

October 6, 2023

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency (EPA)
William Jefferson Clinton Building
1200 Pennsylvania Ave, N.W.
Washington, D.C. 20460

Subject: Request for SBREFA Panel on Proposed Formaldehyde Management Standards under the Lautenberg Act

Dear Administrator Regan,

We, the undersigned small business trade associations, are writing to formally request the convening of a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel regarding the forthcoming proposal to regulate commercial and industrial activities involving formaldehyde and formaldehyde-based products under the Lautenberg Act. We assert that this proposal will have a significant economic impact on tens of thousands of small firms, necessitating the legally mandated establishment of such a panel. Our primary objective in making this request is to ensure that small businesses have a timely opportunity to provide input to the Agency before it is locked into a proposal to potentially restrict or ban specific uses of formaldehyde, which could significantly hurt numerous industries and reduce substantial environmental, health and other benefits to society.

The undersigned small business trade associations collectively represent industries that include at least 70,000 small firms engaged in the production or use of formaldehyde and formaldehyde-related products. Our shared concern centers on the potential for inadequate scientific analysis of formaldehyde-related risks, which may lead to unwarranted restrictions or bans on these substances and their products. It is crucial to acknowledge that formaldehyde-based products offer substantial benefits to public health, the environment and to our nation. We firmly believe that initiating a SBREFA panel *before* the EPA concludes the drafting of the TSCA-required risk evaluation later this year is essential to prevent the adoption of flawed risk evaluations and the imposition of excessively restrictive formaldehyde-related regulations. Furthermore, scheduling the panel before the draft risk evaluation is completed ensures that a large number of affected small businesses become aware of this rulemaking and can proactively explore alternative methods to replace or reduce their use of formaldehyde.

In contrast, the SBREFA panel for methylene chloride was convened after the final risk assessment had been completed, which unfortunately meant that many small firms were unable to engage with EPA at an earlier stage on critical issues. Consequently, they were ill-prepared for the impending bans on methylene chloride uses. Holding an early panel for

formaldehyde would enable small users of formaldehyde to engage with EPA sooner, providing them with the opportunity to address these vital concerns in a more proactive manner.

In the paragraphs that follow, we elaborate on the widespread utilization of formaldehyde across a multitude of industries, outlining the potential adverse consequences of TSCA-based risk management controls, and substantiate our assertion that the proposed regulations would have a significant economic impact on a substantial number of small firms. This substantiated finding underscores the necessity for EPA to establish a SBREFA panel to explore regulatory alternatives that align with the statute while alleviating small business burdens.

I. Formaldehyde is Used in the Production of Hundreds of Products and Thousands of Industrial and Commercial Applications

Formaldehyde is a critical chemical building block in the production of hundreds of items and plays an important role in everyday life. As an essential reactive intermediate (or ingredient) in the production of many common products and used by many sectors (e.g., building materials, flooring, medical devices, automobiles, agriculture applications), the chemistry of formaldehyde is helping to improve the standard of living by creating products that last longer, and are higher in quality, performance, and safety with little to no formaldehyde remaining in the final product. Formaldehyde supported 961,000 jobs and \$506 billion in sales in 2021.¹

The August 2020 EPA Final Scope of the Risk Evaluation for Formaldehyde lists 16 pages of industrial and commercial activities and uses for formaldehyde, confirming the extremely broad use of formaldehyde.² Formaldehyde is commonly used in the following applications:

RESINS AND ADHESIVES: One of the primary uses of formaldehyde is in the production of resins and adhesives. Formaldehyde-based resins, such as urea formaldehyde and phenol-formaldehyde, are used in the manufacture of wood products, including plywood, particleboard, and laminates. These resins provide binding properties and help create strong and durable materials.

TEXTILES AND PAPER: Formaldehyde is employed as a finish or treatment for textiles to improve wrinkle resistance and color fastness. In the paper industry, formaldehyde-based resins enhances the properties of paper products.

PLASTICS: Formaldehyde is used in the production of various plastics, such as polyoxymethylene (POM), which is a high-performance engineering plastic known for its stiffness, strength, and low friction properties.

¹ <https://www.americanchemistry.com/industry-groups/formaldehyde/benefits-applications>

² https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf

PRESERVATIVES: Formaldehyde-base solutions, such as formalin, are used as preservative in laboratories and for the preservation of biological specimens, including for embalming at funeral homes.

DISINFECTANTS AND BIOCIDES: Formaldehyde-based disinfectants are used in various applications, including water treatment, health care, and the preservation of industrial processes.

PERSONAL CARE PRODUCTS: Some personal care products, such as cosmetics and shampoos may contain formaldehyde-releasing ingredients, which can act as preservatives.

AEROSPACE: Chemicals and polymers derived from formaldehyde are used for their flame resistance, thermal protection, and impact resistance. Formaldehyde is used in multiple plane components, including for the seats, flooring, wings plane body.

