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Revised Draft Human Health Risk Assessment for Formaldehyde

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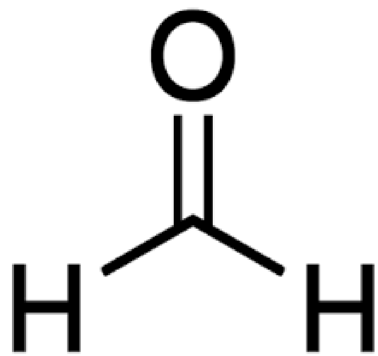

This draft redline reflects the implementation of the Updated Draft Risk Calculation Memorandum within this document of the Revised Draft Risk Evaluation for Formaldehyde. See the associated Updated Draft Risk Calculation Memorandum and December 2025 Federal Register Notice for more detail.

December 2025

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX TABLES

ACKNOWLEDGEMENTS

This report was developed by the United States Environmental Protection Agency (U.S. EPA or the Agency), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

Docket

Supporting information can be found in public docket, Docket ID (EPA-HQ-OPPT-2018-0438).

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This document was reviewed and cleared for publication by OCSPP leadership.

Formaldehyde – Human Health Risk Assessment – Key Points

Formaldehyde is a highly reactive gas that is ubiquitous in indoor and outdoor environments. It is widely used in a range of industrial applications, consumer products, and building materials (*e.g.*, composite wood products, plastics, rubber, various adhesives, and sealants). It also occurs as a product of combustion, a product of normal metabolism in the human body, and is formed naturally through the decomposition of organic matter (*i.e.*, biogenic sources such as leaves).

Health effects of concern for formaldehyde include cancer, sensory irritation, and respiratory effects such as increased asthma prevalence, reduced asthma control, and reduced lung function. People may be exposed to formaldehyde at work, through indoor air, through use of consumer products, and through outdoor air near sources of formaldehyde. People are often exposed to more than one source of formaldehyde concurrently, some of which are regulated under the Toxic Substances Control Act (TSCA), some of which are regulated under other laws, and some of which are not regulated at all (*e.g.*, the decomposition of leaves).

This human health risk assessment for formaldehyde evaluates the risks of formaldehyde exposures for workers, consumers, and the general population resulting from TSCA conditions of use (COUs).

Risk estimates include inherent uncertainties and the overall confidence in specific risk estimates varies. The analysis provides support for the Agency to make a determination about whether formaldehyde poses an unreasonable risk to human health and to identify drivers of unreasonable risk among exposures for people (1) with occupational exposure to formaldehyde, (2) with consumer exposure to formaldehyde, (3) with exposure to formaldehyde in indoor air, and (4) who live or work in proximity to locations where formaldehyde is released to air. Concurrent with this Human Health Risk Assessment, EPA is releasing a risk determination for formaldehyde.

EPA considers the standard risk benchmarks associated with interpreting margins of exposure and cancer risks. However, the Agency cannot solely rely on those risk values. If an estimate of risk for a specific exposure scenario exceeds the benchmarks, then the decision of whether those risks are unreasonable under TSCA must be both case-by-case and context driven in the case of formaldehyde. EPA is taking the risk estimates of the human health risk assessment (HHRA), in combination with a thoughtful consideration of other sources of formaldehyde, to interpret the risk estimates in the context of making an unreasonable risk determination.

EXECUTIVE SUMMARY

This draft redline reflects the implementation of the updated draft risk calculation memorandum within this document of the Revised Draft Risk Evaluation for Formaldehyde. See the associated Updated Draft Risk Calculation Memorandum and Federal Register Notice, or "the Notice," for more detail.

Sixty-three conditions of use of formaldehyde were determined to be within the scope of TSCA and were assessed by OPPT. These conditions of use were identified as part of the *Final Scope for the Risk Evaluation for Formaldehyde; 50-00-0* (U.S. EPA, 2020c) and recently updated to better reflect the Agency's understanding of the sources of formaldehyde. Examples of the conditions of use considered in the TSCA risk evaluation are listed below with a comprehensive list provided in the *Conditions of Use for the Formaldehyde Risk Evaluation* (U.S. EPA, 2024c). These include

- manufacturing of formaldehyde,
- processing and manufacturing of articles and products,
- composite wood products,
- plastics used in toys,
- rubber materials, and
- various adhesives and sealants.

Reasonably available information indicates that formaldehyde is released to air, land, and water from various TSCA conditions of use. Although the formaldehyde risk evaluation considered each of these pathways of exposure, some of these releases result in negligible exposure based on the chemistry, fate, and transport properties of formaldehyde. Formaldehyde exposures by those pathways were not assessed further. These include

- sediment and water including drinking water, and
- soils, biosolids, and landfills.

Similarly, some conditions of use were considered for consumer scenarios and result in negligible exposure based on the chemistry, fate, and transport properties of formaldehyde. Other conditions of use could not be quantitatively assessed due to the limitation of available models and data. These conditions of use are

- portable toilet cleaner and sanitizer,
- water treatment,
- laundry detergent, and
- lawn and garden products.

This Human Health Risk Assessment focuses on human exposure to formaldehyde from industrial, occupational, and consumer activities via inhalation of indoor and outdoor air and dermal (skin) routes. Exposure to workers, consumers and people within the general population have been assessed under specific conditions of use. Not all conditions of use result in formaldehyde exposure for all populations. Among the populations assessed are potentially exposed or susceptible subpopulations, which are people who have higher exposures or are more susceptible so may be at greater risk of adverse health effects from formaldehyde. Example populations (including PESS), routes of exposure, and conditions of use include the following:

- worker inhalation and dermal exposure during manufacturing, processing, distribution, use and disposal of formaldehyde;
- consumer (based on highest expected exposure among all ages) inhalation and dermal exposure from use of paint, textile and leather finishing products, varnishes and floor finishes, rubber

mats, adhesives, caulks and sealants, liquid photographic processing solutions, and non-spray lubricants that contain formaldehyde;

- general population (all ages) inhalation exposure to indoor air from articles used in new construction of homes and mobile homes (*e.g.*, wood materials, furniture seat covers); and automobiles with articles that contain formaldehyde; and
- general population (all ages) inhalation exposure to outdoor air near industrial facilities that release formaldehyde.

As mentioned, there are many formaldehyde sources. Not all sources are evaluated in the *TSCA Risk Evaluation*, for instance because they occur naturally or because they are excluded from the TSCA "chemical substance" definition under TSCA section 3(2)(B). These include

- biogenic sources (like trees and wood chips);
- forest fires;
- embalming fluids and products used to preserve animal specimens;
- other pesticides as defined in Federal Insecticide, Fungicide, and Rodenticide Act;
- drugs for fisheries and hatcheries;
- animal feed;
- pacifiers and baby bottles;
- plastic products used for food storage and distribution;
- other formaldehyde uses that meet the definition of "food, food additive, drug, cosmetic, or device" as defined in the Federal Food, Drug, and Cosmetic Act;
- tail-pipe emissions from cars, trucks, and other vehicles; and
- secondary formation.[1]

These other sources can produce substantial amounts of formaldehyde resulting in exposures in the occupational, indoor, and outdoor environments. For example, biogenic concentrations can contribute upwards of 25 percent of the total formaldehyde concentration and secondary formation can account for as much as 80 percent in ambient air, depending on the circumstance.

Hazard Values

Human health hazard data for this assessment were obtained through collaboration with ~~ORD and~~ OPP as well as through the TSCA systematic review process. In addition, OSCPP is relying on the peer reviews provided by the National Academies of Science, the TSCA Science Advisory Committee on Chemicals, and the Human Studies Review Board on certain aspects of the human hazard assessment.

OPPT is using a revised inhalation point of departure (POD) of 0.3 ppm for sensory irritation and an uncertainty factor of 1 (1×) as described in the Federal Register Notice (FRN) Formaldehyde. ~~the inhalation unit risk for nasopharyngeal cancer as derived in the EPA IRIS Toxicological Review of Formaldehyde-Inhalation. Although inhaled formaldehyde has been associated with multiple types of cancer in humans including nasopharyngeal and myeloid leukemia, the myeloid leukemia findings are not sufficient to develop quantitative estimates of cancer risk. While there may be uncertainty on the extent to which other mechanisms contribute to the carcinogenicity of formaldehyde, the IRIS assessment concluded that a mutagenic action contributes to risk of nasopharyngeal cancer from inhaled formaldehyde. To account for the potential increased susceptibility that may be associated with early life~~

[1] Formaldehyde is also largely found in the environment due to secondary formation of the chemical after degradation of other compounds, for example when a chemical undergoes chemical reactions in the air and forms formaldehyde. Some secondary formation may be a result of TSCA conditions of use, but these cannot be distinguished from all other secondary formations because they are so abundant.

exposure to formaldehyde, OPPT used a cancer value adjusted with age dependent adjustment factors for exposure scenarios that include early life.

Formaldehyde exposure is also associated with a range of respiratory and non-respiratory health effects in humans including reduced pulmonary function, increased asthma prevalence, decreased asthma control, allergy-related conditions, and sensory irritation (including eye irritation and respiratory irritation). OPPT is using a an acute inhalation POD of 0.3 ppm that is appropriate as the critical effect to protect for all other potential hazards, including cancerchronic point of departure for pulmonary function in children derived from the EPA IRIS Toxicological Review of Formaldehyde-Inhalation. Sensory irritation (*e.g.*, eye irritation) observed in adults is the critical effect for non-cancer effects from acute exposure to formaldehyde in air. Skin sensitization observed in adults is the critical effect for assessing formaldehyde exposure via the dermal routes.

Oral hazard data are also available for formaldehyde but were not used in the risk assessment because exposure was not expected.

Revised Risk Calculations Resulting in Substantial Change

For COUs that the Agency found significantly contribute to the unreasonable risk presented by formaldehyde in the Risk Evaluation for Formaldehyde, the revised POD and corresponding uncertainty factor impacts five COUs for workers where the central tendency or high-end inhalation estimate no longer exceeds the benchmark. These COUs are shown in Table ES-1.

Table ES-1 Acute MOE Calculations for Workers Where Central Tendency Risk or High-End Risk Is No Longer Below the Benchmark for Workers or Occupational Non-Users

COU	Draft Revised Central Tendency MOE for Acute Inhalation (UF = 1)	Draft Revised High-End MOE for Acute Inhalation (UF = 1)
Lawn and garden products	7.18	1.77
Oxidizing/reducing Agent	3.24	1.31
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	2.00	0.10
Recycling	1.38	0.51
Laboratory chemicals	1.98	0.10

In addition, three COUs would have central tendency and high-end inhalation estimates for ONUs that no longer show risk above the benchmark. These estimates are shown in Table ES-2.

Table ES-2. Acute MOE Calculations for ONUs Where Central Tendency Risk Is No Longer Below the Benchmark

COU	Draft Revised Central Tendency MOE for Acute Inhalation (UF = 1)	Draft Revised High End MOE for Acute Inhalation (UF = 1)
Laboratory chemicals	1.99	0.232
Recycling	1.38	0.51
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	1.62	0.46

Exposure for Workers and the General Population

Many data sources were used to evaluate exposures to humans (workers; consumers and general population, both including children) from indoor and outdoor air as well as dermal exposures. These include measured and model estimated concentrations data. There are many conditions of use and many different exposure scenarios for each population assessed.

Workers: Worker exposure to formaldehyde via inhalation and dermal are expected to result in the highest formaldehyde exposures among the assessed populations. Workplace concentrations of formaldehyde vary based on activities performed (*i.e.*, manufacturing, processing, industrial, and commercial settings). Individuals in workplaces whose duties are not directly associated with manufacturing, processing, or use of formaldehyde (*i.e.*, occupational non-users [ONUs] such as supervisors) which may be near or within the same workspace (*i.e.*, breathing the same air) are also expected to be exposed to formaldehyde at similar concentrations.

Inhalation exposures were estimated based largely on measured formaldehyde concentrations in occupational settings. Monitoring data were available for many scenarios. However, monitoring data are not available for four conditions of use in commercial settings and were thus modeled. These model estimates broadly fell within the range of monitored workplace concentrations available for other conditions of use. Across all conditions of use, full work shift (8–12 hours) inhalation exposure estimates were between 0.0114 to 17,353.3 μg/m^3. Peak inhalation estimates for workers were between 2.5 to 209,815 μg/m^3 across all conditions of use. The highest inhalation exposure was based on modeled estimates for use of formulations containing formaldehyde in automotive care products. Occupational exposure concentrations, as expected, are generally higher than modeled and measured outdoor and indoor formaldehyde air concentrations. EPA has an overall medium confidence in the reported exposure estimates because most of the values are based on recent (1992–2020) real workplace monitoring data from multiple sources and therefore are expected to be reflective of current industrial practices. EPA does not have higher overall confidence in the reported exposure estimates because the sources did not always provide supplemental information such as worker activities and associated process conditions. Therefore, the Agency made assumptions in integrating monitoring data.

Short-term dermal exposures were estimated based on liquid contact with formulations containing formaldehyde. Dermal exposure estimates ranged from 0.56 to 3,090 μg/cm². The highest dermal exposure was estimated during spray application of products such as paints and automotive care products. EPA has medium confidence in the dermal exposure estimates because the estimates were derived using a standard peer-review model based on measured data on the retention of liquids on the skin surface. The Agency does not have higher confidence in the reported values because EPA did not have monitored formaldehyde dermal exposure data to ground truth these exposure estimates.

General Population – Consumer Exposures in Residential Settings: Frequent users of products containing formaldehyde are anticipated to be the next highest population effected due to its use in products and articles that are available to most people for purchase. Some examples of these consumer products that contain formaldehyde include automotive care products; fabrics, textiles, and leather products; and adhesives or sealants. Exposure estimates for these products varies due to the different durations (or activity) of use along with formaldehyde amount acquired from safety data sheets. This assessment considered concentrations of formaldehyde during and following use of consumer products in residential settings. Specifically, peak (15-minute) inhalation exposures as well as short-term dermal exposures were estimated.

Several conditions of use were evaluated for peak inhalation exposures. Fifteen-minute concentration estimates ranged from 1.72 to 2,500 μg/m³. The highest concentrations were for products like floor covering, foam seating, bedding, etc. EPA has medium confidence in the inhalation exposure estimates based on the number of monitoring data sources, use of the EPA's *Exposure Factors Handbook* and survey data on consumer behavior and activities, and chemical amounts report on product-specific safety data sheets. Monitoring data that can be tied to specific consumer conditions are not available. Formaldehyde concentrations from consumer products are expected to be represented in the available indoor air monitoring data as an aggregate concentration with other consumer and indoor air sources.

Dermal short-term exposures for consumers were estimated based on contact with products containing formaldehyde. Dermal conditions of use were evaluated with estimated short-term formaldehyde dermal loading rates ranging from 1.03 to 3,090 μg/cm². The highest concentrations were estimated to be for exterior car waxes and polishes followed by photographic processing solutions. EPA has medium confidence in these estimates because there are no monitoring data available to ground truth these concentration estimates.

General Population – Indoor Air Exposures in Residential and Vehicular Settings: There are many sources of formaldehyde within residences (homes and mobile homes) and vehicles. As mentioned, these include both TSCA sources such as building materials, finishes such as wood flooring and paint, and foam cushions on furniture, and other sources such as combustion sources like candles, fireplaces, and stoves. Additionally, consumer products containing formaldehyde may also contribute to indoor concentrations of formaldehyde.

The highest formaldehyde concentrations from TSCA sources are expected in newly constructed homes and mobile homes. In these settings, multiple sources of formaldehyde contribute to total indoor air concentrations especially during the peak product emission period when new formaldehyde containing articles and products are introduced. These concentrations substantially diminish within the first two years of the product life based on open literature data. The peak exposure to formaldehyde from these products is expected to occur within one year of use or manufacture. Indoor air concentrations can also be higher when new materials like hardwood floors or wallpaper are installed in homes. Similarly, fabric in new furniture may also release formaldehyde in indoor environments after being introduced.

Therefore, formaldehyde concentrations in indoor environments are expected to vary over longer time periods (*e.g.*, an individual's lifetime) and are highly dependent on an individual's propensity to move to new homes as well as their purchasing behaviors and the length of time between manufacturing and installation.

Four conditions of use in both automobiles and homes were evaluated. The highest concentration comes from construction and building materials that cover large surface areas like hardwood floors. These modeled concentrations represent high-end estimates for each condition of use. Furthermore, many of the products that fall within this condition of use are subject to the emission standards under TSCA Title VI (15 U.S.C. §2697), which for laminated products, have only been fully implemented as of March 2024 (see 40 CFR part 770).

Monitoring data from the American Healthy Homes Survey II suggests that concentrations of formaldehyde range from 0.27 to 124.2 μg/m^3 for all homes, with 95 percent of homes having concentrations below 46 μg/m^3. Thus, indoor exposures to formaldehyde are in general agreement across available data and sources of formaldehyde; but monitoring values represent all sources of formaldehyde in indoor air (including sources that are not subject to TSCA) and cannot be attributed to a single TSCA condition of use. Similarly, measured concentrations are not expected to reflect full implementation of TSCA Title VI (15 U.S.C. §2697), which for laminated products has only been fully implemented as of March 2024 (see 40 CFR part 770). Therefore, it is reasonable to expect that less formaldehyde will be released from many wood products in the future than occurred in the past.

Overall, EPA has high confidence in the indoor air concentration estimates because the values are based on article-specific emission rates and article-specific formulations of formaldehyde. In addition, EPA integrated various indoor air monitoring data sources including the American Healthy Homes Survey II (AHHS II), which is a robust nationally representative monitoring dataset representing multiple home types and home characteristics for formaldehyde, monitoring data from outside the home to characterize the spectrum of formaldehyde concentrations in the indoor environment, and two models which were used to characterize expected concentrations in the indoor environment. Though, there were some uncertainties in the precise indoor air concentration estimates because the models used were not able to predict precise long-term concentrations due to model limitations (*e.g.*, changes in emission rates over time) and available monitoring data cannot be directly tied to specific articles (*e.g.*, wood and fabric) and associated conditions of use.

General Population – Outdoor Air Exposures: As previously mentioned, formaldehyde exposures in outdoor air (ambient air) come from many sources including biogenic sources, secondary formation, and TSCA COUs. Outdoor air exposure concentrations are mostly lower than those in other settings (indoor air, occupational, consumer) under TSCA COUs, but can still substantially contribute to overall exposures. The outdoor air exposure assessment evaluated daily average and annual average inhalation exposures, focusing on a subset of the general population living within a half mile of releasing facilities.

Daily average exposures primarily attributable to TSCA COUs ranged from 0.0004 to 66.2 μg/m^3. The highest modeled daily average exposures attributable to TSCA COUs came from wood product manufacturing and paper manufacturing industry sectors.

Daily average exposures primarily attributable to combustion like airplanes, on-site vehicles, process heaters, turbines and reciprocating internal combustion engines (RICE) ranged from 2 to 662 μg/m^3. The highest modeled daily average concentrations came from the Wholesale and Retail Trade and Oil and Gas drilling, extraction, and support activities industry sectors.

Annual average exposures primarily attributable to TSCA COUs ranged from 0.0001 to 5.75 µg/m^3. The highest annual average exposures come from operations within nonmetallic mineral product manufacturing and textile, apparel, and leather manufacturing industry sectors.

Monitoring data from Ambient Monitoring Technology Information Center archive, based on data collected between 2015 to 2020, range from 0 to 60.1 µg/m^3 with a median of 1.6 µg/m^3 across more than 300,000 monitored values from 214 sites. Monitoring data could not be linked to specific conditions of use.

Because monitored concentrations represent total aggregated concentrations from all contributing sources, while these values are not directly comparable to IIOAC modeled concentrations alone, by considering multiple data sources (modeled concentrations, biogenic and secondary sources) EPA found considering these three primary contributors together represent a large portion of the total monitored concentrations and does not result in concentrations outside of or well above any monitored concentration.

EPA has medium confidence in the IIOAC modeled results used to characterize exposures in this ambient air assessment, due to uncertainties related to input parameters and spatial and temporal differences seen across the multiple lines of evidence considered. This assessment is a conservative assessment that is not site specific. Ambient air modeling for formaldehyde does not account atmospheric degradation (i.e. photolysis) and how local weather patterns may affect the presence of formaldehyde over time. Furthermore, the assumption that individuals reside in the same location for the duration of their life (i.e. 78 years) is conservative. Similarly, the assessment was conducted independent of the size of the facility footprint, the precise location of the release, and the relative location of residences. Additional modeling with HEM results provides additional context on the spatial variability of formaldehyde concentrations across the U.S. and an approximate understanding of populations exposed.

Risk Characterization

People are regularly exposed to formaldehyde in their workplace, in their vehicles, and in their homes. People may also be exposed to formaldehyde due to its natural formation in the environment and as a natural part of human metabolism.

Worker Risk Characterization: Based on available occupational monitoring data and exposure modeling estimates, worker exposure to formaldehyde is expected to be higher than exposures from naturally occuring sources. This assessment does not assume personal protective equipment use to account for a range of possible workplaces. Both high-end and central tendency exposure estimates were used with the available hazard data to evaluate cancer and non-cancer risks. Sensory irritation is being used by EPA to evaluate acute air exposure to formaldehyde. Sensory irritation is commonly used as a parameter for setting occupational exposure limits. The Agency is using skin sensitization to evaluate risks from dermal exposure to formaldehyde.

EPA recognizes that chronic inhalation exposure is likely for many workers and has calculated non-cancer and cancer risk estimates for worker. However, the non-cancer chronic effects EPA used in its calculations are based on effects observed in children, and some SACC peer reviewers indicated concerns with determining risk to workers based on health effects observed in children.

At high-end exposure scenarios, results indicate workers may be at increased risk for acute sensory irritation and nasopharyngeal cancer. Acute sensory irritation effects are based in controlled human exposure studies. Cancer effects are based on human studies in occupational settings. The risk estimates for occupational exposures reflect use of standard risk assessment approaches considering an abundance of high-quality workplace monitoring data that clearly exceed concentrations of formaldehyde from other sources including natural sources and human hazard data. Likewise, risk estimates are generally consistent across central tendency and high-end exposure scenarios for workers. While there are some uncertainties in the assessment, these uncertainties are not expected to change risk estimates enough to shift the overall risk assessment conclusions but may be great enough to change risk estimates for specific conditions of use.

Results indicate that effects to workers from dermal exposure that could lead to sensitization with repeated exposure for all conditions of use except one. All exposure estimates were based on standard modeling approaches including the assumption of the amount of liquid left on the skin after contact which is not specific to formaldehyde. The hazard data for skin sensitization is based on controlled human exposures in adult volunteers and is corroborated by animal and in vitro evidence. The dermal sensitization data are based on controlled human exposures studies in adults.

Consumer Risk Characterization: Consumer risk estimates were calculated for acute inhalation effects as well as dermal sensitization.

Consumers may experience acute sensory irritation when inhaling peak concentrations of formaldehyde in their residences when using products that contain high amounts of formaldehyde for short durations. These acute effects are based on a robust dataset of evidence for sensory irritation in humans, including several high-quality controlled exposure studies with relevance for acute exposure scenarios. The risk estimates reflect use of standard risk assessment approaches and best available data.

Consumers inhaling formaldehyde may also experience decreased pulmonary function and other chronic effects when those products are used frequently. These effects are based on data from humans at sensitive lifestages, but it is unclear whether exposure scenarios represent how all people use these products and articles containing formaldehyde. EPA has substantial data on use patterns of these products based on surveys conducted on consumer activities and behaviors. Similarly, EPA's *Exposures Factors Handbook* was used to support consumer exposure analyses. Lastly, safety data sheets were used to identify concentrations of formaldehyde in consumer products. It is worth noting that conservative estimates from these data sources may not represent exposures to all consumers using products and articles containing formaldehyde. The risk estimates reflect use of standard risk assessment approaches considering best available data for consumers who frequently use products containing formaldehyde; but understanding the commonness of these practices has some uncertainty because it is unclear how older data from surveys represents current behaviors and uses.

At high-end exposure scenarios, results indicate consumers may have increased risk for developing nasopharyngeal cancer, but this is expected to be rare in the general population. The data for cancer effects are based on human studies that are corroborated in animal studies. EPA believes these risk estimates are for consumers who frequently use products containing formaldehyde over the course of many years. However, EPA does not have information on how common it is that consumers would use these products for this length of time, and it is unclear how older data from surveys represents current behaviors and uses.

Consumers using products containing formaldehyde may experience dermal sensitization after acute exposures to their skin. The hazard data for skin sensitization is based on controlled human exposures in adult volunteers and is corroborated by animal and in vitro evidence. Risk estimates for these dermal exposures is based on estimated dermal loading from models. Monitoring data are not available to determine how common these exposures may be for consumers. Thus, EPA has less certainty in how common these exposures result in skin sensitization for consumers in the general population.

Indoor Air Risk Characterization: Indoor air risk estimates were calculated for acute, chronic non-cancer, and cancer inhalation effects. People who are living in homes where high concentrations are present may experience decreased pulmonary function and other chronic effects. These effects are based on data from humans at sensitive lifestages. However, the exposure scenarios where these effects are seen are mostly limited to homes where high surface area products like hardwood floors and wallpaper may be introduced. Similarly, these effects may occur in new homes and mobile homes where all new products may be contributing to high concentrations of formaldehyde in air. As previously mentioned, the dissipation rate of formaldehyde from these TSCA conditions of use could not be fully characterized. However, concentrations are anticipated to decrease with time and ventilation. Generally, new products are expected to have substantially reduced formaldehyde emissions within two years.

In addition to TSCA sources, other sources of formaldehyde may contribute substantially to indoor air concentrations of formaldehyde. Formaldehyde concentrations from candles, incense, cooking, wood combustion, and air cleaning devices fall within the range of formaldehyde concentrations from TSCA conditions of use. Furthermore, the range of concentrations estimated fall within the range of available monitoring data.

Many of these other sources of formaldehyde represent temporary emission sources, which may affect the overall impact on indoor air quality. Further, qualities such as the frequency and duration of use of these temporary formaldehyde sources (*e.g.*, burning candles or the use of a fireplace), age of the home and formaldehyde-containing home finishes and furnishings, and ventilation rate will impact the total concentration of formaldehyde in indoor air and the relative contribution of TSCA and other sources to the indoor air. Combined, the many factors that may contribute to overall indoor air concentrations and relative concentrations from TSCA and other uses introduce a significant source of uncertainty in the indoor air exposure assessment.

EPA has high confidence in the conclusion of the inhalation risk assessment for indoor air. This is because the assessment is based on product-specific emission rates, data, and standard methods. While the monitoring data cannot be tied to individual conditions of use, it is expected to represent aggregate exposure to formaldehyde resulting from multiple sources. As such, EPA has confidence it is not underestimating formaldehyde exposure resulting from TSCA conditions of use or across all sources of formaldehyde.

Ambient Air Risk Characterization: Based on modeling estimates, individuals of the general population living within half mile of a releasing facility may be exposed to formaldehyde at high concentrations. In some locations some individuals may be at increased risk for developing nasopharyngeal and other cancer types. However, this is contingent on the assumption that an individual lives within a half mile of a releasing facility their entire life.

EPA has medium confidence in the conclusion of the inhalation risk assessment for the general population. EPA has this confidence because the assessment is based on a large amount for formaldehyde reported release data, standard methods, and previously peer reviewed models.

~~Furthermore, the range of concentrations estimated fall within the range of available monitoring data. While the monitoring data cannot be tied to individual conditions of use, it is expected to represent aggregate exposure to formaldehyde resulting from multiple sources. However, this assessment is a conservative assessment that is not site specific. Similarly, the assessment was conducted independent of the size of the facility footprint, the precise location of the release, and the relative location of residences. Therefore, EPA has high confidence it is not underestimating formaldehyde exposure resulting from TSCA conditions of use or across all sources of formaldehyde due to conservatism but medium confidence because of the uncertainties described above.~~

1 INTRODUCTION

1.1 Background

Formaldehyde is a high priority chemical undergoing the Toxic Substances Control Act (TSCA) risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016. It is concurrently undergoing risk assessment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This *Human Health Risk Assessment* is a TSCA-specific assessment that will serve to support risk management needs by the Office of Pollution Prevention and Toxics (OPPT) and is one of many documents comprising the formaldehyde risk evaluation.

In April 2022, EPA's IRIS program released a draft *Toxicological Review of Formaldehyde – Inhalation* (U.S. EPA, 2022c) for public comment and peer review. In August 2023, the NASEM released its Review of EPA's 2022 Draft Formaldehyde Assessment (NASEM, 2023). Subsequently, IRIS released the final *Toxicological Review of Formaldehyde – Inhalation* in August of 2024 (U.S. EPA, 2024k) (also referred to as the "IRIS assessment" or final IRIS assessment throughout this document). IRIS provided responses to NASEM and public comments on the draft in Appendix F of the Supplemental Information document (U.S. EPA, 2024k). ~~EPA is relying on the IRIS assessment to identify relevant chronic hazards to consider for inhalation exposure to formaldehyde under TSCA and FIFRA.~~ OPPT and Office of Pesticide Programs (OPP) have coordinated to evaluate additional information on environmental fate and transport, human health hazard, and environmental hazard consistently across programs. From January 2021 through December 2024, OCSPP leadership directed program offices to rely on the chronic non-cancer reference concentration (RfC) and cancer inhalation unit risk (IUR) values being established by the IRIS program. Consistent with statutory obligations and Executive Order (EO) 14303, "Restoring Gold Standard Science," EPA is committed to the highest standards of scientific integrity and reliance on the best available scientific information. As such, OCSPP has re-evaluated the use of the IRIS chronic RfC and cancer IUR in the formaldehyde risk evaluation.

A list of the regulatory history of formaldehyde can be found in Appendix D of the *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0* (U.S. EPA, 2020c), which includes regulation under the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, and other EPA regulatory programs and non-EPA programs.

Following publication of the final scope document, EPA considered and reviewed reasonably available information in a systematic and fit-for-purpose approach to develop this formaldehyde risk evaluation, leverage existing EPA assessment work, collaborate across offices, rely on best available science, and base it on the weight of the scientific evidence as required by EPA's Risk Evaluation Rule under TSCA. Reasonably available information was reviewed, and the quality evaluated in accordance with EPA's *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021c), which underwent external peer review by the Science Advisory Committee on Chemicals (SACC) in July 2021.

In March 2024, EPA released the *draft TSCA Risk Evaluation for Formaldehyde* for public comment and for peer review by the SACC. The SACC meeting was held May 20-23, 2024, with the minutes and final report released on August 2, 2024 (U.S. EPA, 2024w). SACC and peer review input has been incorporated, as appropriate, in this document.

1.2 Risk Evaluation Scope

The formaldehyde risk evaluation comprises a series of assessments spread across many documents. A basic diagram showing the layout and relationships of these assessments is provided below in Figure 1-1. In some cases, these assessments were completed jointly under TSCA and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These assessments are shown in dark gray. This human health risk assessment is shaded blue. High level summaries of each relevant assessment are presented in this risk assessment. Detailed information for each supporting assessment can be found in the corresponding document.

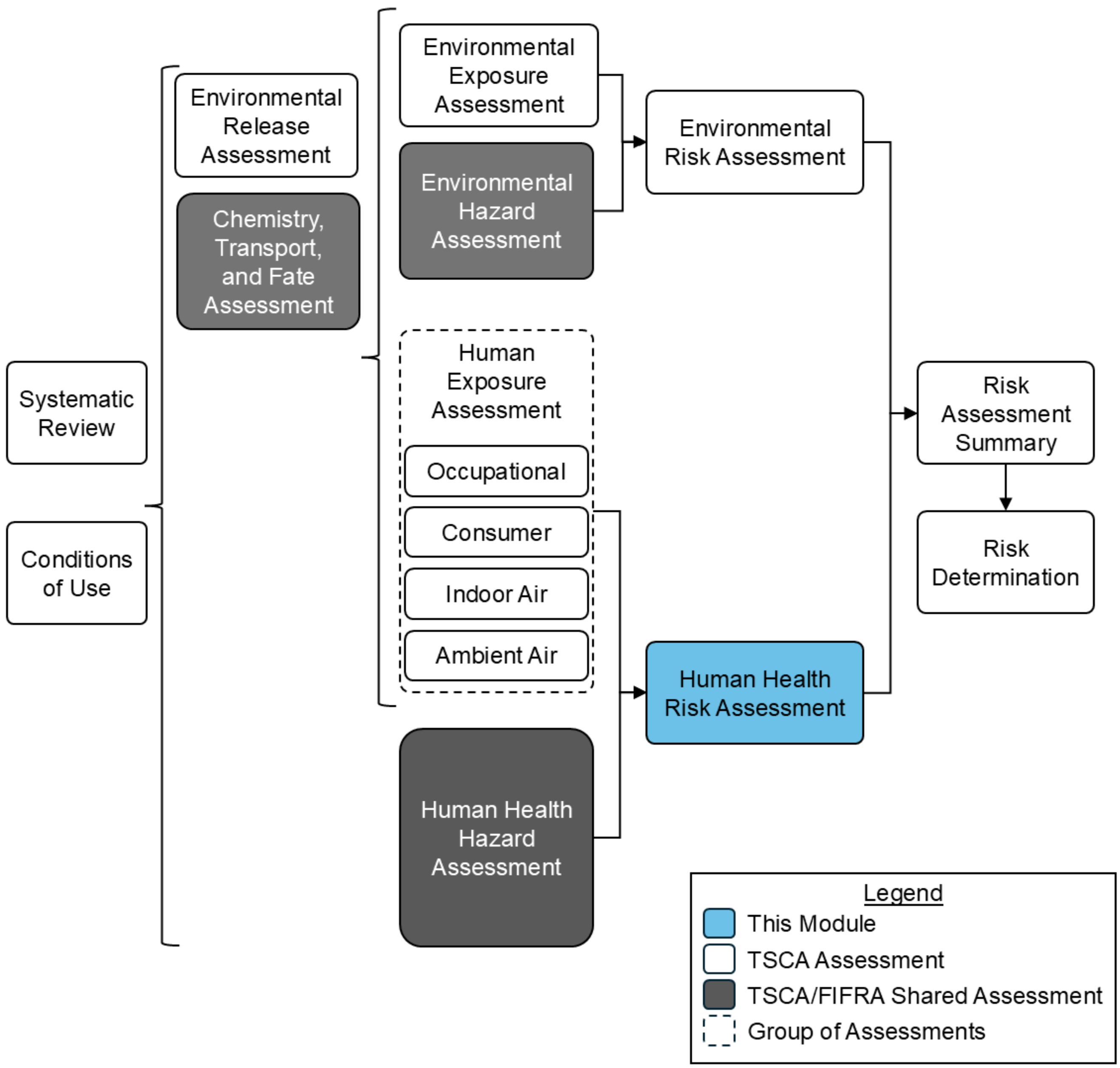


Figure 1-1~~1-1~~. Risk Evaluation Document Summary Map

These modules leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (U.S. EPA, 2020c). OPPT conducted a comprehensive search for "reasonably available information" to identify relevant formaldehyde data for use in the risk evaluation. In some modules, data utilized were also located in collaboration with other

EPA offices. ~~As previously noted, OPPT is relying on the EPA's IRIS *Toxicological Review of Formaldehyde – Inhalation* (U.S. EPA, 2024k) in the formaldehyde risk evaluation (shaded light gray in Figure 1-1). The IRIS assessment is not part of the TSCA risk evaluation bundle.~~ The approach used to identify specific relevant risk assessment information was discipline-specific and is detailed in *Systematic Review Protocol for the Formaldehyde Risk Evaluation* (U.S. EPA, 2024m), or as otherwise noted in the relevant modules.

