AmericanCoatings ASSOCIATION℠

May 14, 2024

Michal Friedhoff
Assistant Administrator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC

Submitted via www.regulations.gov
Re: Docket No. EPA–HQ–OPPT–2023–0613

Dear Assistant Administrator Freedhoff:

The American Coatings Association ("ACA")[1] appreciates the opportunity to submit comment regarding EPA's proposed risk evaluation of formaldehyde. ACA is committed to working with EPA to help ensure an accurate understanding of chemical risk through implementation of the *Lautenberg Amendments*. The Association's membership represents 90% of the paint and coatings industry, including downstream users of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture a variety of formulated products including paint, coatings, sealants and adhesives and their raw materials. ACA and its members respectfully submit the following comment:

I. Evaluating paints and adhesives separately from processing formaldehyde into resins would provide a more accurate assessment.

Regarding the condition of use for processing as a reactant (all industries), EPA evaluates worker exposure during manufacture of formulated products such as paint, coatings and adhesives within a condition of use defined as processing as a reactant, all industries (see p. 44,

[1] ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

Occupational Exposure Assessment). This condition of use includes both upstream activity of resin manufacture and downstream processing of resins into a formulated product. Not distinguishing upstream from downstream activities drives the assessment of paint, coatings and adhesive formulation towards higher worker exposure than realistically experienced on site.

ACA recommends differentiating data sets for formulation of downstream products[2] from upstream resin formulation while performing separately modeled worker exposure assessments. Currently EPA aggregates data across all activities within this condition of use, with the majority of data being relevant to resin manufacture. Resin manufacture is clearly not representative of exposure occurring during manufacture of formulated products. EPA notes that during resin manufacture, "formaldehyde arrives at the site in the form of formalin, a solution that typically consists of 37 to 40 percent formaldehyde." These are then processed into a resins with significantly lower formaldehyde content for use downstream.

EPA identifies about 14 types of resins containing formaldehyde. EPA notes significant data gaps related to resin formaldehyde concentrations and transport:

> EPA does not know the specific starting concentration of formaldehyde for each process under processing as a reactant, but it is expected to vary between different desired reaction products. The Agency did not identify specific information about containers used for processing formaldehyde as a reactant; however, EPA expects formaldehyde to arrive as a liquid in tank trucks, drums, or rail cars received directly from manufacturing sites.
>
> (p. 46, Occupational Exposure Assessment of Formaldehyde)

The aggregated data representing this condition of use does not adequately represent formulation of paint, coatings, sealants and adhesives. EPA integrated a total of 232 peak and full-shift samples. Of these, 78 are data sets taken at facilities processing formaldehyde into resins, formaldehyde polymers and other raw materials, with varying sample sizes. EPA integrates 158 workplaces data sets taken by OSHA identified by NAICS codes for Plastic Material and Resin Manufacturing, Adhesive Manufacturing, Petrochemical Manufacturing, and All Other Miscellaneous Chemical Product and Preparation Manufacturing. Here again, these samples focus on chemical manufacturing where formaldehydes is handled in larger quantities than during manufacture of paint, coatings and adhesives. Included number of samples will also vary across these data sets. ACA recommends publication of a list of data sets and studies, by condition of use with summaries and dates of the study to provide greater transparency. Ideally,

[2] EPA explains, "The CDR indicates that formaldehyde is processed as a reactant in the following industrial sectors: plastics product manufacturing; wood product manufacturing; paper manufacturing; plastics material and resin manufacturing; all other basic organic chemical manufacturing; agriculture, forestry, hunting, and fishing; paint and coating manufacturing; construction; adhesive manufacturing; petrochemical manufacturing; and synthetic rubber manufacturing (U.S. EPA, 2020a). Within these industrial sectors, formaldehyde is listed under the industrial function categories . . . "

this would occur at the draft risk evaluation stage, to provide an opportunity for meaningful review and public input.

II. ACA recommends clarifying data parameters for the condition of use identified as "Processing – Incorporation into an Article – Paint Additives and Coating Additives Not Described by Other Categories in Transportation Equipment Manufacturing."

The condition of use related to "incorporation into an article" refers to application of adhesives and paints at the OEM level, including automotive. EPA may have referred to outlying, non-representative products, with unusually high formaldehyde content, and EPA may have inaccurately described the paint application process at the OEM level, relying on outdated data. However, it is unclear how EPA incorporates paint and adhesive application and concentration levels into its assessment of exposure.

