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Industry Signals Data Law Attack On EPA Air Rules Over Formaldehyde Risks

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Chemical manufacturers are signaling they may bring a data quality challenge to EPA's pending air toxics rules for the oil and natural gas drilling sector because the agency relied on safe exposure limits in its 1991 cancer assessment of formaldehyde, which the industry says is outdated and overly stringent.

The warning, contained in Nov. 30 comments to the agency from the American Chemistry Council (ACC), highlights the struggle EPA faces to craft rules regulating formaldehyde since a National Academy of Sciences (NAS) panel earlier this year strongly criticized the agency's 2010 draft risk assessment of the substance that set conservative new exposure limits and had, for the first time, deemed the substance to be a leukemogen.

In addition to using the 1991 formaldehyde risk value in its pending oil and gas rules, EPA has also applied the estimates in its final rule, promulgated Nov. 21, that seeks to limit air toxics risks from wood furniture manufacturers.

While EPA is in both cases required to issue the air toxics rules according to court-ordered deadlines, there is no deadline for EPA to complete its pending Integrated Risk Information System (IRIS) assessment -- leaving the issue unresolved, for now.

EPA in its draft national emissions standards for hazardous air pollutants (NESHAP) for the drilling sector is proposing to set first-time maximum achievable control technology (MACT) standards for glycol dehydrators and storage vessels, and to expand its definition of "associated equipment" which could apply the new standards to previously unregulated sources at drill sites.

But the agency's NESHAP includes a residual risk review of formaldehyde, which is commonly used in hydraulic fracturing operations at oil and gas development sites.

The risk review is riling industry because the agency has relied on what critics say is a flawed 1991 agency assessment of the chemical's lifetime cancer risks.

EPA in the proposed rule says it is using the 1991 dose-response value for estimating lifetime cancer risk associated with inhalation exposure to the chemical as the basis for its risk review rather than a significantly weaker 2004 estimate crafted by Chemical Industry Institute of Toxicology (CIIT) -- now known as the Hamner Institutes -- and favored for regulatory use by the Bush EPA.

CIIT in 2004 estimated the potency of formaldehyde to be 5.5 x 10-9 per micrograms per cubic meter (µg/m3), which the Bush administration said at the time incorporated "better science" than its stricter 1.3 x 10-5 per µg/m3 dose-response value from EPA's 1991 IRIS assessment.

By contrast, EPA's draft IRIS assessment criticized by NAS estimated the substance's cancer potency value at 1.1x10-4 per ug/m3 -- which is stricter than EPA's previous cancer risk estimate by a factor of 10. EPA based its draft IRIS finding and its cancer risk calculations on human epidemiology data -- National Cancer Institute data of some 23,000 workers at 10 different factories where they worked with formaldehyde -- rather than using animal data and the CIIT's model.

Industry previously objected to EPA's use of the 1991 risk value instead of CIIT's estimate as the basis for its residual risk review of air toxics emissions from the wood furniture manufacturing sector, and is renewing the same criticism in the proposed drilling NESHAP. Industry argues that the CIIT value is superior to the IRIS assessment because it is based on a more recent biological model and more accurate data.

ACC's Formaldehyde Panel says in Nov. 30 comments on the proposed drilling rules that EPA is failing to rely on the "best available science" by reverting to the 1991 IRIS value for determining formaldehyde inhalation risk and therefore failing to comport with the Data Quality Act (DQA) guidelines. *Relevant documents are available on InsideEPA.com.* (*Doc ID: 2384214*)

"In particular, EPA incorporates the 1991 IRIS dose-response model -- an overly conservative and outdated model -- for determining the level of risk presented by formaldehyde exposure and ignored, without any rationale, nearly 25 years of research," the panel says in the comments. "The utilization of the [1991] IRIS model is all the more egregious considering the availability of the CIIT biologically based dose-response (BBDR) model, which better reflects the available science."

EPA says in the proposed rule that subsequent research conducted by the agency in 2010 found that the CIIT model was inappropriate and that the 1991 cancer value is believed to be "more health protective." Further, the proposed rule says that EPA is still reviewing the NAS review of its draft IRIS assessment, which would update the 1991 assessment.

"In the interim, we will present findings using the 1991 IRIS value as a primary estimate, and may also consider other information as the science evolves," the proposal says.

But ACC points out that the NAS review was "highly critical" of the draft IRIS assessment and specifically supported use of the CIIT BBDR model for assessing formaldehyde's cancer risks, recommending that EPA consider an approach that would adopt the CIIT model as a means of quality-checking EPA's own methodology. EPA rejected use of the CIIT model in 2010 because it believed it was not sufficiently health protective.

ACC says in its comments that the BBDR model is superior because it incorporates newer research on regenerative cellular proliferation and DNA-protein cross-link formation in formaldehyde carcinogenicity, and points out that the Clean Air Act gives EPA significant leeway in relying on risk assessments outside of its IRIS program.

"The need for a careful examination of recent, relevant data and research in determining an appropriate toxicological value is quite evident in the case of the formaldehyde dose-response value where the IRIS dose-response value is based on a study that is over twenty years old," ACC says. "The NAS panel's unequivocal support of the CIIT BBDR should be considered when determining the best available science."

The proposed rule identifies formaldehyde, which EPA classifies currently as a probable human carcinogen, along with benzene, as a major driver of cancer risks associated with emissions of HAPs from the natural gas sector.

EPA found in the residual risk review that of 990 oil and natural gas production facilities subject to the MACT standards included in the agency analysis, the facility wide maximum individual risk (MIR), for cancer risk of someone living nearby the facility, was estimated to be 100-in-1 million based on actual emissions. Of the 990 facilities, only one facility was found to have a facility-wide MIR of 100-in-1 million, mostly due to nickel and formaldehyde emissions at the plant.

However, an agency analysis of transmission and storage facilities calculated a facility-wide MIR of 200-in-1-million for cancer risk, and EPA notes in the proposal that the MIR would be significantly weaker at 100-in-1 million if the CIIT risk value had been used instead of the 1991 IRIS assessment. -- *Bridget DiCosmo*