



# Formaldehyde regulation that seeks to protect U.S. workers may end up hurting them instead

by Cristine Villena Amurao

FORMALDEHYDE AND ITS DERIVATIVES ARE USED in an array of different products in disparate industries, including metalworking as a preservative, as well as in the cosmetic and beauty industry. Most people are familiar with the use of formaldehyde in embalming and tissue preservation, but it is also used as a disinfectant in hospitals, as a preservative in make-up, as an adhesive in making plywood and particle board furniture. It is used in some laser toner powders and in cigarettes. You might not see formaldehyde on the list of active ingredients in some of those products, but it might be present in a different form.

It is also an interesting fact that everyone naturally produces formaldehyde. It doesn't matter how clean our surroundings are or how healthy we are, we will breathe out and excrete (in our urine) a small amount of formaldehyde. So, if you are smoking and using an old laser printer in a newly painted room, you have just inhaled higher than normal amounts of formaldehyde!

Different industries may use different formaldehyde-releasing preservatives. One such chemical used in metalworking fluids is Hexahydro-1,3,5-tris (2-hydroxyethyl)-s-triazine (HHT). As such, there are more than 30 agencies in the United States alone trying to influence or regulate formaldehyde and formaldehyde release bactericides. These include the U.S. Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Cancer Institute (NCI) and the National Toxicology Program (NTP).

In April 2008, the EPA published a notice in the Federal Register (FR) asking for comments on its risk assessment of HHT. This allowed all stakeholders to give their inputs before the agency decides to allow or to discontinue the use of HHT in different products and industries. The EPA then issued its decision called the Reregistration Eligibility Decision (RED) on June 27, 2008. Based on this RED, HHT can no longer be used in paints, stains, coatings, institutional and household cleaning products. Although the EPA allowed the reregistration of HHT for use in metalworking fluids, certain mitigation measures and label changes need to be undertaken by the registrants. These changes will have a great impact on the industry and may have some unintended consequences.

The biggest change is the drastic reduction of the treat rate for HHT. Due to the potential inhalation exposure of workers handling metalworking fluids, the EPA reduced the maximum application rate of HHT from 1,600 parts per million (PPM) to 500 PPM. "However, decreasing the treat rate of HHT to 500 PPM as active ingredient is not effective and may cause more harm than good because under treatment will allow a build-up of endotoxins in the workers," according to Philip Miller, global compliance manager, metalworking additives at Wickliffe, Ohio-based Lubrizol Corp.

Perhaps indicative of the acute interest in formaldehyde regulations, Miller spoke before a standing-room audience at the Annual Meeting of the Society of Tribologists and Lubrication Engineers (STLE) in Atlanta, Georgia, in May.

HHT is supposed to keep levels of bacteria in metalworking fluids low, but if under treated, endotoxin-producing bacteria will thrive in the fluid. The endotoxins will be released in the air as the machines using the fluids are operated and inhaled by workers. In effect, the regulation that seeks to protect workers may end up hurting them instead.

Miller, who is based in Spartanburg, South Carolina, said metalworking fluid formulators will probably have 12 months to supply products at the current treat rate of 1,500 PPM and end users will have 12 months to use HHT at the 1,500 PPM level.

The provision on labeling changes is not very clear. The RED document states that "conditions for the distribution and sale of products bearing old labels will be established when the label changes are approved. However, specific existing stocks time frame will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors."

The EPA has not given a definitive time-frame for the implementation of its mitigation measures and labeling changes. This stems partly from the severe critique by the National Academy of Sciences (NAS) of the EPA 2010 Integrated Risk Information System or IRIS assessment on formaldehyde. The NAS criticism is particularly noteworthy because EPA itself asked for the NAS, through the National Research Council (NRC), to conduct an independent review of its draft IRIS report on formaldehyde. A pre-publication copy of the NAS review was released in April 2011.

This is significant because EPA rulemaking, such as the RED on HHT, is influenced by IRIS reports. Adrian Krygsman, director, product registration for Florham Park, New Jersey-based Troy Corp. and a co-author of the STLE presentation, has proposed a meeting of all formaldehyde condensate biocide registrants with the EPA this summer. Until this is settled, no change in labeling will be required.

