that two issues, arising from the evaluation of this report, should be evaluated further as they are of generic nature and, therefore, should be assessed under a broad perspective.

- The apparent increase in the sensitivity of successive generations. From the available information it is not clear if this is a real issue or it is just related to methodological test design. However, if confirmed, should be of critical relevance in the risk assessment process and, therefore, this issue should be urgently addressed.
- The higher sensitivity of some taxonomic groups, particularly within the invertebrate group, for which data are not available in most cases. The sensitivity of some mollusc species has also been identified for other endocrine disrupting chemicals, and the need of proper tests for covering invertebrate toxicity was already pointed out in a previous CSTEE opinion on endocrine disruption.