1.2.1 Life Cycle and Production Volume

The Life Cycle Diagram (LCD)—which depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages, including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal—is shown below in Figure 1-2. The LCD has been updated since it was included in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (U.S. EPA, 2020c). The commercial and consumer uses for agricultural use products (non-pesticidal) have been included; it was inadvertently omitted under the industrial, commercial, and consumer uses lifecycle stage in the diagram in the final scope document (U.S. EPA, 2020c).

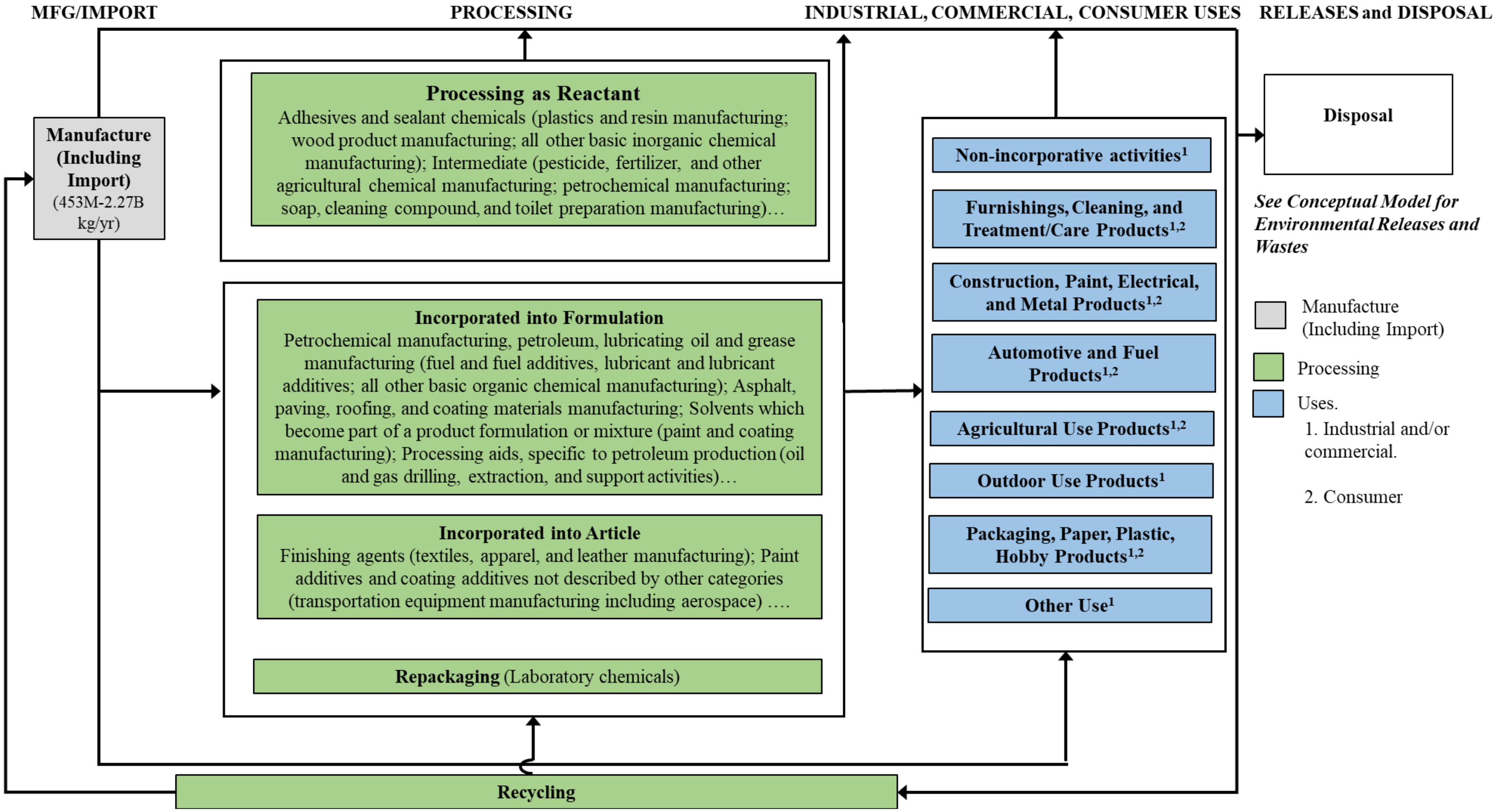


Figure 1-21-2. Lifecycle Diagram of Formaldehyde

Based on data collected under the Chemical Data Reporting (CDR) Rule in 2019, domestic formaldehyde production volume is between 453 million and 2.3 billion kg/year. CDR requires U.S. manufacturers (including importers) to provide EPA with information on the chemicals they manufacture or import into the United States every 4 years. Data collected for formaldehyde is further detailed in the *Use Report for Formaldehyde (CAS RN 50-00-0)* (Docket: EPA-HQ-OPPT-2018-0438).

1.2.2 Conditions of Use

As part of the TSCA risk evaluation, OPPT assessed formaldehyde COUs that were included in the revised COU technical support document (U.S. EPA, 2024c) including industrial, commercial, and consumer applications such as textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants. The COUs were evaluated using the corresponding environmental exposure scenarios for aquatic and terrestrial organisms. A description of COUs is available in the *Conditions of Use for the Formaldehyde Risk Evaluation* (U.S. EPA, 2024c).

1.2.3 Other Sources of Formaldehyde in Air

Formaldehyde is ubiquitous in both indoor and outdoor (ambient) air because it is formed naturally in the environment and from numerous anthropogenic sources, which include both TSCA (Section 0) and other activities. As a result, people are routinely exposed to formaldehyde in indoor and outdoor air, with indoor air generally having higher concentrations than outdoor air. Robust monitoring data are available to estimate the concentrations of formaldehyde across common outdoor and indoor environments. However, attributing measured concentrations to TSCA COUs versus other sources is complex. This section will provide an overview of these data sources and seeks to differentiate between sources when possible. This section is not intended to be a comprehensive review of the scientific literature on this topic but instead provides context for understanding and interpreting the exposures of formaldehyde from a variety of sources as part of risk characterization and risk determination of COUs under TSCA.

Formaldehyde has been measured in outdoor air across the country. EPA's Ambient Monitoring Technology Information Center (AMTIC) archive maintains a database of spatially and temporally diverse air quality monitoring data that meet specified collection and quality assurance criteria. The Agency used monitoring data extracted from EPA's AMTIC archive (U.S. EPA, 2022a) from 2015 through 2021 to contextualize modeled values as well as characterize total aggregate exposures to formaldehyde from all possible contributing sources—including sources associated with TSCA COUs and other sources out of scope for this assessment and not associated with TSCA COUs (*e.g.*, biogenic sources).These data are described in detail in Sections 2.4.1 and 3.3.2 of the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). In addition, satellite data have measured formaldehyde concentrations across the United States, providing insights on temporal and geographic trends that help to characterize ambient formaldehyde concentrations (Wang et al., 2022; Harkey et al., 2021; Zhu et al., 2017).

Comprehensive modeling efforts were undertaken to characterize formaldehyde concentrations that vary across the county. EPA's AirToxScreen is one example that uses release data with chemical transport and dispersion models to estimate average annual outdoor ambient air concentrations of air toxics across the U.S. and is validated against available monitoring data. For formaldehyde, this model estimates concentrations from different sources contributing to ambient air concentrations including biogenic sources, secondary formation, and point sources. Other sources of formaldehyde are included but may not be relevant to the scope of this risk evaluation for formaldehyde. Accordingly, the 2019 AirToxScreen estimates that secondary formation of formaldehyde accounts for up to 80 percent of formaldehyde in ambient air and direct biogenic sources contribute up to 15 percent. Based on the 2019 AirToxScreen estimates, the calculated ninety-fifth percentile biogenic concentration of formaldehyde in ambient air was 0.28 μg/m^3.

Much like outdoor air, many efforts have been made to characterize formaldehyde in the indoor environment. Data from a recent national survey provides a representative sample of formaldehyde concentrations in indoor air, showing average residential levels an order of magnitude higher than outdoor concentrations. The American Healthy Homes Survey II (AHHS II), sponsored by the U.S. Department of Housing and Urban Development (HUD) along with EPA, was conducted from March 2018 through June 2019 and measured indoor air concentrations of formaldehyde in U.S. homes of various ages, types, conditions, and climates (QuanTech, 2021). Across all housing, the weighted-mean concentration is 23.2 μg/m^3 (95% confidence interval 21.6–25.2 μg/m^3) with 10 percent of homes higher than 41.8 μg/m^3. Formaldehyde is introduced into residential indoor air from numerous TSCA sources (*e.g.*, building materials, finishes such as flooring and paint, and furniture) and other sources (*e.g.*, fireplaces, gas stoves, candles, photocatalytic air purifiers, and tobacco use). The TSCA sources are expected to consistently release formaldehyde over long periods of time, with release rates decreasing over time as the materials age. In contrast, many of the other sources are temporary emission sources and contribute formaldehyde to the indoor air intermittently. Overall, due to differences in the ages of building materials, home finishes, and furnishings and differences in presence and use patterns of other formaldehyde sources in the residence, the relative contributions of formaldehyde from TSCA and other sources to residential indoor air varies both among homes and over time within a single home. Thus, despite the availability of quality monitoring data, it remains difficult to discern source apportionment for the residential environment and there are uncertainties related to assessing exposures tied to specific TSCA COUs based on this monitoring data. OPPT solicited comment from the SACC and the public on additional sources of information that could inform the attribution of other sources of formaldehyde to support risk characterization. No data was identified from this solicitation to inform source attribution in indoor air.

1.3 Changes made between Draft and the Revised Risk Evaluation

1.3.1 Occupational Exposure Assessment

Substantial updates have been incorporated into this assessment. A full description of the changes is included in the Occupational Exposure Assessment for Formaldehyde. The key changes were:
EPA expanded the acute exposure analysis by including multiple short-term estimates categorized by sample durations. In the draft risk evaluation, the Agency only extracted full-shift estimates and 15-minute samples from the OSHA database. In the revised assessment, EPA provides the central tendency and high-end estimates based on 15-minute samples, as well as samples taken for more than 15-minutes but less than the cut-off for full-shift estimates (330 minutes). Based on public comments, the Agency also provides the estimates for samples taken between 15-minutes and 60-minutes.

EPA received additional information on the use of fertilizers containing formaldehyde. EPA revised the approach for the Commercial Use- Lawn and garden products COU to incorporate submitted information on the maximum concentration expected, container sizes, and types of fertilizers developed using formaldehyde. In addition, EPA revised the approach to estimate a use rate based on generic information on fertilizer use for agricultural and landscape applications. EPA employed a probabilistic approach that addressed variation in the expected exposure frequencies and durations.

EPA initially relied on monitoring data to support Industrial Use- Non-incorporative activities- Process aid in: oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing COU. However, there were uncertainties noted in sites monitored and a lack of data for acute risk characterization. EPA has modeled the exposures for this COU using the ESD on Chemicals Used in Hydraulic Fracturing (U.S. EPA, 2022b) and formaldehyde-specific information reported in FracFocus 3.0 database (GWPC and IOGCC, 2022).

EPA also incorporated directly or indirectly submitted monitoring data submitted during the public comment period as well as modified assignment of OSHA data as needed.

1.3.2 Consumer Exposure Assessment

No substantive changes were made to the analytical approach for the consumer exposure assessment. However, some COUs published in the *Draft Consumer Exposure Assessment* have been removed as formaldehyde appears to have been removed from their formulation based on reasonably available information. These COUs and a rationale for why they have been removed are provided below.

For the *Draft Consumer Exposure Assessment*, EPA identified a safety data sheet (SDS) published in 2017 for a portable toilet cleaner and sanitizer (Port-o-Loo) with a formaldehyde weight fraction of 10 percent that was relevant to a drain and toilet cleaner exposure scenario. As of 2023, this product no longer contained formaldehyde in its formulation and no similar products could be identified. As a result, this use is not reasonably foreseen to occur now or in the future. Therefore, it has been removed for the *Revised Consumer Exposure Assessment*.

Also for the *Draft Consumer Exposure Assessment*, EPA identified a safety data sheet (SDS) published in 2018 for a laundry and dish washing products (WOOLITE® Darks Laundry Detergent), with a formaldehyde concentration of less than 0.01%. As of June 1, 2021, this product has been discontinued and no similar products could be identified. As a result, this use is not reasonably foreseen to occur now or in the future. Therefore, it has been removed for the *Revised Consumer Exposure Assessment*.

Lastly, EPA assumed consumer uses of products containing formaldehyde were chronic and continuous (*i.e.*, 24 hours per day, 7 days per week) in the *Draft Consumer Exposure Assessment*. For the revised assessment, the Agency assumes that uses are less frequent for consumer products and focuses on peak exposures. In addition, *Revised Consumer Exposure Assessment* presents the 1-year average estimated consumer formaldehyde concentrations in Appendix C (U.S. EPA, 2024d).

1.3.3 Indoor Air Exposure Assessment

Substantial updates have been incorporated into this assessment. The most substantial change is the use of a second EPA model to better characterize indoor air concentrations of formaldehyde. The *Draft Risk Evaluation for Formaldehyde* relied on the CEM to estimate 365-day average formaldehyde concentrations from articles that may be contributing to long-term indoor air concentrations. This model is commonly used by EPA to estimate exposure to chemicals in consumer products and articles for TSCA conditions of use.

In this revised assessment, EPA maintains the CEM assessment. In addition, EPA used the Simulation Program for Estimating Chemical Emissions from Sources and Related Changes to Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones or IECCU to estimate short-term (15-minute peak), intermediate (3-month), and long term (1-year) concentrations. This model is better parameterized for volatile organic chemicals like formaldehyde. It provides exposure decay curves allowing for better characterization of exposure concentrations over time (*i.e.*, after an article is introduced to the home). However, available data suggest IECCU may underestimate long-term exposure concentrations. As such, modeled concentrations for both CEM and IECCU are presented in the results of this assessment to characterize the potential range of formaldehyde concentrations in indoor air.

In addition to this updated modeling, this technical support document further characterizes formaldehyde concentrations in trailer homes, athletic fields with tire crumb surfaces, and government buildings. Furthermore, feedback and resources from data submissions to the docket (Docket ID: EPA-HQ-OPPT-2023-0613) were incorporated throughout this assessment.

1.3.4 Ambient Air Exposure Assessment

The ambient air exposure assessment for formaldehyde developed to support this human health risk assessment has been updated to reflect SACC and public comments. A full description of revisions are included in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). Relevant revisions impacting this human health risk assessment include:

Daily average modeled formaldehyde concentrations are used to derive acute risk estimates and are summarized in Section 2.4.2.1.1. Daily average modeled formaldehyde exposures and associated risk estimates are further characterized by separately presenting exposures and risk estimates attributed to TSCA COUs and attributed to other sources like airplanes, on-site vehicles, process heaters, turbines, and reciprocating internal combustion engines in Section 2.4.2.1.1 (exposures) and Section 1.1.1.1 (risk estimates).

Annual average modeled formaldehyde exposure estimates are used to derive chronic non-cancer and cancer risk estimates which are now summarized in Section 4.2.4.2 (risk estimates). In addition, data from both the Toxics Release Inventory and the National Emissions Inventory have been incorporated (see Section 4.2.4). Lastly, high frequency monitoring data from Texas are included to understand variation in daily concentrations.

In addition to these changes, EPA lowered the overall confidence in the Ambient Air Exposures Assessment to medium after reviewing uncertainties in the approach. These include uncertainties related to input parameters and spatial and temporal differences seen across the multiple lines of evidence. This assessment was conservative and not site specific. Similarly, the assessment was conducted independent of the size of the facility footprint, the precise location of the release, and the relative location of residences. Additional modeling with HEM results provide context on the spatial variability of formaldehyde concentrations across the U.S. and an approximate understanding of populations exposed.

1.3.5 Human Health Hazard Assessment

The human health hazard assessment has been updated to reflect SACC and public comments as well as revisions made to the final IRIS assessment (U.S. EPA, 2024k) published August 2024. Specific revisions include:

The narrative around the cancer IUR and cancer mode of action has been revised to acknowledge SACC comments and point to sections of the IRIS assessment that are responsive to these comments.

The acute inhalation POD remains the same, but the narrative explaining the selection and interpretation of that POD has been revised for clarity. The uncertainty factor applied for sensory irritation has been revised from 10 to 3 and the rationale for the selected uncertainty factor has been expanded.

The chronic inhalation POD and uncertainty factor remain the same, but the narrative has been updated to reflect changes made in the final IRIS assessment, acknowledge SACC comments, and point to sections of the IRIS assessment that are responsive to these comments.

The dermal POD and UF remain the same. The narrative has been updated to provide a more robust explanation for the selection and interpretation of that POD.

The oral PODs and UFs remain the same. The narrative has been revised throughout for clarity and transparency.

1.4 Changes Made After Publication of the 2025 Risk Evaluation

Based on the weight of scientific evidence and informed by the best available science, OCSPP is considering a revised acute inhalation POD, revised uncertainty factors, and corresponding revised MOE calculations:

- an acute inhalation POD of 0.3 ppm is appropriate as the critical effect to protect for all other potential hazards, including cancer;
- the acute inhalation POD can be applied to all durations of exposure (including chronic and cancer) and all populations, including occupational scenarios; and
- a total UF_H of 1x is appropriate.

For the draft ~~supplemen~~revised risk characterization ~~t~~ OCSPP is only including the MOE calculations for acute (15-minute) inhalation exposure. Based on the scientific evaluation presented herein, OCSPP proposes to rely on the acute exposure scenarios for determinations of unreasonable risk. Given the mode of action (MOA) of formaldehyde, chronic non-cancer and cancer health effects are not expected if EPA is protecting for acute exposure and effects. Previously estimated chronic exposure values for occupational, consumer, and general population pathways remain in the risk evaluation for formaldehyde. It is important to note that acute exposure was assessed for all COUs and associated exposure scenarios in the risk evaluation for formaldehyde and considered in this revised draft-. There are no exposure scenarios where only chronic exposure was assessed in the risk evaluation for formaldehyde. Because the acute risk estimates are protective of risk presented by chronic exposures, the Agency is using the acute risk estimates presented in this Updated Draft Risk Calculation Memorandum to identify COUs that contribute to the unreasonable risk of formaldehyde. Repeated or sustained long-term exposures to formaldehyde above the revised POD increases the potential for chronic effects including cancer.

The dermal POD and UF remain the same. The narrative has been updated to provide a more robust explanation for the selection and interpretation of that POD.

The oral PODs and UFs remain the same. The narrative has been revised throughout for clarity and transparency.

~~1.4~~1.5 Chemistry, Fate, and Transport Assessment Summary

EPA considered reasonably available information identified by the Agency through its systematic review process under TSCA and submissions under FIFRA to characterize the physical and chemical properties as well as the environmental fate and transport of formaldehyde. This was done as a joint effort with the OPP. Physical and chemical properties of formaldehyde, as well as some known environmental transformation products (methylene glycol, paraformaldehyde), are provided in Table 1-1. Formaldehyde is expected to be a gas under most environmental conditions. Due to the reactivity of formaldehyde, it is not expected to be present in most environmental media but may be abundant in air due to continual release from multiple sources including from TSCA releases, biogenic sources, and formation from secondary sources.

Table 1-1. Physical and Chemical Properties of Formaldehyde and Select Transformation Products[a]

Chemical Properties	Formaldehyde	Methylene Glycol	Paraformaldehyde
Molecular formula	CH_2O	$CH_2(OH)_2$	$HO(CH_2O)_nH$ (n = 8–100)
CASRN	50-00-0	463-57-0	30525-89-4
Molecular weight	30.026 g/mol	48.02 g/mol	$(30.03)_n$ g/mol (Varies)
Physical form	Colorless gas	Colorless liquid	White crystalline solid
Melting point	−92.0 to −118.3 °C	−43.8 °C	120 to 170 °C
Boiling point	−19.5 °C	131.6 °C	None identified
Density	0.815 g/cm^3 at 20 °C	1.20 g/cm^3	1.46 g/cm^3 at 15 °C
Vapor pressure	3,890 mmHg at 25 °C	3.11 mmHg at 25°C	1.45 mmHg @ 25 °C
Vapor density	1.067 (air = 1)	None identified	1.03 (air = 1)
Water solubility	<55%; 400 to 550 g/L	Miscible	Insoluble
Octanol/water partition coefficient (log K_{OW})	0.35	−0.79	N/A
Henry's Law constant	3.37E−07 atm/m^3·mol at 25 °C	1.65E−07 atm/m^3·mol at 25 °C	N/A

[a] Physical and chemical properties for formaldehyde, methylene glycol, and paraformaldehyde are considered best estimates. Because the chemical substance often exists in a mixture at varying concentrations, these properties can vary based on the equilibration with other chemical substances present.

In water, formaldehyde quickly hydrates to form methylene glycol, which can polymerize to form oligomers of various chain lengths and paraformaldehyde (U.S. EPA, 2024b)—all structurally different compounds when compared to formaldehyde (Figure 1-3). Formaldehyde is not expected to be found in aquatic systems (U.S. EPA, 2024e).

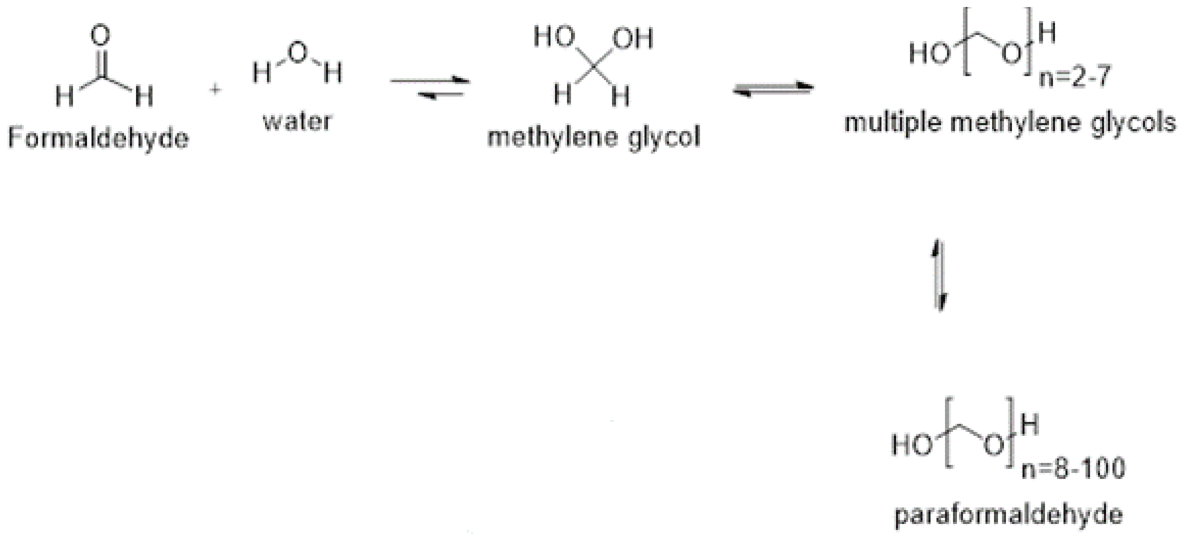


Figure 1-3~~1-3~~. Chemical Equilibria for Formaldehyde in Aqueous Solutions
Adapted from (Boyer et al., 2013).

In soil, formaldehyde is also expected to quickly transform to products that are structurally dissimilar to parent formaldehyde; thus, formaldehyde is not expected to be found in soil (U.S. EPA, 2024b). Formaldehyde can be formed in the early stages of plant residue decomposition in soil and is reportedly degraded by bacteria in the soil (U.S. EPA, 2024b). Formaldehyde is expected to undergo abiotic (hydration and nucleophilic addition) chemical reactions in soils to form other compounds.

In air, formaldehyde is susceptible to direct and indirect photolysis; however, it may be present in air environments with low or no sunlight (*e.g.*, nighttime, indoor). As such, the primary exposure route for formaldehyde is expected to be the air pathway (U.S. EPA, 2024e). More specifically, the half-life of formaldehyde in air depends on the intensity and duration of sunlight and ambient conditions such as temperature and humidity. Under direct sunlight, formaldehyde will undergo photolysis with a half-life up to 4 hours yielding mainly hydroperoxyl radical (HO_2), carbon monoxide (CO), and hydrogen (H_2). In the absence of sunlight, formaldehyde can persist with a half-life up to 114 days.

Due to the physical and chemical properties of formaldehyde including a log K_{OW} (0.35), bioconcentration and bioaccumulation are not expected (U.S. EPA, 2024b). Therefore, human exposure to formaldehyde via consumption of fish was not expected and therefore not assessed.

EPA has high confidence in the overall fate and transport profile of formaldehyde and paraformaldehyde; however, EPA is less confident in the overall fate and transport of the transformation products methylene glycol and poly(oxy)methylene glycol. Key sources of uncertainty for this assessment are related to formaldehyde equilibrium in various media and subsequent transformation. In cases where there are little fate and transport data, EPA relied on physical and chemical properties to describe the expected fate and transport of the respective chemical. As such, although EPA has some uncertainty in the precision of a specific parameter value, it has confidence in the overall fate and transport profile of formaldehyde. Additional details can be found in the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b).

~~1.5~~1.6 Environmental Release Assessment

Formaldehyde is directly released to all three environmental media (air, land, and water) from TSCA COUs (U.S. EPA, 2024g). It is also released to the environment during other uses (*e.g.*, use as a pesticide as defined in FIFRA, or use as a food, food additive, drug, cosmetic, or device as defined in the Federal Food, Drug, and Cosmetic Act), as a transformation product of different parent chemicals, and from combustion sources.

EPA used release data from TRI (data from 2016 to 2021), Discharge Monitoring Report (DMR; data from 2016 to 2021), and the 2017 National Emissions Inventory (NEI) to identify releases to the environment that are relevant to the formaldehyde TSCA COUs. In addition, total releases reported in 2022 were incorporated into the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g). Based on a review of these databases, waste streams containing formaldehyde are directly discharged to surface water, indirectly discharged to publicly owned treatment works (POTW) or other wastewater treatment (WWT) plants, disposed of via different land disposal methods (*e.g.*, landfills, underground injection), sent to incineration, and emitted via fugitive and stack releases.

Based on TRI and DMR reporting from 2016 to 2021, less than 150,000 kg each year of formaldehyde are directly discharged to surface water for TSCA-related activities based on reporting from 168 facilities. Approximately 2 million kg each year are transferred to POTW/WWT plants for treatment based on reporting from 168 facilities (U.S. EPA, 2024g). For these wastewater streams transferred to POTW or WWT plants, biological wastewater treatment systems have shown a mean removal efficiency of 99.9 percent for formaldehyde based on literature and 92 percent removal of methylene glycol through biodegredation based on EPISuite™ estimates (U.S. EPA, 2024b). These disposal methods provide additional time for formaldehyde and methylene glycol to further transform to chemically dissimilar products in the presence of water and chemical, biological, and physical treatment processes prior to being discharged to surface water.

Based on TRI reporting from 2016 to 2021, most waste of formaldehyde is disposed of via land disposal methods. The most significant method of land disposal of formaldehyde is via underground injection with 22 sites disposing of more than 5 million kg of formaldehyde annually. The amount of waste reported to be disposed of in RCRA Subtitle C landfills and other landfills varies across the reporting years from 200 facilities reporting a total of 423,517 kg/year in 2016 to -127,348 kg/year in 2021. Other land disposal methods (*e.g.*, surface impoundments, solidification/ stabilization) are also reported at lower levels. Formaldehyde is not expected to persist in water or soils; thus, EPA determined that additional analyses of releases to water or land were not needed and targeted its review of release information to fugitive and stack emissions of formaldehyde from TSCA COUs.

EPA identified more than 150,000-point source emission data (includes unit-level estimates) for formaldehyde across the two EPA databases (TRI data from 2016 to 2021and 2017 NEI). To characterize this amount of data, EPA utilized the self-reported NAICS codes to assign sites into CDR industrial sectors (IS). These industrial sectors can be directly correlated with the TSCA COUs, as further discussed in the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g). Most TSCA COUs indicate one or more industrial sectors, and in some cases an industrial sector can appear in more than one TSCA COU. Therefore, an industrial sector may be associated with multiple formaldehyde TSCA COUs.

For this fit-for-purpose TSCA risk assessment, EPA targeted its review of environmental releases to point sources, and did not review the road, nonroad, and other automotive exhaust information identified, as formaldehyde produced from combustion sources is not assessed as an independent COU subcategory in this risk evaluation. EPA focused its environmental release assessment on total facility emissions which can include emission from both uses of formaldehyde and combustion sources at the same facility or, potentially, only combustion sources from that facility.

EPA categorizes the facilities and corresponding release information by industrial sectors that can be directly correlated to the TSCA industrial COUs. For commercial TSCA COUs, EPA used professional judgement to assign the industrial sector to commercial TSCA COUs, where applicable. For a few TSCA COUs (Commercial use – chemical substances in treatment/care products – laundry and dishwashing products; Commercial use – chemical substances in treatment products – water treatment products; Commercial use – chemical substances in outdoor use products – explosive materials; and Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals), releases were only qualitatively assessed due to limited use information. Additional details are provided in the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

In the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g), EPA identified approximately 800 TRI facilities between 2016 and 2021 and approximately 50,000 NEI facilities in 2017 with reported air releases of formaldehyde (U.S. EPA, 2024g). From these facilities, EPA identified the maximum release reported through TRI was 10,161 kg/year-site (IS: Paper Manufacturing) for a fugitive release reported in 2019 and 158,757 kg/year-site (IS: Wood Product Manufacturing) for a stack release reported in 2017. The NEI program identified sites reporting as high as 138,205 kg/year-site (IS: Wholesale and Retail Trade) for fugitive releases and 1,412,023 kg/year-site (IS: Oil and gas drilling, extraction, and support activities) for stack releases reporting in 2017, in which the higher releases are associated with sectors not required to report to TRI. The high release sites in NEI program were associated with natural gas compressor stations and airport operations, which EPA expects is due to formaldehyde produced from combustion sources. EPA analyzed the release information by the industrial sector, providing the minimum, median, 95th percentile, and maximum releases across the entire distribution of reported releases within each industrial sector, as further discussed in the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g)

In general, EPA has medium to high confidence in environmental releases for industrial TSCA COUs[2] and low to medium confidence in commercial TSCA COUs.[3] EPA has high data quality ratings for TRI and NEI, which are supported by numerous facility-reported estimates. Some sites that emit formaldehyde may not be included in these databases if the release does not meet the reporting criteria for the respective program. EPA used total emissions per site, which may combine formaldehyde emissions from multiple TSCA COUs if the site's formaldehyde-generating processes are applicable to more than one TSCA COU. For example, a facility may manufacture formaldehyde as well as process formaldehyde as a reactant. In some cases, the formaldehyde-generating process may also fall outside of scope of the risk evaluation.

EPA categorizes the facilities and corresponding release information by industrial sectors that can be directly correlated to the TSCA industrial COUs. EPA developed this approach to streamline analysis using the facility's primary NAICS code. This approach does not use the TRI use codes or NEI SCC codes, which EPA views as a higher tier characterization. There is some uncertainty if a site's primary

[2] TSCA COUs that are included under the life cycle stage of manufacturing, processing, and industrial use.
[3] TSCA COUs that are included under the life cycle stage of commercial uses.

NAICS code will assign it to the appropriate COU. For commercial COUs, EPA used professional judgement to assign the industrial sector to commercial COUs, where applicable. For a few COUs (Commercial use – chemical substances in treatment/care products – laundry and dishwashing products; Commercial use – chemical substances in treatment products – water treatment products; Commercial use – chemical substances in outdoor use products – explosive materials; and Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals), releases were only qualitatively assessed due to limited use information. For distribution in commerce, formaldehyde released accidently during transit has occurred based on available information, but it was not quantified due to uncertainties in the frequency or volume that may occur in the future. Additional details are provided in the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

~~1.6~~1.7 Human Health Risk Assessment Scope

Generally, EPA expects inhalation[4] to be a major route of exposure for occupational, consumer, indoor air, and ambient air. Dermal sensitization from formaldehyde exposure is a rapid effect. Thus, for occupational and consumer COUs where dermal contact to formaldehyde may occur, EPA expects the dermal route to be another significant route of exposure to formaldehyde.

