

Department of Defense Comments on the Formaldehyde Charge Questions to the Expert Panel

Comments submitted by: Office of the Secretary of Defense Chemical and Material Risk Management Directorate

Organization: Department of Defense

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*Comment categories: Science or methods (S); Editorial, grammar/spelling, clarifications needed (E); or Other (O). Also please indicate if Major i.e. affects the outcome, conclusions or implementation of the assessment.

Comment No.	Section	Page & Paragraph or Global	Comment	Suggested Action	Category*
1			The document proposes a hypothetical mode of action (MOA) to explain how inhaled formaldehyde might induce leukemia, lymphoma, and a variety of other lympho-hematopoietic malignancies in occupationally exposed workers. Some scientists think that formaldehyde is unlikely to have effects at sites other than the upper respiratory tract (NCI, etc.), yet some laboratory studies suggest that formaldehyde may affect the lymphatic and hematopoietic systems. Thus, we believe that it is worth asking the peer review panel to critically evaluate the existing scientific support for the proposed new paradigm within the context of EPA's guidelines for evaluating the MOA of chemically-induced cancers. This would result in a better understanding of differing etiologies and risk factors for the various malignancies related to formaldehyde exposure.	<p>We recommend that the U.S. EPA consider including an additional charge question concerning whether it also would be useful to have a quantitative analysis using the current paradigm that aplastic anemia is the cause of leukemia.</p> <p>Although we recognize that EPA may conduct their cancer risk assessments differently than the methods recommended in their guidance documents for many reasons, these judgments to use differing approaches should be tested through peer review.</p>	S
2			In develop of the inhalation unit risk value, unit risk estimates for different tumor types were added together and an age adjustment is recommended for the entire sum. While similar approaches have been presented in recent toxicological reviews, it has not been laid out or described in EPA guidance or policy.	We recommend that a charge question be added to address development of the inhalation unit risk to get the panel's opinion on whether this approach is valid.	S/M

