

due entirely to its tendency to form ozone. Section 112(b)(2) of the CAA provides that no air pollutant which is listed under CAA section 108(a), such as ozone, may be added to the HAP list. It further provides that a pollutant that is a precursor to a pollutant listed under section 108(a), such as EGBE, may not be included on the HAP list unless it "independently meets" the HAP list criteria. As explained in this preamble, we feel that the petitioner has demonstrated that EGBE does not independently meet the criteria for listing as a HAP under section 112 of the CAA.

The CAA established requirements for reducing the emission of air pollutants, and deals separately with HAP (which are to be listed and regulated under CAA section 112) and criteria air pollutants (which are to be listed under CAA section 108 and regulate under various other sections of the CAA). Precursors of criteria air pollutants, such as VOC, are regulated for their contribution to ambient levels of criteria pollutants under statutory provisions that do not apply to HAP. This structure would lose its significance if EPA were to include substances on the HAP list solely as a result of their contribution to concentrations of criteria air pollutants.

G. Public Comments

We requested public comment as a part of the **Federal Register** notice announcing the receipt of a complete petition to delist EGBE (64 FR 42125–27). The comments contained no technical information or data which was relevant to our review of this petition. Copies of the comments have been included in the docket for the proposed rule.

H. Conclusions

Uncertainty is an inherent part of risk assessment. It arises because risk assessment is a complex process, requiring the integration of multiple factors, and because it involves predictions of risk that are not directly observable. In the analysis, uncertainty arises for the following reasons. The IRIS database, used as the source of the human health effects decision criteria, is imperfect and leads to uncertainty in the RfC. We also recognize that there is uncertainty in the computer models used to predict the fate and transport of EGBE in the environment. These models are simplifications of reality and some variables are excluded.

For decisions which are based largely on risk assessments, some degree of uncertainty is acceptable. Such is the case for this proposed delisting decision. We do not interpret CAA

section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list. The use of the terms "adequate" and "reasonably" indicate that the Agency must weigh the potential uncertainties and their likely significance. To this end, the assessment applies conservative assumptions to bias potential error toward overstating human and ecological health effects. Thus, EPA is confident that even when we consider the uncertainties in the petition's initial assessment and in the additional analyses, the results are more likely to over-estimate rather than under-estimate true exposures and risks.

Based on our evaluation of the petition and the subsequent analyses, we judge that the potential for adverse human health and environmental effects to occur from projected exposures is sufficiently low to provide reasonable assurance that such adverse effects will not occur. For example, the petitioner appropriately applied EPA's model guidelines and EPA's tiered dispersion modeling approach which we designed to be conservative. Also, the petitioner used sound analytic principles in modifying the standard assessments described in the Tiered Approach, the inverted tier 1 and the CARTSCREEN analyses. In addition, the petition did not apply a formal exposure assessment to the predicted ambient air concentrations. Instead, the petition used the maximum annual ambient average air concentrations alone as a surrogate for exposure. Based upon the likely proximity of inhabitable areas and knowledge of human activity patterns, we feel that actual exposures will be far less than predicted exposures that were derived from the dispersion analysis. Further, when modeling clusters of EGBE sources, the petition showed that concentrations resulting from both closely located major and area sources are not likely to adversely affect health. Finally, the petition's analysis using available data from monitors suggest that ambient concentrations of EGBE in urban areas are over two orders of magnitude lower than the modeled maximum concentrations.

With regard to toxicity, the information available to the Agency at this time indicates that nonlinear modes of action are likely responsible for the increased incidence of tumors observed by the NTP (2000) in mice following chronic EGBE exposure. Application of nonlinear quantitative assessment methods indicate that the noncancer RfD of 0.5 mg/kg/day and the RfC of 13 mg/m³, which EPA developed for EGBE, are adequately protective of these

carcinogenic effects. This determination assumes a nonlinear mechanism that requires exposure levels to be high enough to cause certain lesions that are precancerous. Information is currently inadequate to dismiss the potential contribution of a linear mechanism associated with the possible mutagenic metabolite BAL. Additional research (e.g., verification of existing physiologically based pharmacokinetic modeling results and improved genotoxicity assays) would assist the Agency in making a more certain decision concerning the potential for BAL to contribute to the adverse effects seen in animals following EGBE exposure and use of the proposed nonlinear assessment approach. If additional information on BAL becomes available between the proposal and the final action on the delisting decision, EPA will evaluate and peer review such information. We may or may not determine that any new information would be relevant to our analysis of EGBE emissions.

As described above, EPA's proposed decision to remove EGBE from the list of HAP is based on the results of a risk assessment demonstrating that emissions of EGBE may not reasonably be anticipated to result in adverse human health or environmental effects. In addition to the analyses presented and the uncertainties inherent in risk assessment, we have considered other information related to EGBE in making this decision, namely the transformation of EGBE into other HAP as it decomposes in the ambient air. We conclude that ambient concentrations of the transformed HAP are very small, and that they decompose rapidly. Therefore, we do not anticipate that EGBE transformation will be significant enough to have an adverse impact on human health.

We also considered the fact that EGBE is reported to the Toxics Release Inventory (TRI) as part of the group of glycol ethers. The 2000 TRI shows the air emissions of the class of chemicals "Certain Glycol Ethers" to be ranked number 12 by volume. Under the proposed rule, it would no longer be regulated as a HAP, but it will continue to be reported in the TRI, as part of the group "Certain Glycol Ethers" and regulated under EPA's criteria pollutant (ozone) program.

In conclusion, EPA has made an initial determination, after careful consideration of the petition and after completing additional analyses, that there are adequate data on the health and environmental effects of EGBE to determine that emissions, ambient concentrations, bioaccumulation of