A quantitative assessment of the water pathway was not conducted in this risk assessment given the relatively limited release of formaldehyde directly to surface water, and due to the rapid transformation of formaldehyde in water based on the physical and chemical properties governing the environmental fate of formaldehyde in water. Water monitoring data, while limited, demonstrate formaldehyde is rarely detected in water as described in more detail in the environmental exposure assessment (U.S. EPA, 2024e). Based on these lines of evidence, EPA does not expect human exposure to formaldehyde will occur via surface water. In addition, formaldehyde is not expected to persist in land or leach to groundwater that may be sourced for drinking water based on the physical and chemical properties governing the environmental fate of formaldehyde in land. Therefore, EPA does not expect human exposure to formaldehyde will occur via soil, land, or groundwater.

~~1.6.1~~1.7.1 Conceptual Exposure Models

~~1.6.1.1~~1.7.1.1 Industrial and Commercial Activities and Uses

The conceptual model in Figure 1-4 presents the exposure pathways, exposure routes and hazards to people from industrial and commercial activities and uses of formaldehyde. EPA evaluated exposures to workers and occupational non-users (ONU) via inhalation routes and exposures to workers via dermal routes as shown in Figure 1-4. Oral exposure may occur through products that can generate particulates such as wood or textile dust that deposit in the upper respiratory tract that is then ingested; however, formaldehyde will continue to evaporate and there is uncertainty on the amount inhaled that is ingested. For this risk evaluation, these exposures were evaluated as an inhalation exposure.

[4] In this formaldehyde risk evaluation, references to "acute inhalation" exposure, hazard and risk are intended to refer broadly to air concentrations of formaldehyde that may cause sensory irritation from both eye exposure and from inhalation (breathing in air).

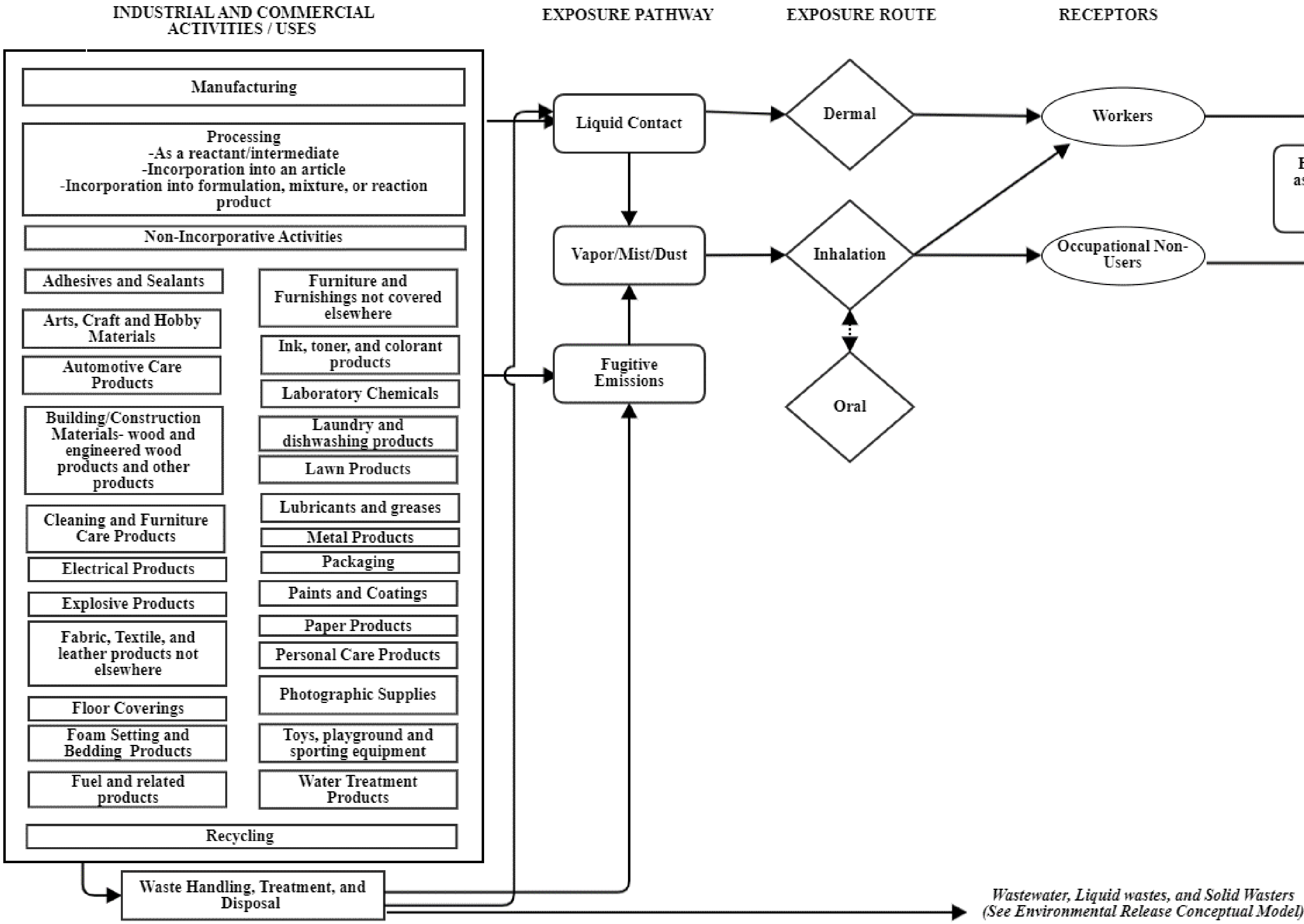


Figure 1-41-4. Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

Note that fugitive air emissions, as described in Figure 1-4, are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

~~1.6.1.2~~1.7.1.2 Consumer Exposure

Formaldehyde is found in consumer products and articles that are readily available for public purchase at common retailers and through online shopping venues. Formaldehyde may be either a chemical ingredient in a consumer product or a component in material(s) utilized in the manufacturing of consumer products or articles (adhesives, resins, glues, etc.) or both. Use of such product is expected to result in exposures to both consumers who use a product (consumer user) and bystanders (individuals who are not directly using a product but are exposed while the product is being used by someone else).

Figure 1-5 presents the conceptual model for consumer activities and uses that are in scope for the TSCA formaldehyde risk evaluation. Formaldehyde-containing consumer products include textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including roofing), furniture, toys, and various adhesives and sealants. EPA identified these formaldehyde COUs from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders for products currently in production or not discontinued.

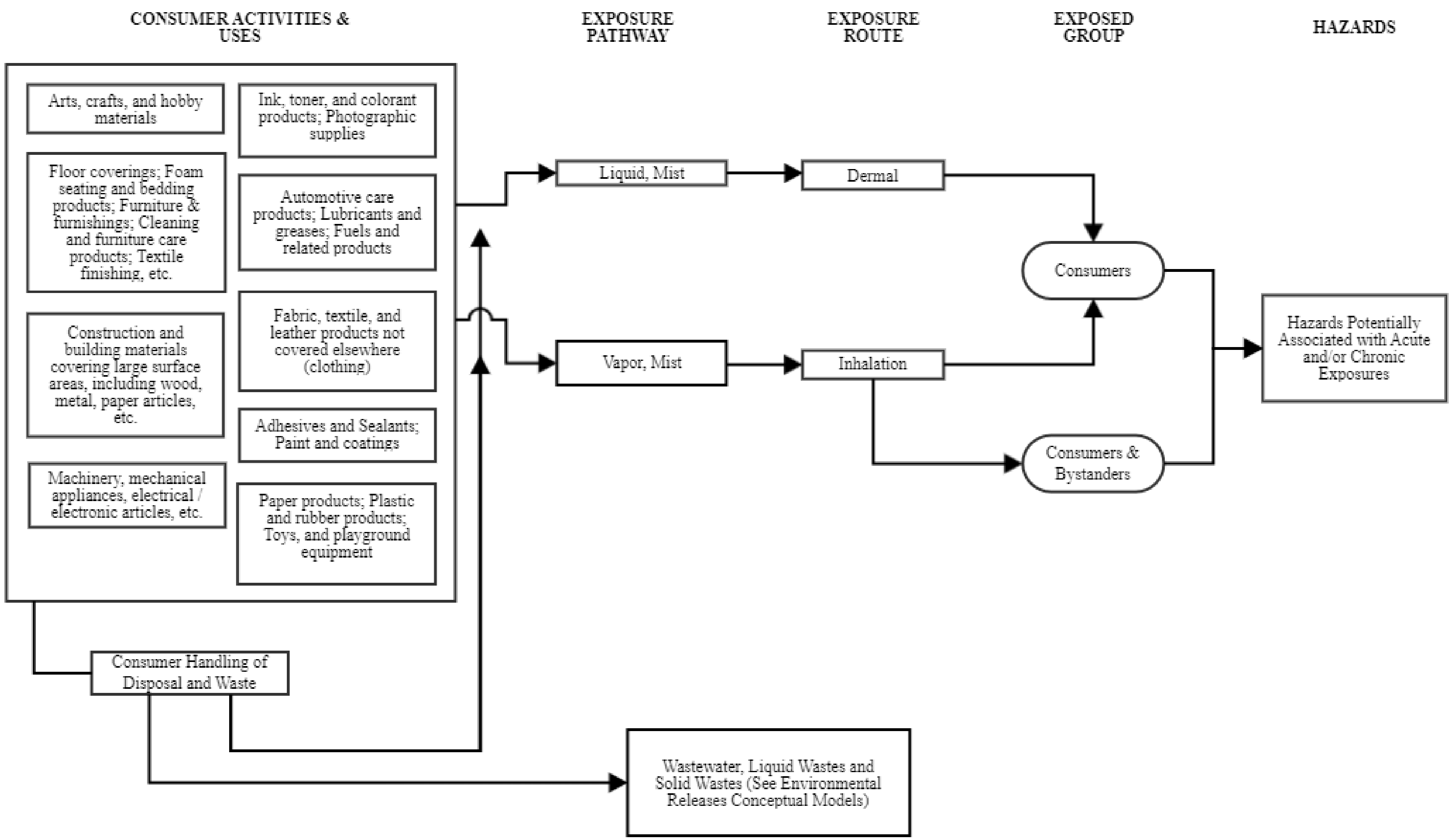


Figure 1-51-5. Formaldehyde Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Some consumer products assessed may also have commercial applications. Inhalation is the primary expected route of exposure for formaldehyde resulting from consumer activities, however, dermal exposures are also expected. EPA considered potential oral exposure pathways associated with TSCA COUs, including lawn and garden products and oral mouthing behaviors in infants and young children. However, because EPA lacks sufficient data to quantify exposures and risks for any of these pathways, oral exposures were qualitatively assessed for relevant COUs (*e.g.*, lawn and garden products). Section 2.2 of the *Consumer Exposure Module for Formaldehyde* (U.S. EPA, 2024d) provides more detail about the COUs within the scope of this risk evaluation.

~~1.6.1.3~~1.7.1.3 Indoor Air Exposures

People are exposed to formaldehyde regularly indoors due to off-gassing of formaldehyde from various sources. Some of these exposures may be caused by the offgassing from TSCA COUs while others are from other sources of formaldehyde like wood burning in a fireplace. The conceptual model in Figure 1-6 presents the exposure pathways, exposure routes and hazards to people from assessed TSCA COUs.

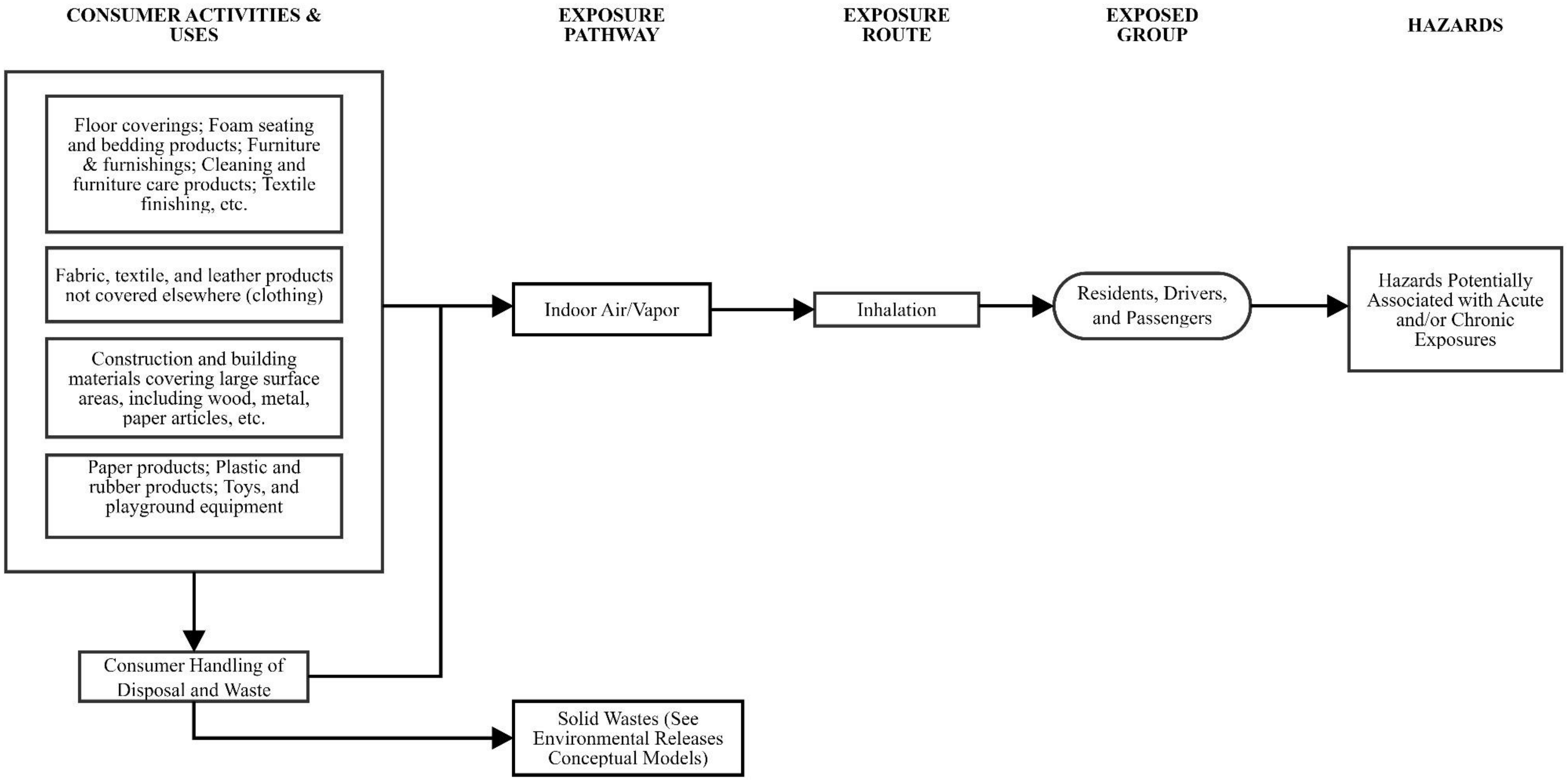


Figure 1-61-6. Formaldehyde Conceptual Model for Indoor Air: Residential Exposures and Hazards from Article Off-Gassing

~~1.6.1.4~~1.7.1.4 Ambient Air Exposures

Ambient air formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde. Communities – particularly those near releasing facilities and especially some facilities with releases attributed to combustion – were considered in this human health risk assessment.

While formaldehyde is susceptible to direct and indirect photolysis, it is expected to be present in the ambient air for at least several hours in direct sunlight (and many more hours in no sunlight) based on the chemical, fate, and transport properties of formaldehyde as described in the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and Section 1.2.3. Formaldehyde is consistently present in ambient air based on monitoring and testing programs implemented under the Clean Air Act and other EPA programs and statutes. This can be due to TSCA sources of formaldehyde as well as other sources formed through biological activity (biogenic) or through the breakdown of other chemicals (secondary formation). Data from the Air Tox Screening Assessment demonstrate the potential contribution of some of these sources. Considering these lines of evidence, EPA quantitatively assessed the ambient air pathway in this risk assessment.

Figure 1-7 provides a detailed conceptual model of all pathways and all routes considered for this assessment. While environmental releases are reported to all three environmental media, formaldehyde is not expected to be present in water or land based on the chemical, fate, and transport properties of formaldehyde as described in the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and discussed in Section 1.2.3. As such, EPA does not expect general population exposure to formaldehyde to occur via either the water or land media and therefore did not quantitatively assess exposures via these media in this risk assessment. This is depicted in Figure 1-7 by the dashed lines.

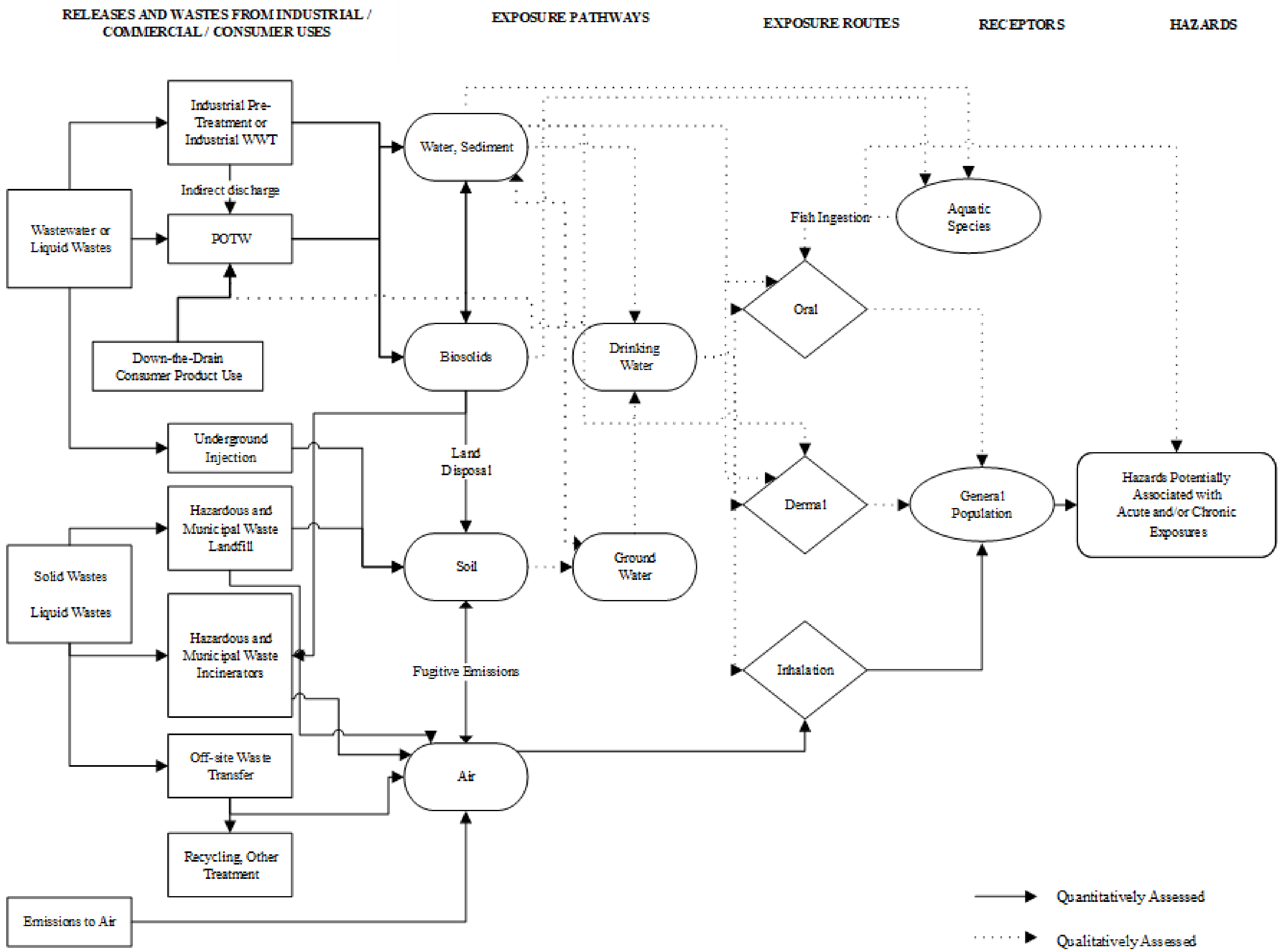


Figure 1-71-7. Formaldehyde Conceptual Model for Environmental Releases and Wastes: General Population Exposures and Hazards

Figure 1-8 provides a simplified visual representation of how industrial releases to ambient air can lead to exposure for communities located near industrial releases. In general, formaldehyde is released from industrial facilities as either uncontrolled fugitive releases (*e.g.*, process equipment leaks, process vents, building windows, building doors, roof vents) or stack releases that may be either uncontrolled (*e.g.*, direct releases ~~out~~ from a stack) or controlled with some pollution control device prior to release to the ambient air (*e.g.*, baghouse, scrubber, thermal oxidizer). Once released, formaldehyde will mix with air in the atmosphere, move into the surrounding areas, and may be subsequently inhaled if communities are located nearby. Thus, EPA assessed exposures for individuals living near industrial facilities associated with TSCA COUs that are releasing formaldehyde.

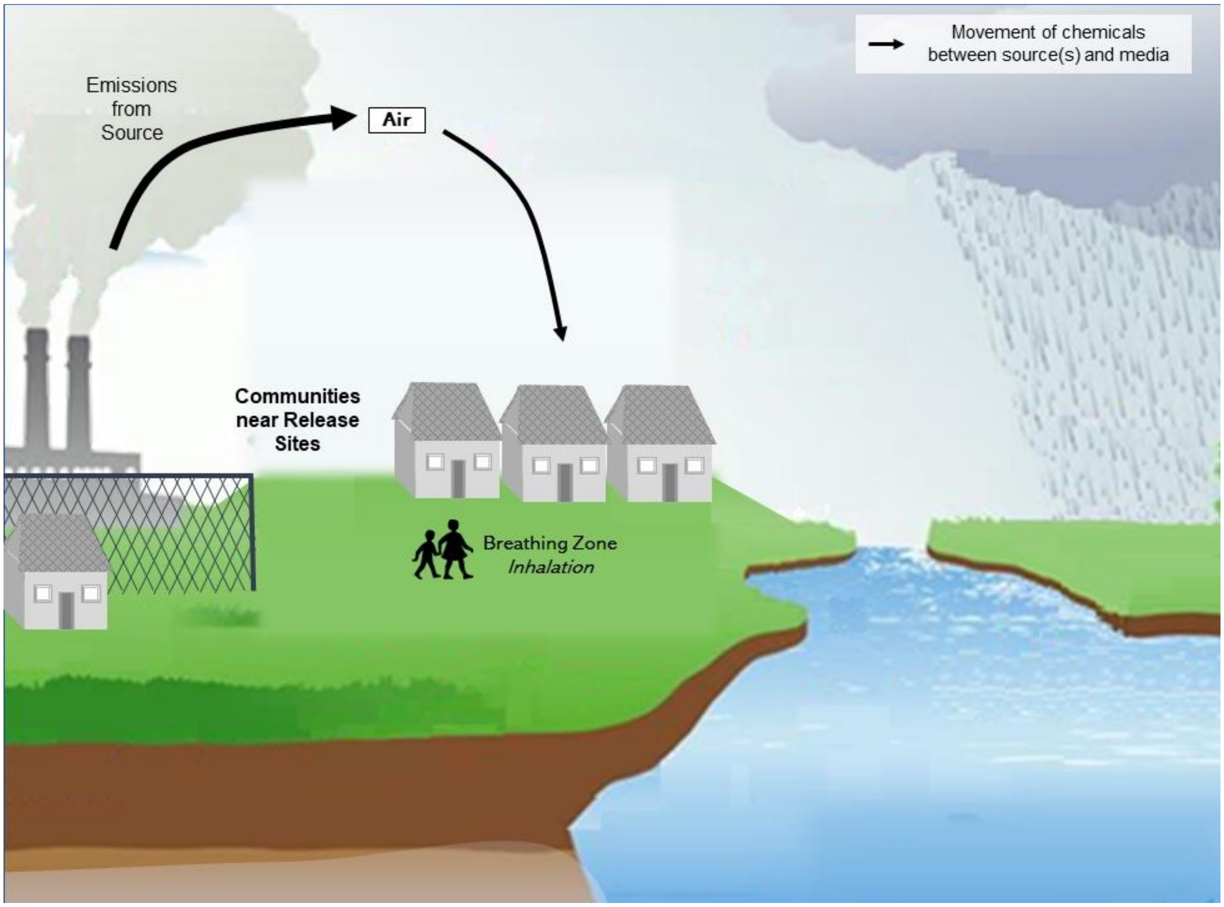


Figure 1-8~~1-8~~. Industrial Releases to the Environment and Pathways by Which Exposures to the People May Occur

~~1.6.2~~1.7.2 Potentially Exposed or Susceptible Subpopulations

This assessment considers potentially exposed or susceptible subpopulation (PESS), a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture. There are many factors that may contribute to increased exposure or biological susceptibility to a chemical, including life stage (*e.g.*, infants, children, pregnant women, elderly), pre-existing disease, lifestyle activities (*e.g.*, smoking, physical activity), occupational and consumer exposures (including workers and ONUs, consumers and bystanders), geographic factors (living in proximity to a large industrial source of formaldehyde), socio-demographic factors, unique activities (*e.g.*, subsistence fishing), aggregate exposures, and other chemical and non-chemical stressors.

Considerations related to PESS may influence the selection of relevant exposure pathways, the sensitivity of derived hazard values, the inclusion of populations, and/or the discussion of uncertainties throughout the assessment.

2 HUMAN EXPOSURE ASSESSMENT SUMMARY

This section summarizes the formaldehyde exposures to occupational workers, ONUs, consumers, bystanders, and general population from both indoor air and ambient air. Detailed information supporting each subsection are available in the associated technical support documents included as supplemental files to this human health risk assessment for formaldehyde.

Each exposure assessment considers peak and long-term inhalation exposures. When available, the highest 15-minute average concentrations are used to represent peak exposures. ~~while annual average concentrations or 8-hour time-weighted averages (TWA) are used to represent longer-term exposure durations~~. ~~The long-term exposure duration depends on the exposure scenario being assessed. Specifically, exposure durations for cancer assessments are based on 31 (central tendency) and 40 (high-end) working years for occupational exposure. Exposure durations for cancer assessment are based on 12- or 57-year residency time and 78-year lifetime exposure for consumer and general population.~~ Acute dermal exposures were estimated for workers and consumers and are based on short-term durations, see Appendix E for additional information on the dermal approaches.

Each exposure assessment integrates modeling methodologies previously peer reviewed as well as monitoring data to assess exposures to the respective populations. The exposure assessment also integrates information from the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

2.1 Occupational Exposure Assessment

EPA identified 50 TSCA COUs under manufacturing, processing, industrial/commercial uses, and disposal. In the *Occupational Exposure Assessment for Formaldehyde*(U.S. EPA, 2024l), EPA evaluated occupational exposure scenarios (OESs) based on the COUs with expected worker activities, inhalation exposure estimates, and dermal exposure estimates for each OES (U.S. EPA, 2024l). Several of the TSCA COU categories and subcategories were grouped and assessed together into a single OES due to similarities in the processes or lack of data to differentiate between them. This grouping minimized repetitive assessments. In other cases, TSCA COU subcategories were further delineated into multiple OESs based on expected differences in processes and associated releases/exposure potentials between facilities. This resulted in assessing 35 OESs for inhalation and dermal exposure. For additional details on the approaches and results, please refer to *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024l).

2.1.1 Inhalation Exposure Assessment

To assess inhalation exposures from formaldehyde, EPA reviewed workplace inhalation monitoring data from government agencies such as Occupational Safety and Health Administration (OSHA), inhalation monitoring data found in peer-reviewed literature, and other inhalation monitoring data submitted to EPA. Where monitoring data were reasonably available, EPA used these data to characterize central tendency and high-end short-term and full shift inhalation exposures for each scenario (OES) to workers and ONUs. The quality of the monitoring data was evaluated using the data quality review evaluation metrics and the categorical ranking criteria described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluation for Chemical Substances* (U.S. EPA, 2021c). Relevant data were assigned an overall quality determination of high, medium, low, or uninformative. For evidence integration, preference was given to discrete monitoring data sampled in the United States, and after the latest update of the OSHA permissible exposure limit (PEL) of formaldehyde in 1992 to 937 µg/m^3 (0.75 ppm) and short-term exposure limit (STEL) to 2,498 µg/m^3 (2.0 ppm). This reduces uncertainties with relying on data that may not reflect the conditions in the U.S. and the current regulatory requirements for TSCA COUs.

For many cases, EPA did not have monitoring data to estimate inhalation exposure for ONUs. In such cases for full-shift exposures, EPA used the central tendency of worker exposure estimates. However, EPA did not quantify short exposures for ONUs. In general, EPA expects ONU exposures to be similar or less than worker exposures.

For some of the OESs, inhalation monitoring data were not identified. For these cases, EPA utilized models including using a Monte Carlo simulation and Latin Hypercube sampling method to estimate inhalation exposures. Where available, the EPA used generic scenarios or emission scenario documents for relevant exposure points and model input parameters.

Monitoring data were available to support exposure estimates for all COUs except for four COUs that relied on modeled estimates:

- Industrial use – Non-incorporative activities – Process aid in: oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing
- Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products;
- Commercial use – chemical substances in agriculture use products – lawn and garden products; and
- Commercial use – chemical substances in treatment products – water treatment products.

Across TSCA COUs for short-term exposure estimates, the central tendency of air concentration estimates were up to 2,002 μg/m^3 (1.6 ppm) and high-end of air concentration estimates up to 209,815 μg/m^3 (171 ppm). The TSCA COU of Manufacturing showed formaldehyde concentrations above other scenarios, with high-end and central tendency of air concentration results of 209,815 μg/m^3 and 736 μg/m^3, respectively. The underlying scenario was based on monitoring data from manufacturing sites within the United States, which included tasks where the workers wore respiratory protection.

Across TSCA COUs for full-shift estimates, the central tendency of air concentration estimates ranged from 0.0114 to 540 μg/m^3 (9.34E-06 to 0.44 ppm) and high-end of air concentration estimates ranged from 8.59 to 17,353μg/m^3 (0.007 to 14 ppm). The TSCA COU of Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products showed formaldehyde concentrations above other scenarios. The underlying scenario was modeled using a Monte Carlo simulation and assumed that no engineering controls were present. The first modeling approach resulted in a high-end and central tendency of air concentrations results of 17,353.3 μg/m^3 and 499.3 μg/m^3, respectively and assumes that formaldehyde within the automotive care product is completely evaporated during duration of application. This results in a very conservative high-end estimate, well above the current OSHA PEL. EPA also used a second modeling approach using monitoring data on total volatile organic compounds to estimate 1,874 μg/m^3 and 371 μg/m^3.

EPA uses short-term exposure air concentration estimates to calculate acute exposure concentrations (AECs), which is used to estimate acute, non-cancer risks. ~~Full-shift exposure estimates can also be used for acute, non-cancer risks. The full-shift (8- or 12-hour TWA concentrations) are used to calculate average daily concentrations (ADCs) and lifetime average daily concentrations (LADCs). The ADC is used to estimate chronic, non-cancer risks and the LADC is used to estimate chronic, cancer risks. These calculations required additional parameter inputs, such as years of exposure (31 or 40 year worker tenure), exposure duration and frequency (167 or 250 days), and lifetime years (78 years).~~ See **Error!**

Reference source not found. for more information about parameters and equations used to calculate acute and chronic exposures.

2.1.2 Dermal Exposure Summary

Dermal exposure data were not reasonably available for any of the formaldehyde OESs. Therefore, the EPA modeled dermal exposure to workers using a modified version of the EPA Dermal Exposure to Liquids Model. As the health effect of concern for formaldehyde is the result of exposure at the point of contact, as opposed to the chemical absorbing into the skin, the absorption factor, body weight, and surface area were not necessary for the calculation of dermal exposure. The calculation reduces to an assumed amount of liquid on the skin during one contact event per day adjusted by the weight fraction of formaldehyde in the liquid to which the worker is exposed.

EPA only evaluated dermal exposures for workers since ONUs are not assumed to directly handle formaldehyde. EPA did not quantify dermal exposure for two COUs: Distribution in commerce and Commercial use – chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment as dermal contact was expected with solid articles that contain low residual formaldehyde concentrations.

EPA used the maximum formaldehyde concentrations, which is the highest concentration level of formaldehyde that a worker handles throughout the process. EPA used concentration data from published literature and CDR to develop high-end and central tendency dermal exposure estimates.

The dermal exposure estimates ranged from 0.56 to 1,140 µg/cm^2 for central tendency exposures, and 0.84 to 3,090 µg/cm^2 for high-end exposures. The high-end dermal retained dose for four COUs had a value of 3,090 µg/cm^2, which is well above the other dermal exposure estimates:

- Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products and
- Processing – incorporation into an article – paint additives and coating additives not described by other categories in transportation equipment manufacturing [including aerospace];
- Industrial use – paints and coatings; adhesives and sealants; lubricants; and
- Commercial use – chemical substances in construction, paint, electrical, and metal products – adhesives and sealants; paint and coatings.

