THE ATTORNEYS GENERAL OF NEW YORK, CALIFORNIA, THE DISTRICT OF COLUMBIA, ILLINOIS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, OREGON, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN

February 2, 2026

Via Electronic Filing

EPA-HQ-OPPT-2018-0438

Administrator Lee Zeldin
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: ***Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability and Request for Comment*, 90 Fed. Reg. 55,726 (Dec. 3, 2025)**

Dear Administrator Zeldin:

The Attorneys General of New York, California, the District of Columbia, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Oregon, Rhode Island, Vermont, Washington, and Wisconsin (together, the "States") submit these comments regarding the U.S. Environmental Protection Agency's ("EPA") updated draft risk calculation memorandum for formaldehyde (the "Draft Risk Calculation"), 90 Fed. Reg. 55,726 (Dec. 3, 2025), which EPA signals it will use to modify the final formaldehyde risk evaluation that EPA published in January 2025 (the "Final Risk Evaluation"), 90 Fed. Reg. 316 (Jan. 3, 2025).

The Draft Risk Calculation, if finalized and incorporated into the Final Risk Evaluation, would weaken the Final Risk Evaluation by almost doubling the concentration of formaldehyde that EPA considers safe to inhale on a short-term basis. Most notably, the Draft Risk Calculation proposes to change how EPA calculates acute and chronic health risks associated with inhaling formaldehyde, a highly toxic chemical that, according to EPA, causes greater risk of cancer than any other toxic air pollutant.[1] The Draft Risk Calculation also manipulates the uncertainty factors associated with these risks and arbitrarily rejects the use of health hazard values derived from EPA's own Integrated Risk Information System ("IRIS"), a health assessment program that employs the best available science. EPA's rejection of this science and failure to adequately justify its reasoning violate both the Toxic Substances Control Act[2] ("TSCA") and EPA's own regulations and guidance. If finalized, the Draft Risk Calculation would undermine EPA's ability to manage the risks associated with formaldehyde. Accordingly, the States oppose the Draft Risk Calculation in its entirety and urge EPA to withdraw it.

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[1] EPA, *2020 AirToxScreen: State Average Cancer Risk by Pollutant*, https://www.epa.gov/system/files/documents/2025-01/national_cancerrisk_by_state_poll.xlsx [hereinafter *2020 AirToxScreen*].
[2] 15 U.S.C. §§ 2601 *et seq.*

I. Background

A. The Toxic Substances Control Act

Congress enacted TSCA in 1976 for the purpose of "prevent[ing] unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances."[3] In 2016, recognizing that TSCA was not achieving its promise, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act")[4] with bipartisan support to "provide broad protection of human health and the environment" and "improve availability of information about chemicals."[5] The Lautenberg Act requires EPA to conduct risk evaluations of "high priority" substances, which are defined as chemicals that, "without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment."[6]

Each risk evaluation must assess whether the chemical under review does in fact present such an unreasonable risk by analyzing the hazards and exposures associated with a chemical's "conditions of use," that is, "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[7] EPA first prepares a scoping document that outlines the focus of the risk evaluation, including a chemical's hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations.[8] EPA then conducts its risk evaluation, pursuant to which it must: (1) integrate and assess the hazards and exposures for all the chemical's conditions of use, including information on potentially exposed or susceptible subpopulations; (2) describe whether EPA considered aggregate or sentinel exposures under the chemical's conditions of use; (3) account for the likely duration, intensity, frequency, and number of exposures under the chemical's conditions of use; (4) describe the weight of the scientific evidence for each hazard and exposure; and (5) omit consideration of costs and other nonrisk factors,[9] *i.e.*, "the costs or benefits of the substance or possible restrictions on the substance" under other statutory schemes.[10] Finally, EPA determines whether the chemical under review presents an unreasonable risk to health or the environment.[11] In conducting this evaluation, EPA must use the "best available science," base its decisions "on the weight of the scientific evidence," and consider all "reasonably available information."[12]

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[3] S. Rep. No. 94-698, at 1 (1976); *see Safer Chems. v. EPA*, 943 F.3d 397, 406–07 (9th Cir. 2019) (discussing Congress's purpose in enacting TSCA).
[4] Pub. L. No. 114-182, 130 Stat. 448 (2016).
[5] S. Rep. No. 114-67, at 6 (2015).
[6] Lautenberg Act § 6(3), 130 Stat. at 461–63 (codified at 15 U.S.C. § 2605(b)(1)(A), (b)(2)(B), (b)(3)(A)).
[7] 15 U.S.C. § 2605(b)(4)(A), (b)(4)(F).
[8] *Id.* § 2605(b)(4)(D). A "potentially exposed or susceptible subpopulation" means "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at a greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." *Id.* § 2602(12).
[9] *Id.* §§ 2602(4), 2605(b)(4)(A), (b)(4)(F).
[10] S. Rep. 114-67, at 17.
[11] 15 U.S.C. § 2605(b)(4)(A).
[12] *Id.* § 2625(h)–(i), (k); 40 C.F.R. § 702.37(a)(2).

Once EPA has completed a risk evaluation and determined that a chemical presents unreasonable risk, it must promulgate a risk management rule that prohibits, restricts, or otherwise regulates the manufacturing, processing, or distribution in commerce of the chemical "to the extent necessary" so that the chemical no longer presents an unreasonable risk.[13] Such regulations include occupational exposure limits, use restrictions, limitations on production, warning labels, recordkeeping, and product and disposal bans.

When conducting a risk evaluation or promulgating a risk management rule under TSCA, EPA must satisfy both the Administrative Procedure Act's ("APA") arbitrary-and-capricious standard[14] and TSCA's requirement that risk evaluations be "supported by substantial evidence in the rulemaking record taken as a whole."[15] TSCA's "substantial evidence" standard is "particularly demanding," requiring "that the reviewing court engage in a searching review of the Administrator's reasons and explanations for the Administrator's conclusions."[16]

B. Formaldehyde Sources and Health Effects

Formaldehyde is a colorless, flammable gas that is found "nearly everywhere."[17] The chemical is naturally occurring, but it is also released into the air by combustion (*e.g.*, exhaust from vehicles, smoke from wood or gas stoves, forest fires) and when used or produced in commercial or industrial operations to make plastics, pesticides, paints, adhesives, sealants, and composite wood products.[18] EPA estimates that between 1 billion and 5 billion pounds of formaldehyde are manufactured in or imported into the United States every year.[19] The chemical is so ubiquitous in part because it is versatile, serving variously as a preservative, binder, and anti-microbial agent.[20]

Formaldehyde is also toxic. Acute inhalation exposure to formaldehyde can cause sensory irritation to the eyes and respiratory tract, including sensations of burning, sneezing, coughing, and sore throat,[21] and exposure to very high concentrations is immediately dangerous to life and health.[22] Long-term exposure can contribute to the development of asthma; a decline in pulmonary and respiratory function; a decrease in fertility, including increased chance of miscarriage; the manifestation of various skin conditions; and the development of various

