

Charge to External Reviewers for the Revised Sections of the Boron Toxicological Review and IRIS Summaries.

The U. S. EPA is conducting a peer review of the scientific basis supporting the health hazard and dose response assessment for Boron that will appear on the Agency's online data base, the Integrated Risk Information System (IRIS). Peer Review is meant to ensure that science is used credibly and appropriately in derivation of these dose-response assessments. The primary function of the peer reviewer should be to judge whether the choice, use and interpretation of the data employed in the derivation of the assessment is appropriate and scientifically sound.

The IRIS Toxicological Review for Boron and IRIS Summary Sheets have previously gone through an internal and external review. However certain sections of the Toxicological Review have been revised since these peer reviews took place. Revisions were made to include new pharmacokinetic data received from U. S. Borax after the internal and external reviews took place. The revised sections of the Toxicological Review and RfD Summary sheet were changed to include new data and have now gone through an Internal EPA Review. Internal reviewer comments have been addressed and these sections now need External Peer Review. This review would include an analysis of Section 3.4, 3.4.1, 3.4.2, 3.5 and Section 5.1.3. of the Toxicological Review and the RfD Summary Sheet which include use of new toxicokinetic data to derive a data derived uncertainty factor. This review is needed before the Toxicological Review and IRIS Summary sheets for Boron are forwarded to the EPA's Consensus Review Process for final approval and adoption by the EPA. These hazard and dose-response assessments will then appear on IRIS and become available as agency consensus health effect information.

Enclosed are the revised oral reference (RfD) summary sheet and Toxicological Review for Boron. The following sections have had additions made to include new data from Pharmacokinetic studies recently submitted by U. S. Borax.

Toxicological Review:

- 3.4 ELIMINATION AND EXCRETION
 - 3.4.1 Urine
 - 3.4.2 Plasma
- 3.5 TOXICOKINETIC SUMMARY
 - 5.1.3 RfD Derivation

RfD Summary Sheet

- I.A.3.UNCERTAINTY AND MODIFYING FACTORS (ORAL RfD)

Questions

1. Are the new data from pharmacokinetic experiments from U. S. Borax

adequately presented in sections 3.4 and 3.5 in the Toxicological Review? If not how would you recommend that the data be presented?

2. Do you think that the new pharmacokinetic data on clearance of boron in rats and humans from U. S Borax should be used for derivation of an uncertainty factor for boron instead of a default Uncertainty Factor ?
3. Do you agree with the current Uncertainty Factor using the data-derived method as it is presented in the Toxicological Review and RfD Summary sheet?