For manual spray applications, EPA expects dermal exposures to be higher. Spray applications are expected for the use of automotive care products and coatings, paints, adhesives, or sealants. In addition, during the use of automotive care products, workers may use immerse rags in the detailing products, which could lead to higher dermal loading. For both OESs, EPA assumed an immersive dermal loading (HE: Q_u of 10.3 mg/cm^2) on the skin during the exposure scenario. For other OESs, EPA calculated dermal exposures assuming lower dermal loadings based on expected worker activities (HE: Q_u of 2.1 mg/cm^2).

2.2 Consumer Exposure Assessment

This *Consumer Exposure Assessment* focuses on users of consumer products and articles and those that may be exposed as a result. EPA identified 24 exposure scenarios (from 12 formaldehyde TSCA COUs) that may lead to consumer or bystander exposures. EPA's Consumer Exposure Model (CEM) Version 3.0 was used to estimate the 15-minute peak and 1 year-average daily concentrations for inhalation exposures to consumer users and bystanders, and the dermal loading during relevant product and article use. For the inhalation route, 15-minute peak exposures were emphasized for risk characterization, as presented below, but all results from modeled exposure durations (*e.g.*, 15-minute, 1 year) are included in the risk calculator (U.S. EPA, 2024j)[5]. The key conclusions of the consumer exposure assessment are summarized in the *Consumer Exposure Assessment* (U.S. EPA, 2024d) and below.

2.2.1 Conditions of Use and Considerations for their Assessment

EPA quantified exposures exposure pathways, routes, and timespans of exposure and exposure scenarios for which EPA had at least a medium confidence. As presented in Table 1-1 of the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), EPA quantified exposures for all relevant COUs for at least one route of exposure where appropriate.

Each TSCA COU may comprise multiple exposure scenarios and multiple scenarios may be applicable to multiple COUs. To simplify, representative scenarios were identified for each TSCA COU per relevant exposure assessment. Representative scenarios were identified according to the highest estimated exposure estimate per assessment. Refer to Appendix B of the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d) for a list of representative consumer exposure scenarios according to TSCA COUs.

EPA did not quantify exposures for COUs in which EPA had a low exposure assessment confidence. For example, no dermal loading estimate was generated for machinery, mechanical appliances, and electrical/electronic articles because the best available tools and data could not support an effective assessment. In addition, EPA is not quantitatively assessing the following COUs:

- Water treatment products: No supporting products could be identified to assess formaldehyde from residential water treatment.
- Laundry and dish washing products: No supporting products could be identified to assess formaldehyde from laundry and dish washing products.

Furthermore, EPA qualitatively assessed Lawn and garden products: The non-pesticidal exposure scenario for this TSCA COU is unclear because when mixed in water, formaldehyde is highly reactive. In addition, EPA's CEM assumes no inhalation exposure from such products. This is likely due to the default assumption that such activities typically occur outdoors where the chemical would be diluted in the ambient air during and after use.

In 1982, the U.S. Consumer Product Safety Commission (CPSC) banned the sale of urea formaldehyde foam insulation (UFFI) for use in residences and schools, as a result of associated health concerns (47 FR 1662, January 13, 1982). However, this ban was reversed in 1983 (see *Gulf S. Insulation v. United States Consumer Prod. Safety Com.*, 701 F.2d 1137 (5th Cir. 1983)). Furniture articles have been reported to contain formaldehyde. During the public comment period for the draft scope of formaldehyde, the North American Insulation Manufacturers Association submitted a comment that stated, "For those insulation products in which formaldehyde is a component of the binder, the products are cured at high temperatures during the manufacturing process after the binder has been applied, virtually eliminating the free formaldehyde content. Any free formaldehyde released from the binder during heat cure is destroyed either during the cure process or by emissions control equipment required by the [Maximum Achievable Control Technology] MACT standard…. Therefore, formaldehyde off-gassing from the majority of finished products is highly unlikely" (Docket ID EPA-HQ-OPPT-2019-0131-0029). Given this information, formaldehyde consumer exposures to foam insulation may be negligible. However, formaldehyde offgassing has been reported from such materials in the literature

[5] The risk calculator for both the Consumer and Indoor Air inhalation exposure assessments are embedded within the supplemental file titled "21. Acute and Chronic Inhalation Risk Calculator for Consumer and Indoor Air for Formaldehyde Supplement C.xlsx"

(Maddalena et al., 2009). Therefore, EPA considered the quantification of such exposures from upholstery that are used by consumers and in indoor air.

Lastly, for electronic products, surrogate information from adhesives and sealants was used to estimate inhalation exposure. The Agency believes this is an appropriate substitution because adhesives and sealants are used in the binding of internal components, especially at the seams.

2.2.2 Summary of Consumer Exposure Assessment Results

A detailed analysis for consumer exposures can be found in *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d). Modeled formaldehyde concentrations depended upon the room of use, amount of the chemical in the product, and consumer use patterns (*e.g.*, amounts used). Peak inhalation results are shown in Figure 2-1. Users of consumer products and articles (Near Field) had higher peak and long-term inhalation exposures when compared to bystanders who are in the same room (Far Field). Similarly, users of consumer products and articles and bystanders in the same room (Zone 1) were estimated to have higher exposures than individuals in the same house (Zone 2). Across all relevant age groups and exposure scenarios, the highest estimated 15-minute peak formaldehyde air exposure was for consumer users of adhesives and sealants; paints and coatings, while the lowest 15-minute peak exposure was for individuals using textiles or clothing that emit formaldehyde (Figure 2-1).

Dermal exposures are shown in Figure 2-2. The highest acute dermal loading for consumer users resulted from use of automotive care products. The lowest acute dermal loading resulted from use of arts, crafts, and hobby materials.

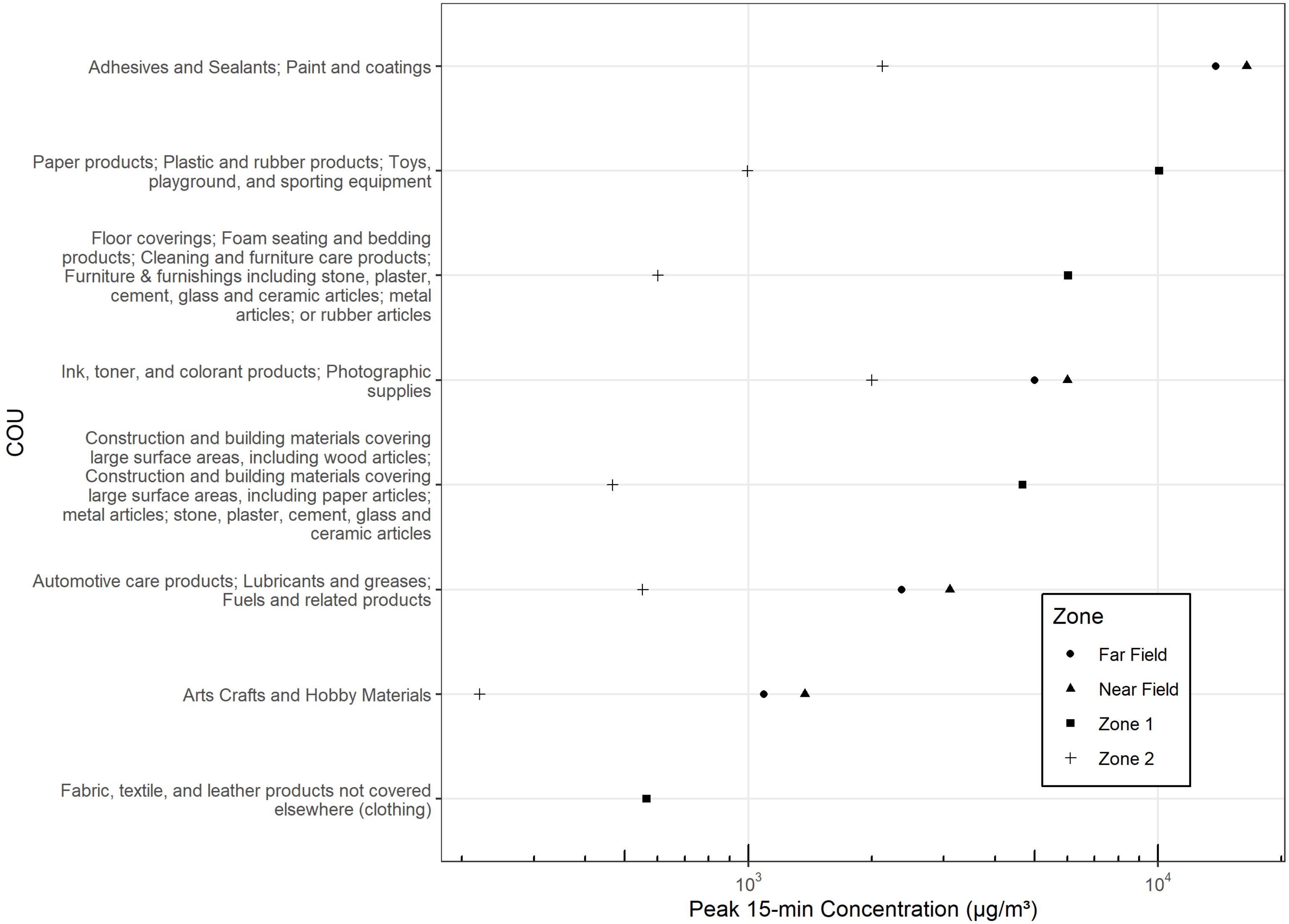


Figure 2-12-1. Summary of 15-Minute Peak Consumer Inhalation Concentrations (Based on CEM)

For some products, air concentrations were modeled for near-field and far-field (generally describing differences in exposure within the same room), while for other products, concentrations were modeled for zones 1 and 2 (generally describing different rooms). Risks from near-field and zone 1 exposures generally represent risks from direct exposures to consumer users while far-field and zone 2 tend to represent risks to consumer bystanders. The x-axis presents the 15-minute peak inhalation non-cancer concentration, and the y-axis presents the modeled TSCA COU.

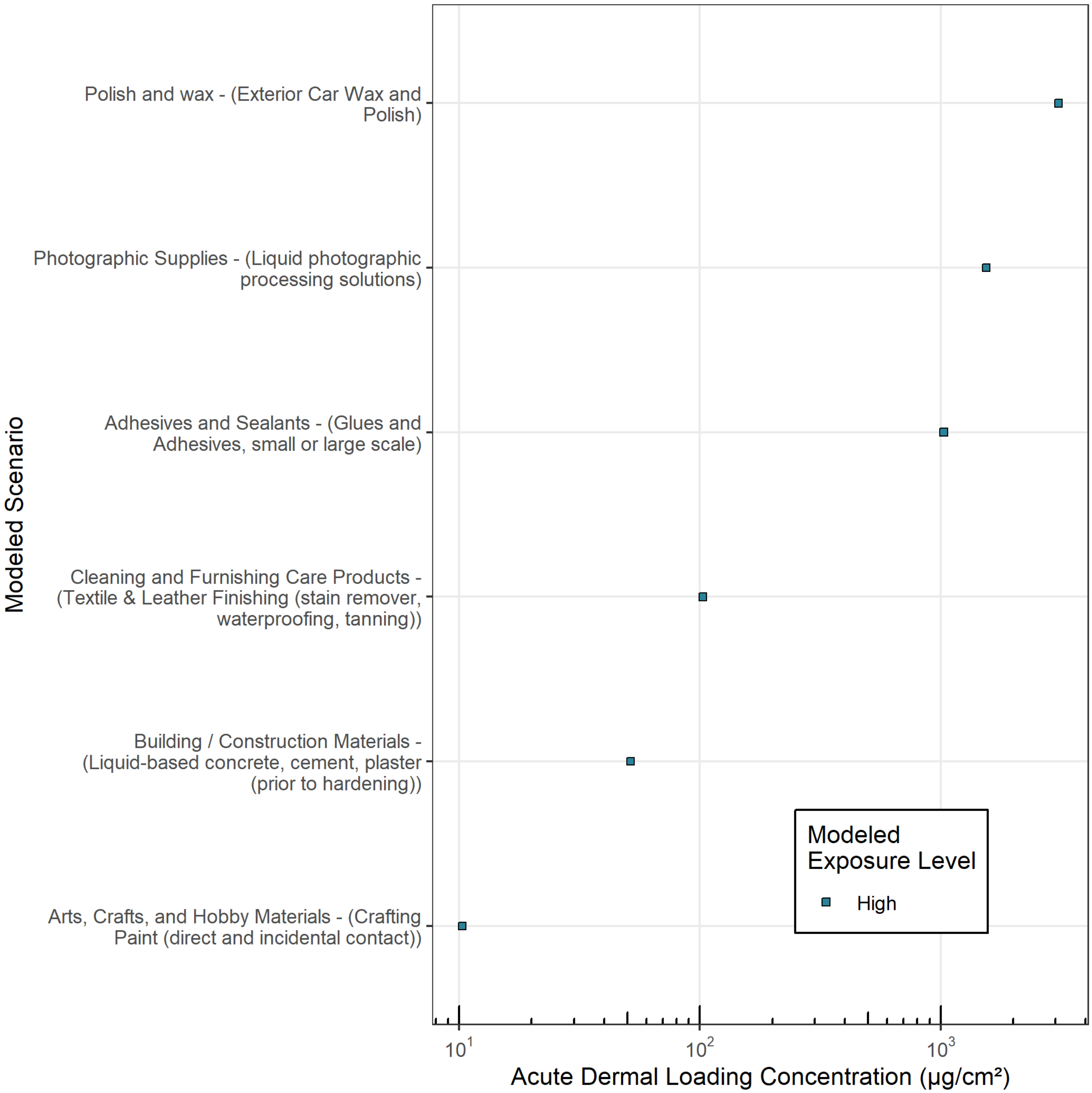


Figure 2-22-2. Summary of Acute Consumer Dermal Concentrations (Based on Thin Film Model)
The x-axis presents dermal loading concentration, and the y-axis presents the modeled TSCA COUs. The term "High" in the figure refers to high-end scenarios as described above.

2.3 Indoor Air Exposure Assessment

A detailed analysis for indoor air can be found in the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j). The separation of the Consumer Exposure Assessment and the Indoor Air Exposure assessment is intentional. As mentioned in section 2.2, the Consumer Exposure Assessment focuses on users of consumer products and articles and those that may be exposed as a result. The Indoor Air Assessment focuses on scenarios where an article may be newly introduced to a home and subsequently off gasses formaldehyde. In the *draft Risk Evaluation for Formaldehyde*, indoor air exposures were expected to be primarily driven by long-term and continuous exposure scenarios, primarily focusing on persistent and/or significant article emissions of formaldehyde after being installed in a home. These exposures were assessed with CEM. For the *revised Risk Evaluation*, EPA additionally assessed short-term (*i.e.*, 15-minute peak), intermediate (*i.e.*, 3-month), and long-term (*i.e.*, 1-year) formaldehyde indoor air inhalation exposures from articles (*e.g.,* wood, wallpaper, seat covers, etc.). These exposures were assessed using IECCU.

2.3.1 Conditions of Use and Considerations for their Assessment

EPA assessed four conditions of use for the Indoor Air Exposure Assessment. The CEM assessment conducted for the draft Risk Evaluation and maintained in the revised assessment includes six exposure scenarios. The revised Indoor Air Exposure Assessment additional uses IECCU to assess the same conditions of use for four representative scenarios and two aggregate scenarios. Both approaches have been included to bolster confidence in this overall assessment.

2.3.2 Summary of Assessment Approach

EPA considered both monitoring data and models to estimate indoor air concentrations of formaldehyde. Measured formaldehyde concentrations were collected for residential, commercial, and automobile environments. Two modeling tools were used to estimate formaldehyde concentrations from TSCA COUs. ~~EPA used CEM to estimate 1-year average indoor air concentrations from articles. In addition,~~ EPA used IECCU to estimate 15-minute~~, 3-month, and 1-year~~ concentrations of formaldehyde for indoor air. For more information on the differences between these two models, see the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j).

As mentioned, EPA used monitoring data to characterize measured indoor air concentrations of formaldehyde. The monitoring data for this assessment is robust and nationally representative. EPA used information collected through the systematic review process and leveraged monitoring data collected through the American Health Homes Survey II. These monitoring data do not differentiate between TSCA COUs assessed in this evaluation and other sources of formaldehyde like gas stoves. Monitoring data are presented and discussed further in Section 2.3.3.

EPA used CEM as a screening tool and IECCU to refine its assessment of formaldehyde in residential indoor air. IECCU is specifically designed to assess indoor air exposures. Using both models provides the potential range of formaldehyde concentrations in indoor air given the uncertainties of both models. CEM is expected to provide the highest concentrations while IECCU is expected to provide the lowest concentrations for TSCA COUs. Where CEM was used to estimate concentrations of formaldehyde in vehicular air, IECCU was not as this is a limitation of that model. Thus, CEM modeling results are the only estimates provided for the associated TSCA COUs and are considered the best available. CEM's results are presented and discussed further in Section 2.3.4 and IECCU's results are presented in Section 2.3.5.

2.3.3 Indoor Air Exposure Monitoring Results

EPA identified over 800 monitoring studies, ~290 of which are specific to the indoor air environment and associated with the 12 TSCA COUs subject to this risk evaluation (see Appendix A of the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j)). As was presented in Section 3.2.2 of the *2016 Formaldehyde Exposure Assessment Report TSCA Title VI Final Rule* (U.S. EPA, 2016b), EPA presents a supplemental summary of formaldehyde concentrations identified from several well-established residential (Table 2-1, Figure 2-3) and commercial (Table 2-2) indoor air monitoring studies to provide additional context to the TSCA formaldehyde indoor air exposure assessment. From a comparison of residential (Table 2-1) and commercial (Table 2-2) indoor air monitoring, residential indoor air exposures to formaldehyde are generally expected to be higher compared to commercial buildings due to expected lower room volumes and air exchange rates in residences relative to commercial buildings.

Table 2-12-1. Indoor Air Monitoring Concentrations for Formaldehyde

Reference	Monitoring Study Description	Formaldehyde Concentrations (μg/m^3)	
		Central Value	Range/Percentiles
(ATSDR, 2007)	96 unoccupied FEMA trailers assessed during the summer of 2006	Mean: 1,280	Range: 12.28–4,500
American Healthy Home Survey (QuanTech, 2021)	Nationally representative sample of 689 U.S. homes of various ages, types, conditions, and climates	Mean: 23.2	Range (lower/upper 95% tiles of mean): 21.4–24.9
(California Air Resources Board, 2004)	Portable and traditional classrooms in 67 California schools (Phase II study)	Arithmetic Mean: 18.42 (portable) 14.74 (traditional)	95th Percentile: 31.93 (portable) 27.02 (traditional)
(Gilbert et al., 2005)	59 homes in Prince Edward Island, Canada	Geometric Mean: 33.16	Range: 5.53–87.33
(Gilbert et al., 2006)	96 homes in Quebec City, Canada	Geometric Mean: 29.48	Range: 9.58–89.91
(Hodgson et al., 2004)	4 new relocatable classrooms	Unspecified Mean: 9.83 (indoor-outdoor)	Range: 4.91–14.74 (indoor-outdoor)
(Hodgson et al., 2000)	New homes in eastern/SE U.S.: 4 new manufactured homes 7 new site-built homes	Geometric Mean: 41.76 44.22	Range: 25.79–57.73 17.2–71.24
(Liu et al., 2006)	234 homes in Los Angeles County, CA; Elizabeth, NJ; and Houston, TX	Median: 20.02	Range: 12.53–32.43 (5th–95th percentiles)
(LBNL, 2008)	4 FEMA camper trailers	Unspecified Mean: 568.67	Range: 330.39–924.85
(Murphy et al., 2013)	Sample: All structures (519) Travel trailers (360) Park models (90) Mobile homes (69)	Geometric Mean: 94.57 99.49 54.04 70.01	Range: 3.68–724.65 3.68–724.65 3.68–196.52 13.51–393.03
(Offermann et al., 2008)	108 new SF homes in CA	Median: 38.2	Range: 4.67–143.33
(Sax et al., 2004)	Inner-city homes: NY City (46) – winter (W), summer (S) Los Angeles (41) – winter (W), fall (F)	Median: 12.28 (W), 18.42 (S) 18.42 (W), 14.74 (F)	Range: 4.91–22.11 (W), 6.14–50.36 (S) 7.37–55.27 (W), 7.37–31.93 (F)

Table 2-22-2. Formaldehyde Monitored in U.S. Commercial Buildings from 2000 to Present

Reference	Monitoring Study Description	Formaldehyde Concentrations (µg/m^3)	Descriptor
(Ceballos and Burr, 2012)	Office space indoor air monitoring for formaldehyde in a commercial building	24.56	Average
(U.S. EPA, 2023)	Indoor air monitoring across 100 randomly selected U.S. commercial buildings	3.68	5th percentile
		14.74	50th percentile
		30.71	95th percentile
(Page and Couch, 2014)	Indoor air U.S. government offices	<61.41	Maximum
(Lukcso et al., 2014)		12.28	Geometric mean
		56.50	Maximum
(Dodson et al., 2007)	Classrooms in school buildings in the United States	17.69	Median

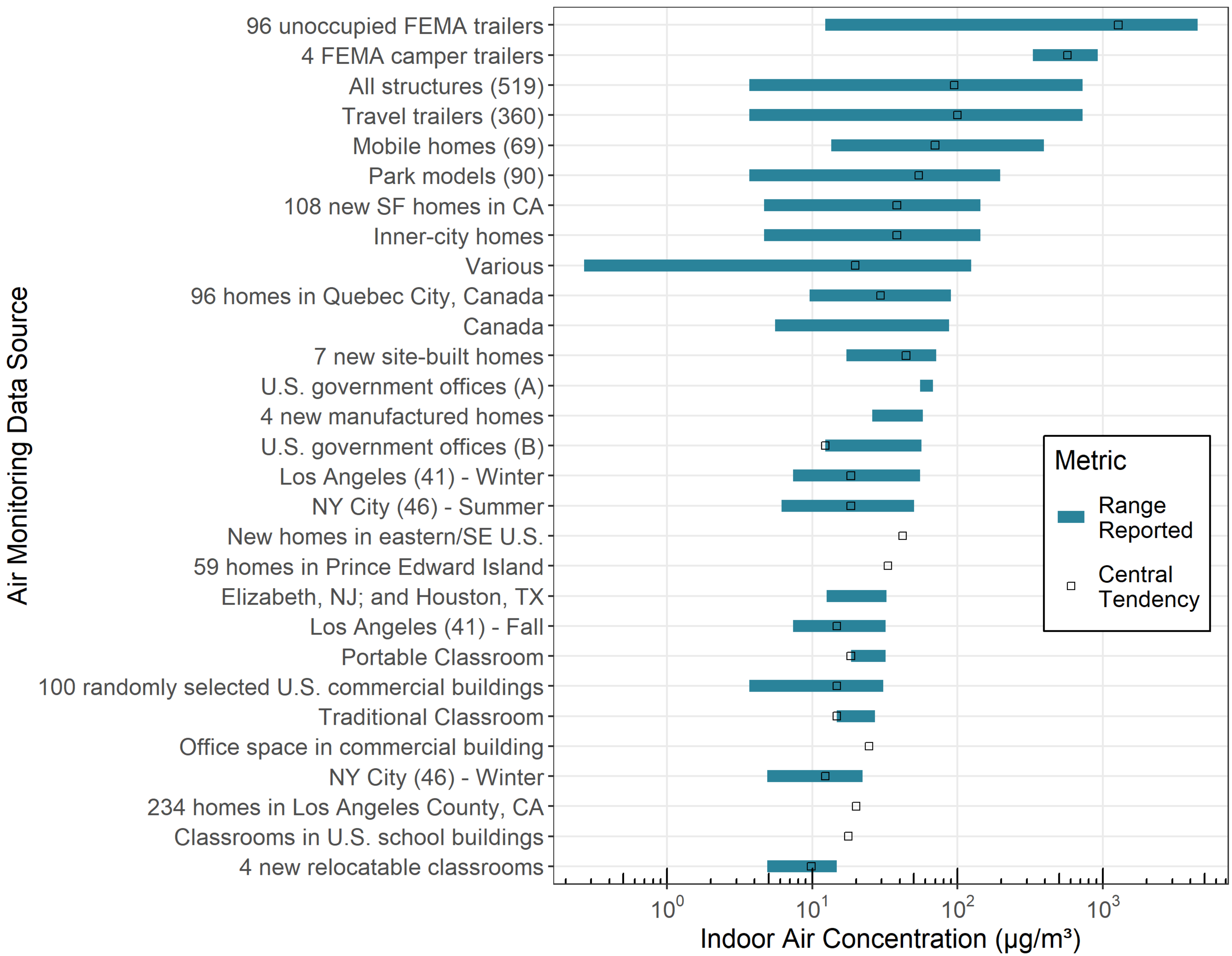


Figure 2-32-3. Long-Term Average Daily Concentrations of Formaldehyde According to Air Monitoring Data Source

Monitoring data from the American Healthy Homes Survey II suggests that concentrations of formaldehyde may range from 0.27 to 124.2 µg/m^3 for all homes (including new homes at the time of survey), with 95 percent of homes having concentrations below 47 µg/m^3 (QuanTech, 2021). Those data include formaldehyde produced from both TSCA sources (Figure 1-2 of the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j) and other sources of formaldehyde such as tobacco smoke or the use of fireplaces, gas-burning appliances, candles, and air purifiers (QuanTech, 2021). These other sources do not contain formaldehyde but rather lead to the formation of formaldehyde during use.

An important consideration in these data is how formaldehyde may dissipate in homes. The most prominent cause is home ventilation either through mechanical systems or through open windows. Due to improved insulation in American homes built after 1990, formaldehyde may persist longer in newer homes compared to older homes as a result of reduced indoor-outdoor air exchange (see Appendix C of *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j)). Sorption is not expected to be a key source of dissipation for homes. Also, the available monitoring data may not reflect future concentrations as energy efficiency and building materials change over time. These factors are not readily presented in the monitoring data but do play an important role in understanding why some homes may have higher formaldehyde concentrations than others.

Unlike residential settings, most commercial settings are not expected to have sources of formaldehyde attributable to combustion. A comparison of formaldehyde indoor air concentrations from both general settings and residential settings (Table 2-1 and Table 2-2) suggest similar concentrations of formaldehyde. It also suggests that, while combustion sources may be notable contributors in some settings, combustion is not a substantial contributor to typical indoor air concentrations that Americans may be exposed.

2.3.4 Indoor Air CEM Exposure Modeling Results

Through a review of key products expected to be significant and persistent emitters of formaldehyde, EPA identified four TSCA COUs as potential significant contributors to residential indoor air environment. EPA used CEM to estimate indoor air concentrations in homes and vehicles based on article specific emission rates for these four TSCA COUs. Central tendency 1-year average daily indoor air exposures estimates were generated (Table 2-32-4 and Figure 2-4) as discussed in Section 2.1.1.1.3 of the *Indoor Air Exposure Assessment* (U.S. EPA, 2024j) for comparability with AHHS II monitoring data and to estimate common indoor air concentrations for most American households.

Table 2-32-4. Estimated Chronic Average Daily Formaldehyde Indoor Air Concentrations (According to CEM)

COU Subcategory	Scenario[a]	Environment	CEM Calculated One-Year Average Daily Concentration (µg/m^3)
Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	**Building / Construction Materials - Wood Articles: Hardwood Floors (Residential)[a]**	Living Room	**423.47**

COU Subcategory	Scenario[a]	Environment	CEM Calculated One-Year Average Daily Concentration (μg/m^3)
Fabric, textile, and leather products not covered elsewhere	Seat Covers (Automobile)	Automobile	7.10
Fabric, textile, and leather products not covered elsewhere	Furniture Seat Covers (Residential)	Living Room	4.01
Fabric, textile, and leather products not covered elsewhere	**Fabrics: Clothing (Residential)**	Bedroom	**5.19**
Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles	**Furniture & Furnishings – Wood Articles: Furniture (Residential**)	Living Room	**108.62**
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	**Paper-Based Wallpaper**	Living Room	**18.05**

[a] The bolded text are representative scenarios for the COU subcategory as it yielded the highest concentrations compared to other modeled scenarios within the relevant COU subcategory.

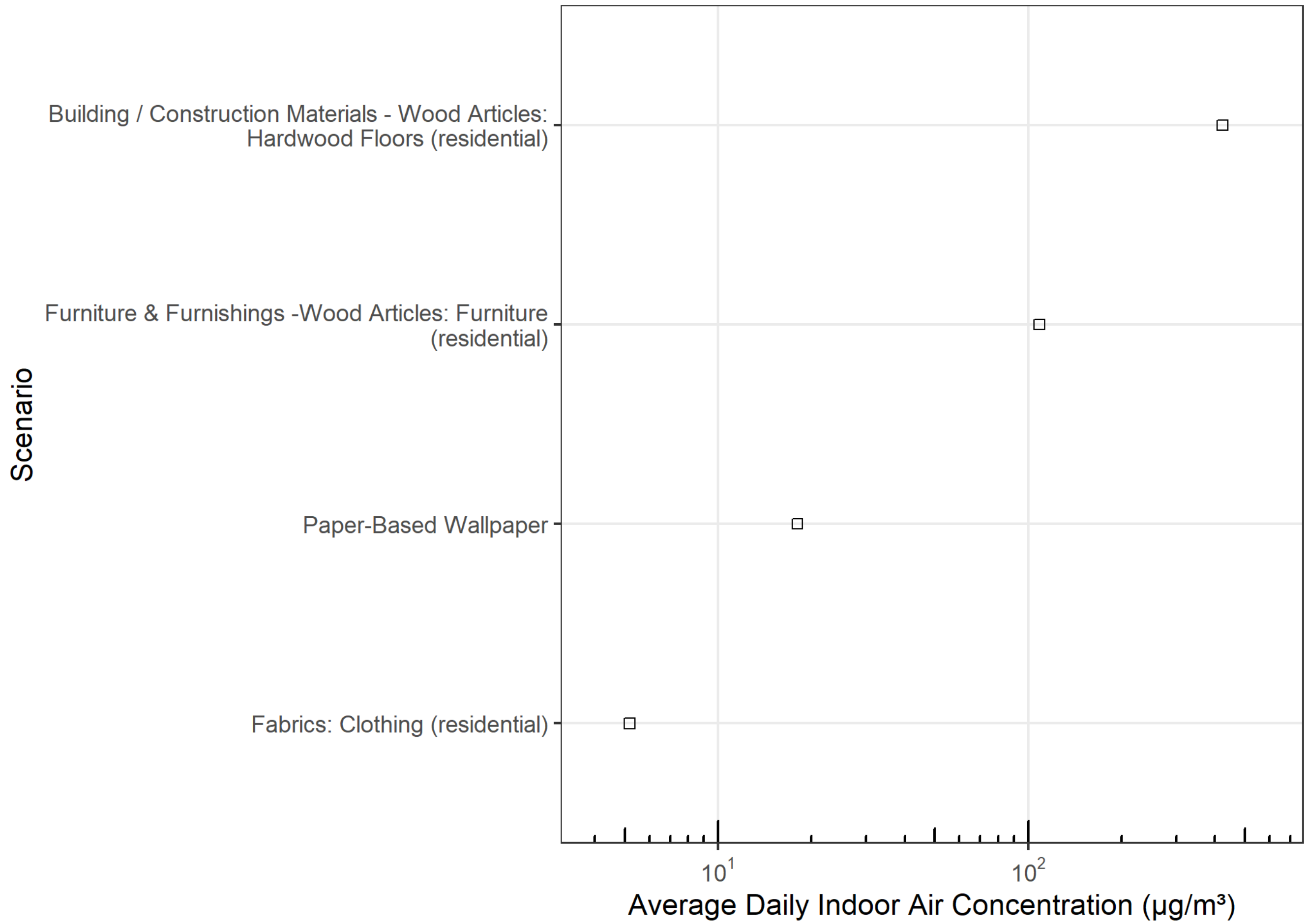


Figure 2-42-4. Modeled Formaldehyde Average Daily Inhalation Concentrations in Indoor Air (According to CEM)
The x-axis presents the average daily concentration, and the y-axis presents the modeled TSCA COUs.

While not directly comparable due to potential differences in individual COU vs total monitoring indoor air estimates, differences in rooms of use, and building configurations among others, modeled concentrations of formaldehyde were within the same order of magnitude as reported in monitoring studies, including the American Healthy Homes Survey II (see Section 2.1 of the *Indoor Air Exposure Assessment* (U.S. EPA, 2024j)). The estimated formaldehyde indoor air exposures likely represent exposures from new articles added to a residence (*e.g.*, wood products).

Over the span of a year, the highest TSCA COU contributor to the residential indoor air environment was building wood products. In additional, several of the modeled COUs may occur simultaneously. Therefore, in consideration of simultaneous exposures in residential indoor air, EPA aggregated exposures to representative TSCA COUs (bolded text in Table 2-32-4). These included hardwood floors, clothing, wood furniture, and paper-based wallpaper. Aggregating the COUs resulted in a total CEM-modeled formaldehyde residential concentration of approximately 555 µg/m^3. While several of the modeled COUs may occur simultaneously, aggregating exposures for all four of these articles may not be reflective of actual exposure scenarios encountered over a lifetime because the combination of these TSCA COUs likely differ from home to home and over time.

2.3.5 Indoor Air IECCU Exposure Modeling Results

EPA used IECCU to model indoor air concentrations in American homes based on TSCA COU-specific emission fluxes and article surface areas, providing an estimate of TSCA COU-specific contributions to formaldehyde in indoor air. Modeled indoor air results are presented in detail in Section 2.3 of the *Indoor Air Exposure Assessment* (U.S. EPA, 2024j) for potential comparability with monitoring studies such as the AHHS II.