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[13] 15 U.S.C. § 2605(a), (c)(1).
[14] *See id.* § 2618(c)(1)(B) (incorporating the APA standard of review from 5 U.S.C. § 706).
[15] *Id.* § 2618(c)(1)(B)(i).
[16] *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 991–92 (D.C. Cir. 1988) (emphasis omitted) (citations omitted).
[17] 90 Fed. Reg. at 317.
[18] *Id.*
[19] *Id.*
[20] EPA, EPA-740-R-24-016, Conditions of Use of the Risk Evaluation for Formaldehyde 32–35, 38, 41, 47–48, 52, 56 (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/12.-formaldehyde-.-conditions-of-use-.-public-release-.-hero-.-dec-2024.pdf.
[21] EPA, EPA/635/R-24/162aF, IRIS Toxicological Review of Formaldehyde (Inhalation) 3-10 to -11 (Aug. 2024), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549612 [hereinafter IRIS Toxicological Review].
[22] Occupational Safety & Health Admin., OSHA Fact Sheet: Formaldehyde (2011), https://www.osha.gov/sites/default/files/publications/formaldehyde-factsheet.pdf.

cancers, including myeloid leukemia and cancers of the upper respiratory tract.[23] The risk of these adverse health impacts may be greater for infants and children, people of reproductive age, and people with preexisting health conditions like asthma or allergies.[24] According to EPA's 2020 Air Toxics Screening Assessment, formaldehyde poses a far greater cancer risk than any other toxic air pollutant, in part because it exists in such large quantities.[25]

Inhalation exposure to formaldehyde is a concern throughout the country. Workers who spend time in workplaces where formaldehyde is made or used are at the highest risk of exposure.[26] EPA previously estimated the numbers of workers in various industries who are directly engaged with formaldehyde-containing substances, as well as the numbers of occupational non-users ("ONUs") who work in places where formaldehyde is present but whose duties are not directly associated with its manufacture, processing, or production. According to EPA, major sources of occupational exposure to formaldehyde include: industries that use automotive care products, such as car waxes, polishes, and coatings (approximately 339,000 workers and 35,000 ONUs exposed); industries that use printing ink, toner, and colorant products containing formaldehyde (approximately 113,000 workers and 53,000 ONUs exposed); and industries that process formaldehyde as a reactant, which include industries that produce plastic products, paper, fertilizer, wood, and petroleum (approximately 63,000 workers and 28,000 ONUs exposed).[27]

Frequent users of formaldehyde-containing products face the next-highest risk. Formaldehyde is present in consumer products and articles, including clothing, composite wood products, plastics, furniture, construction materials, paint, and toys.[28] But even people who do not work with or regularly use formaldehyde-containing products are exposed to formaldehyde, as the chemical is ubiquitous. Indeed, formaldehyde is often present in indoor air, especially in spaces where formaldehyde-containing products have been recently installed, like in new houses

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[23] EPA, IRIS Toxicological Review, *supra* note 21, at 3-36 to -37, -77 to -78, -201 to -202, -393 to -394, -450 to -451; Laura E. Beane Freeman et al., *Mortality from Lymphohematopoietic Malignancies Among Workers in Formaldehyde Industries: The National Cancer Institute Cohort*, 101 J. Nat'l Cancer Inst. 751 (2009).
[24] EPA, IRIS Toxicological Review, *supra* note 21, at 4-2 to -4; EPA, EPA-740-R24-017, Unreasonable Risk Determination of the Risk Evaluation for Formaldehyde 10 (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/37.-formaldehyde-.-unreasonable-risk-determination-.-public-release-.-hero-.-dec-2024.pdf [hereinafter Unreasonable Risk Determination].
[25] EPA, *2020 AirToxScreen*, *supra* note 1; *see also* Sharon Lerner & Al Shaw, ProPublica, *Formaldehyde Causes More Cancer Than Any Other Toxic Air Pollutant. Little Is Being Done to Curb the Risk.* (Dec. 3, 2024), https://www.propublica.org/article/formaldehyde-epa-trump-public-health-danger.
[26] EPA, Revised Draft Executive Summary of the Risk Evaluation for Formaldehyde 3 (Dec. 2025), https://www.epa.gov/system/files/documents/2025-12/10-formaldehyde-revised-draft-executive-summary-of-the-risk-evaluation-for-formaldehyde-public-release-december-2025.pdf.
[27] EPA, Occupational Exposure Assessment for Formaldehyde 270–72, 301–02, 304–05 (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/14.-formaldehyde-.-occupational-exposure-assessment-.-public-release-.-hero-.-dec-2024.pdf [hereinafter Occupational Exposure Assessment].
[28] EPA, Consumer Exposure Assessment for Formaldehyde 7 (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/18.-formaldehyde-.-consumer-exposure-assessment-.-public-release-.-hero-.-dec-2024.pdf.

or mobile homes.[29] Formaldehyde is also present in ambient air, with people living close to formaldehyde-releasing facilities facing the greatest risk of exposure.[30]

C. The Final Risk Evaluation

EPA designated formaldehyde as a high-priority substance for risk evaluation in December 2019.[31] In April 2020, EPA published a draft scope for the risk evaluation.[32] Many of the States submitted comments critiquing the draft scope as missing key information EPA was statutorily obligated to include.[33] EPA finalized the scope of the formaldehyde risk evaluation in September 2020.[34]

In March 2024, EPA published a draft formaldehyde risk evaluation for public comment and external peer review.[35] The draft risk evaluation incorporated hazard information from IRIS's Toxicological Review of Formaldehyde (the "IRIS Toxicological Review"), a comprehensive assessment that was submitted for peer review by the National Academies of Sciences, Engineering, and Medicine ("NASEM").[36] EPA also submitted the draft risk evaluation for peer review by a federal advisory committee, the TSCA Science Advisory Committee on Chemicals (the "SACC"), and submitted a limited portion of the draft for review by another federal advisory committee, the Human Studies Review Board (the "HSRB").

EPA received numerous comments from peer reviewers and the public regarding the draft risk evaluation.[37] While expert peer reviewers generally supported the draft risk evaluation, and while a number of environmental and health advocacy groups urged EPA to acknowledge additional risks stemming from formaldehyde exposure, certain regulated industry groups criticized the draft risk evaluation as overly protective of human health.[38]

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[29] *See generally* EPA, Indoor Air Exposure Assessment (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/22.-formaldehyde-.-indoor-air-exposure-assessment-.-public-release-.-hero-.-dec-2024.pdf.

[30] *See generally* EPA, Ambient Air Exposure Assessment (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/24.-formaldehyde-.-ambient-air-exp-assessment-.-public-release-.-hero-.-dec-2024.pdf.

[31] High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances, 84 Fed. Reg. 71,924 (Dec. 30, 2019).

