# DEATH KNELL FOR FORMALDEHYDE?

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*Critically important health-related developments that could affect formaldehyde and its continued use in embalming*

Today, formaldehyde is under scrutiny worldwide. While the short-term health effects of exposure to formaldehyde are generally well known, there has been less certainty about the potential long-term effects of formaldehyde exposure, particularly the risk of nasopharyngeal cancer, a rare cancer found in the upper part of the throat behind the nose; brain cancer; and leukemia. Epidemiological studies from the 1990s and before found a heightened risk of death from these cancers in funeral directors. To date, however, scientists have been unable to explain the link between formaldehyde exposure and cancer.

Scientists in the United States and abroad are renewing their studies of the long-term health impacts of formaldehyde use and exposure, trying to determine whether formaldehyde causes cancer and, if so, the mechanics of that phenomenon in the human body. The results of these studies will be extraordinarily important for funeral service, as the conclusions could result in far more restrictive (or at least different) standards for the continued use of formaldehyde in embalming, lead to substantive changes in funeral service as we know it or even possibly sound formaldehyde's death knell.

What are the consequences for funeral directors should scientists determine that formaldehyde causes cancer? Will formaldehyde become unacceptable in embalming? Will green burial or cremation without embalming become the predominant focus of funeral service? Will formaldehyde-free products, such as AARDbalm, gain greater acceptance? Will work practices in the preparation room need to change to provide greater protection for funeral directors and their employees?

These and other important questions of impact to the future of funeral service must be answered. Although answers are not yet available, NFDA is closely following these important matters and is poised to provide information to you and to take action on your behalf should advocacy be required. We will continue to keep you informed as these developments take shape. Let us know if you have questions or comments, and stay tuned!

## Formaldehyde Under Review

Described below are the key domestic and international studies and regulatory activities that might affect the fate of formaldehyde. We want you to be familiar with these developments because of their significance to your health, your employees' health and your business. From the perspective of funeral service, the two most important formaldehyde-related developments are the U.S. National Cancer Institute's (NCI) "Funeral Director Study" and the European Union's (EU) "Biocidal Products Directive." Each are described below, followed by a summary of other formaldehyde initiatives.

### NCI Funeral Director Study

NCI will soon complete a decades-long research study evaluating whether formaldehyde used in the preparation room causes cancer. NCI's "Funeral Director Study" is especially significant for NFDA and its members, as it's expected to reflect important new findings about the consequences of formaldehyde use in embalming.

NCI is also finishing two other studies of the impacts of formaldehyde exposure on formaldehyde plant workers. It is expected that together, these formaldehyde studies, involving both professionals and industrial workers, should enable NCI to compare and contrast different kinds of formaldehyde exposure experienced by workers in different fields. As the leading government cancer research agency in the United States since its establishment in 1971, NCI and its studies carry much weight.

In January 2008, we met with NCI scientists Richard Hayes and Robert Hoover, who revealed NCI's plans to issue an updated funeral directors report by fall 2008.[1] Dr. Hayes, a senior investigator in NCI's Division of Cancer Epidemiology and Genetics who has been engaged in funeral director and other NCI research since 1985, told us that he has been studying work practices in funeral homes and the extent to which use of various products containing formaldehyde, such as cavity and arterial fluids, osmotic gels, hardening compounds and drying powders, causes exposure to high levels of formaldehyde.

NCI researchers quite candidly acknowledge that NCI should have been more proactive years ago in bringing these preliminary findings to NFDA's attention. The forthcoming report will be the culmination of studies conducted under the joint auspices of NCI and the Cincinnati College of Mortuary Science, which had led NCI to suspect, as far back as the 1990s, that there was a causal connection between formaldehyde use in the preparation room and some forms of cancer. We hope to be in communication with NCI about its findings.

NCI has gathered additional information to update its 1990 study.[2] NCI studied 24 embalmings conducted at the Cincinnati College of Mortuary Science under controlled conditions – in each instance varying ventilation, solution strength and type of case (intact or autopsied). The embalmings were segmented into work practices, and formaldehyde air emissions from each of the various work practices were tested. Nearly 1,300 interviews were conducted with next of kin and co-workers to elicit information as to work history, number of embalmings (autopsied/intact body) and ventilation in order to determine cumulative formaldehyde exposure, average formaldehyde concentration, eight-hour time-weighted average and highest-peak formaldehyde exposure.

NCI's preliminary studies support the conclusion that preparation room work practices and product substitution can result in significant reduction of formaldehyde exposure. Interestingly, NCI determined that the application of osmotic gel and hardening compounds, and the excessive use of formaldehyde-containing disinfectants produced far greater formaldehyde emissions than use of cavity or arterial embalming fluids. NCI also found that good ventilation and the avoidance of embalming fluid spills and splashes were the most significant factors contributing to reduced formaldehyde exposure. These preliminary findings certainly bear further evaluation, along with NCI's final report. NFDA will soon issue revised best-management practices, with specific recommendations for reducing formaldehyde exposure.

## EU Biocidal Products Directive

In 1998, the EU issued the "Biocidal Products Directive," effective in 2000. The directive was intended to protect human health and the environment and to establish a single system for biocide regulation throughout the entire EU by developing a process for authorizing and marketing products containing biocides, such as disinfectants, preservatives and pesticides. A biocide is a substance intended to destroy or render an organism harmless by chemical or biological means. The EU had found major differences in the way member states regulated biocides and a general lack of information about their potentially harmful effects.