Modeled 15-minute peak, indoor air concentrations for both single item and aggregate scenarios are shown in Table 2-5 and Figure 2-5. For the TSCA COU covering building materials with large surface areas, models were generated for both pressed wood cabinets and laminate flooring. The high-end air peak air concentrations were 51 µg/m^3 for pressed wood cabinets and 142 µg/m^3 for laminate flooring. As such, model results for laminate flooring are reported as the representative article for this COU; model results for pressed wood cabinets are not reported in Table 2-5 or shown in Figure 2-5. However, pressed wood cabinets are included in the modeled results for the new construction aggregate scenario. Zone 1 in Figure 2-5 indicates the primary location or room for articles that were assumed to be placed, while the corresponding zone 2 represents the articles' air contributions to the rest of the home through interzonal (room-to-room) air flow. Also, note that for items modeled in a whole home, a single zone model was used, and Zone 2 concentrations are therefore recorded as N/A.

Table 2-5. Fifteen Minute Peak Formaldehyde Concentrations (μg/m^3) in Indoor Air for Single Representative Article and Aggregate Model Scenarios

COU	Representative Scenario	Level	15-Minute Peak Air Concentration Zone 1 (μg/m^3)	15-Minute Peak Air Concentration Zone 2 (μg/m^3)	3-Month Average Air Concentration Zone 1 (μg/m^3)	1-Year Average Air Concentration Zone 1 (μg/m^3)
Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Laminate Flooring	High	142	N/A	27.5	6.1
		Med	22	N/A	4.3	1
		Low	1	N/A	0.2	0.05
	New Construction Aggregate	High	160	N/A	31.1	6.87
		Med	64	N/A	12.3	2.72
		Low	21	N/A	4.1	0.9
Fabric, textile, and leather products not covered elsewhere	Textile Furniture Covers	High	18	0.3	3.5	0.8
		Med	2	0.03	0.4	0.1
		Low	0.007	0.00009	0.001	0.0003
Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles	Pressed Wood Furniture	High	26	0.4	5	1.1
		Med	7	0.1	1.4	0.3
		Low	2	0.03	0.3	0.1
	Living Room Décor Change Aggregate	High	68	0.9	12.9	2.9
		Med	16	0.2	3.1	0.7
		Low	3	0.04	0.5	0.1
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Wallpaper	-	12	N/A	2.3	0.5

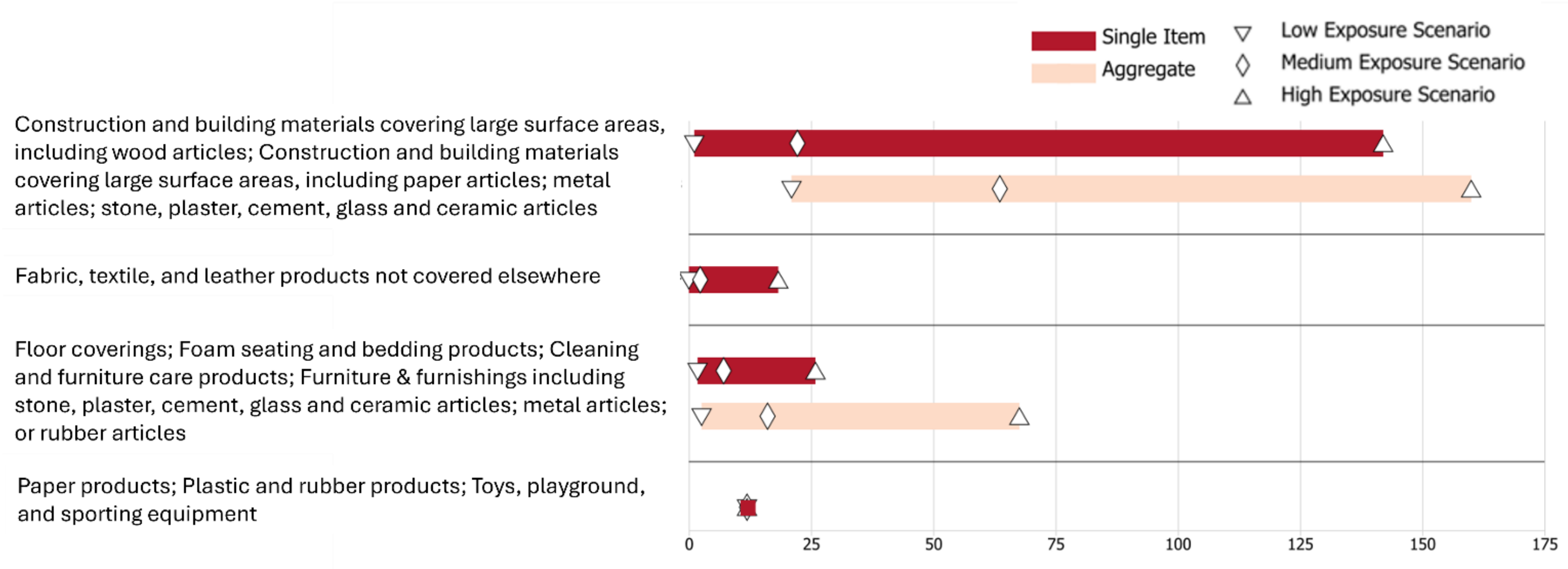


Figure 2-52-5. Fifteen Minute Peak Concentrations (µg/m³) of Formaldehyde in Indoor Air for TSCA COU Representative Article and Aggregate Models

Except for wallpaper, modeled air concentrations for each representative scenario (Section 2.2.2 of the *Indoor Air Exposure Assessment* (U.S. EPA, 2024j)) showed a significant range in values. This was driven largely by variability in emissions factors and estimated surface areas. However, these parameters likely exhibit significant variability due to differences in materials, manufacturing practices, and purchasing preferences. As such, EPA considers it reasonable that the range of estimated concentrations reflects real-world conditions for each COU assessed.

Figure 2-6 shows air concentrations over the full duration of modeling (10,000 hours) for the high-end models and for each representative scenario. The modeled concentrations of formaldehyde in air peaked on the first day the article was installed in the home. Then, the concentrations in indoor air declined rapidly, approaching zero µg/m^3 after a period of approximately three months (U.S. EPA, 2024j).

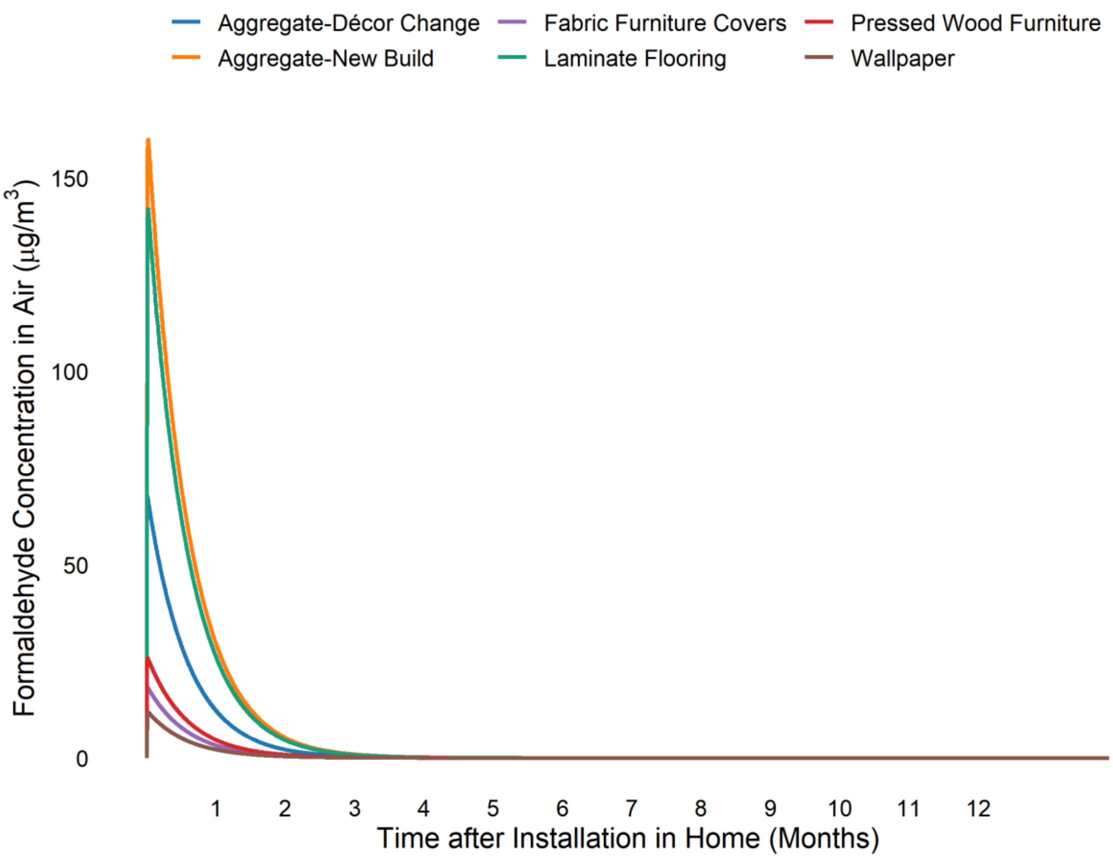


Figure 2-6~~2-6~~. Formaldehyde Concentrations in Indoor Air (µg/m^3) for TSCA COU Representative Article and Aggregate Models Over Time (10,000 hour simulation duration)

2.3.6 Aggregate Indoor Air Exposure

EPA defines aggregate exposure as "the combined exposures from a chemical substance across multiple routes and across multiple pathways" (40 CFR § 702.33). The reported formaldehyde concentrations from the monitoring data may represent aggregate formaldehyde indoor air concentrations, as presented in the AHHS II study across U.S. households (QuanTech, 2021), assuming either at least a 3-hour TWA, or the typical indoor air concentration of formaldehyde in residential environments. An aggregate exposure to formaldehyde via the COUs assessed may occur in the home in which an individual resides.

An individual may be exposed to formaldehyde via residential indoor air, with an estimated COU-specific aggregate indoor air concentration as high as 160 μg/m^3 for a new construction scenario and 68 μg/m^3 for living room décor change scenario. Furthermore, using the AHHS II measured average concentration of formaldehyde (~23 μg/m^3) as a typical residential concentration, and considering the addition of new laminate flooring yielding concentrations as high as 142 μg/m^3, a resident's aggregate exposure may be as high as 165 μg/m^3.

2.4 Ambient Air Exposure Assessment

EPA assessed 43 COUs for the Ambient Air Exposure Assessment. Like the indoor air assessment, this assessment integrates both monitoring data and models to estimate and characterize how people may be exposed to formaldehyde when outside. This assessment used a nationally representative monitoring dataset provided by EPA's Ambient Monitoring Technology Information Center (AMTIC) archive as discussed in Section 2.4.1. Several models were used to a) quantitatively evaluate exposures from industrial releases of formaldehyde to ambient air that are associated with TSCA COUs; b) characterize some of the other sources of formaldehyde in ambient air; and~~,~~ c) spatially represent modeled formaldehyde concentrations from TSCA COUs relative to biogenic or natural sources. These assessments are summarized and discussed in Section 2.4.2. A detailed summary of all the analyses conducted, methodologies used, and all exposure concentration results for formaldehyde are provided in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and associated supplemental files.

2.4.1 Monitoring for Ambient Air Concentrations

EPA identified and summarized monitoring data for formaldehyde from EPA's ~~Ambient Monitoring Technology Information Center (~~AMTIC~~)~~ archive (U.S. EPA, 2022a). These results are presented in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). These data are based on all potential sources of formaldehyde and do not distinguish between biogenic production, secondary production, or point sources. Furthermore, these data are not specific to TSCA COUs. They are, however, useful in understanding spatial and temporal differences in ambient air concentrations in the contiguous United States.

The AMTIC dataset for formaldehyde includes 195 monitoring sites from 36 different states. Data were extracted across 6 years (2015 through 2020). Due to the time it takes for AMTIC to accept submissions, clear, classify, and process the monitored data, the 2020 data was the latest available. The full dataset considered for this risk assessment includes a total of 306,529 observations (untouched/unprocessed raw data). Post processing of the raw dataset by EPA included filtering out error codes, missing/incomplete data files, brought the raw dataset entries down to 233,961. This processed dataset includes monitoring data from 20 air monitoring programs covering 32 states within the contiguous United States.

EPA calculated summary statistics for all 233,961 samples, samples by state, samples by census tract, samples by monitoring site, samples by monitoring site and year, and samples by monitoring site and year and quarter. For purposes of this ambient air exposure assessment, EPA used the overall statistics across all samples to characterize exposures and characterize exposures to the general population (Table 2-6). Monitoring locations and annual summary statistics are provided in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

Table 2-6 presents results for all 233,961 samples and includes the following adjustments (where applicable): Any entries with missing key data were omitted from the analysis (*e.g.,* concentrations, concentration units, method detection limits, methodology used). All concentration and method detection limit (MDL) values were converted to micrograms per cubic meter (μg/m^3) for unit uniformity between submitting programs. Method detection limits were provided along with sample concentrations on a submission-by-submission basis by submitting agencies, from 0.000011 to 1.2 µg/m^3, and varied by sample based on the sampling and analysis methodology. Entries with reported concentrations below the method detection limit were substituted with a value of 0 µg/m^3. Concentrations of formaldehyde ranged from below the method detection limit to 60.1 µg/m^3 and a median value of 1.6 µg/m^3. A summary of the statistics extracted from the overall dataset are provided in Table 2-6.

Table 2-6. Overall Monitored Concentrations of Formaldehyde from AMTIC Archive Dataset

Monitored Concentrations (µg/m^3)						
Aggregation	**Count**	**Minimum**	**Minimum (non-zero)**	**Median**	**Mean**	**Maximum**
All Entries	233,961	0	0.002	1.6	2.1 ± 2.2	60
Daily Mean	3,843	0	0.011	2.5	3.0 ± 2.0	18.4
Annual Mean	64	1.4	1.4	2.9	3.0 ± 1.1	6.5

The individual site data collected by AMTIC represents various sampling techniques and differing sample collection durations ranging from 5 minutes to 24 hours. When using these data for comparison to the presented formaldehyde models, the concentrations were converted to daily and annual averages. AMTIC concentration values were used to calculate daily or annual average only when there was greater than 75 percent sample coverage over the averaged timeframe when converting from sub-hour samples to hourly averages and again for hourly samples to daily averages. Each annual quarter required a minimum of seven valid daily averages and each annual mean required a minimum of three valid quarterly averages per year per site. The high standards for coverage resulted in a drastic reduction in the data available for conversion to daily and annual averages. Of the original 233,961 complete entries, there were 64 site-years and 3,843 site-days with sufficient coverage to calculate daily and annual average statistics (Table 2-6).

Three AMTIC high-frequency sampling locations in Houston, Texas located around the Buffalo Bayou area were isolated from AMTIC data for a more in-depth analysis of ambient formaldehyde concentrations in mixed-use regions. Each of the three sites collected continuous five-minute composite samples seven days a week over approximately one year using a FluxSense sampling system. The sites were located around the Port of Houston in mixed industrial regions with known NEI releasing facilities intertwined with residential neighborhoods (Figure 2-7). Additional details on this case study are included in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

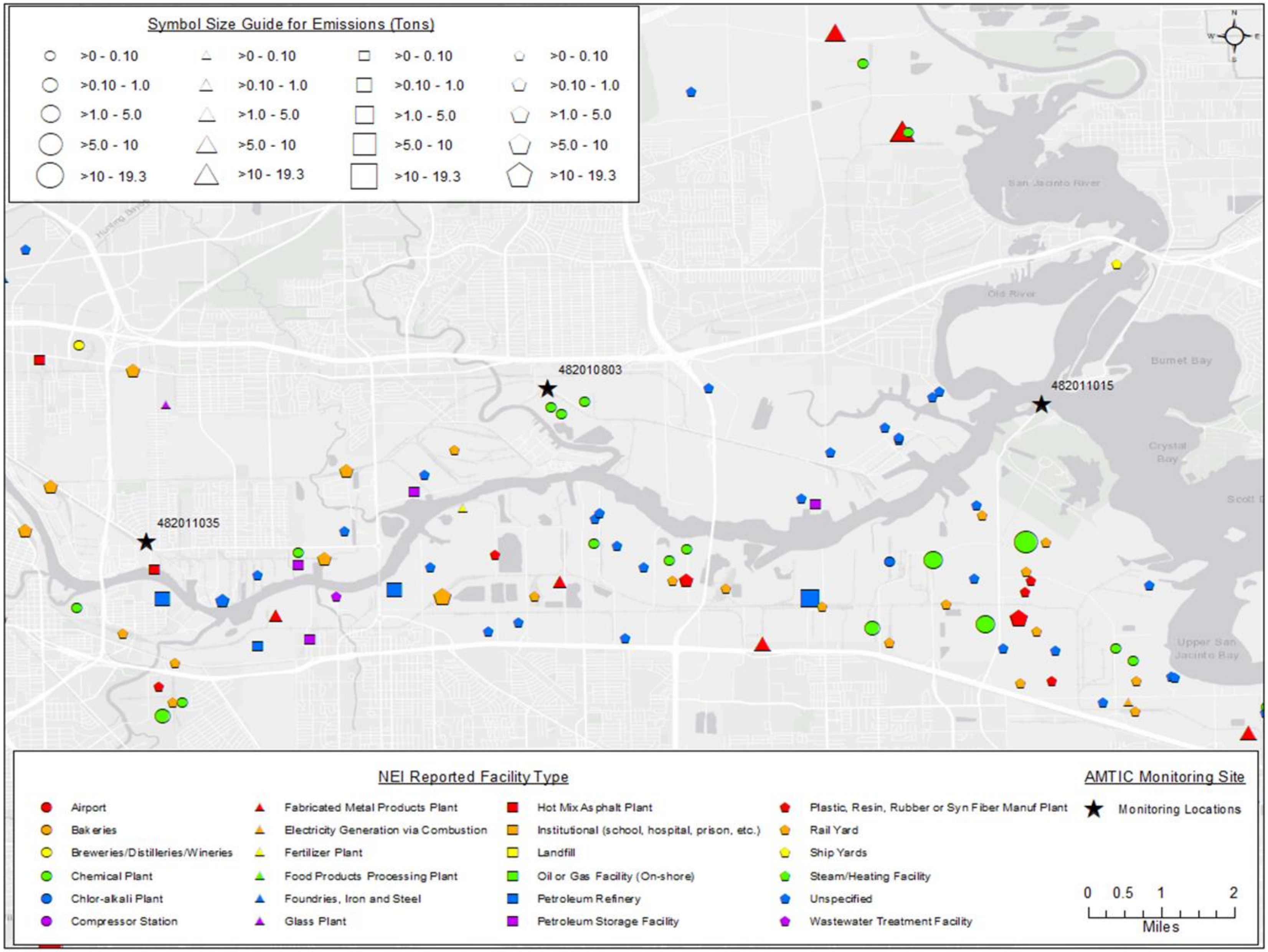


Figure 2-7~~2-7~~. High-Resolution Monitoring Locations in Houston, Texas: 482010803 (N = 42,560), 482011015 (N = 70,126), and 482011035 (N = 71,621).

Approximately 0.5 to 18 percent of measurements fell below the reported 0.159 µg/m^3 method detection limit. Median values ranged from 1.0 to 2.2 µg/m^3 with slightly higher mean 5-minute concentration of 1.3 to 2.9 µg/m^3 with a slight positive skew meaning there is a higher quantity of higher-concentration samples than would be expected in a standard normal distribution (Figure 2-8). Ambient formaldehyde concentrations appear to be stable throughout the monitoring period indicating that formaldehyde in ambient air is generally representative of an ongoing concentration to which the general population may be routinely exposed in day-to-day life (Figure 2-8). There were, however, notable daily trends in formaldehyde concentration that aligned with the working day. Concentration of formaldehyde peaked in the afternoon and evening between the hours of 12:00 PM and 7:00 PM during the day and the lowest concentrations of formaldehyde were typically in the early morning between 12:00 AM and 8:00 AM (Figure 2-8).

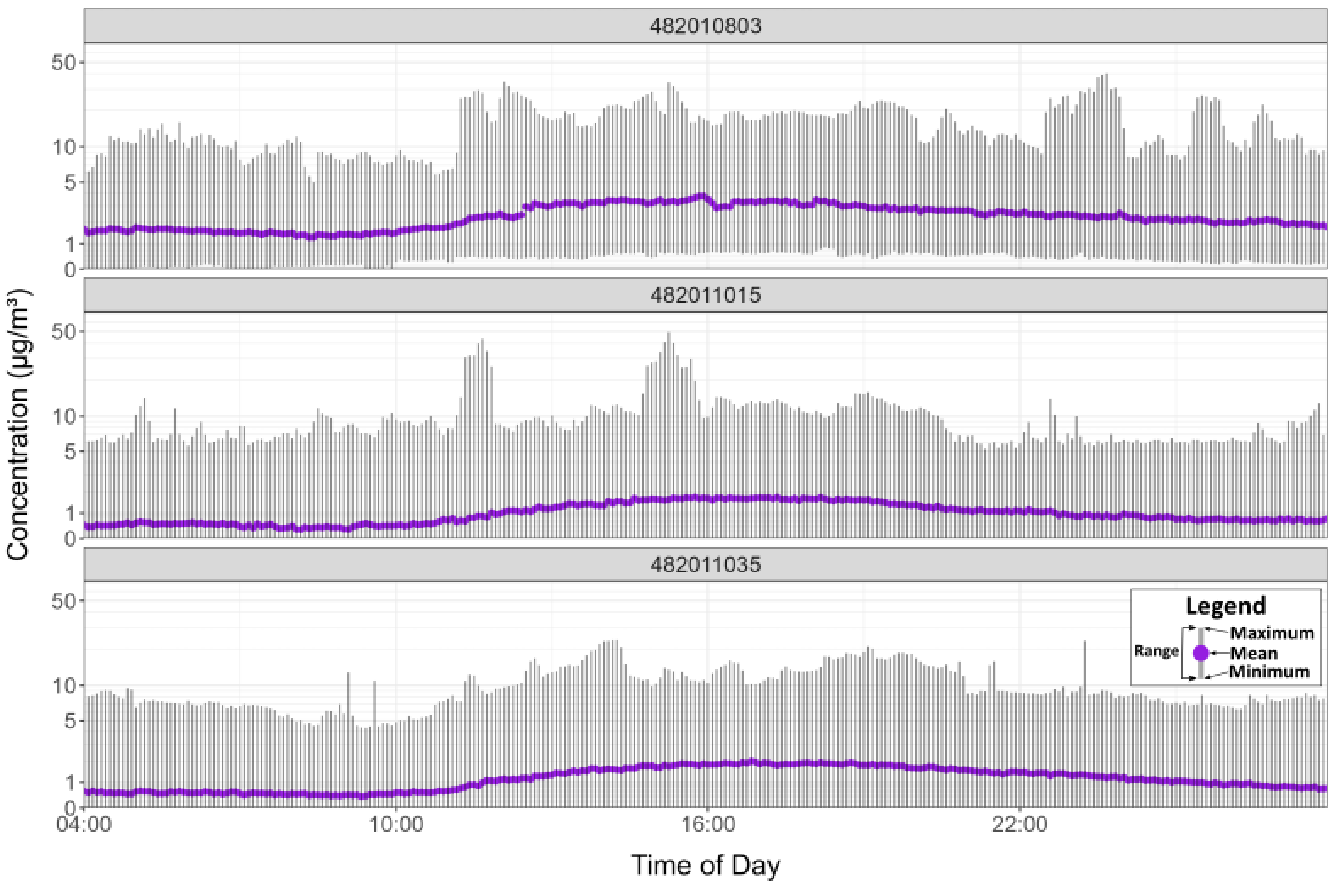


Figure 2-8~~2-8~~. Houston area sites 5-minute concentration data aggregated by time of day.

2.4.2 Modeling Ambient Air Concentrations

EPA used three different models to estimate formaldehyde concentration in outdoor air. These included EPA's Integrated Indoor-Outdoor Air Calculator (IIOAC) Model, the Air Toxics Screening Tool (AirToxScreen), and EPA's Human Exposure Model (HEM). Each model's use served a different purpose in this assessment as described in detail in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

2.4.2.1 Integrated Indoor/Outdoor Air Calculator Model (IIOAC)

EPA used the IIOAC model to estimate daily average and annual average formaldehyde concentrations in ambient air at three pre-defined distances from a releasing facility (100, 100 to 1,000, and 1,000 meters; 0.05 to 0.5 miles). All results from the IIOAC modeling for both TRI and NEI release datasets by industry sector are provided in the *Ambient Air Exposure Assessment Results and Risk Calcs Supplement A* (U.S. EPA, 2024a).

These results include daily estimated concentrations from all reported releases of formaldehyde from industrial processes attributed to TSCA COUs and combustion. The estimated annual average concentration results are also included, but separation between TSCA COUs and combustion is not included because there were no unexpectedly high modeled concentrations outside of the general range of ambient monitoring data as described in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). The IIOAC modeling results were used in this risk assessment to characterize exposures, derive risk estimates, and characterize risks for people living near releasing facilities.

2.4.2.1.1 Estimated Daily Average Formaldehyde Concentrations

EPA uses the modeled concentration results from the following conservative exposure scenario to assess daily average exposures and associated risk estimates in this risk assessment. The basis for selecting this scenario is described in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

Release scenario: Maximum release reported by industry to either TRI or NEI for each industry sector.

Modeled concentration: High-end (95th percentile) modeled air concentrations at the 100-meter finite distance from the release point.

Operating scenario: 365 days per year, 7 days per week, 24 hours per day.

Daily average exposure concentrations attributed to TSCA COUs ranged from 0.0004 to 66.2 µg/m3 and are presented in Figure 2-9. The two highest concentrations in Figure 2-9 are from the Wood Product Manufacturing and Paper Manufacturing industry sectors and are cross-walked to nine different TSCA COUs. These results are carried through to the derivation of risk estimates, risk characterization, and can inform regulatory decision-making for TSCA COUs.

When interpreting the results presented in Figure 2-9, there are several instances where the same concentration is identified for multiple TSCA COUs. This occurs because modeling was done across an entire industry sector, as described in Section 2.1.1. of the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a), and several industry sectors cross-walk to multiple TSCA COUs as described in the *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g). This pattern will carry through the derivation of risk estimates and the risk characterization.

Figure 2-92-9. Daily Average Exposure Concentrations by TSCA COU using IIOAC non-site specific analysis.

Formaldehyde daily average exposure concentrations linked to combustion ranged from 2 to 662 µg/m^3 based on the maximum release reported to TRI or NEI. The highest modeled exposure concentrations from either TRI or NEI are presented in Table 2-7.

The first three columns in Table 2-7 include information on the industry sector, site reporting the fugitive and stack releases, and the major process unit source(s) from which those releases came. The release dataset column notes the source of the reported data, either TRI or NEI. The fugitive and stack columns provide the industry reported source apportioned release values which were used as direct inputs to the IIOAC model. The total exposure concentration column presents the sum of the exposure results modeled for fugitive and stack releases modeled at 100 meters from a releasing facility.

As previously described in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and shown in Table 2-7, all the maximum releases within each of the top five industry sectors attributable to combustion are from combustion sources like airplanes, on-site vehicles, process heaters, turbines, and reciprocating internal combustion engines (RICE). With the exception of the "utilities" industry sector these concentrations attributable to combustion range from 169 to 662 µg/m^3 and are a magnitude greater than the highest monitored concentration obtained from the AMTIC archive. Similarly, these concentrations are much higher than modeled concentrations found with HEM and the 2019 AirToxScreen results. Additional land use analysis revealed these highest releases were from facilities with no homes within 1,000 meters of the release points. Finally, when these handful of combustion sources are excluded from the release dataset, the revised range of modeled daily average concentrations was 0.0004 to 66.2 µg/m^3. This range of concentrations is within the same order of magnitude as the AMTIC archive dataset and other modeled data.

EPA further considers the representativeness of these maximum releases for these five industry sectors attributable to combustion by comparing the reported maximum release to the calculated 95th percentile release within the same industry sectors. EPA's findings from this deeper dive found the highest 95th percentile releases were at least 1 to 2 orders of magnitude lower than the maximum releases within the same industry sector. This can be seen in the TRI/NEI comparison sections of this assessment in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). Based on the additional investigation/deeper dive into the highest maximum reported releases, EPA concludes these combustion releases are likely outliers within their respective industry sectors and not representative of national level releases within the respective industry sectors. While EPA carries these releases attributable to combustion separately through the risk estimates, and risk characterization, caution is required when considering use of these highest release values in a national level assessment to inform regulatory decision-making.

Table 2-7~~2-6~~. Five Highest Exposure Concentrations Attributable to Combustion Based on IIOAC Modeling of Maximum Release Value

Industry Sector	Facility (County, State)	Major Process Unit Source(s)	Maximum Release Value (kg/year)			Total Exposure Concentration (µg/m^3)
			Release Dataset	Fugitive	Stack	
Wholesale and Retail Trade	Columbus AF Base (Lowndes, MS)	Aircrafts	NEI	138,205		662
	Transcontinental Gas Pipeline Company, LLC (Henry, GA)	RICE, Turbines			95,159	
Oil and Gas Drilling, Extraction, and Support Activities	Chevron USA Inc. (Kern, CA)	Process heaters, RICE, Turbines	NEI	22,742		334
	Frenchie Draw Central Compressor Station (Fremont, WY)	RICE			1,412,023	
Non-Metallic Mineral Product Manufacturing	Cemex Black Mountain Quarry Plant (San Bernardino, CA)	On-Site Vehicles	NEI	41,190		198
	Thermafiber Inc (Wabash, IN)	Not reported			36,492	
Services	Pope Airforce Base (Cumberland, NC)	Aircrafts	NEI	34,155		169
	Seneca Energy LFGTE Facility (Seneca, NY)	RICE			63,483	

Industry Sector	Facility (County, State)	Major Process Unit Source(s)	Maximum Release Value (kg/year)			Total Exposure Concentration (µg/m³)
			Release Dataset	Fugitive	Stack	
Utilities	Lorain County LFG Power Station (0247100968) (Lorain, OH)	RICE	NEI	10,108		61
	Basin Creek Power Services (Silver Bow, MT)	RICE			101,968	

2.4.2.1.2 Estimated Annual Average Formaldehyde Concentrations

EPA uses the modeled concentration results from the following exposure scenario to assess annual average exposures and associated risk estimates in this risk assessment for ~~both~~ chronic non-cancer endpoints ~~and cancer~~. The basis for selecting this scenario is described in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

Release scenario: 95th percentile release calculated for either TRI or NEI datasets for each industry sector.

Modeled concentration: High-end (95th percentile) modeled air concentrations at the 100 to 1,000 meters area distance from the release point.

Operating scenario: 365 days per year, 7 days per week, 24 hours per day.

Results for annual average exposure concentrations attributable to TSCA COUs range from 0.0001 to 5.7 $\mu g/m^3$ and are presented in Figure 2-10. The two highest concentrations in Figure 2-10 are from the Nonmetallic Mineral Product Manufacturing and Textiles, Apparel, and Leather Manufacturing industry sectors and are cross-walked to six different TSCA COUs. These results are carried through to the ~~derivation~~ calculation of risk estimates, risk characterization, and can inform regulatory decision-making for TSCA COUs. As described in Section 2.4.2.1.2, instances where the same concentration is identified for multiple COUs occurs because several industry sectors cross-walk to multiple COUs.

Figure 2-102-10. Annual-Average Exposure Concentrations by TSCA COU

2.4.2.2 AirToxScreen

EPA used 2019 AirToxScreen to understand the relative contributions of various sources of formaldehyde to total concentrations in the ambient air. AirToxScreen is an EPA screening tool used to evaluate air toxics from all known sources across the United States and estimates air concentrations at the *census tract scale* using a combination of models and data sources (Scheffe et al., 2016). Census tracts are a statistical subdivision of counties that are usually between 1,200 and 8,000 people. They can be a small as a few city blocks or as large as several square miles. The 2019 AirToxScreen data for biogenic sources, secondary sources, point sources, and total sources are shown in Figure 2-10. Figure 2-11 does not include AirToxScreen results for on-road sources, near-road sources, off-road sources, wildfire sources, etc.

Secondary production of formaldehyde was the largest contributor of formaldehyde to ambient air with modeled concentrations ranging from 0.085 to 1.8 μg/m^3 according to the AirToxScreen results. Secondary production is the atmospheric formation of formaldehyde from natural and manmade compounds. This can include the degradation of isoprene (a compound naturally produced by animals and plants) to formaldehyde and other complex air chemistries. AirToxScreen is not able to apportion the relative contributions from different secondary sources (source apportion).

Biogenic sources also have a significant contribution to total concentration with a range of 0.0014 to 0.67 μg/m^3. Biogenic sources include those emissions from trees, plants, and soil microbes. For this assessment, the 95th percentile of biogenic sources (0.28 μg/m^3) was estimated.

Point source contributions to total formaldehyde concentrations range from 0.0 to 0.88 μg/m^3. However, as described above, the AirToxScreen data are averaged across census tracts, which can result in a considerable underestimation of exposures relative to a source-specific contribution to which populations living nearby releasing facilities are exposed. Additionally, while the AirToxScreen data provides estimates for point sources and may include TSCA sources, the results cannot be apportioned to represent TSCA COUs vs. other sources. Therefore, these results are not directly comparable to the modeled concentrations from IIOAC.

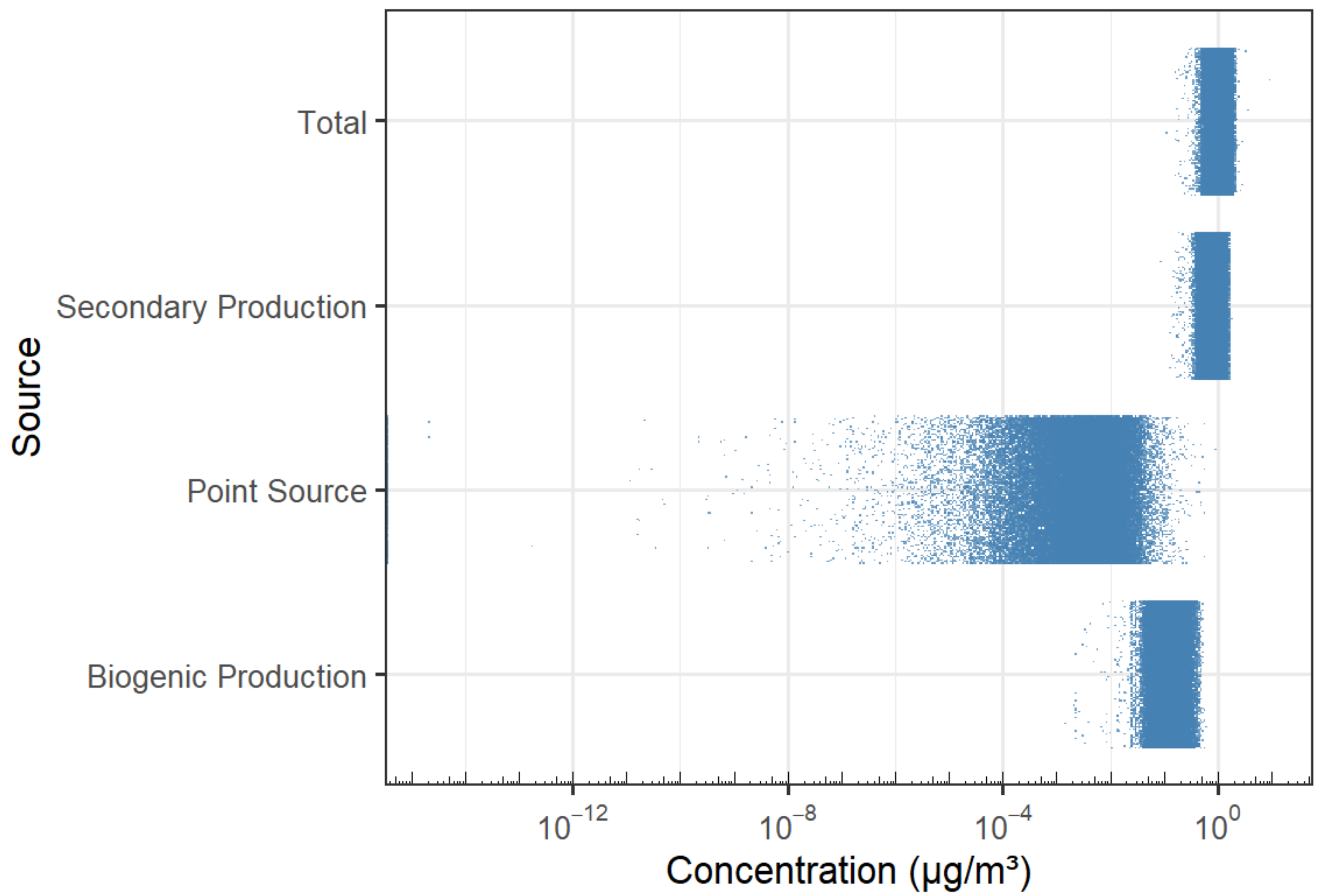


Figure 2-11~~2-11~~. 2019 AirToxScreen Modeled Data for All Sources, Secondary Production Sources, Point Sources, and Biogenic Sources for the Contiguous United States

After the *Draft Risk Evaluation for Formaldehyde* was released, results from the 2020 AirToxScreen assessment were released by the Office of Air and Radiation (https://www.epa.gov/AirToxScreen/2020-airtoxscreen-assessment-results). Total formaldehyde concentrations range from 0 to 17.2 µg/m^3, which has a higher maximum compared to the 2019 results. This difference may be attributed to the scale of the model. As mentioned, the 2019 results are at the census tract scale. The 2020 results are modeled at the census block scale, which is much smaller and provides less area for estimating ambient air concentrations. Several hot spots with elevated concentrations of formaldehyde were present in Oregon (max 17.2 µg/m^3), Puerto Rico (max 9.7 µg/m^3), Texas (max 9.6 µg/m^3), and Colorado (max 9.1 µg/m^3). While some general conclusions may be attempted when comparing 2019 to 2020 AirToxScreen data, the results are not directly comparable between 2019 and 2020. Nonetheless, both results show that secondary formation, biogenic production, and point sources are the largest contributors to total ambient air concentrations of formaldehyde (Figure 2-12).

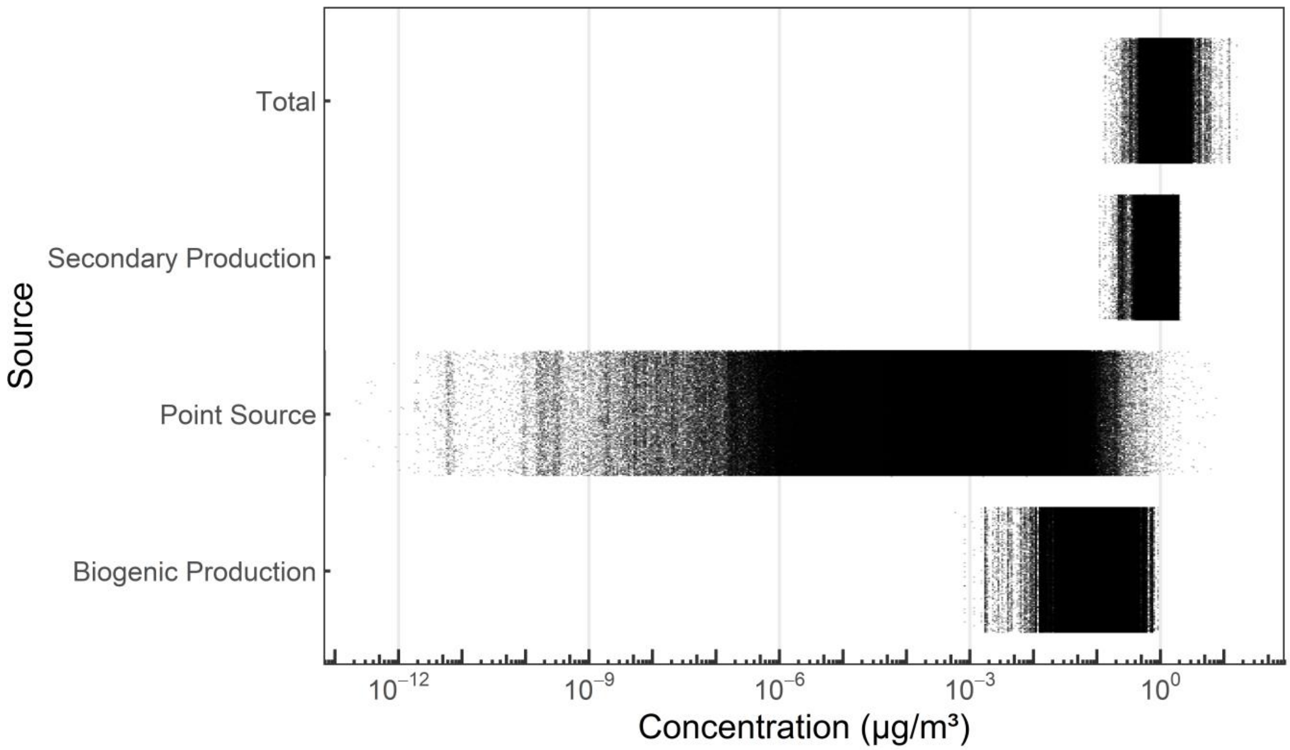


Figure 2-12~~2-12~~. 2020 AirToxScreen Modeled Data for All Sources, Secondary Production Sources, Point Sources, and Biogenic Sources for the Contiguous United States

2.4.2.3 Human Exposure Model (HEM)

EPA used the Human Exposure Model (HEM 4.2) to estimate formaldehyde concentrations on a site-specific basis at multiple distances from releasing facilities. These estimates are based on the highest reported release for each site reporting releases to TRI across the six years of TRI data as described in more detail in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). HEM 4.2 has two components: (1) an atmospheric dispersion model, AERMOD, with included regional meteorological data; and (2) U.S. Census Bureau population data at the Census block level. The current HEM version utilizes 2020 Census data—including all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. AERMOD estimates the magnitude and distribution of chemicals concentrations in ambient air in the vicinity of each releasing facility within user-defined radial distances out to 50 km (about 30 miles). HEM also provides chemical concentrations in ambient air at the centroid of over 8 million census blocks across the United States. This higher tier model was selected to expand on the IIOAC results by providing more granularity in modeling individual facilities and more discrete distances, geospatial data associated with modeling results for mapping and further analysis, and population data associated with modeled results.

Ambient air concentrations at the census block level were modeled by HEM and are shown in Figure 2-13. These aggregated concentrations are the summed stack and fugitive modeled concentrations, which can include the summation of multiple adjacent facilities, at specific locations. The site-specific concentration results represent the expected annual average ambient air concentration attributable from all modeled TRI releases of TSCA COUs, in some census blocks accounting for concentrations from multiple releasing facilities. Concentrations within those census blocks ranged from 0 to 8.9 µg/m³. Census blocks with modeled total concentrations below the 95th percentile biogenic formaldehyde threshold of 0.28 µg/m³ are presented in grey. Turquoise dots show census blocks with concentrations ranging from 1 to 5 times the 95th percentile biogenic concentration, purple dots show concentrations from 5 to 10 times the 95th percentile biogenic concentration, and pink dots show values greater than 10 times the 95th percentile biogenic concentration. In total, the HEM population analysis shows 105,463 people (based on 2020 Census data) across the country live within census blocks where the HEM modeled ambient air concentrations exceed the 95th percentile biogenic concentration.

Elevated ambient air concentrations of formaldehyde from industrial releases appear most densely concentrated in the southeastern United States. Census blocks with elevated concentrations are found throughout the country, with some regions showing fewer overall TRI facilities, and fewer releases resulting in elevated air concentrations.

Patterns in the relative contribution of stack and fugitive releases, and the distribution of results at varying radial distances from the releasing facility were examined (Figure 2-14). Each vertical bar and median line indicate the shape of the distribution of concentrations by release type for individual facilities. These results indicate that concentrations resulting from fugitive emissions are greater than those from stack emissions closer to the releasing facility, but concentrations from stack emissions tend to become greater at further distances. As many facilities report only a single release type (either fugitive or stack), the total concentration distributions represent a greater number of facilities than the corresponding fugitive and stack distributions and tend to fall somewhere between the fugitive and stack values. Total modeled concentrations tend to reach their maximum within 1,000 m of a facility. Values represented in this analysis are directly modeled at the 16 radial points around each distance ring, rather than census block centroids, and can therefore be located much closer to the releasing facility and represent much higher concentrations. These points are not associated with population estimates, and in some cases the modeled distances may still be within a facility property boundary.

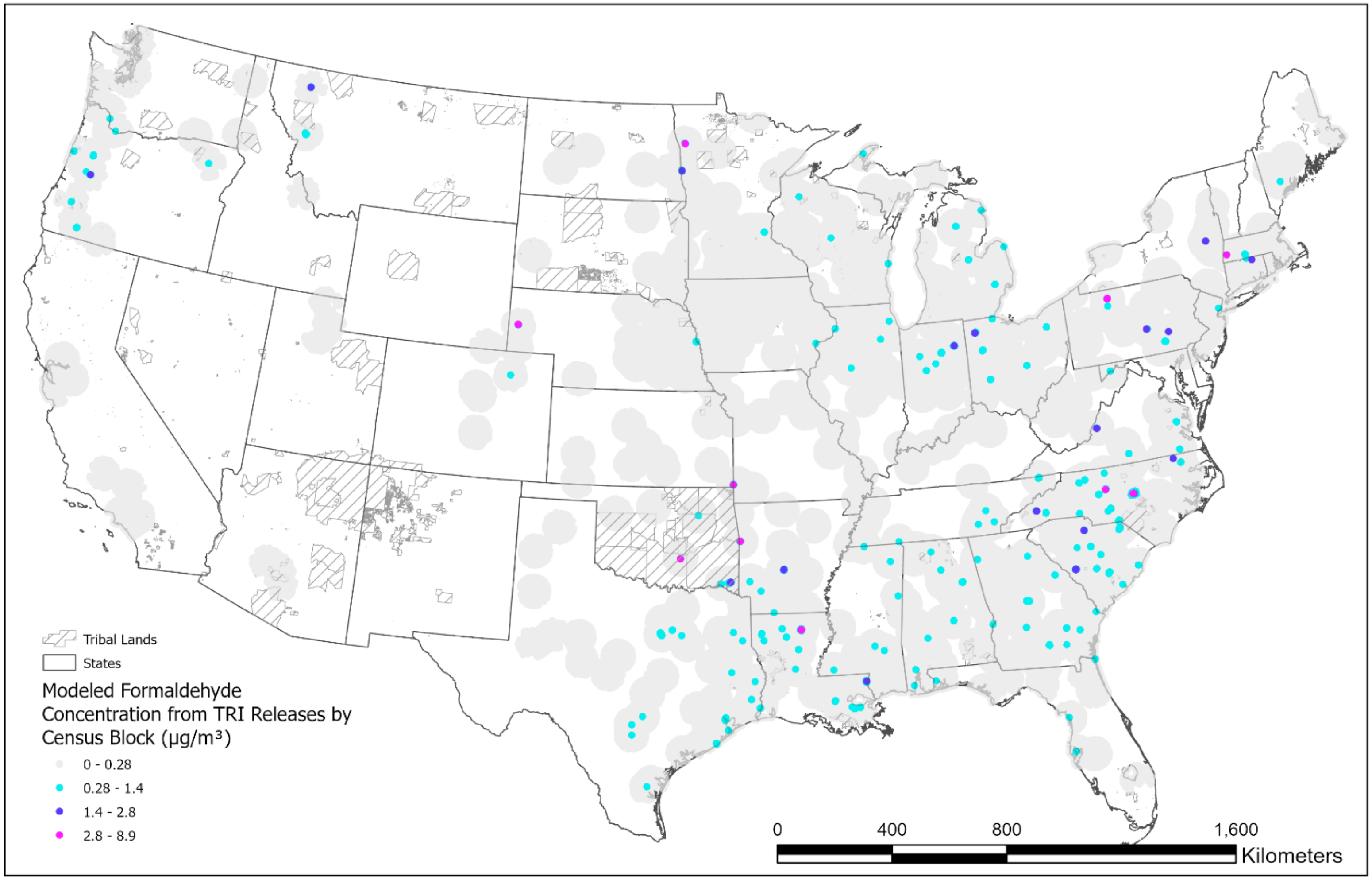


Figure 2-132-13. Map of Contiguous United States with HEM Model Results for TRI Releases Aggregated and Summarized by Census Block

Census blocks with modeled total concentrations below the 95th percentile biogenic concentration of 0.28 µg/m³ are presented in grey. Turquoise dots show census blocks with concentrations ranging from 1 to 5 times the biogenic threshold, purple dots show concentrations from 5 to 10 times the biogenic threshold, and pink dots show values greater than 10 times the biogenic threshold.

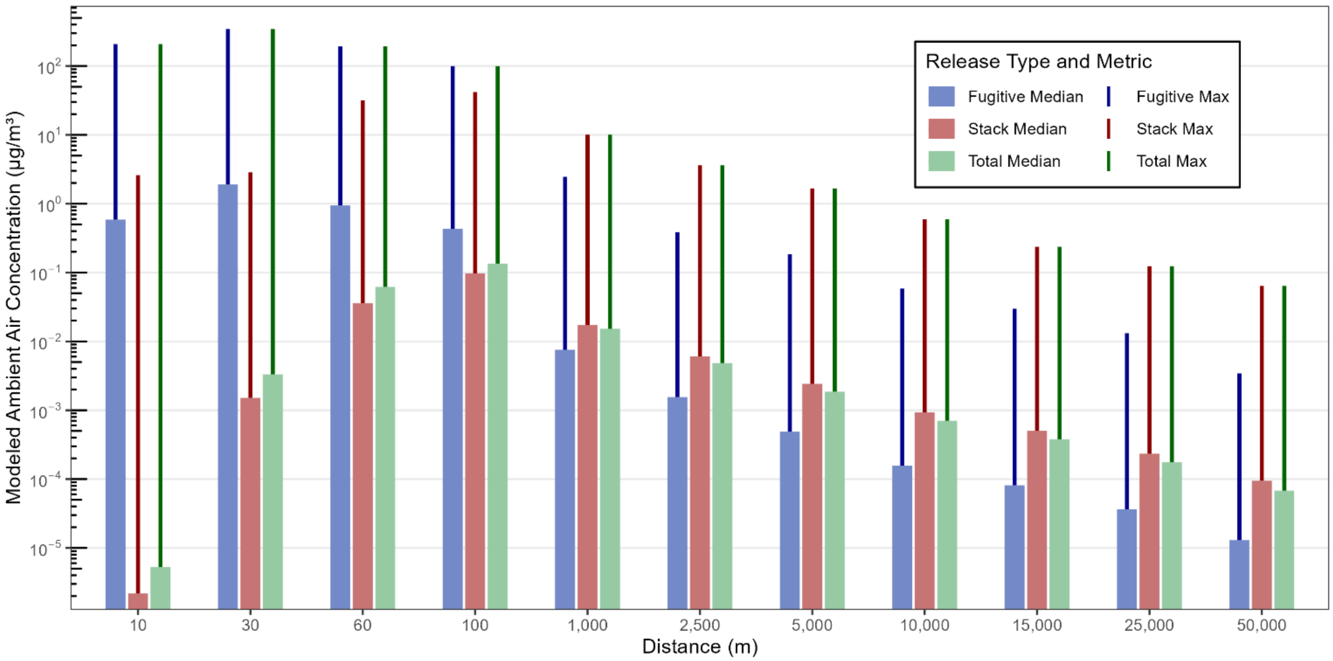


Figure 2-142-14. Median and Maximum Concentrations (Fugitive, Stack, and Total Emissions) across the 11 Discrete Distance Rings Modeled in HEM

2.4.3 Integrating Various Sources of Formaldehyde Data

Monitoring data from AMTIC, modeled exposures calculated from IIOAC, and modeled data from AirToxScreen were compiled to understand how exposures from TSCA COUs fit into the broader context of available information on formaldehyde. Figure 2-15 shows the distributions of data from these datasets. As shown these distributions overlap. At the national scale, populations are exposed to many different sources of formaldehyde (COUs, secondary, biogenic, etc.). Modeled exposure estimates downwind from TSCA COU releases are variable across COUs and locations. In some locations the concentrations from TSCA COUs dominate total concentrations of formaldehyde in ambient air. In most of the country however, ambient air concentrations are dominated by other sources (secondary, biogenic, etc.) according to AirToxScreen.

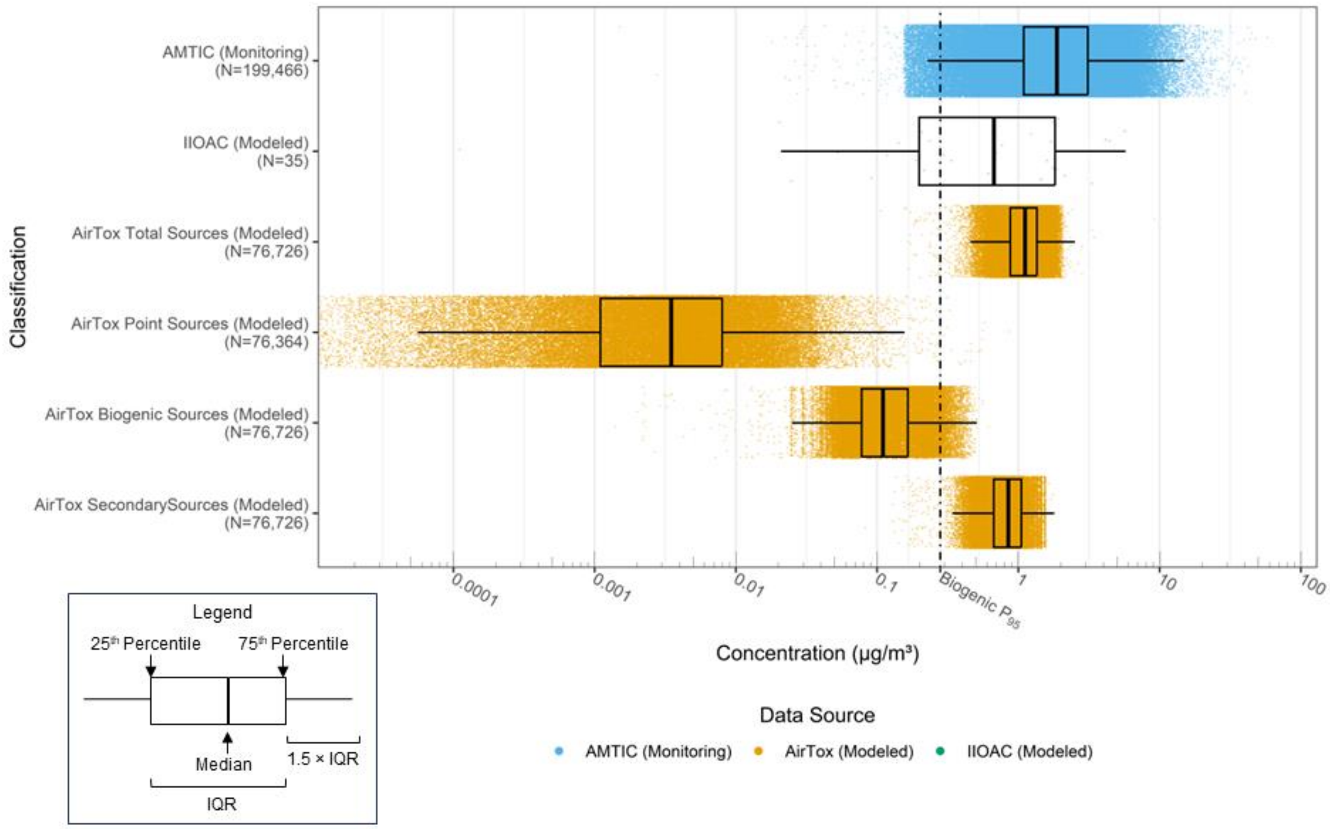


Figure 2-152-15. Distributions of AMTIC Monitoring Data, IIOAC Modeled Data, and AirToxScreen Modeled Data

EPA recognizes that the different model estimates are not directly comparable. For example, the IIOAC results represent a 95th percentile annual average concentration between 100 to 1,000 m from the release point. In contrast, AirToxScreen concentrations represent annual average concentrations at the census tract scale. Given the spatial scale difference it is expected that AirToxScreen results could considerably underestimate concentrations on a smaller scale (*i.e.*, near facilities) or have lower concentration estimates than IIOAC and this difference can be seen in Figure 2-15. Additionally, only point source data within AirToxScreen may represent a broader set of formaldehyde releases that include releases associated with TSCA COUs.

Furthermore, the AMTIC data represent a range of samples collected at various locations (independent of TSCA releases of formaldehyde) and collection durations are much shorter than a year (5 minutes to 24 hours). Despite these uncertainties, these data suggest that formaldehyde concentrations from TSCA sources are higher than formaldehyde concentrations that are expected to occur due to natural formation. These higher concentrations will be driven by the location of release. These COUs are listed in Section 2.4.2.1 and this conclusion is further supported by the HEM analysis.

2.5 Weight of Scientific Evidence and Overall Confidence in Exposure Assessment

As described in the *2021 Draft Systematic Review Protocol* (U.S. EPA, 2021c), the weight of scientific evidence supporting exposure assessments is evaluated based on the availability and strength of exposure scenarios and exposure factors, measured and monitored data, estimation methodology and model input data, and, if appropriate, comparisons of estimated and measured exposures. The strength of each of these evidence streams can be ranked as either robust, moderate, slight, or indeterminate. For each component of this exposure assessment, EPA evaluated the weight of scientific evidence for individual evidence streams and then used that information to evaluate the overall weight of evidence supporting each set of exposure estimates. General considerations for evaluating the strength of evidence for each evidence stream are summarized in Table 7-6 of the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021c). Specific examples of how these considerations can be applied to overall weight of scientific evidence conclusions are provided in Table 7-7 of the Draft Systematic Review Protocol (U.S. EPA, 2021c). The weight of scientific evidence supporting each element of the human health exposure assessment are discussed in the occupational exposure assessment (U.S. EPA, 2024l) consumer exposure assessment (U.S. EPA, 2024d), indoor air assessment (U.S. EPA, 2024j) and ambient air assessment (U.S. EPA, 2024a) modules.

Overall confidence descriptions of high, medium, or low are assigned to the exposure assessment based on the strength of the underlying scientific evidence. When the assessment is supported by robust evidence, overall confidence in the exposure assessment is high; when supported by moderate evidence, overall confidence is medium; when supported by slight evidence, overall confidence is low.

2.5.1 Overall Confidence in Occupational Exposure Assessment

The confidence in the occupational exposure assessment varies from low to high, the confidence is based on the strengths, limitations, and uncertainties associated with the exposure estimates for each individual occupational exposure scenario. Most COUs have medium confidence based on moderate to robust and moderate weight of scientific evidence conclusions. The primary strength of most of the inhalation assessments is that it uses monitoring data that is chemical-specific and is directly applicable to the exposure scenario. The use of applicable monitoring data is preferable to other assessment approaches such as modeling or the use of occupational exposure limits. The principal limitation of the monitoring data is the uncertainty in the representativeness of the data due to some scenarios having limited exposure monitoring data in the literature or the available monitoring data lacking additional contextual information. For many of the COUs, the EPA received aggregated data from industry; therefore, EPA was unable to distinguish each site's contribution to the exposure estimates. EPA also assumed 250 exposure days per year based on continuous formaldehyde exposure for each working day for a typical worker schedule. It is uncertain whether this captures actual worker schedules and exposures.

Some of the COUs lacked monitoring data; therefore, EPA used models to estimate inhalation exposures. EPA addressed variability in inhalation models by identifying key model parameters to apply a statistical distribution that mathematically defines the parameter's variability. EPA defined statistical distributions for parameters using documented statistical variations where available. Where the statistical variation was unknown, assumptions were made to estimate the parameter distribution using available literature data, such as General Scenario (GS) and Emission Scenario Document (ESDs). However, there is uncertainty as to the representativeness of the parameter distributions with respect to the modeled scenario because the data are often not specific to sites that use formaldehyde. In general, the effects of these uncertainties on the exposure estimates are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distributions of each of the model input parameters.

As described in the *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024l), EPA has low confidence in the inhalation estimates for the three COUs below based on a slight weight of scientific evidence:

- Commercial use – chemical substances in treatment/care products – laundry products and dishwashing products
- Commercial use – chemical substances in outdoor use products – explosives materials
- Commercial use– chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment

This was mainly due to the low number of monitoring samples available, lack of information specific to formaldehyde usage for the given COUS and uncertainties with the representativeness of the monitoring data. However, EPA concluded that the underlying data still provides a plausible estimate of exposures for these OESs.

EPA had moderate weight of scientific evidence conclusions for all dermal scenarios assessed. The primary strength of the dermal assessment is that most of the data that EPA used to inform the modeling parameter distributions have overall data quality determinations of either high or medium from EPA's systematic review process, such as the 2020 CDR (U.S. EPA, 2020b). A limitation of the assessment is that some COUs lacked formaldehyde weight concentration data.

2.5.2 Overall Confidence in the Consumer Exposure Assessment

EPA has medium confidence in the exposure assessment for consumers. As detailed in Section 3.2 of the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), some key strengths of the assessment are listed below.

- Consumer inhalation exposure assessment supported by 41 high-quality air monitoring studies associated with uses of TSCA COUs and other sources, allowing EPA to identify inhalation as a key driver of exposure for consumers.
- SACC peer reviewed inhalation and dermal modeling approaches which have been used in previous and ongoing chemical risk evaluations.
- Inhalation and dermal modeling of products and articles on the consumer market at the time of this risk evaluation.
- CEM modeling parameterized with weight fractions acquired from product and article-specific safety data sheets, 2020 CDR (U.S. EPA, 2020b), activity, and product use pattern data from the EPA's *Exposure Factors Handbook* (U.S. EPA, 2011) and 1987 Westat Survey (Westat, 1987)**.**
- Thin Film Model used for dermal exposure estimates is derived from CEM and was parameterized using product and article-specific safety data sheets, 2020 CDR (U.S. EPA, 2020b), and the associated dermal loading constant (*Qu*) was obtained from a robust dermal loading study published by OPPT (U.S. EPA, 1992) and has been extensively been applied in previous and current dermal exposure assessments by OPPT and OPP including OPP's formaldehyde dermal exposure assessment from pesticides.

On the other hand, there are some uncertainties and limitations of the consumer exposure assessment. These are listed below.

- For CEM inhalation exposure modeling, there is some uncertainty around the applicability of the 1987 Westat Survey (Westat, 1987) data for modern product and article use patterns. While the survey is the best available source of information, the survey may not represent current use patterns.
- For Thin Film dermal exposure modeling, EPA assumed the consumers' hand(s), finger(s) or other skin layer may be covered with a viscous layer of the liquid product during use and may linger until washed away.

EPA had slight confidence in, and as a result did not assess, any consumer exposures to potential exposures to water treatment, laundry and dish washing, and lawn and garden products, as EPA did not identify relevant products currently on the market. EPA also had slight confidence in, and as a result did not assess, any oral exposures to consumers as there were no evidence of reasonably foreseen uses of consumer products now or in the future which could lead to consumer oral exposures as products are used. Lastly, EPA had a slight confidence in its assessment of dermal formaldehyde exposures from clothing to skin due to a lack of information of on the diffusion of formaldehyde from clothing and whether a vapor-to-skin assumption isf appropriate to formaldehyde due to its high volatility.

2.5.3 Overall Confidence in the Indoor Air Exposure Assessment

EPA has high confidence in the overall findings for the indoor air exposure assessment. As detailed in Section 4 of the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j), the exposure assessment is supported by a robust monitoring dataset and robust modeling approaches. EPA has medium confidence that the exposure scenarios evaluated in this assessment are reasonable and representative of people who spend most time indoors. The indoor air exposure scenario assumes continuous exposure to indoor air over a lifetime.

Strengths of the indoor air assessment:

- Formaldehyde has a robust nationally representative monitoring dataset representing multiple home types and home characteristics;
- Monitoring data from outside the home are also integrated to characterize the spectrum of formaldehyde concentrations in the indoor environment;
- Emissions data from real products which were used to parametrize modeled concentrations of formaldehyde;
- Two models were used to characterize expected concentrations in the indoor environment; and.
- CEM may be more conservative at estimating long term exposures.

EPA has high confidence in the quality and representativeness of indoor air monitoring data. The set of 20 studies used as an indication of indoor air concentrations and as a basis for comparison to modeled concentrations were rated high quality. This dataset includes the American Healthy Homes Survey II, a quality nationally representative formaldehyde residential indoor air monitoring study administered by EPA and the U.S. Department of Housing and Urban Development (HUD). Though, indoor air monitoring data, even if recent, may not represent future potential exposures in homes. This may be an artifact of how monitoring data cannot fully reflect how and when formaldehyde-emitting materials (including imported articles from places with varying wood standards) are installed. Similarly, monitoring data cannot explain how frequently these materials are replaced. Lastly, the monitoring data may not reflect changes in energy efficiency home improvements that reduce ventilation (*e.g.*, leaks). Therefore, modeled concentrations are reasonable and representative of concentrations to which individuals are exposed and can be relied upon for purposes of deriving risk estimates and informing regulatory decisions under TSCA.

EPA has a medium confidence in its CEM screening exposure assessment which were generally received from the SACC. However, since CEM was not used to estimate peak exposures for the draft evaluation and due to uncertainties with CEM's potential overestimation of long-term exposure along with an inability to consider first-order exponential decay for articles in the long-term, based on the E5 emission condition, this EPA also utilized IECCU as a higher tier modeling tool to characterize 15-minute peak, 3-month average and 1-year average formaldehyde residential indoor air concentrations. EPA had a high confidence in the higher-tier indoor air modeling approaches using IECCU which depended on article and formaldehyde specific input data. Though, the one-year results for IECCU were significantly lower than CEM and are likely an underestimate of indoor air exposures. Available data suggest a biphasic emission profile (rapid emission of formaldehyde when the product is new followed by a much slower emission of formaldehyde) for laminated wood products that is not captured in the modeling results. This biphasic emission profile may also occur for other urea-formaldehyde based products; however, data are not available to confirm this. As such, CEM was presented in conjunction with IECCU to characterize 1-year average indoor air concentrations and provide an upper bound on longer-term formaldehyde exposures.

Since the highest emissions of formaldehyde are expected from composite wood articles that are newly manufactured and introduced into the home or other indoor air environment, and because such newly manufactured composite wood products would be subject to the TSCA Title VI emission standards set forth at 40 CFR part 770, EPA's IECCU modeling uses emission factors that incorporate the Title VI emission standards. EPA expects estimated formaldehyde concentrations from wood articles made of composite wood materials to be lower after full implementation of the Formaldehyde Standards for Composite Wood Products regulations (40 CFR part 770) enacted under TSCA Title VI, but EPA does not know whether full implementation will lower them beneath hazard benchmarks.

EPA's confidence in the monitoring and modeled indoor air exposure assessments reflects a consideration of the associated strengths and weaknesses of available indoor air exposure lines of evidence described in more detail in the weight of scientific evidence discussion in Section 4 of the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j).