[32] Draft Scopes of the Risk Evaluations to Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act, 85 Fed. Reg. 22,733 (Apr. 23, 2020).

[33] Multistate Comments on EPA's Draft Scopes of the Risk Evaluations to Be Conducted for Seven Chemical Substances Under the Toxic Substances Control Act (June 8, 2020), https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0131-0046.

[34] Final Scopes of the Risk Evaluations to Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act, 85 Fed. Reg. 55,281 (Sept. 4, 2020).

[35] Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC), 89 Fed. Reg. 18,933 (Mar. 15, 2024).

[36] 90 Fed. Reg. at 317; EPA, IRIS Toxicological Review, *supra* note 21.

[37] EPA, Response to Science Advisory Committee on Chemicals (SACC) Peer Review and Public Comment on the Human Health Risk Evaluation for Formaldehyde (Dec. 2024) [hereinafter Response to Comments], https://www.epa.gov/system/files/documents/2025-01/59.-formaldehyde-.-response-to-comments-.-public-release-.-hero-.-dec-2024.pdf.

[38] *See* Am. Chem. Council's Formaldehyde Panel, American Chemistry Council Comments on the 2024 Draft Risk Evaluation for Formaldehyde Prepared Under the Toxic Substances Control Act 6 (May 14, 2024), https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0235/attachment_1.pdf ("By relying on hazard information developed for the IRIS program, the TSCA risk evaluation is now relying on endpoints that define and mitigate risk well beyond the level required by statute.").

On January 3, 2025, EPA published the Final Risk Evaluation.[39] In it, EPA evaluated risk from inhalation and dermal exposure on various population groups, including (1) workers who are directly engaged with the manufacture, processing, or production of formaldehyde, (2) ONUs, whose duties are not directly associated with formaldehyde's manufacture, processing, or production, (3) consumers of formaldehyde-containing products, and (4) the general public.[40] In evaluating the potential harm to workers and ONUs, EPA calculated risk estimates for both "high-end" exposure—representing the 95th percentile of anticipated exposure—and "central tendency" exposure—representing the 50th percentile of anticipated exposure.[41] "[T]o account for a range of possible workplaces," EPA did not assume that workers wore personal protective equipment ("PPE") when calculating their expected risk.[42] And recognizing that formaldehyde may affect some individuals more or differently than others, EPA used an intraspecies uncertainty factor of 3 to estimate the amount of formaldehyde that humans can inhale before they begin to suffer acute, non-cancer symptoms.[43]

Relying in large part on the results of the IRIS assessment, EPA, in the 2025 Final Risk Evaluation, found that formaldehyde presents an unreasonable risk of injury to human health through acute inhalation and dermal exposures, as well as through long-term inhalation.[44] EPA determined that 50 out of 51 occupational conditions of use and 8 out of 12 consumer conditions of use significantly contributed to this finding.[45] These conditions of use include, for example, the processing of agricultural chemicals and asphalt, construction activities, and consumers' use of various fabrics, bedding, paper, and automotive products.[46] EPA found that formaldehyde's conditions of use unreasonably contribute to the risk of cancer and non-cancer effects in workers and ONUs, as well as non-cancer effects in consumers and bystanders.[47]

With the Final Risk Evaluation complete, EPA stated that it would initiate risk management actions to ensure that formaldehyde does not present an unreasonable risk under its conditions of use, as required by 15 U.S.C. § 2605(a).[48] Pursuant to TSCA, EPA was required to propose a formaldehyde risk management rule by January 5, 2026, and to finalize that rule by January 4, 2027.[49] EPA, however, has already missed the deadline to propose the formaldehyde risk management rule.

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[39] 90 Fed. Reg. 316.
[40] EPA, Unreasonable Risk Determination, *supra* note 24, at 9.
[41] EPA, EPA-740-R-24-015, Human Health Risk Assessment for Formaldehyde 93 (Dec. 2024), https://www.epa.gov/system/files/documents/2025-01/13.-formaldehyde-.-human-health-risk-assessment-.-public-release-.-hero-.-dec-2024.pdf [hereinafter Human Health Risk Assessment].
[42] *Id.* at 29.
[43] *Id.* at 86.
[44] EPA, Unreasonable Risk Determination, *supra* note 24, at 4.
[45] *Id.*
[46] *Id.* at 5–7.
[47] *Id.* at 9.
[48] 90 Fed. Reg. at 318.
[49] 15 U.S.C. § 2605(c)(1) (requiring publication of draft risk management rule within one year of publication of final risk evaluation and final risk management rule within two years of publication of final risk evaluation). Because January 3, 2026, was a Saturday, the deadline to publish a draft risk management rule was Monday, January 5, 2026. 45 C.F.R. § 16.19. Because January 3, 2027, will be a Sunday, the deadline for the final risk management rule will be Monday, January 4, 2027.

D. The Draft Risk Calculation

Instead of timely proposing a formaldehyde risk management rule, on December 3, 2025, EPA issued its Draft Risk Calculation, which proposes to reconsider the use of certain hazard values in the Final Risk Evaluation.[50] In particular, and as explained further below, EPA proposes to adopt a revised acute inhalation point of departure and revised uncertainty factor associated with that point of departure, resulting in a less protective acute inhalation standard. In addition, EPA proposes to discontinue the use of the IRIS chronic non-cancer reference concentration ("RfC") and cancer inhalation unit risk ("IUR") in favor of that less protective acute inhalation standard, thereby shirking its obligation to consider the health effects associated with chronic exposure to formaldehyde.

With regard to acute risk, EPA proposes to increase the amount of formaldehyde that is considered safe for humans to inhale on a short-term basis. EPA does this in two steps by simultaneously (1) decreasing the acute inhalation point of departure—the estimated exposure level at which, based on initial extrapolation from human and animal studies, no acute adverse health effects are observed to occur—from 0.5 parts per million ("ppm") to 0.3 ppm, and (2) lowering the uncertainty factor associated with that point of departure from 3 to 1, thereby assuming that there is no variability among humans' response to formaldehyde.[51] While the first step (decreasing the point of departure) by itself would have increased protection against acute exposure, the second step (decreasing the uncertainty factor) cancels out any health-protective effects of the first step and results in a far weaker standard than in the 2025 Final Risk Evaluation. Together, these two proposed changes would almost double the concentration of formaldehyde considered safe for humans to inhale on a short-term basis, from 0.167 ppm (0.5 ppm divided by an uncertainty factor of 3) to 0.3 ppm (0.3 ppm divided by an uncertainty factor of 1).[52] EPA does not adequately explain the practical consequences of changing the uncertainty factor from 3 to 1, and those unfamiliar with TSCA risk calculations could easily be misled into

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[50] 90 Fed. Reg. 55,726.

[51] *Id.* at 55,730; EPA, Revised Draft Human Health Hazard Assessment for Formaldehyde 23 (Dec. 2025), https://www.epa.gov/system/files/documents/2025-12/8-formaldehyde-revised-draft-human-health-hazard-assessment-for-formaldehyde-public-release-december-2025.pdf [hereinafter Revised Health Hazard Assessment]. EPA uses uncertainty factors to account for limitations in its risk assessment process. For example, uncertainty factors are used to account for variation in sensitivity within the human population, uncertainty in extrapolating from animal data to humans, and uncertainty in extrapolating from data obtained from a study involving less-than-lifetime exposure to the risk of lifetime exposure. Generally, to estimate the level of exposure unlikely to appreciably increase the risk of adverse health effects, EPA divides the point of departure by the product of its associated uncertainty factors. EPA, EPA/630/P-02/002F, A Review of the Reference Dose and Reference Concentration Processes 4-38 (Dec. 2002), https://www.epa.gov/sites/default/files/2014-12/documents/rfd-final.pdf [hereinafter Review of Reference Dose]; *see also* EPA, *Conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last updated Jan. 13, 2026) [hereinafter *Conducting a Human Health Risk Assessment*].

[52] EPA, Determination of the Appropriate FQPA for Safety Factor(s) in Tolerance Assessment 8 (Feb. 28, 2002), https://www.epa.gov/sites/default/files/2015-07/documents/determ.pdf (explaining that, in a risk assessment, the "no-observed-adverse-effect-level" is "divided by uncertainty factors" to derive an estimate of daily exposure to the human population that is likely to be without risk of deleterious effects); NASEM, Science and Decisions: Advancing Risk Assessment 128 (2009), https://www.nationalacademies.org/projects/BEST-K-05-02-A/publication/12209 (explaining that, in assessing non-cancer risk, "the POD [point of departure] is divided by 'uncertainty factors' to adjust for animal-human differences, human-human differences in susceptibility, and other factors (for example, data gaps or study duration)").

believing that EPA is proposing to increase protections against acute exposure.[53] This deception underscores the fact that the Draft Risk Calculation was not prepared to protect human health, but rather to serve the interests of the regulated community.

With regard to chronic risk, EPA asserts, with minimal explanation, that it is no longer necessary to calculate a chronic non-cancer RfC[54] or cancer IUR,[55] arguing that the revised acute inhalation exposure point of departure is sufficient to protect against all health risks.[56] In doing so, EPA essentially determines, contrary to the weight of the scientific evidence, that: (1) the duration of one's exposure to formaldehyde has no effect on one's long-term risk of developing cancer or other chronic adverse health effects; and (2) there is a certain concentration of formaldehyde—a "threshold"—below which inhalation exposure poses no risk of adverse health effects, including cancer.

Together, these changes to EPA's risk calculations would result in substantial modifications to the Final Risk Evaluation. As a result of EPA's change in calculations, the Draft Risk Calculation identifies five conditions of use that would no longer contribute to EPA's finding of unreasonable risk to workers and three conditions of use that would no longer contribute to unreasonable risk for ONUs.[57] In turn, EPA states that these conditions of use will no longer be a focus of EPA's forthcoming risk management action.[58] Additionally, if finalized, the Draft Risk Calculation would result in EPA setting higher occupational exposure limits for formaldehyde, allowing workers to be exposed to higher levels of the toxic chemical.[59]

II. The States' Interests

For years, the States have acted to protect their residents from the risks posed by formaldehyde. For example, the California Air Resources Board ("CARB") has regulated formaldehyde since 1992 through the state's Toxic Air Contaminant Identification and Control Act;[60] CARB and several other California agencies also regulate specific uses of the chemical.[61]

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[53] EPA implies as much in the Draft Risk Calculation. *See* 90 Fed. Reg. at 55,730 ("[U]sing the 2024 acute inhalation [point of departure] of 0.5 ppm may not be adequately health protective.").
[54] The chronic non-cancer RfC is an estimate of the continuous inhalation exposure unlikely to cause deleterious effects during a person's lifetime. EPA, *Basic Information About the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last updated Oct. 1, 2025).
[55] The cancer IUR is an estimate of the excess cancer risk from exposure to an ambient concentration of 1 $\mu g/m^3$ on a continuous basis for a lifetime. *Id.*
[56] 90 Fed. Reg. at 55,371; EPA, Revised Health Hazard Assessment, *supra* note 51, at 25–26.
[57] 90 Fed. Reg. at 55,732–33; EPA, 740-D-25-040, Revised Draft Human Health Risk Assessment for Formaldehyde 11–12 (Dec. 2025), https://www.epa.gov/system/files/documents/2025-12/7-formaldehyde-revised-draft-human-health-risk-assessment-for-formaldehyde-public-release-december-2025.pdf [hereinafter Revised Health Risk Assessment].
[58] 90 Fed. Reg. at 55,732.
[59] *See* EPA, *Existing Chemical Exposure Limits Under TSCA*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/existing-chemical-exposure-limits-under-tsca (last updated June 26, 2025).
[60] Cal. AB 1087 (1983).
[61] Cal. Code Regs. tit. 17, §§ 93000 *et seq.*; CARB, *Composite Wood Products Airborne Toxic Control Measure*, https://ww2.arb.ca.gov/our-work/programs/composite-wood-products-program/about; Cal. Code Regs. tit. 17, §§ 93120 *et seq.* California has also set formaldehyde exposure limits for workers, Cal. Code Regs. tit. 8, § 5217, prohibits formaldehyde in hair relaxers, Cal. Health & Safety Code § 108985, and requires warnings for products containing formaldehyde under Proposition 65, *id.* § 25249.6.

In 2013, Minnesota banned formaldehyde and formaldehyde-releasing chemicals in certain children's products.[62] In 2023, Washington State[63] and California[64] both banned formaldehyde in cosmetic products. New York recently banned formaldehyde in all menstrual products.[65]

In 2024, the Washington Department of Ecology and Washington Department of Health identified formaldehyde and formaldehyde releasers as priority chemicals under the Safer Products for Washington program, which aims to reduce toxic chemicals in consumer products.[66] In Massachusetts, formaldehyde is designated as a "higher hazard substance" under the Massachusetts Toxics Use Reduction Act ("TURA").[67] Formaldehyde users that meet threshold quantity requirements must report annually on their use of the chemical and conduct toxics use reduction planning every two years. And formaldehyde is listed in Massachusetts as a hazardous substance under the Commonwealth's Department of Public Health regulations,[68] subjecting the chemical to various hazardous substance rules and regulations. In Oregon, formaldehyde is listed as a toxic air contaminant and facilities must include it when they evaluate whether their air emissions are sufficiently protective of human health under the Cleaner Air Oregon program.[69]

The States also have a significant interest in ensuring that the Draft Risk Calculation is conducted in accordance with TSCA, which requires, among other things, that EPA conduct its analysis using the "best available science."[70] Generally, as discussed *infra* Section III.B, the best available science necessitates integrating the IRIS toxicological review into EPA's risk evaluation. The States are particularly interested in the continued vitality of the IRIS Program, which they rely upon to inform their own health and environmental regulations. For example, the New York State Department of Health uses IRIS toxicity assessments as the starting point from which it develops environmental guidelines and regulations, including short-term and annual guidelines for air,[71] ambient water quality values, soil cleanup objectives, and fish and game advisories.[72] New York's Department of Environmental Conservation also relies on IRIS assessments as a source of hazard information in helping to protect against toxic chemicals in children's products. The loss of IRIS assessments would create significant information gaps for these programs.

