

EU RISK ASSESSMENT OF NONYLPHENOL: INDUSTRY CONCERNS

CEPAD, the industry body that represents producers of alkylphenols and its derivatives, in principle fully supports the EU Risk Assessment process for nonylphenol and the Technical Guidance Document (TGD) on which it is based. While CEPAD accepts many of the conclusions of the draft risk assessment report (RAR), our industry has certain specific concerns, which are detailed below.

Effects Assessment*Ecotoxicity*

- For the effects assessment the standard procedure is based on the application of a safety factor to the lowest available (valid) no observed effect concentration (NOEC). However, in cases where a reasonable number of valid studies are available, a complementary approach that the TGD provides is a statistical method to estimate a NOEC intended to protect ninety-five percent of the species exposed.
- Within the scientific community it is widely acknowledged that the simple application of safety factors to the lowest NOEC is an arbitrary approach to be used when only a limited number of studies is available. There is no scientific basis for the safety factors that are used.
- For nonylphenol, eight valid chronic aquatic toxicity studies¹ are available. Therefore use of the statistical approach would be justified. Yet neither the statistical approach nor the result of a simulated aquatic environment study² was used. In fact, Member State experts agreed to omit an appendix to the draft risk assessment that made use of the statistical approach to derive the "Predicted No Effect Concentration" (PNEC), concluding (*sic*): "the results presented in this appendix are contradictory to the results presented in the already agreed report" (draft minutes, TM IV/1998). If these alternative approaches had been applied, the estimated PNEC would have been at least four times higher than the value that has been used.

¹ Risk Assessment of 4-nonylphenol (Branched) and nonylphenol; report currently being prepared by UK under EU Existing Substances Regulation (793/93/EEC)

² *ibid*

Mammalian Toxicity

- A comprehensive, good quality, multi-generation feeding study on rats (the generally accepted "gold standard" test for reproductive toxicity) conducted according to accepted guidelines by the US National Toxicology Program (NTP) indicated no adverse reproductive effects³. However, the EU RAR chooses to give undue weight to results from non-standard poor quality studies with admitted design weaknesses, and concludes that the observations of oestrogenic activity "raise concerns for reproductive toxicity". Industry and independent experts disagree with this apparently inconsistent conclusion.

Environmental Exposure Assessment

- Monitoring data for rivers measuring background exposures are available for certain areas of Europe⁴ (Germany and Switzerland) and are cited in the draft RAR. These data clearly indicate that nonylphenol concentrations have declined significantly over the last five to ten years. Although these data are mentioned in the draft of the RAR, they are not used in the final draft to estimate the background concentration of nonylphenol, which is based on calculated data, exaggerating the actual figure by a factor of about three.
- The TGD prescribes that monitoring data should be used when available. We consider that unrealistic assumptions are made that do not reflect "realistic, worst case scenarios". For substances with a relatively large number (e.g. hundreds) of small local releases to the environment⁵ it is not feasible to provide realistic data based on exposure monitoring because *a*) guidelines are lacking on what representative monitoring data would be acceptable in the case of such large numbers of releases and *b*) obtaining such data from downstream users is not possible because the Existing Substances Regulation does not require them to collect and provide such information.
- Though the UK rapporteur took several comments from industry into consideration, the environmental exposure assessment is still based on release assumptions rather than real exposures resulting in "predicted environmental concentrations" (PECs) that greatly overestimate the actual concentrations. For example, calculated local releases for metal and textile industry sites result in local PECs of

³ NTP (1997) Nonylphenol: multigenerational reproductive effects in Sprague-Dawley rats when exposed to nonylphenol in the diet. R.O.W. Sciences study no. 8989-30

⁴ Risk Assessment of 4-NONYLPHENOL (Branched) and NONYLPHENOL; report currently being prepared by UK under EU Existing Substances Regulation (793/93/EEC)

⁵ eg NP exposures due to the use of NP ethoxylates

141 µg/L and 350 µg/L, respectively. Both concentrations are higher than the acute toxic concentration for aquatic species (about 140 µg/L) nonylphenol and would imply the eradication of most aquatic life in the neighbourhood of such releases, which is obviously not happening. The EU risk assessment does not adequately take into account that nonylphenol ethoxylates can be effectively treated in waste water treatment plants to reduce nonylphenol to levels which will not harm the environment.

Environmental Risk Characterisation

Due to the application of a safety factor to the lowest NOEC for the PNEC estimation on the one hand, and the use of a conservative approach for deriving local and regional PECs on the other hand, the resulting PEC/PNEC ratios obviously overestimate the actual risk.

Implications for the Risk Reduction Strategy Proposals

With the more reasonable approach to effects assessment described above, and the use of actual monitoring data to estimate aquatic exposures, we believe the risk characterisation would have shown that industrial uses are not in general a risk to the environment.

Therefore, for such uses it would not be justified to propose risk reduction measures via use restrictions, because they would unfairly penalise the vast majority of users who pose no risk to the environment. Our position is that proper treatment of effluents to control emissions to the aquatic environment are the most appropriate means to manage such risks where they may be present.