EPA considered concordance between monitored and modeled concentrations. Monitored concentrations are expected to reflect aggregate concentrations resulting from multiple sources of formaldehyde and are therefore not directly comparable to modeled concentrations estimated for specific sources. While IECCU incorporates formaldehyde's exponential decay from finished articles, according to the literature, it does not incorporate indoor sinks that may capture and re-emit formaldehyde, various forms of barriers (*e.g.*, lamination, coatings, article thickness, etc.) that may delay and/or prolong formaldehyde emissions over time, temperature and humidity fluctuations which may differ across housing units, seasons, and regions. However, given CEM and IECCU modeled concentrations are within the same order of magnitude as monitoring concentrations, EPA has increased confidence in the models' combined ability to predict real world exposures to formaldehyde in American residential indoor air from TSCA COUs. The availability of both modeled concentrations and monitoring data provides information about both the aggregate exposures from all sources contributing to indoor air concentrations as well as information about the relative contributions of individual TSCA COUs.

Based on consideration of the weight of scientific evidence, EPA has high confidence in the overall findings for the indoor air exposure assessment (U.S. EPA, 2024j) due to a high confidence in the monitoring data, medium confidence in the CEM modeling, high confidence in the IECCU modeling.

2.5.4 Overall Confidence in the Ambient Air Exposure Assessment

There are many sources of formaldehyde which contribute to exposures to the general population. The ambient air exposure assessment for formaldehyde also considers multiple lines of evidence including measured (monitored) and modeled formaldehyde concentrations to characterize exposures. Overall, the ambient air exposure assessment finds that the general population living near industrial facilities releasing formaldehyde to the ambient air experience both short-term and long-term inhalation exposure to formaldehyde attributable to TSCA COUs. While individual lines of evidence may not be directly comparable, taken together the data and results support EPA's use of IIOAC daily and annual average modeled concentrations to characterize exposures.

EPA has medium confidence in the IIOAC modeled results used to characterize exposures in this ambient air exposure assessment. Several inputs used for the IIOAC model are generally conservative, including the maximum and 95th percentile releases modeled and relied upon for the exposure concentrations, stack parameters representing a low, slow moving, non-buoyant plume, and the meteorological station within IIOAC used for the ambient air exposure assessment representing a high-end station which leads to higher overall estimated concentrations. However, there are uncertainties in model outputs due to assumptions made when choosing input parameters, including the use of annual average releases to calculate daily releases and the use default parameters used within IIOAC. There is additional uncertainty because IIOAC does not consider the location of residential areas relative to industrial facilities associated with TSCA COUs. Similarly, the assessment was conducted independent of the size of the facility footprint, the precise location of the release, and the relative location of residences. Furthermore, ambient air modeling for formaldehyde does not account atmospheric degradation (i.e. photolysis) and how local weather patterns may affect the presence of formaldehyde over time. Furthermore, the assumption that individuals reside in the same location for the duration of their life (i.e. 78 years) is conservative.

Additional lines of evidence provide context for the use of IIOAC modelling results. Monitoring data from AMTIC represent the aggregate concentration of formaldehyde in the ambient air from all sources, while IIOAC modeled concentrations represent local exposures attributable to TSCA COUs at select distances near a releasing facility. AirToxScreen data provide further context for contributions from multiple sources including biogenic, secondary, TSCA COUs and other sources. HEM results provide additional context on the spatial variability of formaldehyde concentrations across the U.S. While the individual lines of evidence provide context, the individual datasets are not directly comparable to each other, due to spatial and temporal differences. Further, formaldehyde concentrations are highly variable based on geographic location (*e.g.,* HEM results show elevated concentrations in the Southeastern United States), nearby releases, and contributions from other sources of formaldehyde. Taken together, the totality of integrated data can and do allow for a characterization of general population exposures but has some uncertainty.

Strengths and limitations of the ambient air exposure assessment which inform the medium confidence are discussed in detail in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) but summarized here for reference. Overall, the approaches and methodologies presented in this ambient air exposure assessment utilize previously peer reviewed approaches and methods. These approaches and methodologies incorporate several additional components recommended by peer reviewers during earlier peer reviews of other ambient air exposure assessments as well as peer review of the *Draft Ambient Air Exposure Assessment for Formaldehyde*.

IIOAC Modeling: A strength of the IIOAC modelling includes use of environmental release data from multiple databases across multiple years (including data which are required by law to be reported by industry). These databases undergo repeatable quality assurance and quality control reviews (U.S. EPA, 2024g). These release data are used as direct inputs to EPA's peer reviewed IIOAC model to estimate concentrations at several distances from releasing facilities. However, the use of annual release data to estimate daily average concentrations introduces uncertainty in modelling outputs estimated. Since both TRI and NEI report a single annual release value (for stack and fugitive emissions) from each release point, EPA assumes operations are continuous and releases are the same every day of operation in order to calculate daily average concentrations. These assumptions may result in modeled concentrations missing true peak releases (and associated exposures) and therefore may underestimate peak exposures.

Assumptions made when choosing input parameters for IIOAC modelling introduce uncertainty in model estimates, likely resulting in an overestimation of exposure. For example, the maximum stack and fugitive releases for each industry sector were used as input values for IIOAC modelling. However, the maximum stack and fugitive releases within an industry sector are not necessarily associated with the same facility, and it is unknown how likely it is for the maximum stack and fugitive releases to be occuring at a single facility. There is additional conservatism built into the IIOAC modeling inputs including using the maximum and 95th percentile releases modeled and relied upon for the exposure concentrations, stack parameters representing a low, slow moving, non-buoyant plume, and the meteorological station within IIOAC used for the ambient air exposure assessment representing a high-end station which leads to higher overall estimated concentrations.

Limitations of the IIOAC modelling approaches and methods used include the fact that IIOAC modeling is based on pre-run scenarios within AERMOD. As such, default input parameters for IIOAC are confined to those input parameters utilized for those pre-run AERMOD scenarios and cannot be changed. Default input parameters include stack parameters, 2011 to 2015 meteorological data, and the lack of site-specific information like building dimensions, stack heights, elevation, and land use. Ambient air modeling for formaldehyde does not account atmospheric degradation (i.e. photolysis) and how local weather patterns may affect the presence of formaldehyde over time. Furthermore, the assumption that individuals reside in the same location for the duration of their life (i.e. 78 years) is conservative.

AirToxScreen: AirToxScreen has been previously reviewed by EPA's Science Advisory Board (SAB). As, such EPA has confidence in the modeled data. Similarly, these data are based on the NEI, which has been rated as a high-quality data source according to the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021c). However, note that the NEI point source emissions are largely dependent on state-reported emissions inventories to which HAP emission data are voluntarily reported. Furthermore, biogenic emissions are modeled estimates and are likely less certain than point source emission estimates.

The strengths of the AirToxScreen data included in this exposure assessment are that they show the contributions of formaldehyde to the ambient air from all sources of formaldehyde in the contiguous United States. However, the use of AirToxScreen is limited due to the inability to isolate contributions from TSCA COUs. EPA's use of these results provides strength to this assessment because the AirToxScreen data are used to contextualize IIOAC modeled annual average concentrations of formaldehyde relative to other large contributing sources to the ambient air.

HEM Modeling: The base dispersion model run by HEM 4.2 is EPA's AERMOD. AERMOD is EPA's regulatory model which has been peer reviewed as part of the regulatory model process described in "Appendix W" to 40 CFR Part 51. As such, EPA has high confidence in the modeling methods based on HEM's reliance on EPA's regulatory model. However, there may be uncertainty in census population data used as input to HEM for specific locations and populations. A limitation of the HEM model is the exclusion of consideration of photodegradation processes within the AERMOD sub-routines, which may be relevant to modeling ambient air concentrations of formaldehyde since it is known to undergo photolysis within 4 hours in sunlight.

AMTIC Archive Monitoring Data: EPA has high confidence in the AMTIC archive data set (U.S. EPA, 2022a). The AMTIC archive dataset received a high-quality rating from EPA's systematic review process. (U.S. EPA, 2021b). Additionally, the AMTIC archive dataset undergoes review and verification by AMTICs Ambient Air Monitoring Group. This review and verification process includes multiple quality assurance steps to ensure data quality and certification in accordance with 40 CFR 58.15. There is also added value from the AMTIC archive monitoring data set because they are real measured data which reflect concentrations to which the general population would be exposed to in the time and space the sample was taken.

The primary limitations of the AMTIC are that it represents a diverse collection of sampling durations (none of which are annual averages) that are not directly comparable to either IIOAC or AirToxScreen results. Additionally, because monitored data represents a total aggregate concentration from all sources of formaldehyde contributing to ambient air concentrations, the AMTIC data cannot be associated with TSCA COUs for purposes of characterizing exposures from TSCA COUs. Additional limitations of the AMTIC data include the wide variety of monitoring locations represented, which may include sites both near-to and far-from facility release points associated with TSCA COUs.

Other Factors: For industrial TSCA COUs, EPA has a moderate to robust weight of scientific evidence as the databases have high data quality scores and are supported by numerous data points. A primary strength of TRI and NEI data is that these programs compile the best reasonably available release data for large facilities. Limitations are that these programs may not cover some sites that emit formaldehyde as both programs have conditions that must be met prior to being required to report releases. For formaldehyde, the potential contribution of combustion sources is an uncertainty and use of the full facility data complicate singular TSCA COU estimates, such that emissions at one site may include multiple sources under multiple COUs that include combustion sources and non-combustion sources.

In general, for commercial COUs, EPA has a moderate weight of scientific evidence since the generic scenarios on which release estimates are based have a medium to high data quality rating. EPA relied upon professional judgement in mapping TRI and NEI industrial sectors to commercial COUs. There is some uncertainty that a commercial TSCA COU may occur across several industrial sectors beyond the industrial sector used for analysis. In addition, some industrial sectors cover both industrial and commercial operations, so they may overestimate air releases occurring in a commercial setting. Four commercial COUs either lacked sufficient data or were supported by a slight weight of evidence:

- Commercial use – chemical substances in treatment/care products – laundry and dishwashing products;
- Commercial use – chemical substances in treatment products – water treatment products;
- Commercial use – chemical substances in outdoor use products – explosive materials; and
- Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals.

EPA used HEM to estimate the number of exposed population to modeled concentrations in ambient air to further inform exposures and associated risks. EPA's confidence in these exposed population estimates is medium as they are expected to be an underestimate since EPA limited these analyses to the 810 TRI facilities directly reporting with Form R. That TRI dataset is a subset of the approximately 49,000 distinct facilities with estimated emissions in NEI and therefore a smaller dataset on which exposed population estimates rely upon. Additionally, the exposed population estimates from HEM are derived by averaging the modeled annual concentration at the proximate census block centroids across the census block, using site-specific meteorological conditions. Since EPA did not make facility-specific adjustments to modeling receptor files based on land use analysis to capture the highest proximate populations in this analysis, the population estimates are biased against capturing the populations of the most highly exposed residents within rural (and therefore larger) census blocks.

3 HUMAN HEALTH HAZARD SUMMARY

EPA's OPP and OPPT collaborated to develop a joint hazard assessment for formaldehyde (U.S. EPA, 2024i). This joint assessment evaluated available human health hazard and dose-response information for formaldehyde and identified hazard values to support risk assessments in both offices. ~~This hazard assessment also reflects coordination with EPA's Office of Research and Development (ORD) and other EPA offices, including Office of Air and Radiation (OAR), to the extent appropriate. As a result of this collaboration across programs, multiple federal advisory committees – including the National Academies of Sciences, Engineering, and Medicine (NASEM), TSCA Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB) – have provided review of various aspects of this hazard characterization.~~

~~For cancer and non-cancer hazards associated with chronic inhalation exposures, OPP and OPPT are using the analysis presented in the IRIS assessment on formaldehyde inhalation (U.S. EPA, 2024k) and peer reviewed by the National Academies of Sciences, Engineering, and Medicine (NASEM) (NASEM, 2023). The systematic review literature searches, data quality review, evidence integration, dose-response analyses, and peer review performed in support of the IRIS assessment reflect the best available science on formaldehyde hazards from chronic inhalation exposures and are consistent with the needs of both OPP and OPPT. The IRIS assessment derived a chronic reference concentration (RfC) for non-cancer risks and an inhalation unit risk (IUR) for cancer risks from inhalation of formaldehyde.~~

To identify ~~additional~~ available hazard and dose-response information for acute inhalation, dermal, and oral formaldehyde exposures, EPA used a fit-for-purpose systematic review protocol, integrating the needs and approaches of both OPP and OPPT. Details of the fit-for-purpose systematic review protocol used in OPPT's work on this assessment are described in the *Systematic Review Protocol for the Risk Evaluation for Formaldehyde* (U.S. EPA, 2024m). This approach is based in part on the OPPT systematic review approach described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substance*s (U.S. EPA, 2021c).

EPA identified a range of factors that may increase susceptibility to formaldehyde and considered susceptibility throughout the hazard assessment. Descriptions of how EPA incorporated PESS due to greater biological susceptibility into the risk evaluation are provided in Appendix B. Factors that may increase susceptibility to formaldehyde exposures include chronic respiratory disease, lifestage, sex, and co-exposure to chemical and non-chemical stressors that influence the same health outcomes.

3.1 Summary of Hazard Values

The ~~non-cancer and cancer~~ hazard values identified for inhalation, dermal, and oral exposures to formaldehyde in the joint hazard assessment (U.S. EPA, 2024i) are summarized in Table 3-1. Consistent with the recommendations of the Human Studies Review Board, OPPT solicited input on its hazard assessment, particularly with regards to the PODs and uncertainty/extrapolation factors for acute and chronic non-cancer assessment and the extent to which the hazard assessment for formaldehyde appropriately considered recommendations from other federal advisory committees (*e.g.,* NASEM, HSRB, SACC).

Table 3-1~~3-1~~. Hazard Values Identified for Formaldehyde

Exposure Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factor	Study and Toxicological Effects
Inhalation Acute Inhalation Chronic non-cancer[a] (Long-term, >6 months) Inhalation Chronic Cancer	NOAEC ~~and BMCL~~ = 0.~~5~~3 ppm ~~(0.62 mg/m^3)~~ ~~BMCL = 0.5 ppm~~	UF_H = 1~~3~~	Total UF = ~~3~~1	Kulle et al, (1987) LOAEC = 1 ppm (1.23 mg/m^3) based on eye irritation in adult volunteers Mueller et al. (2013) LOAEC = 0.3 ppm over 4 hours, with 15-minute peaks of 0.6 ppm, based on eye irritation in hypersensitive adult volunteers Lang et al. (2008) LOAEC= 0.5 ppm over 4 hours, with peaks of 1 ppm (0.62/1.23 mg/m^3), based on eye irritation in adult volunteers
Inhalation Chronic non-cancer[a] (Long-term, >6 months)	$BMCL_{10}$ = 0.017 ppm (0.021 mg/m^3)	UF_H = 3	Total UF = 3	POD is derived from the IRIS RfC (U.S. EPA, 2024k). The specific $BMCL_{10}$ value used here is based on reduced pulmonary function in children in Krzyzanowski et al. (1990), but is consistent with the RfC, derived based on multiple studies of respiratory effects.
Inhalation Chronic Cancer	IUR (ADAF-adjusted) : 0.013 ppm^{-1} (1.1 × 10^{-5} (µg/m^3)$^{-1}$) Adult-based unit risk: 0.0079 ppm^{-1} (6.4 × 10^{-6} (µg/m^3)$^{-1}$)	N/A	N/A	IUR established by IRIS (U.S. EPA, 2024k) based on data on nasopharyngeal cancer in people reported in Beane-Freeman et al. (2013).

Exposure Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factor	Study and Toxicological Effects
Dermal	Elicitation: $BMDL_{10}$ = 10.5 µg/cm[2] (0.035%)	UF_H = 10	Total UF = 10	Flyvholm et al., (1997) based on threshold for elicitation of dermal sensitization in people
Oral Short-Term/ subchronic (1-30 days),	HED= 6 mg/kg-day	UF_A = 3 UF_H = 10	Total UF = 30	Til (1988) NOAEL= 25 mg/g-day; LOAEL = 135 mg/kg-day based on gastrointestinal histopathology in rats
Oral Chronic	HED = 3.6 mg/kg-day	UF_A = 3 UF_H = 10	Total UF = 30	Civo Inst.(1987); Til (1989) NOAEL= 15 mg/g-day; LOAEL = 82 mg/kg-day based on gastrointestinal histopathology in rats

[a] This value is used to estimate risks from both sub-chronic and chronic occupational exposures.
Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures; NOAEL = no-observed adverse-effect level; LOAEL = lowest-observed adverse-effect level; UF = uncertainty factor; UF_A = extrapolation from animal to human (interspecies); UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (*i.e.*, lack of a critical study). ~~IUR= inhalation unit risk; IUR= inhalation unit risk (includes ADAF adjustment) for calculating cancer risks associated with a full lifetime of exposure, including early life exposure; Adult-based unit risk = unit risk for calculating chronic cancer risks associated with adult exposures not expected to include early life.~~

3.2 Weight of Scientific Evidence and Overall Confidence in Hazard Assessment

As described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021c), the weight of scientific evidence supporting hazard assessment and dose response is evaluated based on the quality of the key studies, consistency of effects across studies, the relevance of effects for human health, confidence in the dose-response models, and the coherence and biological plausibility of the effects observed. ~~The weight of evidence and overall confidence in chronic inhalation hazard values derived by IRIS are described in the IRIS assessment (U.S. EPA, 2024k). The weight of evidence and sources of confidence and uncertainty in dermal, oral, and acute inhalation hazard values derived by OCSPP are described in the hazard assessment (U.S. EPA, 2024i). This section summarizes overall confidence and sources of uncertainty in the hazard values used to develop risk estimates in this risk characterization.~~

3.2.1 Overall Confidence in the Acute Inhalation POD

As described earlier in the Notice, based on the weight of scientific evidence and informed by the best available science, OCSPP is confident in the following determinations for risk assessment/risk evaluation of formaldehyde:

- an acute inhalation POD of 0.3 ppm is appropriate as the critical effect to protect for all other potential hazards, including cancer;
- the acute inhalation POD can be applied to all durations of exposure (including chronic and cancer) and all populations, including occupational scenarios; and
- a total UF_H of 1x is appropriate.

~~Overall confidence in the acute inhalation POD is high. As described in the joint hazard assessment (U.S. EPA, 2024i), the acute POD is based on a robust dataset of evidence for sensory irritation in humans, including several high-quality controlled exposure studies with relevance for acute exposure scenarios. Concordance of reported sensory irritation effects and the effect levels reported across acute exposure studies increases confidence in the final POD. Variability across individuals' response contributes to uncertainty around effect levels that are protective across the population. An uncertainty factor of 3 is applied to account for uncertainty related to intraindividual variability.~~

~~There is some uncertainty around the degree to which duration influences effect levels because there are no studies available that provide direct evidence that effect levels following 8- or 24-hour exposures are the same as effects following 2 to 5 hours of exposure. Therefore, based on the best available information, the acute POD focuses on defining exposure concentrations relevant to any acute exposure duration rather than adjusting specific PODs for defined 8- or 24-hour exposure durations, as recommended by the HSRB and supported by the SACC.~~

Other endpoints may also have relevance for acute hazard, but available studies do not provide sufficient information to characterize hazard or quantify dose-response relationships for acute inhalation exposures. This assessment assumes that sensory irritation is protective of those other endpoints. Although this may be a potential source of uncertainty for the acute POD, available data suggest that sensory irritation is the most sensitive endpoint resulting from acute exposures and is consistent with several other international regulatory bodies.

~~3.2.2 Overall Confidence in the Chronic, Non-cancer Inhalation POD~~

~~Overall confidence described in the IRIS assessment (U.S. EPA, 2024k) for the chronic non-cancer inhalation POD is high. The chronic POD derived by IRIS is supported by a robust database of evidence~~

for a range of endpoints in humans and animals. The overall POD is informed by dose-response information in humans across multiple respiratory endpoints and reflects concordance in effect levels identified across those endpoints. EPA also considered dose-response information for reproductive and developmental effects in selection of the overall POD. While there is more uncertainty around the PODs derived for these endpoints, the overall POD is expected to be protective of these reproductive and developmental effects in humans. Many of the observational epidemiology studies providing the quantitative basis for the chronic POD reflect relevant human exposure scenarios in homes and schools. In addition, several of the studies include children with asthma or other sensitive groups.

EPA acknowledges that some SACC members raised concerns with the chronic RfC and recommended an alternate approach using sensory irritation as the most sensitive endpoint. For non-cancer chronic effects, SACC members raised concerns about the quality of the epidemiology studies used to derive the chronic RfC and the WOE for a causal link between formaldehyde exposure and outcomes other than sensory irritation. Many SACC members expressed reservations and difficulty with reviewing the values due to the draft status of the IRIS assessment at the time of their review. For example, SACC stated "Many members expressed reservations about the specifics surrounding the value of using the unedited 2022 Draft IRIS document since it is not final and the comments from NASEM review have not yet been incorporated" (p. 32). Further the SACC noted that "One needs to access the IRIS document to understand the basis of the 0.007 mg/m^3 RfC. Since the IRIS document has not yet been finalized, it is difficult to understand the review and selection process" (p. 59).

EPA has since finalized the IRIS assessment for formaldehyde. Discussion regarding study selection is provided in Section 5.1.1 of the IRIS assessment. Discussion regarding the weight of evidence for noncancer respiratory effects is provided sections 3.2, 4.2 and 5.1.5 of the IRIS assessment. Comments on study selection, weight of evidence for noncancer effects, and sensory irritation are addressed in Sections F.1 and F.3 in Appendix F of the IRIS assessment supplemental materials.

In addition, some SACC members SACC also commented on the relevance of the chronic inhalation POD for adult populations, stating that "The POD is based on pulmonary function response in children. The POD representing this PESS will be protective of adults and workers. However, several Committee members hold the view that applying the POD (based on responses in children) to adult workers is not appropriate" (U.S. EPA, 2024w).

Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment (U.S. EPA, 2024k) for formaldehyde. Discussion regarding study selection is provided in Section 2.1.1 of the IRIS assessment. Discussion regarding the weight of evidence for noncancer respiratory effects is provided in sections 3.2, 4.2, and 5.1.5 the IRIS assessment. Comments on study selection, weight of evidence for noncancer effects, and sensory irritation are addressed in Sections F.1 and F.3 in Appendix F of the IRIS assessment supplemental materials.

3.2.3 Overall Confidence in the Chronic IUR

Overall confidence described in the IRIS assessment (U.S. EPA, 2024k) for the preferred unit risk estimate is medium. The IUR derived for nasopharyngeal cancer is informed by a robust dataset of both human and animal data. The availability of human data eliminates the need to extrapolate from animal studies, increasing the confidence in the IUR. In addition, the IUR derived from animal data is similar to the IUR derived from human evidence, further increasing confidence in the IUR. Sources of uncertainty in the IUR include reliance on extrapolation from high doses that occur in occupational settings to lower doses that may occur in the general population, reliance on data from a single high quality occupational

~~cohort study that may not capture the sensitivity of susceptible populations or lifestages, and reliance on mortality data as a surrogate for cancer incidence.~~

~~EPA recognizes that the SACC report (U.S. EPA, 2024w) states that "The majority of the information presented in session did not favor a IUR approach, and rather supported a threshold approach." However, the SACC report also states that "Several Committee members disagreed with this approach and supported the IUR approach as the most appropriate." Overall, "The Committee recommended that the EPA consider the best available science to determine if a threshold or non-threshold approach is best for evaluating cancer, and if needed revise the Draft Human Health Hazard Assessment." Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Further discussion on how IRIS derived the cancer IUR is provided in Section 5.2 of the IRIS assessment. Comments suggesting a threshold approach for cancer are addressed in Section F.4 in Appendix F of the IRIS Supplemental Information document (U.S. EPA, 2024k).~~

~~EPA was not able to derive IURs for all tumor sites associated with formaldehyde exposure. This is a source of uncertainty and may lead to an underestimate of risk. Although EPA was able to derive a unite risk estimate for myeloid leukemia, the lack of confidence in the dose-response data and IUR for myeloid leukemia is a source of uncertainty. The cancer risk estimates presented in this risk characterization do not include risks for myeloid leukemia and other tumor sites. Based on the IUR estimated for myeloid leukemia in the IRIS document, IRIS estimated that consideration of myeloid leukemia may increase the age-dependent adjustment factor (ADAF)-adjusted IUR by as much as four-fold.~~

~~EPA acknowledges that some members of the SACC (U.S. EPA, 2024w) questioned the association between formaldehyde exposure and myeloid leukemia, noting that "there is no biologically plausible mode of action whereby formaldehyde can arrive at the bone marrow to result in direct toxicity" (p. 88 of the SACC Report). Other SACC reviewers agreed that there is "evidence that formaldehyde can cause acute and chronic myelogenous leukemia" (p. 103 of the SACC Report). EPA is not quantifying the risk to myeloid leukemia. Discussion of the available evidence for myeloid leukemia can be found in Section 3.3.3 of the IRIS assessment (U.S. EPA, 2024k). The IRIS conclusions for cancer hazard are summarized in Section 4.3. Comments on the IRIS hazard conclusion regarding formaldehyde and myeloid leukemia are addressed in Section F.4.1 in Appendix F of the IRIS assessment supplemental materials (U.S. EPA, 2024k). Ultimately, EPA only included quantitative cancer risk for the nasopharyngeal cancer outcome as part of the final IUR.~~

~~3.2.4~~3.2.2 Overall Confidence in the Dermal POD

Overall confidence in the dermal POD is high. As described in the OCSPP joint hazard assessment (U.S. EPA, 2024i), the dermal POD is derived from an extensive dataset on dermal sensitization in human, animal, and *in vitro* studies. Multiple streams of evidence from studies evaluating elicitation thresholds in sensitive people and induction thresholds in animal and in in vitro assays arrive at similar effect levels. While there are some uncertainties associated with the human studies related to lack of clarity in methods and data reporting, concordance in effect levels across multiple streams of evidence increases confidence in the POD. The potential impact of methanol present in available dermal formaldehyde studies is a source of uncertainty in the POD. While there is substantial variation in sensitization responses across individuals, application of an uncertainty factor of 10 is used to account for uncertainty related to intraindividual variability.

3.2.5 Overall Confidence in the Subchronic and Chronic Oral PODs

Overall confidence in the subchronic and chronic oral PODs is medium. As described in the OSCPP joint hazard assessment (U.S. EPA, 2024i), the subchronic and chronic oral PODs rely on a limited database of animal studies but are supported by three studies that report consistent patterns of gastrointestinal damage at similar dose levels. The chronic oral POD is consistent with the oral POD identified by IRIS as the basis for the 1990 RfD (U.S. EPA, 1990), though it has been modified to reflect more recent guidance on dosimetric adjustments.

Due to technical challenges around generating pure and stable formaldehyde treatments for oral exposure, most of the available animal studies have major limitations and uncertainties. Among the available studies that are not confounded by the presence of methanol, gastrointestinal effects are the most sensitive endpoint evaluated. Reduced drinking water intake in the high dose groups reduced confidence in each of the chronic studies when considered in isolation. However, when considered in conjunction with the results of the 28-day study that included water-restricted controls, EPA has confidence that the reported effects are attributable to formaldehyde exposure.

There is very limited information on reproductive, developmental, and immune endpoints following oral exposure to formaldehyde. While there are some studies that suggest effect levels for these endpoints may be more sensitive than those used as the basis for the POD, the only studies that evaluate immune, reproductive, or developmental endpoints are confounded by the presence of methanol. Evidence of reproductive and developmental effects reported in humans and animals following inhalation exposure to formaldehyde indicates that such effects are possible following formaldehyde exposure. Similarly, the available data do not evaluate factors that may increase susceptibility to oral formaldehyde exposure in sensitive groups or lifestages. The lack of data on these endpoints and sensitive groups and lifestages following oral exposure could be perceived as uncertainty; however, the likelihood of a lower POD being identified based on these outcomes is low given the effect used as the basis of the current PODs (gastrointestinal effects) are close to the portal of entry, first pass metabolism via the oral route, and the reactivity of formaldehyde.

4 HUMAN HEALTH RISK CHARACTERIZATION

4.1 Risk Characterization Approach

The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks from acute and chronic exposures are summarized below in Table 4-1. EPA estimated ~~cancer and non-cancer~~acute risks from occupational, consumer, and general population exposures as described below.

While EPA will consider the standard risk benchmarks shown in Table 4-1 associated with interpreting margins of exposure~~ and cancer risks~~, EPA cannot solely rely on those risk values. Risk estimates include inherent uncertainties and the overall confidence in specific risk estimates varies. The analysis provides support for the Agency to make a determination about whether formaldehyde poses an unreasonable risk to human health and to identify drivers of unreasonable risk among exposures for people (1) with occupational exposure to formaldehyde, (2) with consumer exposure to formaldehyde, (3) with exposure to formaldehyde in indoor air, and (4) who live or work in proximity to locations where formaldehyde is released to air.

Table 4-1. Use Scenarios, Populations of Interest, and Toxicological Endpoints Used for Acute and Chronic Exposures

Populations of Interest and Exposure Scenarios	**Workers** [a] Acute – Adolescent (≥16 years old) and adult workers exposed to formaldehyde in a single workday for 15 min or longer ~~Chronic – Adolescent (≥16 years old) and adult workers exposed to formaldehyde over a full-shift workday for 250 days per year for 40 working years~~
	Consumers and Bystanders Acute – Consumers across all age groups (depending on the product or article) exposed to formaldehyde result from product or article use. Exposures are estimated to be 15-minute peak concentrations. It should be noted that the 15-minute peak concentration for a given TSCA COU and exposure scenario may occur several hours after product use.
	General Population Indoor Air Exposure [b] Acute – People across all age groups exposed to formaldehyde through indoor air over short periods. Exposures are estimated to be 15-minute peak concentrations. ~~Chronic – People across all age groups exposed to formaldehyde through indoor air continuously up to 78 years.~~
	General Population Outdoor Ambient Air Exposure [b] Acute – People across all age groups exposed to formaldehyde through ambient air over short-term. Risk estimates are based on daily average modeled concentrations. ~~Chronic – People across all age groups exposed to formaldehyde through ambient air near industrial release site continuously up to 78 years. Risk estimates are based on annual average modeled concentrations~~
Health Effects, Hazard Values and Benchmarks	**Non-cancer Acute Hazard Values** Acute inhalation health effect: sensory irritation • Acute inhalation POD (15-minute duration) = 0.3~~5~~ ppm ~~(0.62 mg/m³)~~ • Uncertainty Factors (Benchmark MOE) = 1~~3~~ (UF_A = 1; UF_H = 3; UF_L = 1; UF_S=1; UF_D=1) Acute dermal health effect: sensitization (elicitation) • Acute POD = 10.5 µg/cm² • Uncertainty factors (Benchmark MOE) = 10 (UF_A = 1; UF_H = 10; UF_L = 1; UF_S=1; UF_D=1) Acute oral health effect: no acute oral PODs identified ~~**Non-cancer Subchronic Hazard Values**~~

	~~Subchronic oral health effects: Gastrointestinal effects~~ • ~~Oral HED = 6 mg/kg-day~~ • ~~Uncertainty Factors (Benchmark MOE) = 30 (UF_A = 3; UF_H = 10; UF_L = 1; UF_S=1; UF_D=1)~~ ~~**Non-cancer Chronic Hazard Values**~~ ~~An acute inhalation POD of 0.3 ppm is appropriate as the critical effect to protect for all other potential hazards, including chronic.~~ ~~Chronic inhalation health effects: Respiratory effects, including reduced pulmonary function, allergy-related conditions, and asthma (prevalence and degree of asthma control).~~ • ~~Inhalation HEC = 0.017 ppm (0.021 mg/m^3)~~ • ~~Uncertainty Factors (Benchmark MOE) = 3 (UF_A = 1; UF_H = 3; UF_L = 1; UF_S = 1; UF_D = 1)~~ Chronic oral health effects: Gastrointestinal effects • Oral HED = 3.6 mg/kg-day • Uncertainty Factors (Benchmark MOE) = 30 (UF_A = 3; UF_H = 10; UF_L = 1; UF_S = 1; UF_D = 1) ~~**Cancer Hazard Values**~~ ~~An acute inhalation POD of 0.3 ppm is appropriate as the critical effect to protect for all other potential hazards, including cancer.~~ ~~Inhalation cancer hazard for formaldehyde is based on nasopharyngeal cancers~~ • ~~IUR[c] = 0.013 ppm^{-1}(1.1 × 10^{-5} (µg/m^3)$^{-1}$)~~ • ~~Adult-based unit risk[d] = 0.0079 ppm^{-1} (6.4×10^{-6} (µg/m^3)$^{-1}$)~~ ~~Oral and dermal cancer hazards are not quantified because there is insufficient data to support derivation of cancer slope factors for these routes of exposure.~~

[a] Adult workers (≥16 years old) include both female and male workers.
[b] Inhalation exposures are described in terms of air concentrations and do not include lifestage-specific adjustments; risk estimates based on air concentrations are intended to address risks to all lifestages.
~~[c] Age-dependent adjustment factors applied for early life exposures~~
~~[d] Unadjusted IUR applied for exposure scenarios where early life exposure is not anticipated~~
MOE = margin of exposure; UF_A = Interspecies uncertainty factor for animal-to-human extrapolation; UF_H = Intraspecies uncertainty factor for human variability; UF_L = LOAEC-to-NOAEC uncertainty factor for reliance on a LOAEC as the POD

4.1.1 Estimation of Non-cancer Risks

EPA used a margin of exposure (MOE) approach to identify potential non-cancer risks. The MOE is the ratio of the non-cancer POD divided by a human exposure dose. Acute ~~and chronic MOEs for non-cancer~~ inhalation and dermal risks were calculated using Equation 4-1:

Equation 4-1.

$$MOE_{acute\ or\ chronic} = \frac{Non-cancer\ Hazard\ value\ (POD)}{Human\ Exposure}$$

Where:

MOE	=	Margin of exposure (unitless)
Hazard value (POD)	=	HEC (ppm) or HED (mg/kg-d)
Human Exposure	=	Exposure estimate (in ppm or mg/kg-d)

MOE risk estimates may be interpreted in relation to benchmark MOEs. Benchmark MOEs are typically the total UF for each non-cancer POD. If the numerical value of the MOE is less than the benchmark MOE, this relationship is a starting point to determine if there are unreasonable non-cancer risks. On the other hand, if the MOE estimate is equal to or exceeds the benchmark MOE, risk is not indicated. Typically, the larger the MOE, the more unlikely it is that a non-cancer adverse effect occurs relative to the benchmark. When determining whether a chemical substance presents unreasonable risk to human health or the environment, calculated risk estimates are not “bright-line” indicators of unreasonable risk, and EPA has discretion to consider other risk-related factors apart from risks identified in risk characterization.

