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1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

*RE: ACA Comments on the Draft Scope of the Risk Evaluation for Vinyl Chloride (CAS RN 75-01-4); EPA-HQ-OPPT-2018-0448*
*Submitted online at: www.regulations.gov*

Dear Dr. Card:

The American Coatings Association (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The Association's membership represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paints, coatings, sealants and adhesives and their raw materials, whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations. ACA is eager to assist EPA in developing an effective system for chemical risk evaluations with successful implementation of the *Lautenberg Act's* mandates.

ACA appreciates the opportunity to submit comments regarding EPA's draft scope for the risk evaluation of vinyl chloride. We look forward to working with EPA during this process, and we stand ready to provide any information that could assist in an accurate understanding of risk related to our industry. ACA also remains concerned about EPA's risk evaluation procedures. ACA and the coatings industry strongly encourage EPA to evaluate risks while considering current industry practices in safeguarding its workforce. ACA requests EPA consider two general issues when evaluating risks associated with vinyl

chloride: (1) vinyl chloride is used to make polyvinyl chloride (PVC) resins and other vinyl acrylic polymers, containing residual amounts of the vinyl chloride monomer, which is then subsequently used in many paints, coatings, adhesives and sealants, resulting in the final end-use formulated products having only trace amounts of vinyl chloride, if at all; and (2) industry best practices for safety during handling should be considered as EPA evaluates the risk posed to the industry's workforce.

## I. Relevant conditions of use involve low, trace and residual levels of vinyl chloride monomer

ACA members manufacture paint, coatings, sealants and adhesives and raw materials that go into formulation. ACA identifies the following EPA conditions of use as relevant to its members' products:

- Processing as a reactant (intermediate in adhesive manufacturing, monomer in resin manufacturing).
- Processing –incorporating into formulation, mixture, or reaction product (solvent, resin manufacturing).
- Consumer uses (two-component caulks, water-based paint, single component glues and adhesives).

ACA is concerned that EPA may rely on non-representative product samples when considering risk posed by vinyl chloride content. In prior risk evaluations, EPA has relied on non-representative product samples, to drive risk in a manner that is not truly representative of a condition of use. ACA would welcome the opportunity to assist EPA with identifying accurate product composition for these conditions of use.

Certain specialty products, falling within these conditions of use, manufactured with PVC resins or other vinyl acrylic polymers may contain *residual* vinyl chloride monomer in trace amounts. ACA requests EPA consider establishing a *de minimis* threshold for risk, considering these low amounts and existing risk mitigation. PVC resins are formulated from vinyl chloride monomer. Some specialty, high performance coatings products may incorporate PVC resins or other vinyl acrylic polymers to enhance weatherability and durability. One raw materials supplier identifies levels of residual vinyl chloride monomer in PVC resins at about 10 ppm. Further downstream, in an end-use coating, this results in presence of vinyl chloride in some specialty coatings at 0.02% or less. Paint manufacturers also note presence as an impurity in some products.

ACA also encourages EPA to clearly distinguish conditions of use relevant to upstream manufacture of raw materials vs. downstream processing of a raw material into a coating product. In the past, EPA has analyzed both activities as *processing as a reactant* so that data related to manufacture of raw materials reflect risk during downstream processing. This

practice not only results in a highly inaccurate risk evaluation, but also raises ethical concerns regarding EPA's screening for the "best available science."

ACA continues to gather data regarding uses and amounts of vinyl chloride in formulation, if at all. ACA would appreciate the opportunity to coordinate with EPA to provide additional information as needed.

## II. Standard industry practices, such as engineering controls and the required use of personal protective equipment, when handing and processing vinyl chloride should be considered by EPA during the risk evaluation process.

