Submitted Via Email

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Michal Freedhoff, Ph.D.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20640

RE: Consideration of Public Comments and Peer Review of Formaldehyde Science Related to the Draft 2024 Toxics Substances Control Act (TSCA) Risk Evaluation for Formaldehyde

Dear Dr. Freedhoff,

On behalf of the American Chemistry Council (ACC) Formaldehyde Panel (Panel), I am writing to make sure the Environmental Protection Agency's (EPA or the Agency) Office of Chemical Safety and Pollution Prevention's (OCSPP) Office of Pesticide Programs (OPP) and Office of Pollution Prevention and Toxics (OPPT) are aware of the substantial comments submitted to EPA from a diverse group of stakeholders, experts, and peer reviewers raising major issues with the 2024 Draft Risk Evaluation for Formaldehyde (Draft Formaldehyde Risk Evaluation). The Final Formaldehyde Risk Evaluation will be used by EPA to inform potential future regulations under the Toxic Substances Control Act (TSCA) and under the Federal Insecticide, Fungicide, and Rodenticide Act. We respectfully request that the Agency take the public comments submitted to the EPA, along with feedback from peer review bodies, into serious consideration and provide thorough responses to these comments before finalizing the risk evaluation.

The Formaldehyde Panel has provided constructive and actionable written and oral comments to EPA to ensure the Agency is aware of and relying on information consistent with the best available science and based on the weight of the scientific evidence.[1] Any assessment of formaldehyde must begin with the best available science and the fact that formaldehyde is an ever-present part of the natural world that, through decades of responsible innovation and

[1] ACC Comments on Scientific and Legal Issues with EPA's Forthcoming Peer Review of Draft Evaluation of Formaldehyde under the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Mar. 8, 2024, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0007; and ACC Comments for the May 7th Virtual Preparatory Meeting, May 3, 2024; available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0148; and ACC Comments on the 2024 Draft Risk Evaluation for Formaldehyde, May 14, 2024, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0235. See also compiled comments here and in attendant IRIS, TSCA, and NASEM dockets: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0130.

regulation, has become essential to goods including contributing to a sustainable future for wood products, electric vehicles, national security applications, agriculture, lifesaving vaccines, and medical devices.[2]

On October 23, the Panel met with senior OPPT leaders to present new insights derived from EPA's Science Advisory Committee on Chemicals (SACC) review of the Draft Formaldehyde Risk Evaluation as well as interagency concerns raised on the underlying Integrated Risk Information System (IRIS) assessment of formaldehyde made available in August 2024. We were alarmed to hear that, despite the level of major scientific, legal, federal agency, state, Congressional, public, and peer reviewer issues raised this year and outlined in greater detail below, EPA still intends to finalize the risk evaluation by the end of 2024. Your staff also indicated that they have shifted to finalizing and formatting the risk evaluation and, given the timeline for finalizing the risk evaluation later this year following the public comment and the virtual SACC meeting in May, have not had the time to wait for the peer review report. Given TSCA's scientific standards, including the need to base decisions on the best available science (including independent validation of key methodologies), the weight of scientific evidence, and the integration of available information, this timeline and rushed process is troubling.

Finalizing the risk evaluation without addressing the key comments outlined in this communication would be inappropriate, inconsistent with best practices, and could suggest that the resulting regulations are not aligned with the best available science. This letter covers the following topics that must be addressed by EPA:

- Public Comments Received by EPA and its Peer Review Bodies
- EPA SACC Identified Flaws with the Draft Formaldehyde Risk Evaluation
- Diverse Group of Stakeholder Concerns with the Draft Formaldehyde Risk Evaluation
- Comments to EPA on the Lack of Alternatives/Substitutes for Critical Uses of Formaldehyde in Support of TSCA Exemptions that Could be Established Separate from the Risk Management Process
- Comments to EPA from Federal Agencies, State or Tribal Organizations, and Elected Officials
- Recent and Forthcoming Publications Relevant to EPA Formaldehyde Assessment
- Industry Request for Early SBREFA Consultation on TSCA Formaldehyde Review
- Interagency Coordination and Consultation on the Final Risk Evaluation and Ahead of Development of Proposed Risk Management

[2] Benefits & Applications - American Chemistry Council

I. EPA Must Respond to Public Comments Received by EPA and its Peer Review Bodies

EPA's risk evaluation framework rule makes clear that EPA and its peer review bodies must respond to and incorporate public comments.[3] The rule requires that EPA maintain a public docket for each risk evaluation to provide public access to "[a]ny final peer review report, including the response to peer review and public comments received during peer review" and "[r]esponse to public comments received on the draft scope and the draft risk evaluation."[4, 5]

This provision is consistent with EPA policies regarding peer review openness to considering public comment. EPA's Peer Review Handbook strongly encourages that EPA make draft work products as well as draft peer review charge questions available for the public and emphasizes the benefits of seeking these comments in advance of a peer review proceeding. It further outlines how public comments "inform the deliberations of the [federal advisory committee] as it reviews the draft EPA work product," noting that "[M]embers of the public can submit relevant comments pertaining to the group providing advice, the EPA's charge questions, EPA review of background documents, and draft advisory reports prepared by a [federal advisory committee] or its panels." Guidance for members from the EPA Science Advisory Board states "[p]ublic input, through written comments and oral statements at meetings, is an important part of the advisory process. Panel members are expected to consider public comments. If members find scientific information from the public helpful and informative, it is appropriate to acknowledge the information in the panel report." [6]

Four important reviews have been released evaluating EPA's formaldehyde science that are relevant to the draft risk evaluation:

- Most recently, in August 2024, the EPA Science Advisory Committee on Chemicals (SACC) released its final report and meeting minutes on their peer review of the draft risk evaluation of formaldehyde describing fundamental flaws that demonstrate failures to meet TSCA's scientific standards and process requirements.

- In August 2023, the National Academies of Sciences, Engineering, and Medicine Committee on the Review of EPA's 2022 Draft Formaldehyde Assessment (2022 NASEM committee) released a report describing its review of the adequacy and transparency of EPA's methods in the 2022 Draft IRIS Formaldehyde Assessment.

- Also in August 2023, the EPA Human Studies Review Board (HSRB) approved a report that described its review of the ethics and science related to four studies that EPA used in a weight-of-evidence evaluation for acute sensory irritation resulting from formaldehyde exposure.

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[3] EPA Final Rule*: Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, May 3, 2024, available at: https://www.federalregister.gov/documents/2024/05/03/2024-09417/procedures-for-chemical-risk-evaluation-under-the-toxic-substances-control-act-tsca

[4] See 40 CFR 702.49 -- Publicly available information.

