NRC to EPA: Formaldehyde Assessment Needs Significant Improvement

Highlights of the Critical Elements to Improve the EPA's Assessment of Formaldehyde

The National Research Council (NRC) of the National Academies issued its scientific review on the Environmental Protection Agency's (EPA) draft IRIS Risk Assessment on formaldehyde on April 8, 2011. EPA's draft assessment attempts to identify the level at which formaldehyde presents a potential risk for adverse effects on human health. The ACC Formaldehyde Panel believes EPA, which commissioned the NRC review, should implement the recommendations the NRC committee made as it revises its draft IRIS Risk Assessment on formaldehyde.

Overall, we find that the NRC committee's recommendations are consistent with the World Health Organization's (WHO) indoor guidelines on formaldehyde. The levels of formaldehyde to which most people are exposed are not high enough to cause adverse health effects, according to the large body of research available. In its draft assessment, EPA proposes setting a cancer risk value significantly below the levels that occur naturally in the environment. For example, WHO reports people produce formaldehyde in their bodies and exhale it in the range of less than 0.8 to 8 parts per billion. EPA's proposed cancer risk value of 0.008 parts per billion would suggest that human breath poses an unacceptable risk of cancer; yet experience and science tell us that could not possibly be the case.

The following Q&A helps explain the NRC committee's findings and addresses questions about its impact on public health.

What is the takeaway from the NRC committee's report?

The takeaway is succinctly summarized by the National Academies in its press release on the report: **"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."** The NRC committee provides EPA with both specific and general recommendations to improve the draft assessment.

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– The National Research Council

What does the NRC committee say about EPA's attempts to link formaldehyde with leukemia and lymphomas?

According to the NRC committee, "[EPA's] conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data, and the lack of mechanistic data."

The committee criticizes EPA's assessment for grouping various types of leukemias and lymphomas together, because the cancers are not closely related. Specifically the NRC committee writes, "The committee does not support the grouping of 'all LHP cancers' because it combines many diverse cancers that are not closely related in etiology and cells of origin."

The NRC committee also concludes that EPA did not support its determination of causality in the assessment. The committee encourages EPA to revisit its arguments and include detailed descriptions of the criteria that were used to weigh evidence and assess causality.

Does formaldehyde cause leukemia?

Based on the most recent science, there does not appear to be credible evidence that inhaled formaldehyde is capable of triggering the mechanisms in the body that are necessary to cause leukemia.

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The notion that there is a link between leukemia and formaldehyde is based primarily on one epidemiology study conducted by the National Cancer Institute (NCI) of 25,000 workers at 10 different plants where formaldehyde was either manufactured or used. This study was highly questioned by other scientists. The overall leukemia rates in the study were no different from the general U.S. population. By using the most appropriate ways to measure exposures, there was no association between formaldehyde and leukemia.

What does the NRC committee say about EPA's attempt to link formaldehyde with asthma?

The NRC committee says EPA's assessment offers little discussion about how asthma could be caused or exacerbated by formaldehyde exposure, the review of the studies is inadequate, and the discussion of mechanisms is speculative and unreferenced. The committee specifically discounts a study EPA uses to support its assertions because, in the committee's judgment, this study "most likely suffers from misclassification of infection-associated wheezing in young children as asthma." In short, the NRC committee does not find sufficient support for EPA's hazard identification and it encourages EPA to justify its approach and basis for its risk value.

"In general, associations between formaldehyde and lung effects or sensitization in children in homes and schools have not been convincing owing to confounding factors and chance effects."

– World Health Organization

Does formaldehyde cause or exacerbate asthma?

Current scientific evidence does not support a link between exposure to inhaled formaldehyde alone as either causing or exacerbating asthma. When people with known asthma conditions have been intentionally exposed to formaldehyde in clinical chamber studies, they have not experienced asthma attacks. While some studies conducted in residential housing have reported a link with formaldehyde, other studies conducted by the same investigators on the same populations have reported associations with volatile organic compounds (VOCs) and fungal spores. WHO concludes: "In summary, consistent cause-effect and dose-response relationships between formaldehyde and measurable lung effects have not been found in controlled human exposure studies and epidemiological studies below 1 mg/m^3 [800 parts per billion]. In general, associations between formaldehyde and lung effects or sensitization in children in homes and schools have not been convincing owing to confounding factors and chance effects."

What does the NRC committee say about nasopharyngeal cancer (NPC)?

The NRC committee says that EPA has submitted sufficient evidence to establish a causal connection between formaldehyde and the very rare cases of cancer in the nose and nasal cavity; however, it does not find sufficient evidence to establish a connection to cancers in other areas of the nasal tract.

Interestingly, the only correlation between formaldehyde and NPC was noted in one NCI study, which was limited to an excess of NPC from one plant. These data have since been reanalyzed and, as noted by the NRC committee, this: "...reanalysis...provides evidence that the excess of NPC might be explained by other employment in silver-smithing or other metal-working industries in Connecticut." Research has not been conducted that focuses specifically on whether or not there is a connection between NPC and the silver-smithing industry or other metal-working industries. As a result, the committee noted that there is no evidence that those industries are associated with an increased risk of NPC. Importantly, the NRC committee asked EPA to update its assessment with unpublished findings from the NCI follow-up study when these are available.

Does formaldehyde cause NPC?

EPA reports that a review of studies from 2005 or later concluded that the typical (average) indoor levels of formaldehyde are between 16 and 32 parts per billion. WHO reports that formaldehyde does not cause the rare NPC in humans exposed to inhaled formaldehyde at or below levels of 1,020 parts per billion [1.25 mg/m^3] in indoor air and with peak exposures below 4,070 parts per billion (5.0 mg/m^3). In making this conclusion, WHO acknowledges that there is one study of workers by NCI that reported cases of NPC where workers were exposed to formaldehyde at higher levels. The study also reported that the majority of these NPC cases, as mentioned in the answer to the previous question, were from one plant out of the ten plants studied, with most of the workers with this cancer reportedly employed a year or less at that plant and reported to have previously worked at plants in a different manufacturing sector with exposure to other chemicals. Scientists have raised significant questions about whether these worker exposures might have caused or contributed to the NPC cases seen.

For full list of annotated questions and answers about the health effects of formaldehyde, visit **www.formaldehydefacts.org.**

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