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[62] 2013 Minn. Laws ch. 58, § 2 (codified at Minn. Stat. § 325F.177).
[63] Wash. Toxic-Free Cosmetics Act, 2023 Wash. Sess. Laws ch. 455, § 3 (codified at Wash. Rev. Code § 70A.560.020); Wash. Admin. Code § 173-339-110.
[64] 2023 Cal. Stat. ch. 441 (codified at Cal. Health & Safety Code § 108980).
[65] 2025 N.Y. Laws S. 1548 (to be codified at N.Y. Gen. Bus. Law § 399-aaaa).
[66] Wash. State Dep't of Ecology, Identification of Priority Chemicals: Report to the Legislature 10 (May 2024), https://apps.ecology.wa.gov/publications/documents/2404025.pdf.
[67] *See* Commonwealth of Mass., Exec. Off. of Energy & Env't Affs., Designation of TURA Higher & Lower Hazard Substances in Massachusetts, https://www.mass.gov/doc/designation-of-tura-higher-and-lower-hazard-substances-in-massachusetts/download.
[68] 105 C.M.R. 650.017.
[69] Or. Admin. R. ch. 340, div. 245.
[70] 15 U.S.C. § 2625(h).
[71] *See, e.g.*, N.Y. Dep't of Env't Conservation, Env't Notice Bull., DAR-1: "Guidelines for the Evaluation and Control of Ambient Air Contaminants" under 6 NYCRR Part 212, "Process Operations" (Jan. 13, 2021), https://dec.ny.gov/news/environmental-notice-bulletin/2021-01-13/notice-of-new-york-state-department-of-environmental-conservation-nys-dec-program-policy.
[72] N.Y. Dep't of Health, *Background Information* (May 2025), https://www.health.ny.gov/environmental/outdoors/fish/health_advisories/background.htm.

New York is not the only state that relies on the IRIS Program. The Illinois Pollution Control Board incorporates IRIS assessments into its regulations, including in its classification of toxic air contaminants as "carcinogens"[73] and in setting the allowable values of certain contaminants in soil.[74] Washington's regulations identify IRIS as the preferred source for toxicity values used to determine whether a cleanup site requires mitigation to protect human health.[75] Oregon's Department of Environmental Quality relies on EPA in general as an "authoritative source" when reviewing and updated toxicity values for toxic air contaminants.[76] IRIS toxicity values are also used in other Department of Environmental Quality programs.[77] And the California Department of Toxic Substances Control uses IRIS toxicity values to develop human health risk assessments, risk-based screening levels, and remediation goals.[78]

III. The Draft Risk Calculation Violates TSCA and EPA's Implementing Regulations and Guidance and Is Arbitrary, Capricious, and Contrary to Law

A. EPA Has Not Demonstrated a Basis to Revise Its Risk Calculation or the Final Risk Evaluation

A final risk evaluation is the product of a years-long process involving notice, comment, and scientific peer review. As discussed above, the formaldehyde risk evaluation process began in 2019 when EPA designated formaldehyde as a "high-priority" substance.[79] In 2020, EPA issued the proposed scope of the risk evaluation for formaldehyde and then, following public comment, issued the final scope.[80] In 2024, EPA issued the draft risk evaluation and then subjected the draft to public comment and scientific peer review by multiple federal advisory committees.[81] In 2025, EPA issued the Final Risk Evaluation, addressing comments from the public and peer reviewers.[82] With the Final Risk Evaluation complete, EPA is now under a statutory obligation to timely propose and finalize a formaldehyde risk management rule.[83] Indeed, EPA was required to propose a formaldehyde risk management rule by January 5, 2026, which it has not done.

EPA's regulations expressly limit the circumstances under which EPA may undertake substantive revisions to a final risk evaluation. EPA is permitted to make such revisions only where EPA has (1) re-initiated the prioritization process or (2) determined that the revisions are in the "interest of protecting human health or the environment[,] . . . considering the statutory

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[73] 35 Ill. Admin. Code § 232.320(a)(4).
[74] *Id.* pt. 742 (tiered approach to corrective action objectives for leaking underground storage tanks, site remediation, and RCRA permits); *id.* pt. 1100 (clean construction or demolition debris fill operations and uncontaminated soil fill operations).
[75] Wash. Admin. Code § 173-340-708(7)–(8).
[76] Or. Admin. R. 340-247-0030.
[77] *See, e.g.*, *id.* 340-122-0081(1)(c)(A) (listing IRIS as an authoritative source of toxicity information for the Department of Environmental Quality's hazardous substance cleanup program).
[78] Cal. Code Regs. tit. 22, § 69021(b).
[79] 84 Fed. Reg. 71,924.
[80] EPA, EPA-740-R-20-014, Final Scope of the Risk Evaluation for Formaldehyde (Aug. 2020), https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf.
[81] 89 Fed. Reg. 18,933.
[82] *See* EPA, Response to Comments, *supra* note 37.
[83] 15 U.S.C. § 2605(c)(1).

responsibilities and deadlines under 15 U.S.C. § 2605."[84] Neither of these circumstances applies here. While EPA claims it has not yet decided to revise the Final Risk Evaluation,[85] the agency's decision to publish revised risk calculations and to make a determination that certain conditions of use no longer pose an unreasonable risk to human health signal that EPA intends to do so. Using the Draft Risk Calculation to revise the Final Risk Evaluation would violate TSCA by failing to meet the statutory criteria referenced above and would be arbitrary, capricious, and contrary to law, in violation of the APA.

First, EPA has not re-initiated the prioritization process for formaldehyde, nor should it. As EPA has previously explained, "[r]evisiting risk evaluations outside of re-prioritizing the chemical substance results in unanticipated and potentially unbudgeted work that can siphon resources from statutorily mandated responsibilities under TSCA section 6."[86]

Second, EPA has not determined that the proposed revisions are in the interest of protecting human health or the environment. In fact, the revisions are less health protective. Compared to the Final Risk Evaluation, EPA's proposed revisions nearly double the amount of formaldehyde considered safe to inhale on a short-term basis. Furthermore, despite acknowledging that chronic inhalation of formaldehyde increases the risk of adverse health effects,[87] EPA proposes not to calculate the associated cancer and non-cancer risks.[88] Indeed, EPA's proposed revisions reflect EPA's accession to the demands of the American Chemistry Council, the chemical industry's main trade group,[89] which has long pushed EPA to adopt laxer chemical regulations.[90]

Accordingly, EPA has demonstrated no basis to revise its risk calculation for formaldehyde or to revise its Final Risk Evaluation, if it intends to do so. Indeed, revising the Final Risk Evaluation to incorporate the revisions set out in the Draft Risk Calculation would fly in the face of EPA's statutory responsibility to eliminate unreasonable risk and to promulgate a formaldehyde risk management rule by January 5, 2026.

