John H. Fitch Jr. and Carol Lynn Green

Formaldehyde Update

Bringing you up to speed on developments in the review of formaldehyde risk and potential regulatory changes in the United States

"Facts are stubborn things, and whatever may be our wishes, our inclinations or the dictates of our passions, they cannot alter the state of facts and evidence." John Adams

In last May's *Washington Wire,* I described domestic and international regulatory developments likely to affect the future of formaldehyde use in embalming products. Formaldehyde's fate is on the line as the chemical is under review worldwide. Here is an update on the most critical formaldehyde developments and a heads-up about regulatory changes in the United States that might affect the use of formaldehyde-based embalming products.

Recent Developments

For funeral directors, the two most important developments concern the National Cancer Institute's (NCI) funeral director study and the European Union's (EU) biocide's review process for formaldehyde embalming products.

When will NCI issue its funeral director study, and what is it likely to report?

We expect that NCI will issue its funeral director study in time to be considered by the International Agency for Cancer Research (IARC) at its October 2009 meeting in Lyon, France. IARC scheduled a formaldehyde update for the October meeting and at that time plans to consider new data on the relationship between formaldehyde exposure and cancer. Richard Hayes, lead author of NCI's 1990 funeral director study, has been named an IARC working group member. Hayes' appointment likely signals an interest in the funeral director study and, accordingly, a rush by NCI to make it public.

IARC last considered formaldehyde in 2004, and at that time changed the formaldehyde cancer classification to human carcinogen due to respiratory exposure. This means scientists have already determined that formaldehyde causes cancer. At the upcoming meeting, IARC will consider formaldehyde cancer studies completed since '04 and determine whether these new studies require a change in the cancer classification, such as recognizing that formaldehyde causes other cancers in other parts of the body. NCI's funeral director study and other earlier studies found a heightened risk of death from these cancers in funeral directors.

NCI issues plant workers study on formaldehyde exposure.

In May 2009, NCI issued its latest formaldehyde study, looking at industry workers at formaldehyde manufacturing and resin plants. The study concluded that high levels of formaldehyde – above the Occupational Safety and Health Administration's (OSHA) short-term exposure limit of 2 parts per million (ppm) – caused cancer. NCI found that formaldehyde plant workers exposed to formaldehyde concentrations of greater than 2 ppm were likely to have a somewhat higher rate of death due to cancers of the blood and lymph system than those plant workers exposed to lower concentrations.

At this writing, NFDA does not know what NCI's funeral director study will reveal and when NCI will issue it to the public, but the institute is staying in touch with NFDA. If earlier studies of funeral directors and the recent findings of NCI's plant workers study are any guide, we would expect that NCI would highlight the connection between exposure to formaldehyde from highly concentrated formaldehyde compounds (such as osmotic gel, used externally for tissue repair, and hardening compounds used in organ donation cases) and cancer. NCI already mentioned its concern about osmotic gels in a January 2008 meeting between NFDA and leading NCI researchers, including Richard Hayes.

When will the EU determine whether formaldehyde embalming products are safe for continued sale in the EU?

In connection with its evaluation of all biocides (substances that kill living organisms), the EU is examining the health effects of formaldehyde in order to decide whether to ban or restrict its sale, including embalming products in which formaldehyde is an active ingredient. The Dodge Company, along with a consortium of other companies that sell formaldehyde and formaldehyde-based products for other biocide uses, is defending formaldehyde embalming products. We have been advised by Dodge that the filing fees charged for the review are significant, estimated at more than $100,000, and the funeral industry has contributed monies for formaldehyde's defense. Dodge also says that in addition to a health effects review of both formaldehyde and formaldehyde products, the biocides process also requires manufacturers to demonstrate that the product does "what it says on the tin."

Dodge does not expect the formal EU biocides assessment process to be completed for at least another two years, although the scientific dossier for formaldehyde has now

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Don't miss it! "Does Formaldehyde Cause Cancer – How NFDA's Formaldehyde Best Management Practices Can Protect You" is a workshop being offered Sunday, October 25 (12:15-1:15 p.m.) at the NFDA International Convention & Expo in Boston. Carol Green and Ed Ranier, NFDA's environmental and OSHA experts, respectively, will discuss late-breaking developments and NFDA's Formaldehyde BMPs.

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been accepted as complete by the EU reviewing authorities and forwarded to each of the 28 EU member states for their input. If the EU approves formaldehyde, then each of the formaldehyde biocides product manufacturers will have an additional two years to present their products to an EU member state of their choice for further review and licensing if the product is deemed safe. Because many of the formaldehyde products have similar formulations, a process called frame formulation might allow the same data to be used for similar products. Once a product is accepted by one member state, it can be recognized by another member via a less complex process called mutual recognition, which allows other member states to recognize the product based on the original dossier and to be assessed lower filing fees. An additional year is allowed for mutual recognition.

The end result of the EU biocides process may be 1.) approval or disapproval of formaldehyde use; 2.) registration or rejection of formaldehyde embalming products by one or more EU member states; or 3.) registration of the formaldehyde product with usage restrictions imposed as a condition of registration.

In the meantime, EU authorities have been urged to simplify the details and expense of the process. The bottom line is that until formaldehyde or formaldehyde embalming products are either registered or rejected, formaldehyde embalming products can be sold on the EU market.

Will the EU biocides process and other similar EU chemical review processes set a precedent for U.S. chemical review?

