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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: **Updated Draft Risk Calculation Memorandum for Formaldehyde**

Docket Number: EPA-HQ-OPPT-2018-0438

To EPA Administrator Lee Zeldin:

Thank you for the opportunity to submit comments on the Environmental Protection Agency's (EPA's) draft risk calculation memorandum for formaldehyde.

We will not mince words: America's moms, dads, and caregivers are shocked and appalled by your formaldehyde proposal. **Rather than Make America Healthy, your memorandum is about boosting petrochemical industry profits at the expense of our families' health.** This is the latest episode in EPA's feverish rush to tear down the health and safety protections on which children and families depend.

Formaldehyde is a widely used industrial chemical, one that surrounds us as we go about our everyday lives. Its pickled, pungent smell wafts into the air from furniture, new shoes and clothes, printer toner, car interiors, synthetic playing surfaces and running tracks, and thousands of other sources. In this week's icy weather, formaldehyde and other volatile organic compounds are readily conspicuous in the sharp stench of the exhaust from our cars – the so-called "cold start problem," due to inefficient and incomplete combustion and inactive catalytic converters, which can elevate the [emissions of formaldehyde](#) and other toxic chemicals by [hundreds of times](#). At the industrial scale, each year hundreds of facilities collectively release [more than 19 million pounds](#) of formaldehyde to the air and water, threatening the health of communities across the country. Formaldehyde is perhaps best known as the primary chemical in embalming fluid, used to preserve dead bodies. It was also used in the toxic [FEMA trailers](#) that sickened displaced New Orleans residents following Hurricane Katrina.

Formaldehyde is a human carcinogen, and has been [classified](#) as such for nearly 20 years by the world's leading scientific bodies including the World Health Organization's International Agency

for Research on Cancer, the US National Toxicology Program, and the European Chemicals Agency. The chemical is linked to nasal cancers, leukemias, lung damage, and other health effects. Children are particularly vulnerable.

Refusing to accept the conclusions of global scientific authorities and its own research arm – which EPA has now fired – the formaldehyde draft risk calculation memorandum insists that there are safe and acceptable levels of this potent DNA-altering human carcinogen. The extreme revisions EPA is making to long-established, exhaustively peer-reviewed scientific principles will subject workers, children, and all people to heightened risk of cancers, lung damage, and other chronic health conditions.

[EPA was founded](#) by President Nixon in 1970 as part of “a coordinated attack on the pollutants which debase the air we breathe, the water we drink, and the land that grows our food.” But the agency appears to have forgotten this mission. Rather than protect us from cancer, EPA is proposing to weaken the safeguards and to erase the peer-reviewed science that its own researchers have meticulously compiled over decades.

Exposing Children and Families to a Dangerous Carcinogen

Formaldehyde causes far more cancers than any other air pollutant. And yet the Zeldin EPA is **proposing to *double* the amount of formaldehyde the government considers acceptable for children and families to breathe.**

Formaldehyde exposures disrupt DNA, trigger chronic inflammation, and lead to uncontrolled cell growth, cancer, and aging. The chemical is genotoxic (damaging genetic material) and mutagenic (causing *permanent and heritable* changes to DNA). Exposures can cause mutations and chromosome damage as well as cancers, including nasopharyngeal cancers (in the upper part of the throat, behind the nose), cancers of the nasal sinuses, and leukemia (cancer of the body's blood-forming tissues, including the bone marrow and the lymphatic system). Formaldehyde can interfere with cells' ability to repair other DNA damage, as well, thus increasing susceptibility to other carcinogens. Formaldehyde also causes non-cancer effects such as asthma and other respiratory damage.

If Americans' cancers came with labels telling us the cause, it is likely that many thousands of those tags would say “formaldehyde.” But science has not developed to the point where we can link individual cases of cancers to specific chemical triggers. What we do know, for sure, is that formaldehyde is aggressively harmful to our health, and that it is off-gassing inside our homes

and vehicles, while also polluting our outdoor air via exhaust, fires, petrochemical facilities and so on.

Under former EPA Administrator Regan, [EPA data revealed](#) that **the average American's cancer risk from formaldehyde is at least 20 times higher than what is acceptable – and 77 times higher when myeloid leukemia is included in the analysis.** EPA scientists determined that exposures to formaldehyde from [living room décor alone](#) can threaten families with cancer risks that are dozens of times higher than EPA's own benchmark.

