

# EPA Human Studies Review Board Evaluation of the Formaldehyde Science



The Human Studies Review Board (HSRB) is a federal advisory committee that is required by law to review, comment, and provide recommendations to the U.S. Environmental Protection Agency (EPA) on scientific and ethical elements of human subject research.

## Areas of Concern in EPA Formaldehyde Studies

As the EPA revisits its formaldehyde regulations under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the HSRB's review identified numerous issue areas of concern that could impact EPA's review of formaldehyde.



The EPA incorrectly favored observational epidemiology studies instead of controlled chamber studies, which have "preferred study design and greater scientific rigor."



Formaldehyde does not follow Haber's Law, which outlines how long a gas must be breathed to produce a toxic effect, and therefore duration adjustments and uncertainty factors should not be applied.



A more coordinated approach between the peer review bodies evaluating the formaldehyde science is needed to develop effective regulations.

## Different Approaches Find Flaws in EPA's Formaldehyde Approach

As identified by the HSRB, the EPA has effectively isolated review boards. It effectively excluded input from others including State and Federal agencies working on formaldehyde guidance/regulations involved. This approach has produced a variety of opinions between review bodies that ultimately highlight deep flaws in EPA's process.



Though NASEM was not charged with reviewing underlying data in the EPA's draft IRIS assessment, HSRB conducted a deep dive into each study. Despite the differing approaches, both called into question EPA's reliance on Hanrahan et al. (1984), with HSRB stating that it cannot and should not be used to support regulatory rulings.



Both HSRB and NASEM found the EPA's methods to be lacking in transparency. HSRB arrived at this conclusion after an in-depth scientific review. NASEM was not charged with reviewing the science yet reached the same conclusion by citing poor transparency and clarity in EPA's draft IRIS assessment.



Ultimately, HSRB and NASEM's reviews support an urgent need for an independent, in-depth review of the science underpinning EPA's regulatory proposals for formaldehyde.