



FRANK MIRER, PhD, CIH, is a professor in the CUNY School of Public Health in New York. He can be reached at (212) 396-7782 or franklin.mirer@sph.cuny.edu.

What's Science Got to Do with It?

BY FRANK MIRER

According to the Pew Research Center, a little less than half of Americans believe global warming is a result of human activity, although a few more concede that there may be warming from other causes. Some prominent opinion leaders have denounced global warming as a “hoax.” Meanwhile, a NASA website notes that upwards of 97 percent of climate scientists believe warming by carbon forcing is a fact. It's likely that the rest of the professoriate, in other disciplines, shares similar views.

Within that super-consensus are many unsettled issues, notably how much will temperature rise and how fast. Many science types (including me) who believe that global warming is proven fact are “Sunday drivers” when it comes to climate models or methods of integrating temperature measurements into a central tendency—we have formed our opinions based on simplified statements by authoritative scientific bodies. Once you have accepted the paradigm (see Thomas Kuhn), apparently contradictory phenomena, such as a polar vortex over the northeastern U.S., are explained away (correctly) rather than used to challenge the prior view.

Now I return to formaldehyde for the third time. Risk assessment and its application continue to evolve with EPA's December 2016 rule on testing formaldehyde emissions from composite wood products. It's worth assessing the authority of the science behind this rule by describing the processes of the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), and the National Academy of Sciences (NAS).

IARC REVIEWS

In 2004, an IARC working group raised

the classification of formaldehyde to “known to be carcinogenic to humans.” The full Monograph 88 was posted in 2006, noting sufficient evidence in humans for certain upper airway cancers, and “strong but not sufficient evidence for a causal association between leukemia and occupational exposure to formaldehyde.” The epidemiological evidence was mainly the National Cancer Institute (NCI) cohort, which showed exposure-response for the upper airway cancers and leukemia, as well as some scattered studies showing an association with leukemia in embalmers. The finding about leukemia was important because leukemia is more prevalent than the upper airway cancers and therefore would translate into much higher observed carcinogenic potency and, hopefully, much stricter controls.

The IARC monograph program is generally considered the most authoritative scientific opinion on the carcinogenic potential of chemicals and exposure circumstances. IARC working group members are appointed by the secretariat, which is in turn governed by the World Health Organization, through a nomination-and-public-comment process. Working group members write all parts of the mono-

graph. These texts are commented on by the other members and the staff, and then edited during a 10-day meeting in Lyons, France, and conclusions voted on. (I've served on three working groups; the meeting is “full-contact” peer review.)

Working group members are active researchers with knowledge of the exposures being considered. They are mostly academics, but some are from governmental research agencies. All are free from conflicts of interest. None are compensated by IARC for their time.

The Monograph 88 group also included an “invited expert” from the Chemical Industry Institute of Toxicology (CIIT). Invited experts are active in the relevant area but have conflicts of interest. They participate in discussions in committees and plenaries but don't write text or vote.

Also in 2004, a series of papers spit-balling the IARC classification began to appear. These papers were sponsored by the Formaldehyde Council. One was a complete reexamination of the NCI cohort based on the full data set provided by NCI to a well-known university-based professor funded by the Formaldehyde Council. This paper concluded no evidence of risk for formaldehyde at either cancer site. Additional sponsored mechanistic studies questioned whether sufficient inhaled formaldehyde was absorbed into the blood to account for leukemia arising from bone marrow, although other independent studies identified genetic damage in circulating blood cells in exposed workers.

Science is what scientists say it is.

Another IARC working group, in 2009, raised the classification of evidence for leukemia to “sufficient”; formaldehyde remained classified as known to be carcinogenic, but the additional human tumor site was noted. The working group identified an NCI study of embalmers as support for reclassifying the evidence.

EPA, NAS, AND NTP

Under pressure from the Natural Resources Defense Council, EPA moved forward with the formaldehyde risk assessment for its Integrated Risk Information System (IRIS). In 2009, then-Senator David Vitter, R-La., pressured EPA into referring the risk assessment to NAS for an additional review before it could be published. An IRIS risk assessment has no immediate regulatory effect, but industry feared its potential impact.