Formaldehyde is notably [harmful to children](#). There are many reasons for this heightened vulnerability. In particular, kids' bodies – including the brain and nervous system -- are undergoing rapid and delicate developmental phases, and their immune systems (the primary defense against infections, diseases, and harmful chemicals) are physiologically immature. In addition, children experience higher exposures for smaller size, relatively fast respiratory rates and volumes, and increased time spent on floors or near the ground, where off-gassed formaldehyde concentrates. These smallest, most vulnerable members of our society face outsized exposures to formaldehyde sources such as furnishings, carpeting, and laminate or pressed wood floors. In addition to cancers, children may be particularly susceptible to asthma and other ill effects, even from relatively low concentrations of formaldehyde. There is also evidence that pregnant women and the unborn face heightened vulnerability.

Despite the human health effects, the Zeldin EPA is telling us that stripping children and families of protections against this extremely toxic chemical is somehow “gold standard.” In truth, there is nothing gold-standard about the agency's updated risk calculation. Forcing Americans to breathe twice as much formaldehyde will make us sick, not well. The science is clear: **No amount of this mutagenic carcinogen is safe to inhale.** We are already breathing in dangerous amounts, so who in their right mind would want to double our exposure?

For EPA's disregard of the science, our families will pay with our health.

Replacing actual science with the chemical industry wish list

The Updated Draft Risk Calculation Memorandum closely tracks key positions championed by the American Chemistry Council (ACC), the chemical industry trade group. It appears that EPA is substituting unproven claims – that will result in weaker protections -- in place of the science developed over decades by EPA scientists and international researchers.

This chart from the [University of California San Francisco Program](#) on Reproductive Health and the Environment shows how the new risk model mirrors the positions of the chemical industry lobby.

Comparison of American Chemistry Council comments and EPA Draft Risk Calculation for Formaldehyde (paraphrased, in part):

Regulatory Focus	ACC Comments	EPA Draft Memorandum (FR Notice)
Abandonment of IRIS RfC/IUR	OPPT's reliance on the Draft IRIS Assessment is a "fatal flaw" that violates TSCA's "best available science requirement." "A Standard IRIS value/Reference Concentration (RfC) approach is inappropriate" because it seeks to mitigate to a level of "no appreciable risk," which is beyond the scope of TSCA's requirement to mitigate only "unreasonable risk." (p. 6)	OCSPP "has revisited the use of the IRIS chronic RfC and cancer IUR values." "The OCSPP is also no longer relying on the EPA IRIS RfC or IUR." EPA has concluded that "managing acute sensory irritation will be health-protective against other effects, including cancer." (p. 55731)
Protecting Against Sensory Irritation as Protective Against Cancer (Threshold MOA)	"Protecting for sensory irritation protects for all other adverse effects of formaldehyde (including nasal tumors) when a threshold-based mode of action (MOA) for nasal tumors is applied." (p. 5)	"OCSPP is continuing to rely upon sensory irritation as the endpoint for evaluating acute inhalation exposures in the Revised Draft." (p. 55729)
Applicability of Haber's Law	"Formaldehyde does not follow Haber's Law, and there is no meaningful difference in formaldehyde-induced sensory irritation regardless of whether the exposure is acute or chronic." (p. 5)	"The sensory irritation effects of formaldehyde are more responsive to the exposure concentration than to exposure duration, which means that formaldehyde does not adhere to Haber's Law." (p. 55729)
Basis for Reduction in UFH, uncertainty factor used to account for human variability in response to chemical exposures among sensitive populations	ACC argues EPA can reduce the human intraspecies uncertainty factor (UFH) on grounds that "younger, healthier population (which is typically the demographic of participants in controlled exposure studies) will be most sensitive to the odor and irritancy of formaldehyde." The EPA HSRB recognized that the key chamber studies included hypersensitive individuals and/or younger individuals. (p. 11)	HSRB noted in the July 2023 report that "younger individuals are more sensitive to sensory irritation than older individuals, and therefore younger individuals are an appropriate population for intentional exposure studies when sensory irritation is the primary objective." Accordingly, OCSPP is "reducing the toxicodynamic portion of the UFH, to 1× leading to a total UFH of 1× to evaluate inhalation exposures." (p. 55730)
Adjustment of Quantitative POD/OEL	"Considering all reasonably available information... the approach taken by the EU SCOEL committee, which set an occupational exposure limit at 300 ppb, is consistent with the best available science." (p. 18)	"For the Draft Memorandum, OCSPP is updating the draft acute inhalation POD to 0.3 ppm for formaldehyde." (p. P. 55730) (Note: 0.3 ppm = 300 ppb).