AUTOMOTIVE: In the automotive industry, formaldehyde-based technologies are used to make interior molded and under-the-hood components that allow for higher fuel efficiency by reducing vehicle weight. It is also used in the production of highly durable exterior primers, clear coat paints, tire-cord adhesives, brake pads and fuel system components.

In summary, it is evident that formaldehyde is used in many thousands of industrial and commercial applications by tens of thousands of small firms. Regulation of its use and manufacture across dozens of critical industries suggests that bans or restrictions would have substantial economic impacts at tens of thousands of small firms, supporting a determination that SBREFA would be triggered, as explained below in more detail.

II. Revision of Formaldehyde Toxicity Values Would Adversely Impact Small Firms

Current industrial practices are designed to conform to existing formaldehyde standards, as established by various federal agencies, including the Occupational Safety and Health Administration (OSHA) and EPA. Presently, OSHA sets the occupational standard for inhalation exposure at a time weighted average (TWA) of 0.75 parts per million (ppm). However, based on a reasonable point of departure, using EPA's most recent April 2022 draft Integrated Risk Information System (IRIS) assessment, we anticipate that a significant revision to the safe threshold is likely to occur, reducing it by approximately two orders of magnitude. Such a revision would pose immense compliance challenges for current formaldehyde-based applications by any reasonable means.

Considering the extensive use of formaldehyde across industries today, any alterations to occupational and other standards are poised to impact a substantial number of firms, likely including tens of thousands of small firms.

III. The Anticipated Economic Impact of the TSCA Risk Management Rule Warrants a SBREFA Panel

As previously mentioned, the potential two-order-of-magnitude increase in stringency for the occupational exposure limit is highly likely to have a significant economic impact on tens of thousands of small firms. The SBREFA statute requires the affected agency to conduct a panel proceeding for all regulations that the Administrator cannot certify as having “no significant economic impact on a substantial number of small entities [businesses, in this case].”³ Consequently, this impact triggers the requirement to establish a SBREFA panel for the risk management standard required by the Lautenberg Act to address unreasonable risks identified by EPA in formaldehyde-related “conditions of use.”

As you will see below in several examples, the economic impact of these risk management standards are substantial, and necessitate a comprehensive evaluation of potential regulatory alternatives. The establishment of a SBREFA panel is essential to ensure a balanced and informed approach to addressing these critical issues.

A. Analysis of the Recent TSCA Proposal for Methylene Chloride and Its Relevance to the SBREFA Finding for Formaldehyde

In evaluating the recent TSCA proposal for managing methylene chloride, valuable insights can be gleaned to shed light on the SBREFA finding for formaldehyde.⁴ Much like formaldehyde, methylene chloride is also widely utilized by hundreds of thousands of small firms across various industries. According to Table 2 in the Initial Regulatory Flexibility Analysis (IRFA), approximately 230,000 small firms would be affected by the EPA proposal.⁵

Notably, the methylene chloride proposal also includes bans and severe restrictions in many applications, a trend that we anticipate will be mirrored for formaldehyde.⁶ SBREFA was invoked by EPA based on the finding that 225,000 small firms would face revenue impacts of less than 1% in costs/revenue, with 5,000 firms exceeding 3% costs/revenue. When considering formaldehyde, we anticipate that the number of small firms exceeding 3% costs/revenue would far exceed 5,000. Consequently, it is evident that the economic effects would be considerably larger for formaldehyde.⁷

³ 5 U.S.C. Section 609(b). At this time, this requirement applies only to EPA, OSHA and the Consumer Financial Protection Board.

⁴ [Risk Management for Methylene Chloride | US EPA](#)

⁵ “Initial Regulatory Flexibility Analysis for Methylene Chloride; Regulation of Methylene Chloride under TSCA §6(a) Proposed Rule; RIN 2070-AK70,” U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, EPA-HQ-2020-0465-0176 (April 2023) at 29.

⁶ Methylene Chloride IRFA, fn.5, Section 7, at 32-44.

⁷ According to EPA’s guidance regarding certifications of “no significant economic impact on a substantial number of small entities”, EPA generally finds that for impacts of greater than 3% costs/revenue for 1000 or more small entities is “presumed ineligible for certification”. EPA Final Guidance for EPA Rulewriters: RFA , Table 2 at 24; US EPA Office of Policy Economic and Innovation, November 2006; <https://www.epa.gov/system/files/documents/2021-07/guidance-regflexact.pdf>

In light of this analysis, it is reasonable to conclude that the establishment of a SBREFA panel is equally warranted for formaldehyde.

IV. Presenting Three Examples of Significant Economic Impact on Industries Using Formaldehyde Under the Expected TSCA Risk Management Rule

In the following examples, we illustrate the significant economic impacts that various industries employing formaldehyde would potentially face under the forthcoming TSCA risk management rule. These examples, though not exhaustive, strongly suggest that numerous industries would encounter substantial economic challenges due to the widespread use of formaldehyde. This serves as compelling evidence for the necessity of a SBREFA panel, as mandated by law.

