

IRIS dataset used to derive the human health effects decision criterion is imperfect and leads to uncertainty in the RfC. This uncertainty is primarily due to the lack of long-term MEK toxicity data and is compensated for in the application of an uncertainty factor of 100 for the prospective RfC. In addition, animal cancer bioassays with MEK by either the oral or inhalation route are lacking from the database, and there is scientific uncertainty in MEK's ability to potentiate the action of other neurotoxins. We also recognize that there is uncertainty in the computer models used to predict the fate and transport of MEK 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 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 protecting human and ecological health. 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, EPA suggested that the petitioner conduct an additional, more site-specific analysis to verify the conservatism of the original analysis. The results of that analysis increased our confidence that the petition over- rather than under- estimates exposure. In addition, the petition did not apply a formal exposure assessment to the predicted ambient air concentrations. Instead, the petition used the air concentrations alone as a surrogate for exposure. Based upon the likely proximity of inhabitable areas and knowledge of human activity patterns, we believe that actual exposures will be

far less than predicted exposures that were derived from the dispersion analysis. Further, when modeling clusters of MEK sources, the petition showed that concentrations resulting from that scenario are not likely to adversely affect health. Finally, available data from monitors suggest that ambient concentrations of MEK in urban areas are over two orders of magnitude lower than the modeled maximum concentrations.

As described above, EPA's proposed decision to delist MEK is based on the results of a risk assessment demonstrating that emissions of MEK 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 MEK in making this decision, namely the transformation of MEK into acetaldehyde and formaldehyde and recently discovered levels of MEK in human blood. The MEK decomposes in the ambient air into two probable human carcinogens (acetaldehyde and formaldehyde). However, given that the actual contribution of MEK to ambient concentrations of these two pollutants is very small, and that they decompose rapidly, we do not anticipate that MEK transformation into these two pollutants will be significant enough to have an adverse impact on human health. We do not expect that ambient concentrations of MEK contribute significantly to the blood level burden due to the small ambient concentrations of MEK in ambient air.

We also considered the fact that MEK is one of the top compounds by volume reported in the TRI. Under this proposal, it would no longer be regulated as a HAP, but it will continue to be reported in the TRI and regulated under EPA's criteria pollutant (ozone) program.

As discussed previously, we will consider the RfC that results from the IRIS review and information combined in industry's submission under tier 1 of the VCCEP before taking final action on the proposal. We also welcome additional data or information that can further clarify these and other issues related to MEK. We will evaluate all substantive information received during the comment period prior to taking any final action on the proposed rule.

## V. References

References cited in the preamble can be viewed in the docket for this proposed rule.

## VI. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector to the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that the proposed action does not constitute a "significant regulatory action" and is, therefore, not subject to OMB review.

### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The proposed action will remove MEK from the CAA section 112 (b)(1) HAP list and, therefore, eliminate the need for information collection under the CAA. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise