

**EPA DRAFT ASSESSMENT OF FORMALDEHYDE:  
COMMENTS FROM THE NATIONAL INSTITUTE OF OCCUPATIONAL  
SAFETY AND HEALTH**

NIOSH appreciates the opportunity to review and provide comments for the draft IRIS Formaldehyde Toxicological Review for Interagency Science Consultation. Given that NIOSH has not performed a study or assessments recently that are not discussed in the EPA risk assessment, our comments are confined to commenting on whether EPA has asked the appropriate questions in the charge to the NAS reviewers. NIOSH defers to the NAS assess some of the scientific issues raised by the draft assessment.

In the draft risk assessment charge to reviewers, the treatment of the biologically-based modeling of the toxicological data for formaldehyde appears to be an area of significant interest, and one for which EPA is seeking reviewers' attention. In particular, it is appropriate to see a reference to the issue in the last sentence of the charge questions "... please consider the analysis of the sensitivity of low-dose estimates of potential biologically-based dose-response models of formaldehyde upper respiratory tract cancer to small changes in model design or model inputs." This was the basis that EPA used to reject the conclusions of a published biologically-based model, so it implies that the reviewers should take a look at the ensuing controversy and weigh in on it.

The other significant area requiring consideration is in the interpretation of the epidemiological data for formaldehyde, particularly the treatment of lymphohematopoietic tumors, which have not been associated with formaldehyde exposures in the toxicological studies. This drives the largest part of the cancer risk in the epidemiological analysis, so it's important to determine whether or not the analysis is adequate. EPA gets at this in a very general and indirect way: "The draft uses as its preferred quantitative estimates dose-response relationships between several cancers and cumulative inhalation exposure to formaldehyde. Please review and comment on the scientific support for the choices made in developing those estimates." While this is adequate, EPA might consider a slightly more focused question, specifically addressing the lymphohematopoietic tumors.