A. Aquaculture Facilities Using Formaldehyde (and Formalin)

A ban or excessively stringent regulation on formaldehyde or formalin (a formaldehyde-derived product), would have adverse consequences for aquaculture facilities, farms and both public and private hatcheries. These facilities, encompassing private companies, tribal enterprises and federal and state government-run entities, rely on formalin-containing solutions to combat fungi and ectoparasites affecting freshwater reared fish and shrimp; species like salmon, steelhead, catfish, largemouth bass and others listed under conservation efforts.⁸ Public and private aquaculture facilities can only treat fish or shrimp with Food and Drug Administration approved therapeutants. There are no products available to substitute for the several approved formalin containing products. The new occupational limits to be proposed by EPA may conflict with the US Fish and Wildlife regulations governing formaldehyde exposure control in federal fish hatcheries, fishery offices, the National Conservation Training Center laboratories and other facilities.⁹ It may also overturn FDA approvals for the several formalin treatments.¹⁰ We estimate approximately 3,600 aquaculture facilities potentially impacted.¹¹

B. Funeral Home Facilities: Formaldehyde Use in Embalming

Funeral homes currently utilize formaldehyde in embalming procedures, with a primary focus on compliance with OSHA standards. A recent study by the National Funeral Directors Association revealed that exposure levels during active embalming activities average 0.68 parts per million (ppm), well below the 0.75 ppm toxic-weighted average (TWA), and the short-term exposure limit (STEL) of 2.0 ppm. If EPA determines that a safe exposure level should be in the low parts per trillion range (ppt), it is highly improbable that funeral homes will be able to comply with such stringent requirements. The Bureau of Labor Statistics reports that there are 60,800 funeral service workers in the US.¹² Consequently, at least 10,000 small funeral homes

⁸ <http://fisheries.tamu.edu/files/2013/09/Use-of-Formalin-to-Control-Fish-Parasites.pdf>

⁹ <https://www.fws.gov/policy/242fw9.pdf>

¹⁰ <https://www.fda.gov/animal-veterinary/aquaculture/approved-aquaculture-drugs>

¹¹ NASS (National Agricultural Statistic Service). 2018. Census of Aquaculture: Table 12. Methods of Aquaculture Production. US Department of Agriculture. Washington DC ([aqua_1_0012_0012.pdf \(usda.gov\)](https://www.nass.usda.gov/publications/aqua_1_0012_0012.pdf)).

¹² <https://www.bls.gov/ooh/personal-care-and-service/funeral-service-occupations.htm>

are likely to face substantial costs as they seek alternative methods of formaldehyde compliance.

C. Kitchen Cabinets: Formaldehyde Use in Composite Panels

EPA standards for formaldehyde were established in December 2016 under the 2010 Formaldehyde Standards for Composite Wood Products Act, with Canada adopting similar standards in 2021. Formaldehyde is a crucial component in numerous wood products, including composite panels used in kitchen cabinets. A substantial increase in stringency concerning formaldehyde emissions from wood products could jeopardize compliance for wood composite product manufacturers, particularly those producing kitchen cabinets. The small firms specializing in kitchen cabinet manufacturing alone number approximately 6,000¹³, and we anticipate that a significant portion of these businesses would experience economic impacts exceeding 3% of costs relative to revenue.

These examples underscore the potentially far-reaching economic consequences of the expected TSCA risk management rule on industries employing formaldehyde. This analysis strongly supports the necessity of convening a SBREFA panel, in accordance with legal requirements, to thoroughly examine the regulatory alternatives and their impact on small businesses.

V. Conclusion

In conclusion, we respectfully request that EPA recognize the imperative need for a SBREFA panel. This panel would serve as a platform for comprehensive evaluation, constructive dialogue, and informed decision-making regarding formaldehyde. We also request that this panel be held before completion of the draft risk evaluation, in order to inform the risk assessment, as well as to keep open regulatory options that would reduce small firm burdens. We are eager to collaborate with the Agency to ensure a thorough examination of the issues. Thank you for considering our request. We look forward to participating in this critical regulatory process. If you wish further information, please contact Andy O'Hare, President of the Composite Panel Association, at aohare@cpamail.org.

Sincerely,

American Feed Industry Association
American Home Furnishings Alliance
Business and Institutional Furniture Manufacturers Association
Catfish Farmers of America
Composite Panel Association
Florida Aquaculture Association

¹³ Statistics of US Businesses, US Census Bureau; <https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html>; NAICS Code 33711 (2020)

Kitchen Cabinet Manufacturers Association
National Aquaculture Association
National Funeral Directors Association

Cc: William Nickerson, EPA Small Business Advocacy Panel Chair
Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Richard Revesz, Administrator, Office of Information and Regulatory Affairs, Office of
Management and Budget
Major Clark, Acting Chief Counsel for Advocacy, US Small Business Administration

EPA TSCA Docket: [EPA-HQ-OPPT-2018-0438](#)