In other words, in the EPA's draft risk calculation:

- EPA now wants to abandon the chronic risk values (both for cancers and for noncancer effects such as respiratory pathologies and reduced lung function) developed by the EPA Integrated Risk Information System (IRIS), a world-renowned research arm that produced peer-reviewed state-of-the-art human health assessments of toxic chemicals – a program that EPA has now gutted.
- Contrary to the way EPA has evaluated risks for decades (also adhered to by the Food and Drug Administration and other agencies), EPA now claims that there are safe and acceptable levels or “thresholds” of this potent DNA-altering carcinogen below which no harm will occur. Specifically, EPA states that even long-term exposures to formaldehyde are safe so long as the amount is at or below 0.3 ppm, the level EPA now estimates to cause acute sensory effects (irritation of the eyes, nose, or throat). Note that 0.3 ppm is double the sensory irritation endpoint of 0.15 ppm that EPA recognized in its 2024 [IRIS report](#). (Note also that independent scientists [do not support](#) EPA's claim that formaldehyde is perfectly safe unless you smell it.)

Absurdly, the agency claims that if exposures are at its proclaimed threshold level of 0.3 ppm or dip below it for “any duration,” then individuals are protected “against all effects, including cancer.”

Note that 0.3 ppm is more than 50 times the EPA IRIS reference concentration of ~0.0057 ppm, an exposure level designed to protect sensitive populations and people with long-term exposures.

Thus, says EPA, no cancer risk calculations are needed: protecting people from acute sensory effects due to short-term formaldehyde exposure will also protect against cancer. The proposal states, “EPA followed the recommendations of federal advisory committees and has concluded that managing acute sensory irritation will be health-protective against other effects, including cancer. Therefore, given the use of a threshold approach, it is not necessary for the Agency to provide a separate quantitative cancer assessment.”

- EPA has adopted the position that formaldehyde toxicity does not follow Haber's Law, the principle that the severity of the toxic effects depends on the concentration and the duration of exposure. The new EPA position is also shared by chemical industry lobbyists.
- EPA makes the false assertion that all populations are equally susceptible to formaldehyde's harms. In doing so, the agency is seeking to reduce protections for children and other sensitive populations, jettisoning the science-based risk factors that the agency has used for decades.
- EPA's newly revised acute exposure level is 100 times higher than the IRIS reference concentration (the continuous inhalation exposure that does not trigger deleterious non-cancer risks). The IRIS value had been supported by external reviewers from the National Academies of Sciences.

How to make sense of the bizarre assertions in the Zeldin EPA's "draft risk calculation memorandum"

Those who wade through [EPA's self-congratulatory proposal](#) will note the many references to EPA's "gold standard" science and their commitment "to the highest standards of scientific integrity and reliance on the best available scientific information." This may sound reassuring. Readers are led to believe that the new risk calculation methods represent a previously overlooked scientific consensus. It is as if this "draft risk calculation memorandum" represents the convergence of evidence from the US and around the world, backed by esteemed scientific advisory bodies and the National Academy of Sciences. Readers may be left wondering, how could prior EPA scientists be so dumb?

A deeper dive reveals what is taking place: EPA is inserting into the risk calculations changes that happen to mirror the chemical industry's wish-list, representing a radical departure from EPA's longstanding practice and precedent. The agency tries to justify the about-face by using the statements from *individual industry-affiliated members* of the peer review committees -- as if those spokespeople were speaking for the full committee. That is to say, the agency is cherry-picking *discrete peer reviewers' comments* as a way to obscure *full advisory committee consensus conclusions* on the dangers of formaldehyde. While "cherries" may sound delicious, there is nothing sweet about selectively inserting certain committee-members' claims while deliberately ignoring contradictory information from EPA's own scientists, esteemed researchers on EPA advisory committees, and peer reviewers from the National Academies of Science.