[5] The Panel has submitted a wealth of public comm

[6] Peer Review Handbook 4th Edition (epa.gov)

- In 2011, a National Research Council (NRC) committee reported numerous still-relevant recommendations of a similar draft IRIS assessment. ACC has previously compiled these recommendations and explained in detail why they are legally required to be incorporated by EPA.[7] In addition, the 2022 NASEM Committee acknowledged that "The present committee did not review specific changes in the 2022 Draft Assessment against the recommendations in the 2011 NRC report…"

FACA requires that the public is afforded an opportunity to provide input into a process that may form the basis of government decisions. While all four peer review bodies held comment periods to hear from the public, only the SACC in 2024, HSRB in 2023 and NRC in 2011 meaningfully considered this input. The 2023 NASEM committee report, beyond mentioning that they had public comment periods, makes no mention of whether or how public input was used to inform its report. Considering the limited nature of the NASEM committee charge, and that the NASEM report states that the committee "was not charged with…. reviewing alternative opinions of EPA's assessment," it seems public comments were not considered by the NASEM committee. The limitations of the 2023 NASEM review should be kept in mind when considering the committee's final report.

II. EPA SACC Identified Flaws with the Draft Formaldehyde Risk Evaluation

From May 20-23, 2024, EPA held a four-day, virtual public meeting of its SACC to review its draft risk evaluation of formaldehyde. On August 2, 2024, EPA released the SACC final report and meeting minutes. The report highlights fundamental flaws that demonstrate that the draft risk evaluation fails to meet TSCA's scientific standards and process requirements. EPA's peer reviewers echoed important concerns the Panel has previously raised, including the failure to incorporate dozens of high-quality studies as well as assessments by authoritative bodies like the World Health Organization and European Union, that have been raised by other peer reviewers, scientific experts, and the public for over a decade.

According to amendments to TSCA adopted in 2016, EPA's TSCA risk evaluations must adhere to important scientific standards, including that they be based on best available science and the weight-of-scientific evidence, while integrating available information to support future regulatory actions. A fulsome review of the SACC report suggests numerous areas in which EPA's process and draft scientific conclusions have failed to achieve these high TSCA standards. The SACC review unequivocally identified many instances where the non-cancer and cancer hazard values presented in the EPA Draft (and now Final) Integrated Risk Information System (IRIS) Hazard Assessment do not rely on the best available science. Confusingly, the Executive Summary, which fails to incorporate the fundamental scientific criticisms in the report as well as

[7] ACC Letter to EPA Administrator Regan, March 10, 2022, Re: National Academies of Sciences, Engineering, and Medicine (NASEM) Review of EPA's 2022 Draft Formaldehyde Assessment, Available at: https://www.americanchemistry.com/content/download/10668/file/Formaldehyde-Panel-Follow-Up-Letter-to-EPA-031022.pdf.

past peer reviews and may not reflect the views of the individual panel members, incorrectly suggests that "the draft documents are comprehensive and rely on the best available science."[8, 9]

The SACC peer reviewers found that the TSCA program's reliance on a draft IRIS assessment inappropriate and they had significant concerns with the science in the assessment, in particular the report stated[10]:

- On chronic noncancer endpoints: "Concerns were raised by some Committee members regarding studies selected by ORD IRIS for chronic non-cancer hazards. These studies are mainly observational and unreliable for identifying a point of departure. The studies identified by ORD IRIS for the weight of evidence for chronic human health non-cancer hazard do not adequately address the chosen endpoint."

- On cancer endpoints: "Many Committee members recommended not using the IUR published in the 2022 Draft Formaldehyde IRIS assessment" with these members recommending use of "a mode of action approach where there is a threshold concentration below which no cancer is anticipated."

The SACC also raised several issues regarding the peer review and risk evaluation development process, similar to issues raised repeatedly by the Panel, for example:

- Failure to address past peer review recommendations, with the Committee noting that EPA received extensive comments from the National Academies of Science, Engineering, and Medicine and EPA's Human Studies Review Board and "the current draft does not… reflect these comments."
- Reliance on a draft IRIS assessment, noting that "[t]his document is heavily based on the Draft IRIS document, which has not been finalized, making it difficult to understand" the selection of health values.
- Failure to incorporate best available science from authoritative bodies, with the SACC describing that "EPA does not appear to have reviewed the work of other regulatory bodies to refine their methodology," including the European Union, World Health Organization, and Germany. Incorporating "international standards and guidelines," the report notes, would "achieve greater credibility, consistency in regulation, and acceptance" as well as "ensure exposure limits are consistent with the best available science."
- Failure to coordinate and consult with other parts of EPA or other federal agencies, identifying this as an "area in which the Committee felt strongly that the evaluation could benefit" from such cooperation and the resolution of differing perspectives.

[8] SACC Meeting Minutes and Final Report for the Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde, Aug. 2, 2024, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0298
[9] ACC Blogpost, Oct 31, 2024, available at: EPA Science Advisory Committee on Chemicals Identifies Issues with Formaldehyde TSCA Risk Evaluation - American Chemistry Council
[10] ACC Statement, Aug. 5, 2024, available at: EPA Science Advisors Confirm Foundational Flaws in Formaldehyde TSCA Risk Evaluation and IRIS Assessment - American Chemistry Council

- A rushed process with limited public interaction, with the Committee acknowledging "that timelines, information complexities, concerns from numerous stakeholders, and budgetary constraints further complicate the implementation of this" risk evaluation.
- Failure to use a transparent process for systematic review and use of weight scientific evidence, with key studies, peer reviews, and authoritative assessments identified as being excluded from EPA's TSCA risk evaluation and IRIS assessment.

III. Diverse Group of Stakeholders Expressed Concerns with the Draft Formaldehyde Risk Evaluation

During the SACC virtual public meeting nearly 40 public commenters from a variety of different sectors and backgrounds presented oral comments during the first two days, highlighting the legal, scientific, and economic issues with EPA's draft risk evaluation.[11] EPA must ensure that responses are provided to the comments raised by the public commentors.

EPA also held a preparatory virtual meeting with the peer reviewers on May 7 and peer reviewers raised a number of critical questions regarding the scope of the review and EPA's charge questions. More than 20 public speakers presented during the preparatory SACC meeting. None of the speakers supported EPA's draft risk evaluation or the limited scope and timing of the peer review. Key themes emphasized the exclusion of key issues from the peer review process, including the underlying IRIS assessment, draft occupational exposure value, and approach for unreasonable risk determinations, and the need to integrate TSCA scientific standards around best available science and the weight of scientific evidence.

