NFDA NATIONAL FUNERAL DIRECTORS ASSOCIATION

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December 7, 2021

The Honorable Michael Regan
Administrator U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail code 1101A
Washington, DC 20460

Dear Administrator Regan:

The National Funeral Directors Association (NFDA) is providing these comments, information, and data in response to the Environmental Protection Agency's (EPA) Final Scope of the Risk Evaluation for Formaldehyde (EPA-HQ-OPPT-2018- 0438). Formaldehyde-based products are the leading products used for embalming in the United States and embalming is listed as one of the conditions of use for consideration in evaluating potential health risks associated with formaldehyde. Founded in 1882, NFDA is the world's largest non-profit professional association representing funeral directors and the funeral profession. As the preeminent national association with over 20,000 individual members and 11,000 funeral homes, NFDA is concerned with the safety of all funeral service professionals and the families they serve. In order to ensure that the EPA has the best and most current data in its risk evaluation, NFDA commissioned a Formaldehyde Exposure study (the Study) in funeral homes across the country to assess the current exposure risk to embalmers and employees of funeral homes using formaldehyde in embalming.

Background:

Formaldehyde has been used in embalming fluids since the early 1900s and is still the primary preservative in the majority of embalming fluids today. Formaldehyde is preferred by funeral service professionals due to its ability to accomplish the three primary purposes of embalming: preservation, sanitation, and presentation of human remains so that families have an opportunity to say one last goodbye and conduct necessary funeral rites.

According to EPA, workers are exposed to formaldehyde during the following tasks: "handling concentrated formaldehyde solutions, preparing diluted solutions, arterial and cavity embalming, spray applications, and equipment cleaning (EPA, 2020, p. 137)." There is an existing body of literature reporting on formaldehyde exposures during embalming, with much of the focus on task-based sampling (i.e., samples are collected over the duration of embalming only). Though this literature is helpful to inform on past formaldehyde exposures during embalming, there are questions regarding the applicability of that data to current day conditions. Much of the literature is out-of-date and is not reflective of current conditions. In addition, the EPA estimates that the concentration of formaldehyde in products used during these processes can be as high as 40% (NICNAS, 2006). However, according to the NFDA Member Formaldehyde Usage and Embalming Study (March 2021), the average index

purchased and used by the end product user (the embalmer) was a 25 index (attached). For arterial embalming, those solutions are further diluted into an embalming solution.

EPA has indicated that in addition to the available published literature, they would consider data on formaldehyde exposure from the OSHA Chemical Exposure Health Data (CEHD) database and National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations (HHE) (EPA, 2020). The CEHD database consists of samples collected by OSHA compliance officers during workplace inspections. As these values are representative of compliance sampling, they likely represent worst-case scenarios and provide limited insight into day-to-day variation in exposure potential (Jahn et al., 2015).

While existing literature may be helpful to determine formaldehyde exposure to embalmers in the past, that data is stale, some decades old, and does not accurately reflect the conditions in which embalmers work today. The current literature is also flawed in its reasoning and conclusions related to estimation of long-term average exposures to formaldehyde. Based on these limitations, the National Funeral Directors Association (NFDA) commissioned a Study to conduct an analysis of exposure to formaldehyde in funeral homes across the country to determine current conditions and to supplement and improve upon existing data and to facilitate a more accurate risk evaluation of this condition of use.

Purpose of the Study:

The purpose of this Study was to collect data on exposures to formaldehyde in the funeral service profession under current conditions in a range of facilities, and to examine this data with supporting statistics (e.g., embalming frequency, duration, etc.) to characterize long-term daily average exposures. The Study was open to all in funeral service, not just NFDA members. It is estimated the participating funeral homes represent a representative range of typical homes across the United States.

Sampling Design:

In order to gather accurate and up to date data on contemporary exposures to formaldehyde in the funeral service profession, the Study was designed to characterize full-shift and task-based exposures (during active embalming) to formaldehyde for individuals who work in embalming and in other positions in funeral homes. The Study collected personal air samples on funeral home employees, including those conducting (or expected to conduct, as needed) embalming and occupational non-users (ONUs) at selected funeral homes. The objective was to characterize exposures at a minimum of 12 funeral homes in various regions of the country.