Evaluation of worker exposure relies on OSHA monitoring data, listed at page 62 of the Occupational Exposure Assessment, consisting of 423 studies. EPA also refers to two industry-submitted studies related to spray painting of lighting components for aerospace products. ACA recommends providing a listing of studies used by each condition of use with a date and information about how to obtain the study. Ideally, EPA would provide summary information with descriptions of products at issue in the study, study conditions and any conclusions.

The current reference provided for OSHA monitoring data is a general reference to the OSHA monitoring database. As such, ACA cannot review or identify the data set EPA relies on when evaluating this condition of use. ACA is not able to evaluate whether the data is "fit for purpose." ACA is not able to consider whether data reflects current PPE, engineering controls and average formaldehyde content in products at issue. These considerations greatly affect accuracy. Although EPA issues findings of "unreasonable risk" without consideration of PPE, EPA has stated that it will consider exposure with PPE and other risk mitigation strategies as part of the risk evaluation. Documentation during the risk evaluation phase is critical for risk mitigation.

To create a more accurate and current understanding of industry practices for the risk mitigation team, ACA recommends updating the risk evaluation regarding the following additional issues:

- EPA notes that CDR submission identifies solvent-based paint with 30-60 percent formaldehyde content. (p. 59, Occupational Exposure Assessment). This value may not be representative of solvent based paints generally, and it is clearly not representative of water-borne paints commonly used by consumers and in most commercial and industrial settings. ACA recommends adding clarification about the limitations of this concentration estimate.
- Similarly, for adhesives, EPA identified formaldehyde concentrations in the range of 1 – 30% maximum concentration. EPA should provide some context regarding limited use of

higher concentration products. Conversely, in the unlikely event that high concentration products are widely used and/or available to consumers, EPA should make note of it for further consideration of the risk mitigation team.

- EPA references a 2011 OECD report to note process of OEM paint application generally. (p. 59, Occupational Exposure Assessment). EPA should note that over the past 13 years, OEM equipment manufacturers have minimized or eliminated manual application, using automated spray booths instead. The automotive industry typically uses enclosed, automated spray application, with minimal fugitive emissions, if at all.

ACA may be able to provide supporting information, as needed, at a later time.

III. ACA recommends updating the confidence factor based on data limitations.

Regarding the condition of use for processing as a reactant (all industries), EPA does not consider differentiation of upstream processing and downstream formulation of products when evaluating overall confidence factor. EPA concludes that, "weight of scientific evidence for this assessment is moderate to robust for both 15-minute and 8-hour and provides a plausible estimate of exposures. (p. 50, Occupational Exposure Assessment). This conclusion is largely based on confidence in the quality of underlying data as being medium to high, with data largely being highly reliable and representative in geography.[3] Table 4-7 listing confidence as medium to high for most data sets speaks to the quality of the data set and not the quality of the aggregated risk assessment or is accuracy in representation of all worker activities included in the condition of use.

ACA recommends that EPA revise its confidence factor to "low" for certain worker activities to more realistically identify that this condition of use does not include data related to downstream formulation of paint, coatings and adhesives. ACA encourages EPA to revise its risk evaluation to more accurately reflect exposure scenarios. Ideally, the risk mitigation team would consider strength of underlying data sets and confidence factors when developing risk mitigation requirements. So far, EPA has made a policy decision not to consider confidence factors when developing risk mitigation requirements, compromising risk mitigation requirements so they are overly broad.

IV. ACA recommends a stronger emphasis on establishing relevant data for risk mitigation.

Differentiating downstream processing of resins from manufacture of resins would provide EPA's risk mitigation team with a better understanding of exposure pathways and degree of exposure. ACA recognizes that under EPA's "one chemical, one risk determination" policy, processing of

[3] EPA excluded studies from the Australia's occupational safety agency establishing formaldehyde levels, similar monitoring data from the EU and one study from an adhesives manufacturer in Iran. (p. 50, Occupational Exposure Assessment)

resins into formulated products is likely a contributor to EPA's unreasonable risk finding, as a policy choice. Here, ACA believes further description of data relevant to processing of resins into formulated products would establish a realistic framework for risk mitigation, while acknowledging EPA's understanding of contribution to overall chemical risk.