During the SACC meetings, peer reviewers made it clear that the EPA had imposed upon them a rushed timeline that does not allow adequate and independent peer review. In advance of the meetings, a number of organizations asked EPA to extend the public comment period or hold in-person public meetings. EPA denied this request in April. It seems that EPA is prioritizing a hurried timeline over adherence to their peer review process. This is concerning, as it undermines the role of peer reviewers and may lead to a scientifically unsound risk evaluation.

In addition to ACC, numerous elected officials, trade associations, companies, and scientific experts have also submitted comments on the TSCA risk evaluation echoing these concerns and highlighting additional ones. The section below provides some illustrative examples of these comments.

[11] ACC Blogpost, May 31, 2024, available at: Diverse Group of Stakeholders, Experts, and Peer Reviewers Identify Major Issues with EPA's Draft Formaldehyde Risk Evaluation Under TSCA - American Chemistry Council

IV. Excerpts from Comments to EPA on Lack of Alternatives/Substitutes for Critical Uses of Formaldehyde in Support of TSCA Exemptions that Could be Established Separate from the Risk Management Process

For nearly all uses of formaldehyde, including uses that are essential to the national economy, national security, and critical infrastructure, there are no technically and economically feasible alternatives or cost-effective substitutes as required by sections 6(c)(2) and 6(g) of TSCA.[12] EPA has an obligation to ensure the final risk evaluation upholds the rigorous standards of TSCA while not impeding or unduly creating economic barriers. Below we have summarized comments from a wide variety of stakeholders expressing concerns regarding the lack of alternatives/substitutes for critical uses of formaldehyde.

Food, Agriculture, and Aquaculture

US Department of Agriculture (July 2024): "Given the significance and ubiquity of formaldehyde in commerce and in production, and the sheer volume of information contained in this review, USDA would note that the time provided for review was very short. USDA requests a more formal process to address issues related to this chemical. USDA also requests additional interagency conversations to discuss potential implications of this draft toxicological review on future regulatory actions for formaldehyde…. USDA notes that formaldehyde is both directly and indirectly very important in agriculture…. If those uses are threatened due to an overly conservative toxicological assessment of formaldehyde, that assessment could have a net adverse impact on human health and the environment."

California Department of Food and Agriculture (May 2024): "Due to the limited number of effective, FDA-approved or - allowed antiparasitics available to the aquaculture industry, access to formalin is highly critical for both food security and continued economic growth of the California and national aquaculture industries. With only three companies in the United States approved to manufacture and sell formalin for use in aquaculture, if the EPA's formaldehyde risk analysis inadvertently results in supply chain disruptions and/or significant price increases, aquaculture producers may face prohibitive costs and undue delays or barriers in accessing this critical therapeutic, which could ultimately increase the need to use antibiotics and threaten food security for our great state and nation."

American Association of Veterinary Laboratory Diagnosticians (May 2024): "Banning use of formaldehyde in the diagnostic laboratory setting would damage human and animal health. Formaldehyde, as a component of formalin, is an essential part of preparation of samples for microscopic examination in pathology. Despite extensive research, no suitable alternative for formalin has been identified to fix samples prior to processing…. Current alternatives to formalin

[12] For example, section 6(g) provides that the Administrator may, including in a separate rule, grant an exemption for a specific condition of use from TSCA requirements if they make certain findings related to that use. Two of the findings in support of such exemptions do not require consideration of compliance with a particular requirement ("the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure" or "the specific condition of use…, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.").

do not adequately replicate the performance of formalin for routine veterinary diagnostics. All current equipment in both human and veterinary diagnostic laboratories are designed to work with formalin-fixed tissues; if formalin cannot be used, all equipment may need to be replaced or modified to work with alternative fixatives. This would be cost-prohibitive for many University and state diagnostic laboratories, which are the current foundation of zoonotic disease and epizootic surveillance and response in the United States."

Association of Fish and Wildlife Agencies (June 2024): "State fish and wildlife agencies raise fish to be stocked in public waters for several reasons: to provide sportfishing opportunities for the public, to restore ecosystem balance, to conserve species, and to support the recovery of threatened and endangered species. Formalin, an aqueous solution of formaldehyde, has been used for many years to kill fungus on fish eggs and treat fish for external parasites. In many cases, there is no suitable alternative treatment for these applications. Formalin is therefore critical both to the efficiency of hatchery operations and to the welfare of raised fish…. While we acknowledge that the EPA cannot consider these impacts during its risk evaluation stage, we wanted to ensure that your office has this information so that these critical uses can be considered once the EPA moves into the rulemaking stage. We trust that any restrictions on the manufacturing and usage of formaldehyde-based products will be based on the best available science and will take into consideration the availability of alternatives and the negative impacts on end users, including State fish and wildlife agencies."

American Feed Industry Association (May 2024): "Formaldehyde is a very important tool in our toolbox to help keep salmonella out of our food chain by helping keep it out of animal food…. If we have an [African swine fever virus or ASF] outbreak in the United States, formaldehyde could prove to be the best tool in our toolbox to mitigate the risk of spreading the virus through feed. Estimates indicate that an ASF outbreak in our country could decimate the U.S. pork industry, reducing live hog prices by 40 percent to 50 percent, resulting in nearly $50 billion in economic losses to America's farmers. Shortages caused by such an outbreak would strain the U.S. food system and dramatically raise prices for consumers…. [TSCA] requires the EPA to consider the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health. Section 6(g) allows the EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the specific condition of use is a critical or essential use for which no technically and economically feasible safe alternative is available. The AFIA implore the SACC to seriously consider the public health consequences if formaldehyde containing feed additive products would no longer be available for use in the U.S. as a result of its review."

Northwest Indian Fisheries Commission (May 2024): "[I]t is also important to highlight the essential role of formalin (37% of formaldehyde dissolved in water) as a treatment in aquaculture settings and the lack of viable alternatives. Formalin is an FDA-approved fish drug commonly used to control mortality from external parasites and fungus in salmonid eggs and fish in aquaculture. It is one of the best understood and most effective drugs for this purpose. Untreated, external parasites and fungus can result in losses that are devastating to a hatchery program…. [We] request that EPA implement changes that allows the continued use of Formaldehyde in aquaculture operations until effective alternatives for use are identified and available. We respectfully request that the EPA stay mindful of the potential impacts to tribes and our treaty

rights that could result from the inadvertent burden of decreased accessibility to hatchery drugs during this risk evaluation process."