Funeral service professionals from across the country were invited to volunteer for this project. Parameters with potential impact on formaldehyde exposure, such as ventilation rates, present engineering controls, volume of cases, etc., were random and variable as they were not considerations in selection of the locations. Where possible, these parameters were documented during sample collection to understand robustness of the dataset with respect to a range of potential conditions under which embalmers may operate.

Sampling was conducted at 13 funeral home facilities of varying age, geography, and number of annual embalming cases in an effort to include a range of exposure scenarios for workers in the profession. Additionally, sampling was conducted at one non-funeral home background location. Details of the Study design are found in Section 3 of the report on the Study (attached). Results of formaldehyde monitoring (presented in Section 4) were used in coordination with industry survey data to reconstruct typical annual formaldehyde exposure for embalmers, including long-term 8-hour time-weighted averages (TWAs) for workers. ONU samples were collected from the funeral homes to characterize their potential exposure, as well. The results from sampling provide an updated dataset upon which to more accurately predict potential risk of occupational exposure to formaldehyde in the funeral profession today.

Results:

The results of the Study show that even the mean task exposure concentration (0.68 ppm) was below the current permissible 8-hour TWA permissible exposure limit (PEL) of 0.75 ppm, and far below the short-term exposure limit (STEL) of 2 ppm (the maximum exposure allowed during a 15-minute period).

The mean full-shift exposure concentration (0.152 ppm) was also significantly below the current 8-hour TWA PEL of 0.75 ppm as well. Formaldehyde was rarely detected in background or occupational non-user samples.

In addition to measured concentrations, 8-hr TWAs were reconstructed based on data collected in the Study and information on industry embalming frequency. The reconstructed 8-hour TWAs also indicate typical long-term average exposures to formaldehyde are predicted to be very low:

- Typical Exposure of 0.03 ppm
    - Based on 50th percentile for formaldehyde concentrations, task duration, and embalming frequency
- Reasonable Upper-Bound of 0.08 ppm
    - Based on 50th percentile for formaldehyde concentration and task duration and 95th percentile for embalming frequency
- Worst-Case of 0.24
    - (Improbable) Based on 95th percentile for formaldehyde concentrations, task duration, and embalming frequency

Conclusion:

When comparing the results of this Study to the previously published literature, stark differences are observable, and it is clear that the previously existing dataset does not accurately represent contemporary exposures to formaldehyde during embalming, particularly as it relates to typical, long-term average exposures. Notably, this Study acknowledges that long-term daily average exposures to formaldehyde are not best represented by full-shift sampling on days of embalming, as workers typically perform less than one embalming per day on an annual basis.

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Though the use of formaldehyde has not substantively changed, nor has the formaldehyde content of products used in embalming, the Study shows exposures to formaldehyde during active embalming are lower than are typically reported in the outdated published literature, particularly with respect to upper-bound exposure concentrations.

Reliance on data in the published literature overestimates exposures to formaldehyde experienced by embalmers, especially for long-term averages. The Study uses relevant, contemporary data to characterize exposure to formaldehyde in typical funeral homes, which affords the EPA the ability to consider the Study's data set, as well as the limitations associated with using stale data from existing, outdated literature. The concentrations measured in the Study represent a more discrete range than that available in the dated, published literature. Further, the reconstructed 8-hr TWAs use updated exposure data and frequency estimates to provide an appropriate metric for comparison to health benchmarks with longer averaging times, which allows for a better comparison of cancer risks. Understanding this is crucial when estimating risk associated with exposure to formaldehyde in this profession as the use of the best available science, founded on data showing actual current exposure, affords the opportunity to make well-informed risk management decisions.

If you have questions or comments regarding the Study, I'm available to meet at your earliest convenience. Thank you for your attention to this important matter.

Respectfully submitted,

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