

EPA's draft health assessment for formaldehyde needs improvement: report

April 11 2011

A U.S. Environmental Protection Agency draft assessment of the potential health effects associated with formaldehyde exposure needs substantial revision, says a new report from the National Research Council, which recommends improvements for EPA's final assessment. The report finds that EPA supports its conclusions that formaldehyde can cause irritation to the eyes, nose, and throat; lesions in the respiratory tract; and genetic mutations at high concentrations. Furthermore, the report finds that the evidence is sufficient for EPA to conclude that formaldehyde exposures are a cause of cancers of the nose, nasal cavity, and upper throat. However, the draft assessment has not adequately supported its conclusions that formaldehyde causes other cancers of the respiratory tract, leukemia, or several other noncancer health outcomes. Also, the assessment should consider additional studies to derive noncancer reference concentrations (RfCs), which are estimates of lifetime concentrations to which someone could be exposed without appreciable risk of particular adverse health effects.

Formaldehyde is an important industrial chemical used to produce a wide array of materials, but it is also generated naturally by the human body. When inhaled, it is absorbed primarily at the site of first contact, where it is metabolized and reacts with cellular components; thus, inhaled formaldehyde remains predominantly in the tissue that lines the airways. Given the pervasive exposure of the general population to some concentration of formaldehyde, federal agencies tasked with protecting public health are concerned about the health effects. In June 2010, EPA released its draft health assessment of formaldehyde, and a Research

Council committee that wrote the report reviewed the assessment and key literature to determine whether EPA's conclusions were supported. The committee did not perform its own assessment or conduct additional literature searches.

Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies. Moreover, many of the general problems with the EPA formaldehyde health assessment have been identified by other Research Council committees that reviewed other EPA chemical assessments in recent years. For instance, there have been recurring problems with clarity and transparency of the methods, even though the documents have grown considerably in length. The committee concluded that if the methodologic issues are not addressed, future assessments may suffer from the same general problems highlighted in this report.

Various cancerous and noncancerous health effects attributed to formaldehyde were evaluated in EPA's draft assessment, including:

- Leukemia and lymphoma. The committee did not support EPA's grouping of all types of leukemias and lymphomas because it combined diverse cancers that are not closely related. Although EPA presented an exhaustive description of studies and speculated extensively on how formaldehyde reacts in the body, the determinations of causality are not supported in the assessment. EPA should revisit its arguments and include detailed descriptions of the criteria that were used to weigh evidence and assess causality.
- [Respiratory tract](#) cancers. The committee found that EPA's

assessment had sufficient evidence to conclude that formaldehyde causes cancer in the nose, nasal cavity, and nasopharynx (upper throat). However, the evidence regarding the chemical's relationship to cancer in other sites in the respiratory tract was considered insufficient.

- **Asthma.** EPA should strengthen its discussion of asthma to reflect current understanding of the disease, as the term "asthma" is commonly applied to a broad category of respiratory diseases, the committee said. EPA's assessment provides little discussion about how asthma could be caused or exacerbated by formaldehyde exposure.
- **Nervous system function.** EPA's conclusion that formaldehyde harms the nervous system was overstated, the committee said. The human data used as evidence are insufficient and the candidate animal studies deviate substantially from testing guidelines and common practice.
- **Reproduction and development.** The report finds that the evidence is insufficient to support EPA's conclusion that there is a "convincing" relationship between formaldehyde exposure and adverse reproductive outcomes, such as infertility in women. Rather, the human data suggest a pattern of association -- meaning the evidence indicates there could be an increased risk for an adverse reproductive outcome but uncertainty limits any conclusion. Although the animal data also suggest an effect, EPA should weigh the positive and negative results more rigorously, evaluate study quality more critically, and consider carefully potential confounding factors.

In addition, the report suggests improvements to the development and presentation of EPA's calculated RfC values and strongly encourages a

more informative approach similar to that previously proposed by other Research Council committees and used in other recent EPA assessments. The committee recommended that EPA use an appropriate graphical display to help identify a central value, isolate especially high or low values that might not be consistent with the literature, and improve the ability of the assessment to make a compelling case that the RfC proposed is appropriate.

The report also offers general recommendations to help revise the formaldehyde draft assessment, including rigorously editing to reduce the volume of text, adding clear and concise statements on the methods used, standardizing evidence tables, and thoroughly evaluating all critical studies for strengths and weaknesses. The committee also provided a "road map" for improving the assessment process in general.

Provided by National Academy of Sciences

Citation: EPA's draft health assessment for formaldehyde needs improvement: report (2011, April 11) retrieved 27 April 2024 from <https://phys.org/news/2011-04-epa-health-formaldehyde.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--