Charge to Reviewers for Peer Review of the Draft Toxicological Review and IRIS Summary for Phosgene

BACKGROUND/INTRODUCTION

The National Center for Environmental Assessment (NCEA) has produced a draft Toxicological Review and IRIS Summary for Phosgene which have been internally peer reviewed by EPA scientists. The next step in the review process is to conduct this external review to evaluate the accuracy of the content and interpretation of the findings presented in these documents.

Peer reviewers are requested to prepare written comments addressing the general and specific questions/issues below. Format and submission guidelines are provided at the end of the charge.

I. Overall Document Quality

Reviewers are asked to make comments on the overall quality of the document and provides advice on approaches to improve the assessment from both a technical and communication standpoint, as well as comments on the integration of data into an overall characterization of hazard.

In particular, EPA seeks comments on:

- How well the data from individual studies are characterized
- On the conclusions that are drawn from each study
- How well the data are integrated into an overall conclusion and characterization of hazard as presented in Sections 4.5, 4.6, 5 and 6.

Next please address the following specific questions and issues:

II RfC Derivation

1. ***Principal Study. Section 5.2.1***. The subchronic inhalation rat study has been selected as suitable for development of a chronic RfC (Kodavanti et al. 1997).

   A) Is the rationale for selection of the principal study appropriate? Are there any other studies that would serve as a better basis for deriving an RfC?

2. ***Methods of Analysis, Section 5.2.2.***

   A) Is the point of departure (POD#)determined appropriately, including analysis of critical effects using three assessment methods (NOAEL/LOAEL, BMD, categorical regression)? Is the justification of the selection of which approach to use sufficient and scientifically justified.

3. ***NOAEL/LOAEL/Approach, Section 5.2.3, Item 2.*** In adjusting to continuous exposure from the intermittent exposure received by the animals (6 hrs/day, 5 days/week), the traditional C x T assumption has been made in the document. This assumption might appear to contradict the finding in the critical study that the effect depends on concentration, rather than C x T for exposures of 0.2 ppm for 5 days/week and 1.0 ppm for 1 day/week. The rationale for using the default C x T relationship is that no data exist to invalidate the C x T dose metric for a fractional day of durations.

   A) Is this rationale appropriate?
   B) Would it be more appropriate to retain the 6/24 hour adjustment and delete the 5/7 day adjustment, make some other adjustment, or leave the concentration unadjusted?

4. ***Uncertainty Factors, Section 5.2.6.***

   A) Are the appropriate uncertainty factors applied? Is the explanation for each transparent?

III Cancer Weight-of-Evidence Classification

The weight of evidence and cancer characterization is discussed in Section 4.7.

1) Have appropriate criteria been applied from the Draft Final Guidelines for Carcinogen Risk Assessment (External Review Draft) February 2003 NCEA-F-0644?

IV Other Comments

1. Can your provide any other recommended revisions that would provide a more scientifically sound assessment of the health effects of long-term exposure?

DUE DATE: WEDNESDAY, May 9, 2003

When sending review comments via e-mail to ERG, please attach them as WordPerfect 6, 7, or 8 or Word 97 and save with the appropriate file name extension (.wpd for Word Perfect documents or .doc for Word documents). If you send your comments electronically, please also express mail or fax a hard copy so we can ensure the electronic data was not corrupted.

If you send a fax for the deadline, please also express mail a hard copy and a copy on diskette to ERG.

Format Guidelines:

Your comments will be submitted to EPA as received. Please prepare your comments addressing the issues and questions as stated above. To assist you in preparing your comments, ERG has sent you an electronic version of the charge so you may cut and paste each question into your text to be followed by your comments. Additional format recommendations are as follows:

TYPE SIZE: 11 point
PAPER SIZE: 8 ½" x 11"
SPACING: 1.5 line spacing
MARGINS: 1 " left-hand margin
1" right-hand, top, and bottom margins

- Please use a header with your name in the upper right-hand corner of each page of your comments.
- Organize your comments following the order of the charge issues/questions for each section of the document. Please include each charge question, followed by your comments.
- Remember to spell out acronyms when first used.
- Avoid incomplete sentences, abbreviations, and terms that might confuse the reader.
- If illustrations or tables are included, be sure that they are suitable for reproduction.

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Thank you for your efforts. Please feel free to contact Erin at 781-674-7260, or Kate Schalk at 781-674-7324 with any questions or concerns.