The Fertilizer Institute (May 2024): "There are no commercially available alternatives for FBRs (formaldehyde-based reactants) in urea [fertilizers] today…. As well, adoption of the draft evaluation as proposed could have severe economic impacts on the fertilizer industry and agricultural industry more broadly, potentially affecting the supply chain and global food production…. In the production of urea fertilizers, there are no established alternatives for formaldehyde-based reactants. If nitrogen manufacturers are unable to use formaldehyde to produce urea, there would be cascading impacts on the global fertilizer market and would increase the vulnerability to global supply chain disruptions. This decision could risk national food security, which is ultimately national security."

National Aquaculture Association (May 2024): "There is no known substitute or alternative to formalin that provides an equivalent balance of effectiveness and safety to fish, particularly with respect to the fungal parasites that are ubiquitous and cannot be eradicated or controlled through normal biosecurity practices."

National Corn Growers Association (May 2024): "NCGA urgers EPA to reflect on the real-world evidence presented by the fertilizer industry to fully appreciate the true risk in the supply chain for this critical input for the U.S. corn industry and the limited availability of alternatives…. If fertilizer manufacturers are not able to use formaldehyde and supply urea-based options domestically, this will shift demand to other, less efficient options for corn production, creating more disruptive measures into an already unpredictable market."

American Feed Industry Association, National Chicken Council, National Pork Producers Council, National Turkey Federation, U.S. Poultry & Egg Association (May 2024): "[Formaldehyde] is utilized as an essential tool for pathogen control in animal feed production as well as sterilization and disinfection in egg hatcheries. Formaldehyde also plays a critical role in disinfection for live production operations on poultry farms. Moreover, formaldehyde-based products can be used to inactivate highly contagious viruses, such as African swine fever (ASF) and Highly Pathogenic Avian Influenza (HPAI)…. If products become unavailable at the manufacturing and product formulation stage due to new TSCA regulatory burdens, some of the most important anti-microbial and biosecurity tools for poultry, egg, livestock and animal feed operations could be eliminated."

Other relevant comments from Anitox Corporation, U.S. Poultry & Egg Association, American Soybean Association, RISE, Pennsylvania Grange

Building & Construction

American Wood Council (May 2024): "Wood products made in the U.S. are a solution to reducing this overall footprint by reducing greenhouse gas emissions in two distinct ways – they store carbon and displace emissions from conventional carbon-intensive building materials…. Wood products also contain naturally occurring formaldehyde. The beautiful mass timber buildings that allow us to use smaller diameter trees that were not valued previously but that can

now be used to make taller structures use phenolic resins to glue the lumber together. You simply cannot have wood products without formaldehyde."

The Adhesive and Sealant Council (May 2024): "Members have expressed that there are no alternatives to formaldehyde for these conditions of use in the adhesives and sealants industry…. For this member, nearly 75% of their wood glue sales ($30 million) are comprised of cross-linking glues. At this time, there are no reasonable alternatives to provide the water-resistance, ease of use, safety, performance and value that their products currently provide. There are not formaldehyde-free alternatives to crosslinking PVAs used in water-resistant applications. Other types of technologies that might work are at present unproven and would likely be highly cost prohibitive…. The use of formaldehyde in water-resistant end use products, to date, has no proven alternate technologies. Formaldehyde in adhesives and sealants are also used in aerospace (which supplies the U.S. government) and medical markets. There are national security implications as products are supplied into aerospace markets for defense applications if formaldehyde were removed from the marketplace. There will be considerable impacts for consumers for critical products for their daily use, such as products supplied into electronics markets (e.g. semiconductors), automotive, packaging, building materials, and various consumer and commercial adhesives (formaldehyde residual/impurity). Essential items (automotive, electronics etc.,) for an average consumer, if re-formulation is needed or if EPA imposes workplace requirements, could result in substantially higher costs for consumers for the same products."

Asphalt Roofing Manufacturers Association (May 2024): "There is no viable substitute for asphalt shingles to meet the majority of residential roofing needs in the U.S. A ban on using formaldehyde-containing materials in asphalt roofing or fiberglass mat manufacturing, or a de facto ban in the form of unreasonably strict regulation of worker formaldehyde exposures in this industry, will result in a long-term disruption to the supply of a product that is essential to the nation's infrastructure. Moreover, the burden of needlessly strict regulations that significantly increase the initial cost of asphalt shingles or increase their maintenance and repair costs by compromising their longevity and fire/weather resistance, will fall disproportionately on low-income populations."

North American Insulation Manufacturers Association (May 2024): "While use of formaldehyde-based resins in the fiber glass insulation industry has been greatly reduced over the years, these resins continue to be used in certain products where a suitable substitute does not exist. A substitute is suitable only if it maintains product safety and performance requirements…. Some other products must still use PF binder because performance specifications cannot be met with non-formaldehyde alternatives."

Alliance for Chemical Distribution (May 2024): "Phenol formaldehyde resins are used in a wide range of building materials due to their flame retardancy, high thermal stability, water and chemical resistance, low cost, and flexibility. They are used in electrical components, paints and coatings, insulation, particleboard, and more. Alternative replacements are available and continue to be studied. Some are known or suspected human carcinogens however, including epichlorohydrin. These alternatives typically require more energy to produce and are not as effective as formaldehyde. There is also more waste associated with alternative materials."

Other relevant comments from the American Home Furnishings Alliance, International Wood Products Association, and National Retail Federation cautioned: “Before EPA considers actions that could disrupt businesses and jobs across the United States and have wide ranging implications beyond its regulations, EPA must consider the best information and science available.”

Other Manufacturing Uses

Aerospace Industries Association (May 2024): “[T]hese applications do not currently have qualified alternatives readily available. In cases where qualified alternatives may already exist, it is also important to recognize that they may not be considered drop-in replacements, and significant production changes and requalification may be necessary to facilitate a transition away from the material in question….it could take as long as 10 years to complete the necessary research and development.”

Alliance for Automotive Innovation (May 2024): “As EPA is aware, formaldehyde is a basic building block chemical that is essential to the manufacturing and processing of many products that serve as components of thousands of everyday consumer products. In the automotive sector, '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.'”

American Chemistry Council Diisocyanates Panel (May 2024): “Formaldehyde is a key building block for MDI production, and, by extension, the related polyurethane products used and relied on every day…. Without formaldehyde, the U.S. MDI industry would not be able to continue to support various key downstream sectors of the economy.”