Individuals who are paid by companies that manufacture, process, and profit from formaldehyde have a direct financial interest in the results of the formaldehyde risk evaluation. Thus, such people are not permitted to serve on the federal advisory committee that reviews formaldehyde risks. Yet *despite federal rules and laws proscribing the appointment of advisory committee members who have [conflicts of interest](#)*, EPA has appointed to its chemical advisory committee petrochemical industry scientists tied to ACC, the chemical industry lobbying arm, and its affiliated companies.

Those voices played a vocal role in the Science Advisory Committee on Chemicals ([SACC](#)) report, and it is their claims that EPA is selectively lifting, without attribution, to justify its dangerous rollbacks of human health protections. EPA uses this same approach to cherry-pick comments from the Human Studies Review Board (HSRB), an ethics committee that oversees the use of human subjects in research. This group was not asked – and does not have the expertise – to weigh in on many of the key issues in the formaldehyde risk evaluation. EPA's use of HSRB comments is misleading.

Perhaps most shocking, EPA's new risk models reject the thoroughly analyzed and peer-reviewed findings of EPA's own scientists in their more than 2,000-page assessments of formaldehyde. For the past 40 years, independent scientists in EPA's Integrated Risk and Information System developed human health toxicity assessments for toxic chemicals, and for 15 of those years, the IRIS scientists had been working on their formaldehyde report. The IRIS review found that formaldehyde presents increased cancer risks at all levels of exposure, with no safe threshold. Their evaluation process included in-depth and independent scientific analysis by EPA scientists, interagency scientific review, public comment, and external peer review. Shamefully, EPA has rejected the IRIS report and their entire division: Last year Lee Zeldin and Elon Musk fired nearly the entire Office of Research and Development including the IRIS scientists as part of their thousands of DOGE layoffs.

EPA also brushes aside the detailed findings by the IRIS assessment's peer reviewers at the National Academies of Sciences, Engineering, and Medicine (NASEM). The [NASEM peer review](#) report on formaldehyde supported and affirmed all of the core findings of the EPA IRIS assessment -- and rejected many of the very arguments that EPA is now adopting. The National Academies concluded, among other key points, that "EPA used approaches consistent with its state-of-practice methods to derive the inhalation unit risk estimates" in undertaking its dose-response assessment for cancer endpoints, and that EPA's IRIS assessment "follows the advice of prior National Academies committees, and its findings on hazard and quantitative risk are supported by the evidence identified." EPA's new approach contradicts the results of the NASEM peer review.

EPA adds no new data to the formaldehyde risk evaluation, nor does it re-analyze any existing data. It disregards contrary views from independent scientists not tied to the chemical industry. It has not sought peer review for its fundamental shift in risk evaluation methodology.

There is no way readers could pick this up from simply reading the EPA draft risk calculation memo.

Setting a Dangerous Precedent for Genotoxic Carcinogens

EPA's proposed risk calculation seeks to take a wrecking ball to decades of systematic, peer-reviewed experiments, observations, and analyses. **They are radically changing how EPA evaluates health risks, rejecting a wealth of internationally recognized, peer-reviewed science that has withstood the last four presidential administrations.** They are ignoring EPA's own cancer guidelines. If allowed to move ahead, the agency will set a menacing new precedent

for the management of toxic chemicals, particularly those that pose a danger at low levels of exposure.

As a genotoxic, DNA-damaging carcinogen, formaldehyde poses what is called a “linear no-threshold” risk, meaning that even small amounts can be harmful. There is no safe level of formaldehyde. But the Zeldin EPA is now claiming that lower-level exposures to this potent carcinogen are perfectly safe, even for children and babies. Such exposures may happen while snuggling on an off-gassing sofa, crawling on formaldehyde-laden floors and carpets, wearing formaldehyde-treated wrinkle-resistant clothes, doing art projects using glues, paints, felt, and other supplies that contain formaldehyde, and so on. So long as the level emitted by the particular source is below EPA’s “acceptable” threshold, the agency is now claiming that no regulation is needed.