The paint and coatings industry may use raw materials containing vinyl chloride or poly-vinyl chloride during manufacturing process of certain specialty paints, coatings, adhesives and sealants. Potential for workplace exposure exists during activities such as handling, storage and processing of resins or other raw materials containing vinyl chloride or poly-vinyl chloride. The Occupational Safety and Health Administration (OSHA) has established regulations for safe handling of vinyl chloride. The pertinent regulation is found at 29 CFR 1910.1017(c)(1) and (2), stating that:

> "no employee may be exposed to vinyl chloride at concentrations greater than 1 ppm average over any 8-hour period, and [that] [n]o employee may be exposed to vinyl chloride at concentrations greater than 5 ppm average over any period not exceeding 15 minutes."

Standard industry practices regarding safety rely on information relayed in safety data sheets for vinyl chloride which clearly indicate the use of proper personal protective equipment. ACA encourages EPA to evaluate risks of workplace exposure when proper PPE and engineering controls are in place, while recognizing exposure limits adopted by industry that are lower than OSHA PELs. Further, industry typically implements an "action level," triggering exposure mitigation, when monitored levels are half of the reference exposure limit.

ACA remains concerned that if EPA operates under the assumption that all OSHA PELs are outdated and industry has no other exposure reference values, EPA-determined ECELs (Existing Chemical Exposure Limits) will introduce significant variation from current exposure reference values, without adequate scientific justification. In some cases, a revised exposure value may be justified, but ACA encourages development of any revised exposure values with adequate data and engagement of the community of industrial hygienists and scientists. Inaccuracies in ECELs can be compounded by EPA's practice of not considering PPE or other risk mitigation strategies when making risk determinations.

As EPA has referenced in prior risk evaluations, OSHA notes on its website for PELs that:

> *OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Several OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time*.[1]

The reason for this disclaimer is to alert industry that mere compliance with OSHA PELs does not meet legal obligations established under Section 5 of the Occupational Safety and Health Act, that is the "general duty clause:"

That section requires:

> *"Each employer . . . shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."* (*Section 5, OSHA Act*)

On the same OSHA PEL website, a few paragraphs below the opening statement, OSHA proceeds to explain that employers may need to refer to "alternate occupational exposure limits that may serve to better protect workers." OSHA recommends employers review limits of California Department of Industrial Relation (Cal OSHA), the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits, the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and values established by foreign governments. Industrial hygienists commonly review these sources as well as AIHA Workplace Environmental Exposure Levels (WEELs), limits established by the German government and others.

OSHA requires that industry must take action if an individual could be exposed at the industry action level, usually set at half the PEL, but this could potentially vary as determined by industrial hygienists consulting a variety of sources. The required action is determined on a case-by-case basis, due to the potential risk posed by use. The "industry action level" is legally enforceable. ACA has provided EPA with citations based on violations of these limits.

Recognized bodies develop exposure levels that are largely uniform, creating a uniform understanding of workplace exposure. When an exposure limit diverges, industrial hygienists evaluate and discuss the value to understand reasons for divergence. EPA's prior risk evaluation methods posed grave concerns that it is developing methods and practices not generally accepted as sound science by the community of industrial hygienists. In

[1] https://www.osha.gov/annotated-pels (last visited on April 1, 2025).

effect, EPA is poised to derive exposure limits that are wildly divergent from those of recognized by established bodies, undermining the agency's credibility. It also undermines the credibility of industry management when implementing safety programs, where management must justify its revisions to existing risk mitigation plans on EPA's determinations, potentially at odds with global norms.

If EPA has data to justify such a shift, it must engage with recognized authoritative bodies in industrial hygiene to review and contextualize the information as part of the risk evaluation process. Without closer alignment with standard methods, EPA's evaluations could undermine the field of industrial hygiene and credibility of the TSCA program, at a global level.