American Foundry Society (May 2024): “Formaldehyde is used in foundries primarily in the form of chemical binder systems, or resin systems, produced from formaldehyde. These resin systems are used to produce molds and/or cores using a variety of different processes. While some chemical binder systems do not employ formaldehyde chemistry (particularly silicate and alkyd resins), these are niche applications. Approximately 96-97 percent of the binders sold today use formaldehyde-based resins in at least one component.”

Dow Chemical (May 2024): “Formaldehyde is considered a critical raw material in the production of 1) chelating agents and 2) polymeric Methylene Diphenyl Diisocyanate (PMDI). As there are no alternatives to date and without the ability to use formaldehyde, Dow and other manufacturers in the chemical industry would no longer be able to produce chelating agents or PMDI in the United States, which impacts downstream markets such as cleaning, agriculture, energy efficient appliances, cold chain supply chain, food and pharmaceutical security and infrastructure.”

Hexion (May 2024): “Formaldehyde’s versatile properties make it essential to a wide variety of end-uses, and formaldehyde and formaldehyde-based resins lack viable cost-effective or

technically feasible alternatives. In most instances, because of formaldehyde's unique physical and chemical properties, no compounds can replace it as a raw material without reducing critical performance characteristics or significantly increasing costs. In many cases, substitutes simply do not exist. For example, earlier this year, the Composite Panel Association released cradle-to-grave lifecycle assessments of North American particleboard and medium density fiberboard (MDF), critical components in the building, construction, and housing industries. In each case, 100 percent of resins used for particleboard and MDF production were amino-phenolic resins (including urea formaldehyde, melamine urea formaldehyde, and phenol formaldehyde resins) or polymeric methylene diphenyl di-isocyanate resins, all of which depend on the chemistry of formaldehyde manufacturing or import as a critical feedstock. U.S. EPA has failed to consider, assess, and integrate available information on the significant health, environmental, public safety, economic, security, and infrastructure benefits of formaldehyde usage. These omissions are part of an inconsistent, arbitrary, and capricious approach, with unclear criteria, for how EPA decides which uses and risks it evaluates and how it determines 'unreasonable risk' for these uses. ACC has catalogued the critical and essential sectors which rely on formaldehyde, including housing, building and construction, food and agriculture, aerospace, science and preservation, semiconductors, automotive, national security, and medicine and medical technologies…. Manufacturing, importing, and processing formaldehyde allows for: wood products that use more than 95 percent of a tree; FDA-approved therapeutants to combat fungi and ectoparasites for aquaculture facilities raising endangered or threatened species; housing affordability; sterilants and disinfectants to inactivate African Swine Fever; and slow-release fertilizers that increase yields, reduce runoff, and protect aquatic organisms."

Independent Lubricant Manufacturers Association (May 2024): "And while the industry has, for many years, endeavored to develop alternatives to formaldehyde-donor biocides, there are no meaningful substitute chemistries available on the market today."

IPC International, Inc (May 2024): "IPC's comments are focused on the use of formaldehyde as an essential reducing agent in electroless copper formation."

Ohio Chemistry and Technology Council (May 2024): "The economic impacts of limiting or banning the use of formaldehyde would be substantial. The chemistry is used in the processing and manufacturing of essential goods in a wide variety of industry sectors. The properties of formaldehyde make the substance affordable and effective, and alternatives will either sacrifice quality of our products or increase production costs further exacerbating inflation. In Ohio, formaldehyde is used in the automotive sector to make interior molded and under-the-hood components that allow for higher fuel efficiency. Formaldehyde is also critical in durable paints, primers, clear coats, and braking systems. Ohio also has a burgeoning semiconductor industry. Formaldehyde is used in specialty coatings, adhesives, solvents, and resins that are needed to manufacture those chips."

The Toy Association (May 2024): "Additionally, formaldehyde is a critical building block used in the production of a number of consumer and commercial products (such as plastics, processed wood materials and other catalyst and preservative functions). Due to formaldehyde being a critical building block of many materials, there are no substitutes for a number of the uses and applications that involve formaldehyde."

U.S. Tire Manufacturers Association (May 2024): "Our member companies operate tire manufacturing facilities which may use formaldehyde-containing reinforcing and tackifying resins, resorcinol formaldehyde latex dips, and formaldehyde-containing mold release agents."

Elected Officials

Congressman Bruce Westerman, Chairman of the House Natural Resources Committee and a forester, April 2024: "I write to share my concerns regarding the EPA's [IRIS] program, its risk assessment of formaldehyde, and the way this risk assessment could negatively impact important sectors of the economy *and* the environment…. it is hard to overstate the importance of formaldehyde as a chemical compound and the impact that an unachievable standard or an outright ban of this chemical could have. Among other uses are its role in developing more efficient wood products, preventing unnecessary deforestation, and protecting forest-dwelling animals and birds. Formaldehyde also plays a critical role in protecting salmon and steelhead populations, which is critical to hatcheries and fisheries across the United States, by controlling for disease and parasites."

Bipartisan Letter led by Rep. Don Davis (D-NC) and Lori Chavez Deremer (R-OR), April 2024: "Formaldehyde is an essential building block chemical that has been used safely for decades…Formaldehyde-based products are used in car interiors and under the hood parts. These products make cars safer and lighter, allowing for greater fuel efficiency…. Formaldehyde is used to protect against disease in livestock and aquaculture and helps increase crop yields and reduce fertilizer runoff…. Formaldehyde is used to make compounds found in many medical devices, including pacemakers, EpiPens, prostheses, and inhalers. It also is an ingredient in vaccines for influenza, polio, cholera, and other diseases. "

20 State Attorneys General, May 2024 comments: "As leading agriculture states in America, we worry that the proposed Final Rule will, in effect, ban formaldehyde and place billions of dollars of livestock at risk of disease, jeopardize the food supply, and threaten the entire agricultural industry. We urge the EPA to look at the best available science, reconsider its draft evaluation, and maintain the current regulatory levels."

