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Stripped Down

BY FRANK MIRER

Methylene chloride (MC) is again on a public health agenda because of proposed new rules under the Toxic Substances Control Act, which seems to be the only public health initiative still in town, and a revised assessment of carcinogenic potential by the International Agency for Research on Cancer.

Back in 1986, the United Auto Workers petitioned OSHA for a new occupational standard, which OSHA eventually promulgated in 1998. That standard required a reduced permissible exposure limit (to 25 ppm from 500 ppm), monitoring, medical surveillance, and regulated areas. Despite the new rules, thirteen acute deaths of workers refinishing bathtubs with methylene chloride paint strippers have been reported since 2010. These deaths are likely the tip of an iceberg enabled by small employers ignorant of the danger and not observing the standard's monitoring requirements. The Agency for Toxic Substances and Disease Registry has a minimal risk level of 0.3 ppm for exposures to methylene chloride longer than one year, suggesting that the hard-won OSHA PEL is not nearly protective enough.

EPA has proposed to ban the manufacture and use of methylene chloride (and of an MC substitute, N-Methylpyrrolidone) for paint-stripping applications, prohibit distribution in containers smaller than 55 gallons for remaining uses, require suppliers to notify downstream users of the rules' requirements, and record who's buying the product. EPA was moving on these and several other chemicals even before passage of the

Frank R. Lautenberg Chemical Safety for the 21st Century Act, which authorized release of these rules, possibly short-circuiting regulatory delays. The Act also requires EPA to come up with 10 additional candidate regulations each year.

A case report of a bathtub refinisher's death in Michigan following use of a small amount of MC estimated that the concentration of methylene chloride vapor could have been higher than 150,000 ppm in the bathtub and nearly 8,500 ppm in the bathroom. The worker's estimated time-weighted average exposure to methylene chloride, based on one hour of exposure, was as high as 1,000 ppm in the bathroom and 19,000 ppm in the tub. These astronomical exposure levels would likely not have been permitted if the employer had conducted an exposure assessment, but it's too late for that now. OSHA, NIOSH, and several state agencies have published fact sheets and warnings, but these have no force of law.

EPA'S APPROACH

Clearly, it's much more efficient to regulate the product at the source (where OSHA authority would be novel) rather than ask OSHA to chase down remodeling contractors; in addition, some of

the refinishers are likely consumers or self-employed (that is, beyond OSHA's reach). EPA can take some credit for this innovative regulatory approach, first formulated in 2012, and we can hope it will survive the new leadership at EPA. However, some risk assessment issues relative to MC induce some concern.

First, the discussion of the mechanism of acute death from high concentrations of MC doesn't include cardiac arrhythmia, known to be a short-term effect of many solvents and especially chlorinated hydrocarbons. Medical response to cardiac arrhythmia might be different for workers affected by MC than that for arrhythmia triggered by anesthesia. The rate of onset might also be more rapid with less warning than in the case of anesthesia-related arrhythmia.

Second, the carcinogenic potency estimates adopted by EPA would seem to lead to substantially weaker protections than plausible competing estimates (for example, by OSHA). A former OSHA standards official submitted public comments that EPA's estimate of carcinogenic potency (that is, the slope factor, which predicts cases arising for the same exposure level) was 15 times lower than OSHA's estimate in 1998, based on the same toxicity data set. These extrapolations stem from "black box" mechanistic models not easily parsed by educated observers, including me, but I can do the arithmetic confirming the divergence. The EPA slope factor has been around since 2011, so it would appear that nobody in the NGO public health

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community (again including me) noticed the estimate or multiplied out the differences, possibly because there was no arena in which to complain until now.

Third, the EPA level of concern for noncancer effects would appear to diverge substantially from the ATSDR MRL of 0.3 ppm for longer-term exposures and 0.6 ppm for short-term exposures.

CARCINOGENICITY OF METHYLENE CHLORIDE

In 2016, IARC upgraded the level of certainty for the carcinogenicity of methylene chloride to “probably” carcinogenic, which IARC designates as Group 2A, from “possibly” carcinogenic (Group 2B). The progression reflects new data from studies of people, as well as mechanistic data.