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[84] 40 C.F.R. § 702.43(g)(3). In September 2025, EPA proposed to amend this regulation. Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 90 Fed. Reg. 45,690, 45,708 (Sept. 23, 2025). However, EPA has not finalized its proposal, so the existing regulations govern.

[85] 90 Fed. Reg. at 55,727.

[86] Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 37,028, 37,045 (May 3, 2024).

[87] 90 Fed. Reg. at 55,727–28.

[88] *Id.* at 55,729.

[89] The American Chemistry Council represents over 190 companies. Am. Chem. Council, *About ACC*, https://www.americanchemistry.com/about-acc.

[90] It is a matter of public record that Nancy Beck and Lynn Dekleva, who now lead EPA's Office of Chemical Safety and Pollution Prevention, both previously worked for the American Chemistry Council. Sharon Lerner, ProPublica, *Under Former Chemical Industry Insiders, Trump EPA Nearly Doubles Amount of Formaldehyde Considered Safe to Inhale* (Dec. 8, 2025, at 5:00 a.m.), https://www.propublica.org/article/epa-formaldehyde-risk-assessment; *see also* Press Release, Am. Chem. Council, EPA's Final TSCA Risk Evaluation for Formaldehyde Potentially Jeopardizes Domestic Production and Critical American Industries (Jan. 2, 2025), https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2025/epa-s-final-tsca-risk-evaluation-for-formaldehyde-potentially-jeopardizes-domestic-production-and-critical-american-industries (criticizing the Final Risk Evaluation as overly protective).

B. EPA's Proposed Revisions Fail to Use the Best Available Science

Each of EPA's proposed revisions in the Draft Risk Calculation must also be withdrawn because the changes fail to use the best available science, as required by TSCA and EPA's implementing regulations, and because they are arbitrary, capricious, and contrary to law under the APA.

When conducting a risk evaluation, EPA must "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."[91] "[T]he 'best available science' is science that is reliable and unbiased."[92] As EPA has explained, "[u]se of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."[93]

1. *The Best Available Science Requires EPA to Use the IRIS Assessment*

For years, EPA has conducted chemical risk evaluations using data from its IRIS Program, a reliable and unbiased human health assessment program that develops health hazard and dose-response assessments of chemicals that humans encounter in the environment. The 2025 Final Risk Evaluation is no different; in it, EPA incorporated the IRIS analysis of cancer and non-cancer hazards associated with chronic inhalation exposure to formaldehyde.[94]

Now, just 11 months later, EPA proposes to exclude the IRIS assessment's findings from its formaldehyde risk calculation, which would also mean excluding the IRIS assessment from EPA's risk evaluation, a dramatic departure from the Agency's standard practice and the best available science.

EPA created the IRIS Program in 1985 to serve as a database for its health assessments of chemicals found in the environment.[95] The goal, according to EPA, "was to foster consistency in the evaluation of chemical toxicity across the Agency."[96] In 1996, EPA further standardized its chemical review process by creating the "IRIS toxicological review," a peer-reviewed, "Agency-wide, comprehensive health assessment document" that summarizes the evidence for a given chemical's cancer and non-cancer health effects from different routes of exposure.[97] Since that time, EPA has continued to strengthen the IRIS Program by, for example, establishing the Chemical Assessment Advisory Committee to provide advice on IRIS assessments and creating a seven-step review process that includes numerous opportunities for public and independent

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[91] 40 C.F.R. § 702.37(a)(2)(i).
[92] 89 Fed. Reg. at 37,043.
[93] *Id.*
[94] Human Health Risk Assessment, *supra* note 41, at 83.
[95] EPA, *Basic Information About the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last updated Oct. 1, 2025).
[96] *Id.*
[97] *Id.*

expert participation.[98] Today, the IRIS Program is the "largest database of authoritative toxicity values in the world."[99] EPA's program offices use IRIS data to inform their risk assessments and risk management decisions, as do other federal agencies and states, localities, and tribes.[100]

Although IRIS has long been the subject of attacks from regulated industry, IRIS assessments incorporate the best available science,[101] and researchers and EPA career staff have long considered them the "gold standard for health assessments for chemical pollutants."[102] This is "[b]ecause the IRIS process is so rigorous."[103] The IRIS Toxicological Review, which took more than a decade to develop and involved an open workshop and interagency scientific consultation, is no different.[104] In 2023, NASEM, an independent body of the nation's leading scientific experts, assessed the Toxicological Review and found that EPA's findings on hazard and quantitative risk were supported by the relevant evidence.[105]

For these reasons, EPA's proposal to exclude the IRIS assessment's findings from its formaldehyde Draft Risk Calculation and its apparent intention to revise the Final Risk Evaluation in a way that excludes the IRIS assessment violate TSCA's best available science requirements. EPA's proposal to exclude IRIS assessments is also arbitrary and capricious and contrary to law under the APA. The revision of EPA's Draft Risk Calculation after publication of the Final Risk Evaluation is subject to the change-in-position doctrine under the APA. Under that doctrine, EPA is required to "provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests." *FDA v. Wages & White Lion Invs.*, LLC, 145 S. Ct. 898, 917 (2025). EPA has not provided a reasoned explanation for its change in position or considered the serious reliance interests of the States, who depend on EPA to develop science-based protections against toxic chemicals.

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[98] EPA, *Developments in the IRIS Program*, https://www.epa.gov/iris/developments-iris-program (last updated Nov. 20, 2025); *see* EPA, *Enhancements to EPA's Integrated Risk Information System Program* (2013), https://www.epa.gov/sites/default/files/2014-06/documents/irisprocessfactsheet2013.pdf.

[99] Sharon Lerner, ProPublica, *Industry-Backed Legislation Would Bar the Use of Science Behind Hundreds of Environmental Protections* (Mar. 6, 2025), https://www.propublica.org/article/legislation-targets-epa-science-toxic-chemicals.

[100] NASEM, Review of U.S. EPA's ORD Staff Handbook for Developing IRIS Assessments: 2020 Version (2022), https://www.nationalacademies.org/read/26289; EPA, EPA's Integrated Risk Information (IRIS) Program: Report to Congress (Jan. 2018), https://www.epa.gov/sites/default/files/2018-02/documents/iris_report_to_congress_2018.pdf (describing how EPA uses IRIS assessments for decisionmaking under the Clean Air Act, Safe Drinking Water Act, and Comprehensive Environmental Response, Compensation and Liability Act).