Rep. Consuelo Hernandez (D-Tucson) in *Arizona Capitol Times*, December 2023: "But the recent reports around the EPA's assessment of formaldehyde, and the possibility of a risk evaluation that significantly overstates the risk associated with the chemical, runs counter to what the agency has done well in the past. Instead of protecting the country, the agency continuing down this path would hurt it. Formaldehyde, at its base, is a naturally occurring chemical that's used to produce numerous everyday products. It's used in car manufacturing, the airplanes we fly in, the vaccines we receive, the construction of buildings we live and work in. The list could go on. "

V. Excerpts from Comments to EPA from Federal Agencies, State or Tribal Organizations, and Elected Officials

Interagency consultation is extremely important. Federal agencies are the repositories of significant substantive expertise and experience. Interagency coordination ensures that actions taken by one agency do not conflict with the policies or actions of another agency, which could lead to inconsistent, incompatible, or duplicative policies. The interagency review process provides for identification and then aggregation of views and perspectives from numerous federal agencies. Additionally, it allows an agency to receive the specialized knowledge held by other agencies with related or overlapping jurisdiction. Numerous federal agencies have raised concerns about the scope of the review for formaldehyde for over a decade. Those concerns are summarized below.

Department of Defense (July 2024)

- "Because the draft IRIS formaldehyde assessment formed the basis of the now publicly available TSCA Formaldehyde risk evaluation, it is important that the IRIS final assessment is reviewed in the context of both the NASEM report and the SACC report. This is important from multiple perspectives including:
    1. Per the EPA draft policy on scientific integrity, EPA should 'Ensure peer review charge questions address all relevant scientific questions, including those raised in DSOs, and are free from any interference, especially interference that may inappropriately limit the scope of the review.'
    2. Ensuring that the SACC technical concerns regarding the IRIS assessment are addressed so that the toxicity assessment of formaldehyde is deemed by the SACC to be scientifically sound and appropriate for evaluating risk in the TSCA context and development of existing chemical exposure limits that will determine unreasonable risk from use of mission critical products that support defense and US critical infrastructure."

- "DoD requests that the SACC review report of the TSCA formaldehyde risk evaluation be made available prior to concluding review of the IRIS formaldehyde assessment so that the interagency is able to review SACC technical points of view relevant to the IRIS assessment and that the assessment addresses relevant scientific questions, including those raised in DSOs."

- "Since the SACC review is not available yet, DoD requests this IRIS interagency review be extended to provide additional time to consider SACC comments as they pertain to the IRIS assessment. Ultimately this will ensure a more robust and scientifically and legally defensible IRIS risk assessment, TSCA risk evaluation, and any subsequent EPA rulemakings for formaldehyde."

- "DoD requests that the interagency review process allow 45 days (after the final SACC report is published) to review the final IRIS assessment. See Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System | U.S. GAO."

Department of Agriculture (July 2024)

- "Given the significance and ubiquity of formaldehyde in commerce and in production, and the sheer volume of information contained in this review, USDA would note that the time provided for review was very short. USDA requests a more formal process to address issues related to this chemical. USDA also requests additional interagency conversations to discuss potential implications of this draft toxicological review on future regulatory actions for formaldehyde."

- "USDA notes that formaldehyde is both directly and indirectly very important in agriculture…. If those uses are threatened due to an overly conservative toxicological assessment of formaldehyde, that assessment could have a net adverse impact on human health and the environment."

- USDA also called for EPA to provide rationale, clarification, details, characterization, guidance, and explanation on key scientific issues that remain unresolved in the final IRIS assessment, including:

    - "[W]hy it is appropriate to conclude that formaldehyde causes lymphohematopoietic (LHP) cancers including acute myeloid leukemia when there is no evidence that formaldehyde enters the bone marrow or blood when inhaled."
    - "[A]bout the use of sensory irritation as an endpoint and a rationale for the [uncertainty factors] for this endpoint" as well as "clarification on whether IRIS considers irritation itself an adverse effect, or if IRIS considers it to be indicative of a systemic effect."
    - The use of age dependent adjustment factors, given that "it is not clear that different doses were fully considered by EPA."
    - Guidance for application of EPA toxicity values for different populations.
    - More details "about the likelihood of individuals staying in areas with high enough levels of formaldehyde to cause adverse effects…when people are likely to leave areas when they experience sensory irritation."
    - Reality check regarding the attribution of nasopharyngeal cancers.

Agency for Toxic Substances and Disease Registry (ATSDR) of the Centers for Disease Control (July 2024)

- "It is recommended that EPA allow for another round of interagency, peer review, and public commenting on this ToxReview to provide the scientific community time to assess whether they agree with this methodology and resultant [reference concentrations]. This sentiment is echoed by public commenters."

- "It is suggested that EPA convene discussions from the larger scientific community… regarding the issue of mode of action and the impact that it could have on evidence findings in systematic review."

- ATSDR notes that EPA "does not substantively respond to" significant comments from the 2011 National Academy of Science review or the public.

- ATSDR "disagrees with the lack of [EPA] response" to comments regarding failure to incorporate relevant literature, use of uncertainty factors, and lack of transparency, with the Agency explaining this "could detract [from] the confidence in the entire" final assessment.

- "It is recommended that EPA… further clarify, scientifically, why having a hypothesized mechanism of action is not a prerequisite [for identifying a hazard]."

White House Office of Management and Budget (Jan 2022)

- "[W]e are concerned with EPA's judgement of 'evidence demonstrates' for myeloid leukemia. Given the inconsistencies in the epidemiologic data and the lack of proposed MOA, it is not clear …. Claiming 'evidence demonstrates' while the confidence in the unit risk estimate is low and the data are limited may result in an overly conservative appreciation of the degree of hazard for myeloid leukemia, particularly considering no MOA has been established to explain how formaldehyde inhalation can cause myeloid leukemia, a disease that results from systemic exposure. The mechanistic information considered by EPA may support associations with local, route-of-exposure, tumors associated with epithelial cells, but does not support the tumorigenesis or carcinogenesis of disease related to systemic exposures."

Small Business Administration (Jan 2022)

- The Small Business Administration raised concerns about EPA "…making conclusions without being able to establish a MOA or without knowledge of mechanism(s) leading to cancer formation." They identified nearly a dozen key studies that had been excluded by EPA and flagged unanswered questions about the "mechanism by which exogenous formaldehyde create[s] 'extra' risks by adding to the endogenous formaldehyde."

Agency for Toxic Substances and Disease Registry (ATSDR) (Jan 2022)

- ATSDR argued that the lack of mechanistic data "needs to be a reason to down-grade the evidence findings. It is significant." ATSDR also stated that EPA's understanding of toxicokinetics of formaldehyde exposure to develop systemic reference concentrations "…doesn't make any sense" and examining confounding toxicities should happen "before making any evidence conclusion for formaldehyde." Furthermore, experts from ATSDR "disagree completely" with EPA's conclusions on female reproductive toxicity.