The "science" used behind the regulation of formaldehyde may have been politically motivated and flawed, experts say. In 2004, the International Agency Research on Cancer (IARC) reclassified formaldehyde as a Group 1 substance, with *sufficient evidence in humans for carcinogenicity* based largely on a single study. It was previously classified as a Group 2A substance, *probably carcinogenic to humans* with limited evidence in humans for carcinogenicity and sufficient evidence in animals.

Following IARC's lead, the NTP published a draft of the 12th Report on Carcinogens (RoC) in 2010 and recommended that formaldehyde be listed as *known to be a human carcinogen*. It is currently listed as *reasonably anticipated to be a human carcinogen* "based on limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals" in the 11th RoC. It was the addition of lymphohematopoietic cancer and leukemia to this draft paper that has caused the most recent regulatory turmoil.

Gary Marsh, director of the Center for Occupational Biostatistics and Epidemiology of the University of Pittsburgh in Pittsburgh, Pennsylvania, has submitted comments to the NTP's RoC Center, questioning the omission of his publications that would have contradicted the Expert Panel Report. He stated that attributing the workers' nasopharyngeal cancers (NPCs) to formaldehyde exposure was based on "anomalous findings in one study plant." The higher than expected number of deaths due to NPCs in plant one may not be due to formaldehyde exposure, but due to the worker's exposure to sulfuric acid mists, mineral acid, metal dusts and heat, in the ferrous and nonferrous metal industries. His written and oral arguments, presented at the 2009 NTP meeting, were essentially dismissed.

According to Marsh, formaldehyde should not be reclassified

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from its current listing as *reasonably anticipated to be a human carcinogen*.

The EPA IRIS report and the draft 12th RoC report on formaldehyde lump together different kinds of blood and bone marrow cancers into several big groups, namely “lymphohematopoietic cancers and leukemias,” when it should be looked into individually as not all cancers are alike and they develop in different ways. Conclusions on causality need to be more focused and specific.

The Zhang et al, 2007 study, which linked formaldehyde to myeloid leukemia concluded that exposure to formaldehyde in a plant in China caused an increase in the incidence of myeloid leukemia, “remarkably similar to exposure to benzene.” This plant was later found to be highly contaminated with benzene. Studies at the University of North Carolina by Jim Swenberg show that no 13-labeled carbon (a marker used in the study for easy traceability) formaldehyde introduced by inhalation reaches the bone marrow. This implies that even if a worker inhales formaldehyde, there is no direct effect on the bone marrow.

A later study done by Zhang et al, in 2009 in formaldehyde melamine resin factories in Guangdong province acknowledged that exposure levels in China are above the permissible exposure levels in the

United States. The authors stated that, “the subjects in our study were highly exposed and may explain why we were able to see hematotoxic effects in a relatively small population.” This meant a decrease in bone marrow cells, from which white blood cells come from. White blood cells help us fight infections. They suggested further studies with larger sample sizes and lower exposure levels, to see if similar results will still be seen. Dose and exposure levels are significant factors in the development of some cancers.

These conflicting studies and interpretations have caused confusion and concern within the metalworking industry. The EPA will continue using old exposure data until new data are available. The agency is already asking for confirmatory data, such as chronic toxicity and carcinogenicity (rat and mouse) data for HHT and will probably require increasingly expensive hazard data.

It is possible to influence future regulations, as registrants may request the

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EPA to remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate risk to HHT is below the Office of Pesticide Program’s (OPP) level of concern. But stakeholders in the metalworking industry need to provide relevant data. This can be done by helping enlist sites for exposure monitoring and helping recruit machine shop volunteers for an exposure study. The American Chemistry Council (ACC) program has funding from 44 of its member companies for 19 observational exposure studies. This program is being closely coordinated with the EPA and will cost between US\$20 to \$25 million. The metalworking study alone is estimated to cost between US\$1.0 to \$1.5 million.

Looking ahead, attrition of formaldehyde and formaldehyde-releasing biocides is a good possibility if poor science continues to prevail. More REDs are coming in the near future that will involve other chemicals used in the metalworking industry. There are alternatives to HHT, but each chemical has its own pros and cons. Bringing a new biocide into the market may cost an estimated US\$10 million, but companies are sure to hesitate in this regulatory climate, not only in the United States, but in Europe as well. Although going formaldehyde-free is an option, it might not be the solution. ♠

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