## III. EPA should incorporate standard risk mitigation practices into its exposure analysis for vinyl chloride.

ACA cautions against EPA's policy of assuming that standard risk mitigation practices used by industry are not effective and/or not being used. Although this creates a rebuttable presumption, EPA has not established a clear basis for rebutting this presumption. ACA recognizes that EPA may have a broader mandate under TSCA than required by the *Occupational Safety and Health Act*, where TSCA requires consideration of *susceptible subpopulations* as determined by the administrator assessing risk based on purely scientific considerations. In prior risk evaluations, EPA's understanding of risk is driven, in part, by the assumption that subpopulations exist that do not have access to standard risk mitigation controls and/or those controls are not enforceable. When this assumption is coupled with the *whole chemical approach* EPA's understanding of risk can result in excess regulatory controls beyond those required for risk mitigation for certain conditions of use, where existing practices adequately mitigate risk.

To the extent EPA deems it necessary to assess risk for populations not implementing risk mitigation measures, ACA recommends identifying those populations, conditions of use and specific practices. If EPA has data indicating that susceptible subpopulations are engaging in practices prone to unmitigated risk, then it can incorporate this data into its risk evaluation. Absent such data, assuming that such populations exist, penalizes the majority of industry implementing risk mitigation strategies.

ACA recommends considering standard risk mitigation practices during risk evaluation to more realistically understand actual exposure and potential risk. This approach is also supported by the most recent revision of EPA's risk evaluation framework rule, as issued

under the prior administration.[2] ACA has surveyed its members regarding workplace safety practices. When asked about typical PPE requirements during paint formulation, survey results indicate that all respondents include engineering controls (room ventilation, fume/vapor hoods, etc.) along with a mixture of mandatory and optional use of respirators to minimize exposures. ACA members have also reported on the use of closed transfer systems to handle chemicals. According to our survey, the use of gloves during paint manufacturing affords dermal protection (e.g., 16-mil or 40-mil elbow-length, chemical-resistant gloves) and should be accounted for in the exposure estimates. Individual facilities require additional measures based upon the on-site assessment of risks, as well as the chemicals being handled and products being formulated. ACA encourages EPA to consider these factors when evaluating the actual workplace exposure risks associated with vinyl chloride.

## IV. Conclusion

ACA encourages EPA to consider a comprehensive set of factors that could affect exposure, specific to a condition of use, when evaluating risk. This comprehensive approach should consider standard industry practices that are in place for worker safety, such as appropriate engineering controls and PPE. Lastly, ACA encourages EPA to collaborate with the broader community of industrial hygienists to more accurately and effectively characterize the risks association with vinyl chloride as it pertains to the relevant conditions of use of the reasonable exposure methods.

ACA sincerely appreciates the opportunity to submit comment to EPA and looks forward to any questions or further discussions the agency may have. We hope to foster a collaborative environment to develop risk mitigation strategies, as needed, pertaining to actual risk posed by vinyl chloride. ACA emphasizes the following recommendations to EPA as it proceeds with risk evaluation:

- Establish a *de minimis* threshold for risk, based on negligible residual amounts in raw materials and end-use products.
- Consider actual residual amounts in raw materials and end-use products when conducting the risk evaluation.
- Distinguish conditions of use relevant to upstream manufacture of raw materials vs. downstream processing of a raw material into a coating.

[2] See EPA's Preamble to *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)* at 89 Fed. Reg. 87 (May 3, 2024) at 37028, 37037, explaining, "Further, EPA distinguishes ''assumed use'' of PPE from use that is supported by the reasonably available information and therefore known to be inherent in the performance of an activity. For example, where EPA has reasonably available information that substantiates use, fit, and effectiveness of PPE (e.g., information demonstrating that performance of a condition of use is impossible in the absence of PPE), EPA would expect to take that information into account in the risk determination."

- Consider current industry risk mitigation practices, including PPE, during risk evaluation.
- Pursue any deviations from current exposure limits, if justified, with transparency and engagement of the broader scientific and industrial hygiene community.
- Consider the range of exposure levels developed by authoritative bodies, beyond OSHA PELs, as referenced by industry.
- Consider the complete range of existing regulatory controls including those of OSHA and existing air emissions limits.

Please feel free to contact us if we can provide any additional information.

Sincerely,

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