[101] EPA, EPA 600/R-22/268, ORD Staff Handbook for Developing IRIS Assessments, at xiv (Dec. 2022), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=545991.

[102] Gov't Accountability Off., GAO-21-156, Chemical Assessments: Annual EPA Survey Inconsistent with Leading Practices in Program Management 9–10 (Dec. 2020), https://www.gao.gov/assets/gao-21-156.pdf.

[103] *Id.* at 9.

[104] EPA, *Formaldehyde*, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419.

[105] Press Release, NASEM, New Report Provides Scientific Review of EPA's Draft Formaldehyde Assessment (Aug. 9, 2023), https://www.nationalacademies.org/news/new-report-provides-scientific-review-of-epas-draft-formaldehyde-assessment.

2. *The Best Available Science Necessitates the Use of an Uncertainty Factor that Accounts for Variability and Scientific Uncertainty*

In the Draft Risk Calculation, EPA proposes to reduce the uncertainty factor for human intraspecies variability ("UF_H") from 3 to 1, essentially lowering the buffer for what is considered a safe level of formaldehyde to inhale by a factor of 3.[106]

The weight of the scientific evidence does not support such a change. As EPA previously explained, a UF_H greater than 1 is warranted because the studies EPA relied upon to develop the acute inhalation point of departure were based on "relatively small samples of healthy adult volunteers," and the one study that included a subset of "sensitive" participants did not "specifically seek to include a susceptible subpopulation and is not expected to capture the full range of human variability."[107] Developing an reference concentration that is supposedly protective of all acute and chronic health effects certainly warrants a UF_H greater than 1 because there is (1) "direct evidence" that infants and children, people with respiratory conditions, nonwhite individuals, people with genetic variants, and people co-exposed to other environmental pollutants and dietary components are more susceptible to formaldehyde and (2) "indirect evidence" that being a pregnant woman, an older adult, a heavy smoker, a chronic consumer of alcohol, of low socioeconomic status, nutrient deficient, a resident of poor quality housing, or a person who experiences other social stressors may impact susceptibility to formaldehyde via "target organs or biological pathways relevant to formaldehyde."[108] In the past, EPA has applied a UF_H of 10 even while finding "no evidence of increased susceptibility for any single group relative to the general population."[109]

An overall uncertainty factor of 1 is particularly inappropriate given that EPA proposes to treat the acute inhalation point of departure as protective of all durations of exposure and all potential hazards, including cancer. When developing a chronic RfC, the best available science and EPA's own guidance require EPA to account for the uncertainty associated with extrapolating the effects of lifetime exposure from studies analyzing less-than-lifetime exposure by applying a subchronic uncertainty factor ("UF_S") greater than 1.[110] However, in adopting the acute inhalation point of departure to address chronic risk and using an uncertainty factor of 1, EPA ignores this source of uncertainty, which will result in a risk management rule that does not adequately protect against chronic health effects.

3. *The Best Available Science Requires EPA to Consider Exposure Duration When Assessing Risk of Chronic Health Effects*

EPA proposes to adopt a revised acute inhalation point of departure of 0.3 ppm and to treat that point of departure as protective of all "potential hazards, including cancer," "all durations of exposure (including short- and long-term)," and "all populations."[111] In support of

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[106] 90 Fed. Reg. at 55,730.
[107] EPA, Response to Comments, *supra* note 37, at 58.
[108] EPA, Revised Health Risk Assessment, *supra* note 57, at 179–86.
[109] EPA, 740-R-18-015, Risk Evaluation for C.I. Pigment Violet 29, at 76, 83 (Jan. 2021), https://www.epa.gov/sites/default/files/2021-01/documents/1_final_risk_evaluation_for_c.i._pigment_violet_29.pdf.
[110] EPA, Review of Reference Dose, *supra* note 51, at 4-38 to -40, -45 to -46; NASEM, Review of EPA's 2022 Draft Formaldehyde Assessment 78 (2023), https://www.nationalacademies.org/read/27153 [hereinafter NASEM Review].
[111] EPA, Revised Health Hazard Assessment, *supra* note 51, at 6.

this claim, EPA selectively cites statements made by the SACC and a set of World Health Organization ("WHO") guidelines from 2010.[112]

In its August 2024 Supplement to the IRIS Toxicological Review, however, EPA specifically addressed why this approach is inappropriate under the best available science. Responding to public comment, EPA explained that it was "not aware of any evidence to support the hypothesis that protecting against sensory irritation following acute exposure would be protective against chronic health effects."[113] To assume otherwise, EPA stated at that time, would require one to accept that inhaling formaldehyde poses health risks only when the chemical is present in concentrations sufficient to cause detectable sensory irritation, a premise for which "[t]here seems to be no evidentiary basis."[114] EPA also refuted the rationale of the WHO guidelines, explaining that the guidelines are based only on controlled studies of healthy adults and do not provide a basis for their conclusion that exposure duration does not increase the risk of adverse health effects.[115]

Even if EPA were correct that exposure duration does not affect the risk of developing chronic health effects, EPA's decision not to quantify the chronic non-cancer RfC and cancer IUR would still be unreasonable because it will prevent the effective regulation of formaldehyde in EPA's ultimate risk management rule. Pursuant to TSCA, when EPA promulgates a risk management rule, it must detail, among other things, "the effects of the chemical substance or mixture on health and the magnitude of the exposure on human beings to the chemical substance or mixture," "the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health," and "the costs and benefits of the proposed and final regulatory action."[116] Because it fails to quantify the effects of chronic exposure to formaldehyde on human health, EPA will not be able to craft a risk management rule that adequately accounts for the health benefits associated with appropriate formaldehyde management, resulting in a rule that is not sufficiently health-protective and that violates TSCA.

4. *The Best Available Science Necessitates a Linear, Non-Threshold Approach to Cancer Risk*

As described above, EPA proposes to disregard the cancer IUR contained in the 2025 Final Risk Evaluation on the basis that "[r]isk management efforts to reduce risk from acute inhalation risk will address any potential risks from chronic exposures, including cancer."[117] The States oppose this dangerous change.

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[112] *Id.* at 12. EPA also cites to the findings of the HSRB, *see* 90 Fed. Reg. at 55,729, but the HSRB was only charged with reviewing a selection of studies used to establish the acute inhalation endpoints for formaldehyde exposure and did not evaluate EPA's ultimate assessment of chronic risks, *see* HSRB, Report of the U.S. Environmental Protection Agency Human Subjects Review Board 4 (Oct. 5, 2023), https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde.pdf.

[113] EPA, EPA/635/R-24/162bF, IRIS Toxicological Review of Formaldehyde (Inhalation) Supplemental Information, at F-121 (Aug. 2024), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549613.

[114] *Id.*

[115] *Id.* at F-120 to -121.

[116] 15 U.S.C. § 2605(c)(2)(A).