ACA further recognizes that EPA does not want to preempt risk mitigation considerations during the risk evaluation phase. Recognizing this policy choice, ACA urges EPA to consider the quality of data in establishing realistic exposure concerns to assist EPA's risk mitigation team during the next phase.

V. Limitations of background levels and naturally occurring formaldehyde have not been clearly identified in exposure assessments for each condition of use.

EPA clearly recognizes limitations and complexity of formaldehyde exposure, explaining:

> Given this, EPA cannot solely rely on exceedances of the amounts of formaldehyde exposures known to cause specific health effects in the risk evaluation to determine if conditions of use of formaldehyde that are subject to TSCA contribute to the unreasonable risk. What that means is, for the risks described below to workers and people who use formaldehyde-containing products or have formaldehyde-containing furnishings or materials in their homes, those risks may not be any greater than (1) the risks those same people are exposed to daily from the formaldehyde created naturally by plants, animals, and people; (2) formaldehyde produced by natural and human-caused combustion; and (3) formaldehyde produced by the breakdown of other chemicals in the air. Therefore, EPA believes that, in considering whether a formaldehyde condition of use subject to TSCA contributes to unreasonable risks to people's health, any risks—and what to do about them—need to be considered within the broader context of all sources of formaldehyde, some of which people have been exposed throughout the course of human existence.
>
> (p. 3-4, Executive Summary of the Draft Formaldehyde Risk Evaluation)

Despite this caveat, EPA proceeds to issue findings of contribution to unreasonable risk for several conditions of use with a confidence level of medium to high, with no quantification of natural sources or background levels.

Consideration of natural sources and background levels is critical to risk evaluation and risk management. During risk mitigation, EPA's prior practice has been to accept any determination of contribution to unreasonable risk without considering limitations. The risk mitigation team then mandates risk mitigation requirements often based on a speculative understanding of risk. Because of this approach, it is critical that EPA emphasize natural sources and background levels of formaldehyde, often at higher exposure levels than TSCA conditions of use.

ACA strongly suggests incorporating a quantitative adjustment to exposure values based on background levels and naturally occurring sources, if possible. ACA further recommends emphasizing contribution of background levels and natural sources within evaluation of each condition of use, to encourage further consideration during risk mitigation.

VI. Additional explanation regarding effect of PPE would provide a more accurate understanding of exposure.

In implementing the "one chemical, one determination" policy EPA has explained that it will consider exposure both with and without PPE, although its unreasonable risk determination will be based on assumption of exposure without risk mitigation. As noted in ACA's prior comments, this policy minimizes risk considerations so EPA's "risk evaluation" is really a hazard assessment.

ACA appreciates EPA's recognition of PPE during resin manufacture. Sample data seems to be based on air monitoring samples, without consideration of PPE. ACA recommends additional explanation about the effect of PPE on air monitoring and/or differentiating samples identifying worker exposure with PPE. Typical risk mitigation required by ACA member companies includes gloves, eye protection, protective clothing, ventilation, fume/vapor hoods and respiratory protection.

VII. Conclusion

ACA appreciates EPA's willingness to engage with stakeholders during this process. ACA respectfully submits the following suggestions:

- EPA should differentiate processing formaldehyde into resins and other raw materials from processing of those raw materials into formulated products, by differentiating data sets and related exposure assessments.
- To the extent that data is not "fit for purpose" of evaluating processing of resins into formulated products, EPA should revise its confidence factor to low for this exposure pathway.
- ACA recommends further description of how PPE and other risk mitigation strategies affect workplace exposure.
- ACA suggests incorporating a quantitative adjustment to exposure values based on background levels and naturally occurring sources, if scientifically feasible. ACA further recommends emphasizing contribution of background levels and natural sources within evaluation of each condition of use, to encourage further consideration during risk mitigation.

- ACA recommends providing detailed lists of each data set, monitoring information and study used for exposure assessment by each condition of use, with summaries, dates of studies and products identified in the study. ACA further requests including information about how to obtain underlying data and studies.

Please feel free to contact me if ACA can provide any additional information or clarification.

Sincerely,

Riaz Zaman
Sr. Counsel, Government Affairs
901 New York Ave.
Washington, DC 20001
202-719-3715
rzaman@paint.org