For fifty years, EPA has been using the linear no-threshold model for assessing risks from genotoxic carcinogens. It provides the scientific foundation to safeguard people against cancer-causing pollutants under the Clean Air Act, the Superfund law, the Safe Drinking Water Act, and other environmental laws. This model is critical for protecting children and all people. The linear no-threshold model recognizes that even the lowest concentrations of formaldehyde and other potent carcinogens can trigger life-altering effects.

The variations in human vulnerability to cancer-causing substances remain poorly understood – why one person gets sick and their neighbor does not. Regulating chronic low-level exposures to these chemicals is critical in helping to safeguard the entire population including the most vulnerable and most exposed. This includes babies and kids, pregnant people, workers, frontline communities, as well as anyone whose genetic roll-of-the-dice might add to their susceptibility.

Unraveling protections against toxic chemicals

The Zeldin EPA has been putting a sledgehammer to the peer-reviewed models and methods the agency uses for evaluating toxic chemicals. This past fall, we witnessed the agency’s [full-throttled assault](#) against EPA’s risk evaluation procedures under TSCA. The radical changes found in EPA’s draft risk calculation for formaldehyde would further disembowel whatever is left of EPA’s so-called “chemical safety” program.

In its proposed TSCA “Framework Rule,” EPA gives itself full discretion to pick and choose which “conditions of use” to include. EPA divides up the risk evaluation -- pretending that each selected use and pathway of exposure is the only one, and refusing to acknowledge that people face more than one isolated exposure. This approach to risk evaluation would dramatically

under-count the toxic exposures and lead to much weaker protections, if any. **Combining the proposed risk evaluation Framework Rule with EPA's refusal to regulate low doses of carcinogens, as laid out in the formaldehyde risk memorandum, is a recipe for disaster.**

The EPA proposals evoke a fantasy world in which exposures are minimal and restrictions are tightly calibrated to control any possible ill-effects. Nothing could be farther from the truth. Such isolated exposures only take place in a petri dish. In real life we are exposed to toxic chemicals from a multitude of sources. **The low doses are not low when you add them together.... a step that EPA refuses to take.**

Among the worst affected by these terrible EPA precedents – if they move forward -- will be the millions of Americans living in communities plagued by fossil fuel and petrochemical industry buildout. This includes those who reside along the 85-mile stretch between Baton Rouge and New Orleans, Louisiana, a section of the Mississippi River lined by roughly 200 fossil fuel and plastics-making facilities. Also hard hit will be those residing in the 52-mile Houston Ship Channel, where more than 600 factories make plastics, fertilizers, pesticides, and other petrochemicals.

Children and families living in these areas are exposed to a dense mix of potent carcinogens including formaldehyde, ethylene oxide, PFAS, heavy metals, and other potent carcinogens. Parceling out the risk evaluations into individual sources, conditions-of-use, and exposure pathways may lead EPA to conclude that each of these thousands of discrete exposures to carcinogens is “low dose” and thus “safe.”

There is nothing “gold standard” about risk evaluation methods that divide the carcinogenic exposures into itty bitty parts and then claim that each bit is so small that it's safe, no restrictions needed.

Time for EPA to get back on track

The draft risk memorandum is part of the Office of Chemical Safety and Pollution Prevention's frantic efforts to undo essential human health protections against formaldehyde and other toxic chemicals. The proposal represents a cataclysmic shift in the way EPA regulates toxic chemicals, including those that alter DNA and cause cancers. The new approach to risk calculation would endanger the nation's children and families, and would set dangerous precedents. It would undermine EPA's Cancer Risk Guidelines, affecting regulations for carcinogens under the Toxic Substances Control Act, the Clean Air Act, the Safe Drinking Water Act, and other laws meant to keep Americans safe.

Moms Clean Air Force rejects EPA's fictional accounting of risk, its nuking of the linear no-threshold model, its refusal to regulate low levels of exposure, its axing of IRIS and scrapping of decades of world-class science. We urge EPA Administrator Lee Zeldin to abandon this hostile attack on the nation's health and safety protections and to comply with the TSCA's mandate to protect children, families, workers, fenceline communities, and all people.

Respectfully submitted,

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