[117] 90 Fed. Reg. at 55,732.

According to EPA's own guidance, the best available science provides that risk evaluations should, by default, use a no-threshold, linear extrapolation method to analyze cancer risk when a chemical's mode of action—the sequence of events and processes by which a chemical interacts with human cells and causes cancer—is mutagenic, that is, capable of causing genetic mutation. Under a linear, non-threshold approach to dose-response modeling, EPA assumes that there is theoretically no level of exposure to a given chemical that does not pose at least some probability of generating a carcinogenic response, *i.e.*, increase one's risk of developing cancer.[118] In contrast, a threshold, non-linear approach assumes that there is a dose below which no adverse health effects are expected to occur.[119]

In the Draft Risk Calculation, EPA asserts that, because some members of the SACC questioned whether formaldehyde has a mutagenic mode of action, the calculation of the cancer IUR, which incorporates a linear, non-threshold approach, is not warranted.[120] EPA fails to acknowledge, however, that many members of the SACC took the opposite view, and EPA also fails to acknowledge the SACC's conclusion that, in light of the uncertainty around the mode of action, the 2025 Final Risk Evaluation "appropriately followed [EPA's] guidelines for carcinogen risk assessment and *appropriately applied the low-dose linear extrapolation (a non-threshold model) for formaldehyde's cancer IUR estimate, which is a health-protective approach.*"[121] Nor does EPA acknowledge that, according to NASEM, "[w]hile there is uncertainty in the degree to which nonmutagenic processes may also contribute to the carcinogenic activity of formaldehyde inhalation[,] . . . there is sufficient evidence to support the assumption that a mutagenic [mode of action] is involved in the carcinogenesis of formaldehyde . . . in humans."[122] Indeed, the National Toxicology Program's Report on Carcinogens concluded that formaldehyde most likely causes cancer through "several modes of action" and noted that "DNA reactivity" and "gene mutation" are associated with formaldehyde exposure. [123]

According to EPA's own guidelines, the lack of scientific consensus around whether formaldehyde has a mutagenic mode of action warrants the use of a linear, non-threshold approach. EPA's 2005 Guidelines for Carcinogen Risk Assessment provide the following recommendations for when consensus about mode of action cannot be reached: "In the absence of sufficiently, scientifically justifiable mode of action information, EPA generally takes public health-protective, default positions regarding the interpretation of toxicologic and epidemiologic data: animal tumor findings are judged to be relevant to humans, and *cancer risks are assumed to conform with low dose linearity*."[124] EPA also endorses this approach in its Office of Research and Development's 2022 Staff Handbook for Developing IRIS Assessments, explaining that a linear, non-threshold approach—the approach "most commonly used for cancer endpoints"—is

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[118] EPA, *Conducting a Human Health Risk Assessment*, *supra* note 51.
[119] *Id.*
[120] 90 Fed. Reg. at 55,729.
[121] SACC, Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde 64–65 (May 2024), https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0298/content.pdf [hereinafter Peer Review] (emphasis added).
[122] NASEM, NASEM Review, *supra* note 110, at 116,
[123] Nat'l Toxicology Program, Dep't of Health & Hum. Servs., Formaldehyde 4 (15th ed. 2021), https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/formaldehyde.pdf.
[124] EPA, EPA/630/P-03/001F, Guidelines for Carcinogen Risk Assessment (Mar. 2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf (emphasis added).

appropriate when a chemical is "deoxyribonucleic acid (DNA) reactive and ha[s] direct mutagenic activities," *or* "*when data are insufficient to establish the [mode of action] and when scientifically plausible.*"[125]

Accordingly, even if EPA were uncertain about formaldehyde's mode of action, it should have used a linear, non-threshold approach to comport with its own guidelines and the best available science. EPA's use of a threshold approach is not supported by the best available science or the agency's own guidance and sets a dangerous precedent for cancer risk evaluation moving forward.

C. EPA Must Subject the Draft Risk Calculation to Peer Review

EPA's proposed revisions must additionally be withdrawn because EPA has failed to subject them to peer review, as required by TSCA. When EPA seeks to revise a final risk evaluation outside of re-prioritization, as EPA signals that it intends to do for formaldehyde, EPA must follow the same, complete process that is required of all new risk evaluations, including with respect to peer review.[126] Here, though, EPA is not providing the SACC with the opportunity to review the Draft Risk Calculation because, according to EPA, the proposed changes set forth in the accompanying draft risk memorandum "rel[y] extensively on multiple existing and relevant peer review reports."[127] It is true that EPA *cites* multiple peer-reviewed reports in the Draft Risk Calculation. However, as described above, EPA mischaracterizes the central findings of these reports and cherry-picks statements to support its political goals, resulting in scientifically unsound conclusions. *See supra* Section III.B. To remedy this problem, and to achieve compliance with its own regulations, EPA must immediately subject the Draft Risk Calculation to peer review.

D. EPA May Not Consider the Use of Personal Protective Equipment

In the supporting documents accompanying its Draft Risk Calculation, EPA states that it makes determinations of unreasonable risk "in a manner that takes in [sic] consideration reasonably available information regarding the use of respiratory protection or other personal protective equipment (PPE)."[128] However, pursuant to its own regulations, EPA may "not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination,"[129] and doing so would be particularly problematic here, where EPA's analysis estimates that only a fraction of workers exposed to formaldehyde actually use PPE.[130] This point is affirmed by the SACC, which stated that "PPE belongs under risk management, not risk assessment," and that, furthermore, "PPE is the least effective form of risk management—sometimes necessary as a last line of defense, but inferior to [other] strategies . . . due to the need

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[125] EPA, EPA 600/R-22/268, ORD Staff Handbook for Developing IRIS Assessments 8-10 (Dec. 2022), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=545991 (emphasis added).
[126] 40 C.F.R. § 702.43(g)(4); *see also id.* § 702.41.
[127] 90 Fed. Reg. at 55,733.
[128] EPA, EPA-740-R24-017, Revised Draft Unreasonable Risk Determination of the Risk Evaluation for Formaldehyde 8–9 (Dec. 2025), https://www.epa.gov/system/files/documents/2025-12/9-formaldehyde-revised-draft-unreasonable-risk-determination-for-formaldehyde-public-release-december-2025.pdf.
[129] 40 C.F.R. § 702.39(f)(2).
[130] *See* EPA, Occupational Exposure Assessment, *supra* note 27, at 264–66.

for worker training, proper use, and compliance."[131] The States urge EPA to omit assumptions about the use of PPE from its risk calculations.

IV. Conclusion

If finalized, this dangerous and scientifically unsupported Draft Risk Calculation will set a precedent for unscientific decisionmaking and undermine EPA's ability to address formaldehyde's risks to human health. Accordingly, the Attorneys General strongly urge EPA to withdraw it.

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[131] SACC, Peer Review, *supra* note 121, at 56.

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