The directive operates as a market mechanism, prohibiting the sale and distribution of formaldehyde in embalming products (and other chemicals considered biocides) unless formaldehyde is registered; its health effects are studied; and the EU member country assigned to review the data on formaldehyde health effects and each additional country in which the embalming product will be sold determine that formaldehyde use in embalming is free of risk to human health and the environment.

The EU has established stringent scientific standards for registration of uses of toxic chemicals, including formaldehyde. For formaldehyde use in embalming to continue to be practiced in Europe, a scientific dossier is required to be submitted by November 1, 2008, and then approved by Germany, the assigned reviewer. Not surprisingly, the costs of preparation of the dossier and the high fee charged for the regulators' review have operated as a disincentive to proceeding with the process. The formaldehyde chemical manufacturing industry is not interested in preparing the dossier because of its small market in embalming chemicals. In the event that no company shepherds formaldehyde in embalming products through to approval, or alternatively, if formaldehyde in embalming products is not approved by the EU, the formaldehyde-containing embalming products will be banned from sale and distribution.

Embalming products have been designated Product Type 22, "embalming and taxidermist fluids," described as "products used for the disinfection and preservation of human or animal corpses."

The Dodge Company, Ltd., in Great Britain and Omega Holdings (ESCO and Gold Crest in Europe) together have registered to defend for-maldehyde-based embalming products in the EU.[3] The deadline for submission of their technical dossier for embalming products is November 1, 2008, with a decision by Germany, the assigned reviewer, to be completed by May 2010. The dossier they are to submit must include some of the same kind of data under consideration by NCI. The EU's actions in considering and rendering a health and safety judgment on formaldehyde-based embalming products are sure to have repercussions in the United States.

## Other Initiatives

There are other pending formaldehyde-based initiatives as well. This summer, after more than 10 years of study, the U.S. Environmental Protection Agency (EPA) plans to issue a draft formaldehyde risk assessment as a substitute for the current assessment in its Integrated Risk Information System (IRIS). IRIS is widely used by federal and state agencies to establish regulatory action levels. Regardless of when it finalizes its formaldehyde risk assessment, the EPA is expected to rely on the NCI findings.

Two Department of Health and Human Services (HHS) agencies have announced plans to revisit formaldehyde risk. The HHS National Toxicology Program will publish a revised formaldehyde cancer risk assessment in its forthcoming 12th Report on Carcinogens, and the HHS Toxic Substances and Disease Registry is considering whether to update the toxicological profile for formaldehyde, last revised in 1999, to reflect more recent studies.

In February 2008, the Centers for Disease Control and Prevention (CDC) determined that formaldehyde levels in the trailers supplied to Hurricane Katrina victims by the Federal Emergency Management Agency were as much as 40 times what CDC considers safe. The Oversight Committee of the U.S. House of Representatives is gathering information, which will undoubtedly encompass formaldehyde health hazards.

Individual states, too, are assessing formaldehyde and determining how it should be regulated. The

Texas Commission on Environmental Quality issued a draft for-maldehyde development support document in January 2008 to be used, when final, in permit and other regulatory evaluations. This document will assist Texas regulatory agencies in evaluating the potential for adverse effects resulting from exposure to formaldehyde concentrations in the ambient, or outside, air. In both Massachusetts and Vermont, toxic use reduction/formaldehyde ban laws are now under consideration by state legislators.

The EU's regulatory classification of formaldehyde is also under review. In 2004, the International Agency for Cancer Research (IARC), an agency of the World Health Organization, revised the classification of formaldehyde, labeling it a known carcinogen and raising it to the highest cancer risk category, an IARC Group 1 carcinogen, from a Group 3 probable carcinogen, the lowest-risk category for suspected carcinogens. Based on IARC's revised classification, in 2005, France proposed that the EU render a formal determination that formaldehyde causes cancer. Should the EU reclassify formaldehyde as a known carcinogen, this determination will likely guide forthcoming regulatory decisions

affecting formaldehyde use in the EU. In 2006, the German Federal Institute for Risk Assessment (Germany is the reviewer for formaldehyde-based embalming products) issued a white paper assessing the carcinogenicity of formaldehyde, which supported France's request for reclassification of formaldehyde as a carcinogen.

## Conclusion

Organizations around the world are considering the health effects and risks associated with formaldehyde, including in embalming. Formal reports of pending formaldehyde research and risk assessment will be forthcoming. These studies foreshadow potentially very significant implications for formaldehyde, including possible findings documenting a link between formaldehyde exposure and cancer.

Following issuance of these studies, the United States and international bodies will consider taking action that could impact formaldehyde, how it might be regulated and whether it may be used, under any scenario, short term and long term. States, too, will consider additional regulation and legislation. In that regard, state associations will want to be informed of any subsequent state actions once these reports and findings have been issued. Please be sure to keep us advised. Such findings could directly influence regulation and use of formaldehyde-based embalming products in the United States and consequently affect the future of funeral service. ✶

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## References

[1] A leading NCI formaldehyde researcher based in the Netherlands spoke publicly about the NCI study at an international formaldehyde conference in Barcelona, Spain, in September 2007. We learned about the Barcelona forum and requested a meeting with NCI.

[2] For the 1990 study, NCI identified the cause of death of more than 4,000 funeral directors who died between 1975 and 1985 by reviewing death certificates and lists provided by state funeral directors associations, state licensing boards and NFDA. NCI compared the number of funeral director deaths with the expected cause of death of the United States' general population and then examined specific types of cancer deaths.

[3] AARDbalm, Ltd., UK, has applied to defend iodine, with Sweden assigned as the reviewing member state. The Dow Chemical Company and BASF have applied separately to defend glutaraldehyde, with Finland assigned as the reviewing member state.