Department of Defense (Jan 2022)

- "The decision to go forward with a reference concentration that is not simply the lowest one calculated but is based on data in which Agency has higher confidence is appropriate."

In addition, commenters including federal agencies, state or tribal organizations, and elected officials raised fundamental concerns on both the TSCA and FIFRA risk evaluations for formaldehyde that relied on the Draft 2022 IRIS assessment.

The National Association of State Departments of Agriculture (May 2024)

- "EPA's reliance on the draft IRIS assessment is a fatal flaw and violates statutory requirements for best available science." (May 2024)

The California Department of Food and Agriculture (May 2024)

- "Notwithstanding EPA's exclusion of the aquaculture from the TSCA risk evaluation, CDFA AUS respectfully urges the EPA to proceed cautiously and in consultation with the best available science. The formaldehyde risk analysis findings may result in unintended consequences that inadvertently, negatively affect aquaculture and animal feed producers' legitimate access to formaldehyde for FDA-approved uses…. aquaculture producers may face prohibitive costs and undue delays or barriers in accessing this critical therapeutic, which could ultimately increase the need to use antibiotics and threaten food security for our great state and nation."

The Northwest Indian Fisheries Commission (May 2024)

- "EPA must consider how the TSCA process will impact the use of this drug in programs that sustain treaty fisheries and support the recovery of [Endangered Species Act]-listed stocks, and the ecological balance of our marine and freshwater ecosystems."

The Association of Fish and Wildlife Agencies (May 2024)

- Expressed concerns that an unreasonable risk determination for formaldehyde that is based on the IRIS assessment would "lead to reductions in threatened and endangered species husbandry programs, delaying the recovery and delisting of threatened and endangered fish species…We trust that any restrictions on the manufacturing and usage of formaldehyde-based products will be based on the best available science and will take into consideration the availability of alternatives and the negative impacts on end users, including State fish and wildlife agencies. They also expressed concern that "formalin produced overseas may not meet the strict quality controls of the FDA for use as a drug and so may not solve any shortage of the drug in the event of increased regulation."

The U.S. Department of Homeland Security (May 2024)

- Commented on their support for the continued laboratory use of formaldehyde for decontamination at their Plum Island Animal Disease Center which has "served as the nation's premier defense against accidental or international introductory of transboundary animal diseases —highly transmissible diseases of livestock and other animals, including foot-and-mouth disease (FMD) and African swine fever (ASF)—that can significantly affect food security, trade, and the economy."

The U.S. Department of Agriculture (May 2024)

- Provided EPA with information on the benefits of agricultural uses of formaldehyde and paraformaldehyde and its "importance to animal health and food safety."

The Washington State Department of Agriculture (May 2024)

- Provided comments related to a Special Local Need registration that allows use of formaldehyde as a dip-tank treatment for control of nematodes, insects, mites and certain plant pathogenic fungi on bulbs of daffodil in Washington State. The agency stated that it was "submitting this letter to help reframe uncertainties EPA identified regarding this SLN use pattern" and "to help provide realistic use estimates." (May 2024)

Bipartisan Group of Members of Congress (April 2024)

- Building on numerous Congressional letters to EPA raising concerns with EPA's formaldehyde activities under TSCA and IRIS since 2021, a bipartisan group of Members of Congress commented that EPA's risk evaluation which relies on the IRIS assessment could disrupt supply chains for the automotive, aerospace, building and construction, agriculture, defense, health care, and semiconductors industries. They also called on EPA to "undertake a comprehensive interagency review process."

State Attorneys General (May 2024)
Led by Brenna Bird of Iowa, a group of 20 State Attorneys Generals argued that EPA's action could "in effect, ban formaldehyde and place billions of dollars of livestock at risk of disease, jeopardize the food supply, and threaten the entire agricultural industry." These officials urged "EPA to look at the best available science, reconsider its draft evaluation, and maintain the current

VI. Recent and Forthcoming Publications Relevant to EPA Formaldehyde Assessment

The 2024 Final IRIS Assessment fails to fully incorporate the latest peer reviewed publications on formaldehyde. Just this year, several important studies and reviews have been published that are highly relevant to the assessment. In addition, a new multi-center international formaldehyde sensory irritation study is underway with results becoming available in the coming months. Below is more information for your consideration.

Recent 2024 Publications

- Vincent, Melissa J., Seneca Fitch, Lauren Bylsma, Chad Thompson, Sarah Rogers, Janice Britt, and Daniele Wikoff. "Assessment of associations between inhaled formaldehyde and lymphohematopoietic cancer through integration of epidemiological and toxicological evidence with biological plausibility." *Toxicological Sciences* (2024). Available at: https://doi.org/10.1093/toxsci/kfae039.
    - Vincent et al., 2024, conducted a systematic review focusing on the relationship between formaldehyde and LHP cancers, including myeloid leukemia. This systematic review found "no credible explanation linking inhaled formaldehyde to LHP cancers, and no evidence of formaldehyde entering the bone marrow or blood when inhaled" and determined that causation is unlikely.

- Goyak, Katy, and Stewart Holm. "Sensory irritation and use of the best available science in setting exposure limits: Issues raised by a scientific panel review of formaldehyde

human research studies." *Regulatory Toxicology and Pharmacology* (2024): 105587. Available at: https://doi.org/10.1016/j.yrtph.2024.105587.

- Goyak and Holm, 2024, highlight that formaldehyde short-term exposure limits often protect against sensory irritation, scientific panels consistently recommend no adjustment for exposure duration, scientific panels consistently recommend no adjustment for human variability, and scientific consensus should be considered in the upcoming TSCA risk evaluation.

- Lauer, Daniel J., Anthony J. Russell, Heather N. Lynch, William J. Thompson, Kenneth A. Mundt, and Harvey Checkoway. "Triangulation of epidemiological evidence and risk of bias evaluation: A proposed framework and applied example using formaldehyde exposure and risk of myeloid leukemias." *Global Epidemiology* 7 (2024): 100143. Available at: https://doi.org/10.1016/j.gloepi.2024.100143.
    - Lauer et al., 2024 developed a triangulation framework and applied it to occupational formaldehyde exposure and risk of myeloid leukemia and found that "most reported epidemiological results do not demonstrate statistically significant associations between occupational exposure to formaldehyde and risk of ML, AML or CML."

- Salthammer, Tunga. "The reliability of models for converting formaldehyde emissions from wood-based materials to different environmental conditions." *Building and Environment* 247 (2024): 111041. Available at: https://doi.org/10.1016/j.buildenv.2023.111041.
    - Salthammer 2024 compares and evaluates empirical models for the conversion of formaldehyde concentrations, presents parameters for the statistical prediction of formaldehyde concentrations, finds that a simple linear conversion of chamber concentrations for exposure assessments is not possible, and reports that tolerance limits of test chamber settings cause uncertainties that cannot be neglected.