The IRIS process involves EPA staff compiling extensive literature regarding the chemical and making recommendations, followed by internal scientific review, public comment, and response to comments, and culminating with a final cancer potency estimate and a reference concentration for non-malignant effects. Some EPA staff conduct original research in areas relevant to the IRIS review and publish in peer-reviewed journals. The risk assessment in EPA’s 2010 draft included a cancer slope factor based on epidemiology that was five times greater than the 1991 value derived from laboratory data.

Reference concentrations absent from the 1991 assessment were also included.

The NAS review of EPA’s draft was released in 2011, dropping half a bombshell on the process of protections. Lost in industry’s claims of vindication was the committee’s conclusion that formaldehyde was correctly classified as “known” to be a human carcinogen based on the upper airway cancers. But the committee found that EPA did not properly support the association and quantitative assessment for leukemia. The result was a reset back to the 1991 risk assessment, pending a new process to respond to the NAS critique.

The NAS, our highest authority on policy for science-related issues, is a group of hundreds of senior scientists elected by present members. The membership also elects leadership positions in the National Research Council, a nonprofit organization that provides advice, usually to governmental agencies or Congress. NAS reports are written by committees whose members are selected by NRC staff after nominations and a commenting process. The committees comprise an academy member and selected scientists, including those not directly involved in the policy question. Their reports are reviewed within the academies and by outside reviewers. Committees typically hold public meetings to receive comments. Committee members are not compensated.

As the 2010 EPA IRIS assessment

was being tossed into limbo, NTP’s 12th *Report on Carcinogens* (RoC) was moving through its process. The NTP assessment concurred with IARC and EPA by classifying formaldehyde as known to cause cancer in humans, including both leukemia and upper airway cancers. The RoC document was reviewed and approved before release by an external committee of scientists. (I submitted comments to the review committee requesting they upgrade evidence for lung cancer at least to limited; the committee declined to mention this.) Congress responded by demanding and funding another review by the NAS. In contrast with the 2011 NAS report on the IRIS risk assessment, the 2014 NAS report on the NTP classification clearly supported the evaluation of evidence for leukemia and the classification as “known.”

The 2016 formaldehyde emissions rule is based on quantitative risk estimates from the 1991 IRIS assessment. Therefore, if we accept the scientific authority in the history above and assume that the emis-

sions limits are properly derived, we have to question whether it’s sufficiently protective. But, it’s something.

SCIENTIFIC AUTHORITY

We can draw a few lessons from this narrative:

First, authoritative scientific conclusions are derived from institutions governed by senior scientists and from processes that encompass expert review. Science is what scientists say it is.

Second, initial scientific skepticism about whether formaldehyde inhalation causes leukemia (based on epidemiology) has become a minority position, although it’s not a denialist position. Most skeptics have industry funding.

Finally, a political process continues to delay the incorporation of the majority scientific opinion into the EPA risk assessment for formaldehyde. Therefore, a rare exercise in public health protection under the Toxic Substances Control Act, just promulgated, is based on a 1991 assessment. ❸

RESOURCES

EPA: Formaldehyde Emissions Standards for Composite Wood Products, <http://bit.ly/compositewood>.

Journal of the National Cancer Institute: “Mortality from Lymphohematopoietic Malignancies and Brain Cancer Among Embalmers Exposed to Formaldehyde” (December 2009).

NASA: “Scientific Consensus: Earth’s Climate Is Warming,” <http://bit.ly/earthwarming>.

Natural Resources Defense Council: “The Delay Game: How the Chemical Industry Ducks Regulation of Toxic Substances,” <http://bit.ly/delaygame> (PDF, October 2011).

NTP: *14th Report on Carcinogens* (2014).

Pew Research Center: “Public Views on Climate Change and Climate Scientists,” http://bit.ly/climate_scientists (October 2016).