The simple answer is yes. The EU process is significantly ahead of any statutory or regulatory chemical review process currently in

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effect in the United States. In the EU, chemicals that are not biocides are reviewed under a new statute called REACH (Registration, Evaluation and Authorization of Chemicals), which embodies a process similar to the biocides review process.

The Toxic Substances Control Act (TSCA), the primary authority for Environmental Protection Agency (EPA) review of new and existing chemicals in the United States, has not been substantially modified since its enactment in 1976. One of the key deficiencies of TSCA is thought to be one of the strengths of the EU process – imposing on chemical manufacturers and marketers the responsibility to provide scientific information demonstrating that use of the chemical is free of risk.

In August 2009, a broad coalition of health and environmental organizations called "Safer Chemicals, Healthy Families," led by the Environmental Defense Fund, called for fundamental changes to the U.S. system for chemical review and authorization. The coalition's announcement was timed to coincide with Congressional consideration of changes to the TSCA this fall. Among other reforms, the coalition called for immediate action on chemicals already known to be dangerous, specifically naming formaldehyde as an example of the toxic chemicals that have been extensively studied. The coalition advocated that exposure to such toxic chemicals be reduced to the maximum extent feasible. Like the EU biocides process and REACH, the consortium urged that chemical manufacturers should be responsible for demonstrating the safety of their products, rather than the current regime that presumes chemicals are safe until proved harmful.

Why are these studies important for funeral service? Why should funeral directors be informed about and care about formaldehyde research studies and agency decisions?

The results of these studies will be extraordinarily important for funeral service because the conclusions might raise issues about the safe use of formaldehyde. Also, the studies might cause regulatory agencies to propose more restrictive standards for the continued use of formaldehyde in embalming, leading to substantive changes in the practice of funeral service as we know it. NCI's funeral director study is especially significant – we expect it to reflect important new findings about the consequences of formaldehyde use in embalming. NCI's preliminary studies support the conclusion that careful attention to preparation room work practices and product substitution can result in significant reduction in formaldehyde exposure, and that good ventilation and the avoidance of spills and splashes of embalming fluid were the most significant factors contributing to reduced exposure.

What is NFDA doing?

Be assured that NFDA is closely following these important matters and is poised to provide information and guidance and take action on behalf of funeral directors should advocacy be required. NFDA will actively engage the issue with the U.S. EPA and OSHA should they propose more restrictive regulations on the use of formaldehyde in embalming.

Over the past 15 years, NFDA has been very active on this issue. It has offered workshops, seminars, Webinars and teleconferences; published numerous articles in *The Director;* and spent considerable financial resources on seminal research studies dealing

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with environmental best practices, formaldehyde and its impact on the environment (especially underground drinking sources), and much more – all designed to keep NFDA members informed and educated on how to maintain a safe preparation room and to quell state and federal regulators from further regulating formaldehyde or embalming and waste water discharge practices.

Most recently, NFDA issued its Formaldehyde Best Management Practices (see *The Director,* May 2009). The Formaldehyde BMPs are intended to draw on the NCI studies and our own expertise to guide funeral directors in implementing the good practices required for the safe use of formaldehyde. NFDA urges each funeral director to become familiar with the Formaldehyde BMPs and to use them consistently in their preparation rooms.

The key to effective formaldehyde control in the preparation room is good ventilation, and good ventilation is the cornerstone of the Formaldehyde BMPs. Because of the importance of ventilation, NFDA has retained a consulting engineer to study preparation room ventilation in order to provide practical and specific guidance on quality, cost-effective ventilation for the preparation room. The report will be available soon. NFDA determined there was a need to provide ventilation guidance because guidance on techniques and equipment for controlling ventilation and the number of air changes per hour for a preparation room does not exist. NCI has made clear in its studies that adequate ventilation control is a critical factor in reducing formaldehyde exposure.

All of this is part of NFDA's continuing commitment to educate funeral directors about formaldehyde and its cancer risks and to make sure funeral directors have the best and most current information available. NFDA will continue to keep you informed of these critically important formaldehyde developments. Be sure to let NFDA know if you have questions or comments. The issues relating to formaldehyde's safe use and its regulation go to the core of funeral service and how we practice our profession. It is important that you are informed and take the steps needed to reduce formaldehyde exposure in the preparation room, and NFDA stands ready to help. ✶

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Get Involved!

John H. Fitch Jr. and Lesley Witter

Although NFDA's Advocacy Division employs two experienced, full-time, Washington, D.C.-based lobbyists to represent your interests before Congress and federal regulatory agencies, you remain your own best advocate. NFDA offers several easy ways for busy funeral service professionals to get involved in the legislative process and express their thoughts, concerns and real-life stories to the members of Congress representing them. To reach the NFDA Advocacy staff, send an email to jfitch@nfda.org or call 202-547-0441.

• **Congress-at-a-Click** With just a click of your mouse, send a pre-written email to your senators and representatives urging their support on issues critical to funeral service and small business. Visit the Members Only section on the NFDA Website *(www.nfda.org)* for more information.

• **NFDA PAC** Let your wallet speak for you by making a financial contribution to NFDA's Political Action Committee. Every year, the NFDA PAC supports candidates for Congress who understand and support funeral service and small-business issues by donating to their election campaigns. Call 202-547-0877 for more information.

• **NFDA Advocacy Summit** Express your thoughts and concerns to your members of Congress by attending the 2010 NFDA Advocacy Summit March 8-10 in Washington, D.C. Contact John H. Fitch Jr. at 202-547-0441 for more information.