The original listing in 1999 (Monograph 71) relied heavily on an inhalation bioassay of methylene published in 1986 by the United States National Toxicology Program. NTP had found increased lung tumors in mice, in addition to the liver tumors in mice and mammary tumors in rats previously found in oral bioassays. The significance of oral dosing had been denigrated based on route of exposure. The breast tumors in rats, which NTP determined were “clear” evidence for carcinogenicity, were ignored by regulatory agencies and management because they were nonmalignant, even though NTP judged them to be able to progress to malignancy. Industry launched a scientific lobbying campaign pro-

moting a hypothesis that the mouse tumors arose from a metabolic pathway (the enzyme GST) not found in people; this campaign, supported by the Office of Management and Budget, delayed the OSHA standard by several years while extra analyses were conducted. IARC’s 2016 monograph identified substantial numbers of studies in people not available in 1999; the working group concluded, “Positive associations have been observed between exposure to dichloromethane and cancer of the biliary tract and non-Hodgkin lymphoma” and rated this as “limited” evidence. In addition, the GST pathway had been identified in people. “Sufficient” evidence in laboratory tests plus “limited” evidence in people, in conjunction with “strong” evidence of metabolic pathways, yielded a designation of “probably” carcinogenic.

N-METHYLPYRROLIDONE TOXIC POTENTIAL AND POTENCY

I first encountered NMP on the core-making mezzanine of a foundry in Indianapolis in the 1980s. A worker was using a string mop and a bucket to clean caked polyurethane core sand from the hopper above a cold box core-making machine. The worker was complaining of skin problems. The liquid in the bucket was gray and ugly. My literature review revealed that NMP was used as a vehicle for insecticides, indicating skin penetration, but the health effects noted below were not evident at the time.

For NMP, health effects that EPA designates as posing an “unreasonable” risk include developmental toxicity (for example, fetal death or decreased infant birth weight), neurotoxicity, immunotoxicity, liver and kidney toxicity, and reproductive toxicity. The route of exposure is skin penetration, because NMP is not very volatile. The point of departure for setting a health concern was based on levels of absorbed NMP from oral dosing studies, and a 30-fold margin of exposure from the POD was used to evaluate exposure scenarios for risk. Enough of these came within the margin of exposure for EPA to propose the ban on NMP.

REGULATING PAINT STRIPPERS

The OSHA PEL for MC of 25 ppm allows more than three cancers per 1,000 workers (according to OSHA’s risk assessment). It’s feasibility-trapped because OSHA’s regulatory analysis didn’t consider lower levels, such as 10 ppm. Prospects of revisiting the PEL any time soon are slim. OSHA has little precedent for regulating skin absorption. Regulation of the paint strippers under TSCA is the most effective approach, since the prospect of finding workers at the place and time of stripping bathtubs and other substrates, and

then collecting air samples and issuing citations, is remote. Controlling exposures within safe limits also seems infeasible, even with respiratory protection.

Directing regulatory agencies to set standards, as Congress did to produce OSHA’s HAZWOPER and blood-borne pathogens rules, is one way to break the logjam. The 10 TSCA rules EPA has put in the hopper, and the 10 EPA is supposed to propose in the next year, would be more momentum than I ever expected. And I would anticipate that industry will implement some of the protections that would be required by potential rules even while opposing those rules.

That said, the most important impact of TSCA could have been to allow EPA to compel production of information on chemical hazards via test rules set under the existing chemicals program and in response to premanufacturing notices, which must be filed with EPA 90 days prior to manufacturing or importing a new chemical. This issue was in the comments on the proposed TSCA that I drafted for the UAW back in 1976, my first foray into legislation. The failure to promulgate test rules remains the biggest failure of EPA under TSCA. 📍

RESOURCES

ATSDR: Minimal Risk Levels (MRLs) List, <http://bit.ly/astdrmrl-mcl>.

IARC: Dichloromethane, <http://bit.ly/iarcddichloromethane> (PDF, December 2016).

NIOSH: “Tub Refinisher Died Due to Methylene Chloride Overexposure While Stripping a Bathtub,” <http://bit.ly/tubrefinisher>.