- Cox Jr, Louis A., William J. Thompson, and Kenneth A. Mundt. "Interventional probability of causation (IPoC) with epidemiological and partial mechanistic evidence: benzene vs. formaldehyde and acute myeloid leukemia (AML)." *Critical Reviews in Toxicology* (2024): 1-38. Available at: https://www.tandfonline.com/doi/full/10.1080/10408444.2024.2337435
    - Cox et al., 2024 concludes that "no causal pathway leading from formaldehyde exposure to increased risk of AML was identified, consistent with much previous mechanistic, toxicological and epidemiological evidence."

Multi-Center Formaldehyde Sensory Irritation Study

The IRIS Formaldehyde Assessment inappropriately relies on flawed epidemiological studies instead of existing controlled human exposure studies, which are considered the "gold standard" for evaluations of human risks. In a controlled human exposure study, subjects are known, exposures are known, and confounders are known and controlled. It is well accepted that a randomized control study will always be preferred, and, although often difficult and expensive, controlled human exposure studies are the most reliable for evaluating cause and effect.

Formaldehyde's unique chemistry, including the fact that it does not follow Haber's Law, must be appropriately weighed and considered when looking at the best available science to inform the human health assessment.

In the case of formaldehyde, multiple high quality controlled human exposure studies exist and should be used. In particular, the results of an ongoing multi-center formaldehyde sensory irritation study are expected to be available in the coming months. The study is designed to address some of the outstanding questions with controlled human exposure studies of formaldehyde odor, irritation, and symptom response. It is the largest study of its kind ever performed and is being carried out at the Monell Chemical Senses Center in Philadelphia and the Leibniz Center for Working Environment and Human Factors (IfaDo) in Dortmund, Germany. The protocols for these studies have been approved by the respective Institutional Review Boards for the protection of human research participants and the responses to be studied do not represent adverse health effects but rather physiological responses that provide a warning signal of exposure ranging from odor detection to chemesthesis (e.g., tingling or burning) or an adaptive response (e.g., eye-blinking).

More information can be found in the existing EPA dockets:

- The Monell study synopsis and study protocol were shared with EPA and are available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0117.
- Comments from Dr. Pamela Dalton, Principal Investigator, Monell Chemical Senses Center, to the EPA SACC are available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0231.
- Comments from Dr. Christoph van Thriel, Principal Investigator, Leibniz Center for Working Environment and Human Factors (IfaDo), to the EPA SACC are available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0179.

VII. Industry Seeks Early SBREFA Consultation on TSCA Formaldehyde Review

In October 2023, a group of nine small business trade associations formally requested EPA convene a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel *before* finalization of the formaldehyde risk evaluation. As stated in the letter, "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 small business trade associations that signed the request collectively represent industries that include at least 70,000 small firms engaged in the production or use of formaldehyde and formaldehyde-related products, including the American Feed Industry Association, American Home Furnishings Alliance, Business and Institutional Furniture Manufacturers Association, Catfish Farmers of America, Composite Panel Association, Florida Aquaculture Association, Kitchen Cabinet Manufacturers Association, National Aquaculture Association, and National Funeral Directors Association. [13] To date, EPA has yet to announce the formation of a SBREFA Panel..

[13] Request for SBREFA Panel on Proposed Formaldehyde Management Standards under the Lautenberg Act, October 6, 2023, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0126.

VIII. EPA Should Seek Interagency Coordination and Consultation on the Final Risk Evaluation and Ahead of Development of Proposed Risk Management

Section 9 of TSCA contains important requirements related to interagency and interagency coordination and consultation for risk evaluations and risk management rules, and EPA should begin dedicated engagement with other federal agencies immediately to address these obligations and resolve major concerns related to formaldehyde. Section 9(d) directs the Administrator to "consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes." Section 9(b) requires coordination TSCA actions "with actions taken under other Federal laws administered in whole or in part by the Administrator" and, if taking action under TSCA versus other laws, to compare costs and efficiencies of this choice. Section 9(e) further requires that EPA shall make available to other federal agencies and offices any obtained "information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administrated by the Administrator."

Based on a review of the comments from other agencies outlined above and a review of the docket, it appears that no such coordination, consultation, referrals, or comparisons have taken place. We note that, even under EPA's recently updated risk evaluation framework rule, "EPA will consult with other relevant federal agencies" during the risk evaluation process.[14] In addition to the highly critical comments above from agencies that had a brief opportunity to comment on the underlying final IRIS assessment, the U.S. Small Business Administration has also raised similar concerns about the absence of meaningful engagement. This included a request to extend the public comment period on the Draft Formaldehyde Risk Evaluation noting that the 60-day comment period "does not give small entities enough time to analyze both the draft risk assessment and associated materials" and that "[i]t is vital to obtain small entity input early in the regulatory process, at the draft risk assessment stage, rather than wait for an eventual proposed rule."[15] These formaldehyde-specific concerns were also reflected in SBA comments on the risk evaluation process, where the Administration argued that the absence of robust interagency review for risk evaluation "create a significant risk that the resulting risk management regulations will impose unnecessary and duplicative burdens on small businesses with minimal public health benefits" and that "it is not a good use of EPA's resources to duplicate the effort an expertise of these other federal offices."[16]

Starting TSCA-required interagency consultation, coordination, and referral now will lead to a more defensive, less duplicative risk management process that reduces uncertainty and accelerates important consideration of critical uses of formaldehyde for the defense, agricultural, medical, housing, aerospace, and transportation sectors.

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[14] 40 CFR 702.47.
[15] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0091.
[16] https://advocacy.sba.gov/wp-content/uploads/2023/12/Comment-Letter-TSCA-Process-Rule-508.pdf.

The Panel encourages the EPA to ensure that the formaldehyde risk evaluation complies with EPA policies and procedures, effectively addresses public and peer reviewer comments, and is based on the best available scientific. If you have any questions, please reach out to Sahar Osman-Sypher at sahar_osman-sypher@americanchemistry.com or 202-249-6721.

Sincerely,

Sahar Osman-Sypher
Senior Director
Chemical Products & Technology Division
American Chemistry Council
On Behalf of the ACC Formaldehyde Panel

Cc: Elissa Reaves, Mark Hartman, Jeff Morris, US EPA