

# **External Peer Review of the Draft Integrated Risk Information System (IRIS) Assessment for 2-Methylnaphthalene**

## **CHARGE TO REVIEWERS**

### **BACKGROUND and PURPOSE**

The U.S. Environmental Protection Agency (EPA) Region 7, Superfund Program requested information to support regulatory decision-making associated with 2-methylnaphthalene. In response to EPA Region 7's request, EPA's National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) produced a draft *Toxicological Review* and a draft *Integrated Risk Information System (IRIS) Summary for 2-Methylnaphthalene*. Currently, no health assessment for 2-methylnaphthalene is available in the IRIS data base. The draft assessment has been internally peer reviewed by EPA scientists. The next step in the review process is conducting this external review to evaluate the accuracy of the content and interpretation of the findings presented in these documents.

### **INSTRUCTIONS TO PEER REVIEWERS**

We request your thoughtful consideration of the issues and charge questions provided.

#### **I. Overall Document Quality**

Please prepare a statement that addresses the overall quality of the document and provides advice on approaches to improve the assessment from both a technical and communication standpoint; and suggests approaches on the integration of data into an overall characterization of hazard. Questions to consider include:

1. How well were the data from individual studies characterized and are the conclusions that are drawn from each study valid?
2. How well are the data integrated into an overall conclusion and characterization of hazard as presented in Sections 4.5, 4.6, 5, and 6?
3. Do you have any other comments you feel will improve the overall quality of the document?

## **II General Questions and Issues**

4. Are any other data/studies available that are relevant (i.e., useful for the hazard identification or dose-response assessment) to the assessment of the adverse health effects, both cancer and noncancer, of this chemical?

## **III RfD Derivation**

5. *Principal Study, Section 5.1.1:* The RfD is based on an 81-week study in mice fed 2-methylnaphthalene (Murata et al, 1997). The critical effect observed was pulmonary alveolar proteinosis (PAP). This study was conducted concurrently with an 81-week study in mice fed 1-methylnaphthalene (Murata et al, 1993) with a shared control group between the 1- and 2-methylnaphthalene exposure groups. All animals were housed in the same room. The incidence of PAP in controls was increased (for the particular strain of mouse utilized in both studies) and the authors suggested it may have been due to volatilized 1- and 2-methylnaphthalene. Is use of the Murata et al (1997) study justified and is the rationale for this study adequately explained in the Toxicological Review (Section 5.1.1) in light of incidence of the critical effect in the control group?
6. *Critical Effect, Section 5.1.1:* The critical effect is identified as PAP. Is this the correct critical effect and is it adequately described? Is this critical effect biologically significant? Finally, does the information presented from animal studies mirror what is know about the disease in humans and is this information adequately described?
7. *Methods of Analysis, Section 5.1.2:* Is the point of departure determined appropriately (i.e., benchmark dose approach)? Is the 10% response level appropriate and is the use of this response level supported adequately?
8. *Uncertainty Factors, Section 5.1.3:* Are the appropriate uncertainty factors applied? Is the explanation for each transparent? Specifically, is the recommendation for not applying an effect level extrapolation factor justified adequately?

## **IV Cancer Weight-of-Evidence Classification**

9. The weight of evidence and cancer characterization are discussed in Section 4.6. Have appropriate criteria been applied from the 1999 EPA draft revised *Guidelines for Carcinogen Risk Assessment* (Review Draft, NCEA-F-0644, July 1999. Risk Assessment Forum.)?