~~4.1.2 Estimation of Cancer Risks~~

~~Extra cancer risks for repeated inhalations exposures to formaldehyde were estimated using Equation 4-2:~~

~~**Equation 4-2.**~~

$$Inhalation\ Cancer\ Risk = Human\ Exposure \times IUR$$

~~Where:~~

~~*Risk*~~	~~=~~	~~Extra cancer risk (unitless)~~
~~*Human exposure*~~	~~=~~	~~Exposure estimate (LADC in ppm)~~
~~*IUR*~~	~~=~~	~~Inhalation unit risk~~

~~The IRIS assessment (U.S. EPA, 2024k) includes the age-dependent adjustment factor (ADAF) as part of cancer risk assessment, consistent with the approach described in EPA’s Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (U.S. EPA, 2005b). To be consistent with ORD, OPP and OPPT have applied the ADAF to chronic exposure scenarios which include children. For lifetime exposures, the overall impact of applying the ADAF approach is less than a 2-fold change in cancer risk.~~

~~EPA recognizes that some members of the SACC raised scientific questions about the conclusions related to formaldehyde exhibiting a mutagenic mode of action (U.S. EPA, 2024w). EPA IRIS’s mode of action analysis is provided within Section 3.2.5 of the final IRIS assessment and responses to comments on mode of action analysis and consideration of comments suggesting a threshold approach for cancer are addressed in Section F.4 in Appendix F of the IRIS Supplemental Information document (U.S. EPA).~~

~~Estimates of extra cancer risks are interpreted as the incremental probability of an individual developing cancer over a lifetime following exposure (*i.e.*, incremental, or extra individual lifetime cancer risk).~~

4.2 Risk Estimates

4.2.1 Risk Estimates for Workers

EPA estimated ~~cancer and~~ non-cancer risks for workers exposed to formaldehyde based on the hazard values determined in Section 3.1 and occupational exposure estimates that were described in Section 2.1. For many TSCA COUs, EPA did not identify inhalation exposure data for ONUs, and therefore evaluated chronic risks using the central tendency estimates for workers. EPA did not identify information for short-term exposures by ONUs and therefore did not quantify acute inhalation risks for ONUs. Acute risks to ONUs are assumed to be equal to or less than risks to workers who handle materials containing formaldehyde as part of their job.

These risk estimates are based on exposures to workers in the absence of PPE such as gloves or respirators. Section 2.5.1 contains an overall discussion on strengths, limitations, assumptions, and key sources of uncertainty for the occupational exposure assessment. Additionally, the *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024l) contains comprehensive weight of scientific evidence summaries, which presents an OES-by-OES discussion of the key factors that contributed to each weight of scientific evidence conclusion. Overall confidence in risk estimates for workers via inhalation exposure varies per COU, depending on the confidence in the hazard and the exposure assessment for each OES.

4.2.1.1 Risk Estimates for Inhalation Exposures

This section describes the acute non-cancer and chronic cancer risks to workers and ONUs via the inhalation route. In Appendix H, EPA discusses chronic non-cancer risks.

Workers are a population that experience greater exposure to formaldehyde. For each COU, EPA provides a high-end and a central tendency risk estimate. For acute effects, the use of the high-end risk estimate is justified as the hazard effect can occur after experiencing the exposure once, therefore no assumptions on frequency are needed. EPA has incorporated both routine and non-routine exposure data for these estimates. For long-term risks, risk characterization is also based on the high-end risk assessment unless otherwise noted. . This is because EPA is generally using monitoring data (*i.e.*, workplace measured concentrations) that may include a range of worker activities and sites, which in most cases could not be further characterize to a specific worker exposure groups. For example, a worker unloading or loading product at the same site may experiences routine exposures that are closer to the high-end estimate, while an operator's routine exposure may fall within the range of the central tendency estimate.

High-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. For cancer risk, EPA assumes that those exposure levels are experienced for 31 years for central tendency and 40 years for high-end estimates. The distributions may show large variability for given exposure scenarios due to variations in work tasks, different processes and engineering controls across the different sites represented in the data. Providing the central tendency (50th percentile) in addition to the high-end (95th percentile) of the dataset shows a more complete picture of magnitude of the workers exposures within the exposure scenario that may result in risk within U.S. workplaces.

EPA's occupational exposure assessment is supported by a large body of workplace monitoring data specific to the exposure scenarios being assessed. EPA received monitoring data from industry sources, identified data from peer-reviewed journal articles as well as governmental sources. Some of the monitoring data identified (*e.g.*, OSHA CEHD) were limited in contextual information such as worker activities and process conditions, such that EPA used the North American Industrial Classification System (NAICS) codes to assign data to the respective exposure scenario. For example, sites in the commercial printing and publishing industry were used to characterize risk for Commercial Use – Chemical substances in packaging, paper, plastic, hobby products- Ink, toner, and colorant products; Photographic supplies.

4.2.1.2 Acute Inhalation Risks for Workers

Acute risk estimates for workers and ONUs are based primarily on monitoring samples measured for short periods of times (15 to <330 minutes) expected to be peak exposure events, as available. Air concentration ranged up to a central tendency of 2,002 μg/m^3 (1.6 ppm) to a high-end of 209,815 μg/m^3 (171 ppm). These values are the same as reported in the RE and can be found in the *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024e).

4.2.1.2.1 Manufacturing and Processing COUs

The short-term risk estimates, utilizing an acute inhalation POD of 0.3 ppm (370 µg/m^3) and a benchmark margin of error (MOE) of 1 for conditional of use (COUs) during lifecycle stages of Manufacturing and Processing, are presented below in **Error! Reference source not found.**. This figure revises Figure 4-1 from Section 4.2.1.1.1 for the human health risk assessment TSD (U.S. EPA, 2024c). Nine of the 10 central tendency estimates are above the benchmark (highest MOE: 8.7). The central tendency risk estimate for the manufacturing COU falls below the benchmark, with an MOE of 0.5. All high-end risk estimates are below the benchmark MOE.

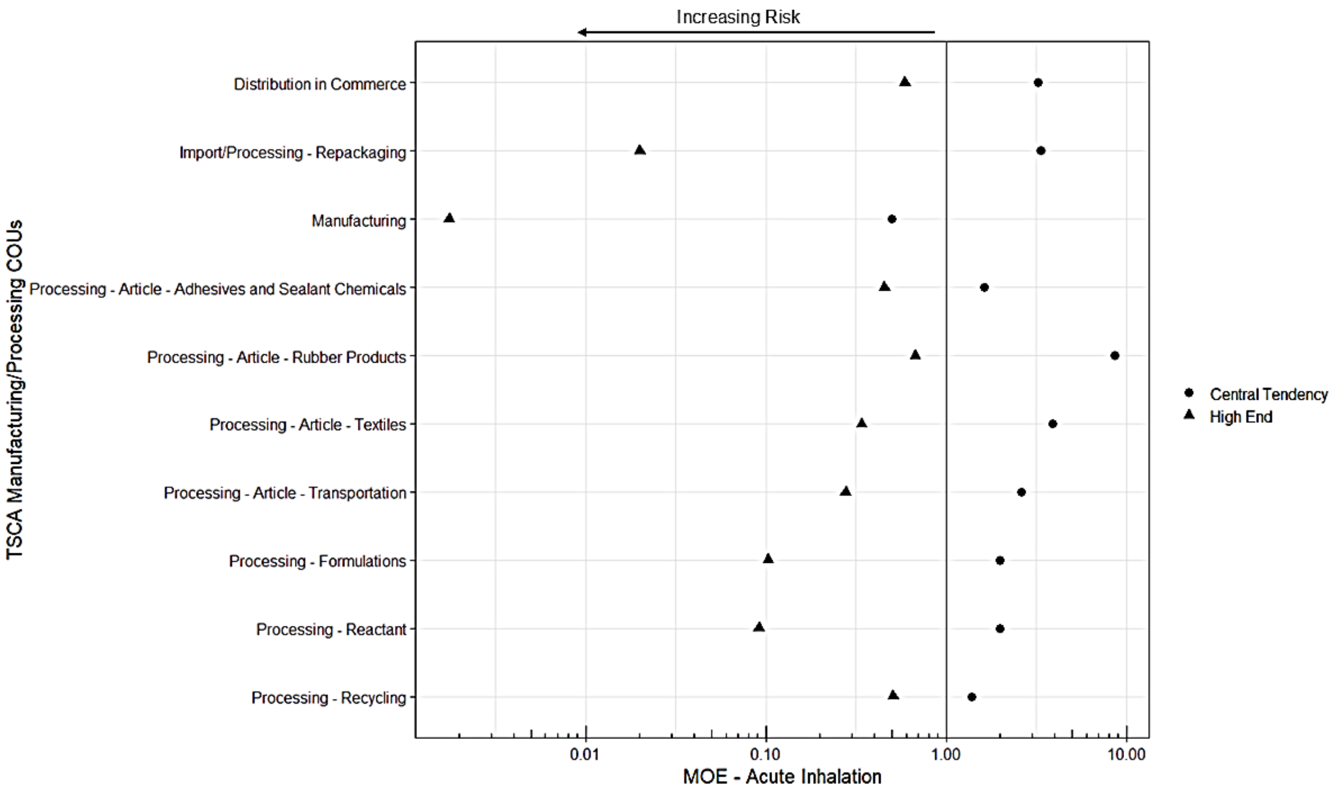
Compared to the final RE, the only notable change for COUs during lifecycle stages of Manufacturing and Processing, pertains to the COUs listed below. These COUs were initially associated with central tendency risk estimates below the benchmark MOE. However, using a POD of 0.3 ppm, the central tendency risk estimates are now above the benchmark MOE of 1.[1] Note that the reported risk estimates also encompass ONUs[2] as the Agency did not identify specific short-term monitoring data for these types of workers. As such, the Agency used the central tendency of the risk estimates to represent ONUs.

- Processing – incorporation into article – adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing
- Processing – recycling

The high-end risk estimates for these two listed COUs continue to remain below the benchmark MOE for all COUs during lifecycle stages of Manufacturing and Processing.

[1] This list of COUs do not include COUs where no unreasonable risks were determined due to slight confidence (*i.e.*, a slight weight of scientific evidence conclusion for occupational exposure), even though risk estimates may have changed from below the benchmark MOE to above the benchmark MOE.

[2] ONUs are employed persons who do not directly handle the chemical substance but may be indirectly exposed to it as part of their employment due to their proximity to the substance.



Revised Figure 4-1. Acute Inhalation MOE for TSCA Manufacturing and Processing COUs for Formaldehyde

Acute non-cancer MOE risk estimates with lower MOE values indicate increased risks. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated.

4.2.1.2.2 Industrial or Commercial COUs

Revised Figure 4-2 presents the risk estimates for the COUs under the lifecycle stages of *industrial or commercial use*. Thirteen of the 18 central tendency estimates are above the benchmark MOE (highest MOE: 174). However, five COUs—namely Automotive care products; Construction and building (metal); Machinery, mechanical; Paints, coatings, adhesives (IU, CU); and Water treatment products—fall below the benchmark; this finding is consistent with the final RE for these five COUs.

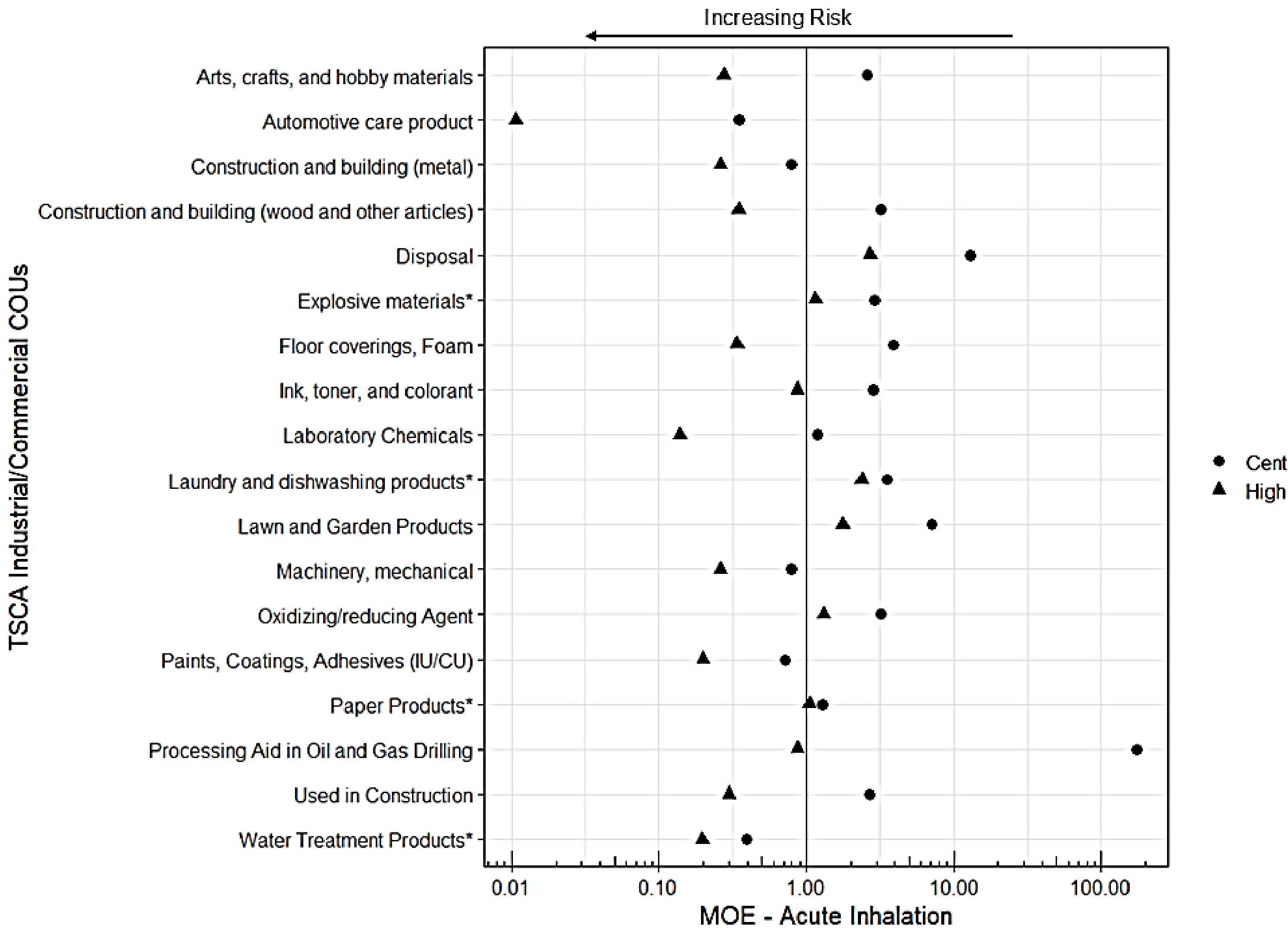
Compared to the final RE, there are only three notable changes for COUs under the lifecycle stages of Industrial or Commercial Use. These COUs are listed below. Initially, the COU listed below was associated with a central tendency risk estimate below the benchmark MOE. However, using a POD of 0.3 ppm (370 μg/m^3) the central tendency risk estimate now is above the benchmark MOE.[3] As before, these risk estimates also represent ONUs, as the Agency did not identify monitoring data specific to ONUs, including:

- Commercial use – chemical substances in products not described by other codes – laboratory chemicals.

[3] These lists of conditions of use (COUs) do not include COUs where no unreasonable risks were determined due to slight confidence (*i.e.*, a slight weight of scientific evidence conclusion for occupational exposure), even though risk estimates may have changed from below the benchmark MOE to above the benchmark MOE.

In addition, the COUs listed below initially had high-end risk estimates that were below the benchmark MOE. However, using a POD of 0.3 ppm the high-end risk estimates are now above the benchmark MOE for workers including ONUs, including the following:

- Industrial use – non-incorporative activities – oxidizing/reducing agent, processing aids, not otherwise listed; and
- Commercial use – chemical substances in agriculture use products – lawn and garden products.



Revised Figure 4-2. Acute Inhalation MOE for TSCA Industrial and Commercial COUs for Formaldehyde

Acute non-cancer MOE risk estimates with lower MOE values indicate increased risks. For COUs with multiple occupational exposure estimates (OESs) or estimation approaches, the estimate with the highest high-end value was illustrated.

*: indicates COUs for which the respective scenarios have a slight weight of scientific evidence conclusion for the OES as detailed in the final RE.

Note: Automotive care products, Lawn and garden products, Processing aid in oil and gas drilling, and Water treatment products COUs are modeled exposures.

~~As shown in Figure 4-1 and Figure 4-2, acute non-cancer risk estimates for worker exposure to formaldehyde in air range from 0.003 to 291 based on sensory irritation effects. Sensory irritation, irritation of eyes and upper airways, is commonly used as a parameter for setting occupational exposure limits. Protection from sensory irritation also protects from other health effects or workplace events that could reduce job performance or lead to undesirable outcomes such as falling or reduced visibility. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated.~~

For acute risks, EPA calculates risk across different distributions of the monitored datasets. First, EPA calculated the 50th and 95th percentiles of the exposure data measured for a 15-minute period. A 15-minute sampling period is the recommended sampling duration for short-term exposure limit (STEL) compliance checks. The current OSHA STEL is 2 ppm, therefore these measurements taken for 15-minutes can be assumed to occur during times of high formaldehyde exposure potential. The selection of when and which tasks to monitor for STEL compliance are usually determined by an industrial hygiene professional who has knowledge of the process and sources of formaldehyde. In cases of enforcement actions, the professionals may have less knowledge on the day-to-day process.

As recommended in public and peer review feedback, EPA also considered estimates based on other ranges of sampling durations. For example, although 15-minute sampling duration is recommended, an industrial hygiene professional may still measure longer durations for the purposes of STEL compliance. EPA added estimates based on samples that were measured for 15 minutes and up to 60 minutes. In addition, EPA considered samples that fell between 15 minutes and 330 minutes, the cut-off EPA used for full-shift estimates. EPA used the highest central tendency and high-end estimates between these distributions to inform acute risks.

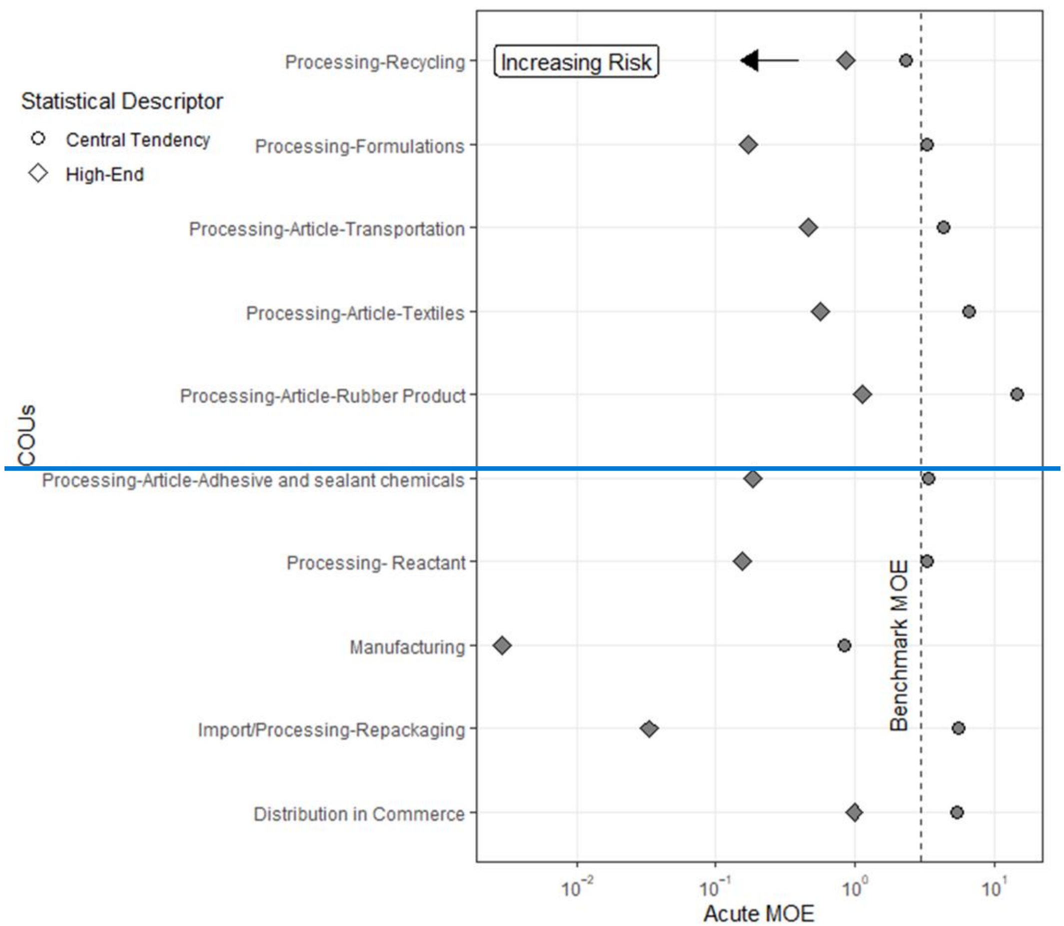


Figure 4-1. Acute, Non-cancer Occupational Inhalation Risk by TSCA Manufacturing/ Processing COUs

Acute non-cancer MOE risk estimates with lower MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated.

For Manufacturing/Processing TSCA COUs, all of these COUs indicate high-end acute risks with MOEs below the benchmark MOE of 3 as illustrated in Figure 4-1. For these COUs, the confidence in the risk estimates range from medium to medium-to-high confidence. For the Manufacturing/Processing COUs, the underlying exposure estimates come from real-world concentrations of formaldehyde measured in U.S. workplaces. All of these estimates used personal sampling measurements, which are taken near the breathing zone of the worker. With the use of this kind of occupational monitoring data, the risk estimates inherently account for the variability in workplace practices and the engineering controls used across U.S. sites. EPA integrated data from industry stakeholders, peer-reviewed literature, and governmental sources to estimate these risks.

The risk estimate at the central tendency are slightly above the benchmark MOE of 3 for all COUs with the exception of Manufacturing. Acute inhalation risk estimates for Manufacturing were derived using 16 personal breathing zone sample data collected at two U.S. formaldehyde manufacturing facilities in 1992, one U.S. manufacturing facility in 2016 and one U.S. formaldehyde manufacturing facility in 2020. Due to a limited amount of recent monitoring data, there is some uncertainty in the representativeness of the estimates at current manufacturing facilities. The acute risks also incorporate a non-routine accidental measurement, which EPA considers for acute risk. Without consideration of this non-routine event, Manufacturing significantly decreases but still indicates risks below the MOE of 3 for both the central tendency and high-end estimates. EPA has medium confidence in the risk estimates for this COU.

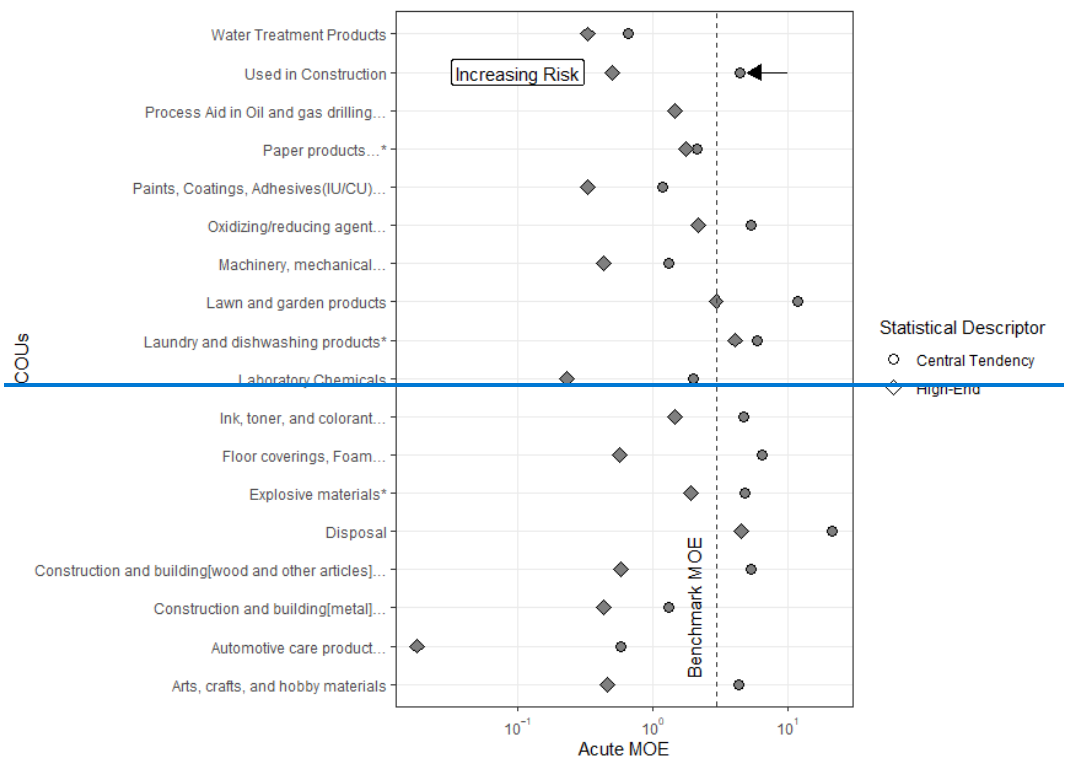


Figure 4-2. Acute, Non-cancer Occupational Inhalation Risk by TSCA Industrial/Commercial Use COUs

Acute non-cancer MOE risk estimates with lower MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated. '*' Indicates that the exposure scenario for the given COU has a slight weight of scientific evidence. For Process Aid in Oil and gas drilling, the central tendency is 291 which is not shown on the graph.

~~For industrial/commercial TSCA COUs, 11 COUs have central tendency risk estimates above the benchmark MOE of 3, indicating no acute risks at the central tendency. However, only two COUs have high-end risk estimates above the benchmark of 3, indicating no acute risks based on high-end estimates via the inhalation route:~~

- ~~Commercial Use- Chemical substances in treatment/care products-laundry and dishwashing products~~
- ~~Disposal~~

~~Therefore, 48 out of the 50 TSCA COUs have risks below the benchmark MOE of 3.~~

EPA has high confidence in the acute inhalation POD. It is based on evidence in healthy adults in controlled exposures. Generally, EPA has medium confidence in the exposure estimates for short-term exposures, but it varies from low to high across the scenarios assessed. EPA considers both the confidence in the hazard value and the exposure estimate in determining the confidence in the risk estimates.

The confidence in risk for Commercial Use- Chemical substances in treatment/care products-laundry and dishwashing products is low based on a slight weight of scientific evidence conclusion for the exposure estimate. EPA identified exposure data from a dry-cleaning shop which used a solvent containing formaldehyde. All of the measurements were either below the detection limit or the quantification limit of monitoring method. Although, formaldehyde was noted to be included in laundry detergents, EPA did not identify data at industrial or institutional laundries nor identify a concentration of formaldehyde in laundry detergent. Therefore, EPA has low confidence in the risk estimates for this COU. The confidence in the disposal risk estimates is medium. EPA relies on exposure data from the 4 sites in the waste treatment industry.

Acute risks for industrial or commercial uses are greatest for Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products. EPA has medium confidence in the risk estimates for this COU based on a high confidence in the acute POD and medium confidence in the exposure estimate. Three occupational exposure scenarios are estimated for this COU, the exposure scenario with the highest central tendency exposure estimate was selected for risk characterization of this condition of use. The automotive care products OES was modeled for the worker activity of applying a detailing product containing formaldehyde. The scenario was modeled using two approaches: an approach that model complete evaporation of the expected formaldehyde contained in the detailing product during application, and an approach using measured VOC data. To account for variability, EPA performed 100,000 Monte Carlo iterations where parameters were varied based on industry defaults such as number of cars detailed per site, amount of product used, and concentration of formaldehyde in the product. EPA calculated vapor generation using the chemical properties of formalin as well as reported VOC emissions in the automotive detailing industry. Some of the limitations of this modeled estimate is that it does not account for if any engineering controls are used during application, and the model use a wide range of concentrations of formaldehyde in the product based on the only available source, 2020 CDR.

Although the commercial Use- chemical substances in packaging, paper, plastic, hobby products- paper products; plastic and rubber products; toys, playground, and sporting equipment, and the commercial Use- chemical substances in outdoor use products- explosive materials have risk estimates that indicate acute risks, EPA has a low confidence in these COUs based on the limitations and uncertainties in the exposure estimates. For commercial Use- chemical substances in packaging, paper, plastic, hobby products- paper products; plastic and rubber products; toys, playground, and sporting equipment, EPA highest estimates were from two 15-minute samples taken at a parcel delivery company. Due to the low number of data points, the highest value of the range was used as a substitute for the 95th percentile of the actual distribution, and the midpoint as the 50th percentile. However, these substitutes are uncertain. The effects of these uncertainties on the occupational exposure assessment are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distribution of formaldehyde air concentrations and the variability of work practices among different sites. For commercial use- chemical substances in outdoor use products- explosive materials, the primary limitation of this data was the high uncertainty that the measurements were associated with exposure from explosives as workers can be assumed to be far away during the use of explosives and therefore uncertainty that the formaldehyde measured at the military sites were from this source of formaldehyde.

4.2.1.2.1 Cancer Inhalation Risks

For chronic risks, EPA uses full-shift exposure estimates. Full-shift estimates are typically 8-hour or 12-hour time weighted averages of the formaldehyde air concentrations. These estimates are inclusive of tasks where a worker may be directly exposed to formaldehyde and tasks that may have little to no formaldehyde exposure during the worker's shift. These air concentrations along with the exposure frequency (*i.e.*, days exposed within a year) as well as worker tenure (*i.e.*, years exposed), are used to calculate the lifetime average daily concentration (LADC) used for the chronic cancer risk assessment. To estimate cancer risks for workers with chronic inhalation exposure to formaldehyde, EPA used an adult-based unit risk without ADAF adjustment.

For cancer inhalation risks, EPA has medium confidence in the cancer inhalation unit risk. Generally, EPA has medium confidence in the exposure estimates but confidence for individual scenarios varies from low to high across the scenarios assessed. For most exposure scenarios, EPA estimated full-shift exposures by integrating discrete data identified from peer-reviewed literature and other sources. EPA establish a cut-off total sampling duration of 5.5 hours to reduce uncertainties by using data most expected to represent full-shift exposures. EPA then calculated an 8-hour TWA assuming that unsampled time was zero. This approach may lead to underestimation of risks if workers were still exposed to formaldehyde for the unsampled time. A sensitivity analysis on these assumptions were included in the *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024l).

EPA expects most manufacturers to operate year-round given the high production volume of formaldehyde and its use as a commodity chemical. EPA does not expect that a worker is exposed year-round (*i.e.*, 365 days/year), EPA generally assumes that workers are exposed for 250 days per year. For commercial uses, the work frequency is likely to vary as workers in retail and commercial businesses may work part-time or for shorter work shifts and weekly schedules (*e.g.*, retail stores). Commercial businesses may also have employees who work longer than 8 hour-shifts and 250 days per year based on the nature of the business. In the absence of chemical-specific data, EPA assumes that commercial workers used the commercial product containing formaldehyde every day; however, it is possible that it is only used for specific or non-routine applications. In the absence of scenario-specific data on the frequency of the chemical exposed, EPA assumes that the worker is exposed for 250 days (8 hrs/day, 5 days per week for 50 weeks) unless additional information suggest otherwise. For Commercial Use – Lawn and garden products, EPA varied the worker frequency based on the type of application (*e.g.*, agricultural vs. landscaping) because the use of fertilizer is a seasonal activity, with most use occurring during a specified time during the growing season for the specific region.

The second parameter in the LADC calculations is the time that the worker may retain a specific job/exposure scenario (*i.e.*, worker tenure). This may vary by individual workers. Data on worker tenure at a formaldehyde manufacturing facility or industrial or commercial site using formaldehyde is not reasonably available. EPA assumes 31 years for central tendency and 40 years for high-end estimates. This is based on survey data from the U.S. census and the U.S. Bureau of labor on the number of years people stayed with their current employer and the number of years worked across all employers, respectively.

Worker cancer risk estimates across all TSCA COUs for inhalation exposure range from 6.7×10^{-9} to 1.3×10^{-2} for both high-end and central tendency exposures, as shown in Figure 4-3 and Figure 4-4. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated. Of the 50 TSCA COUs evaluated, 43 TSCA COUs have cancer risk estimates greater than 1 in 10,000. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Occupational Risk Calculator*.

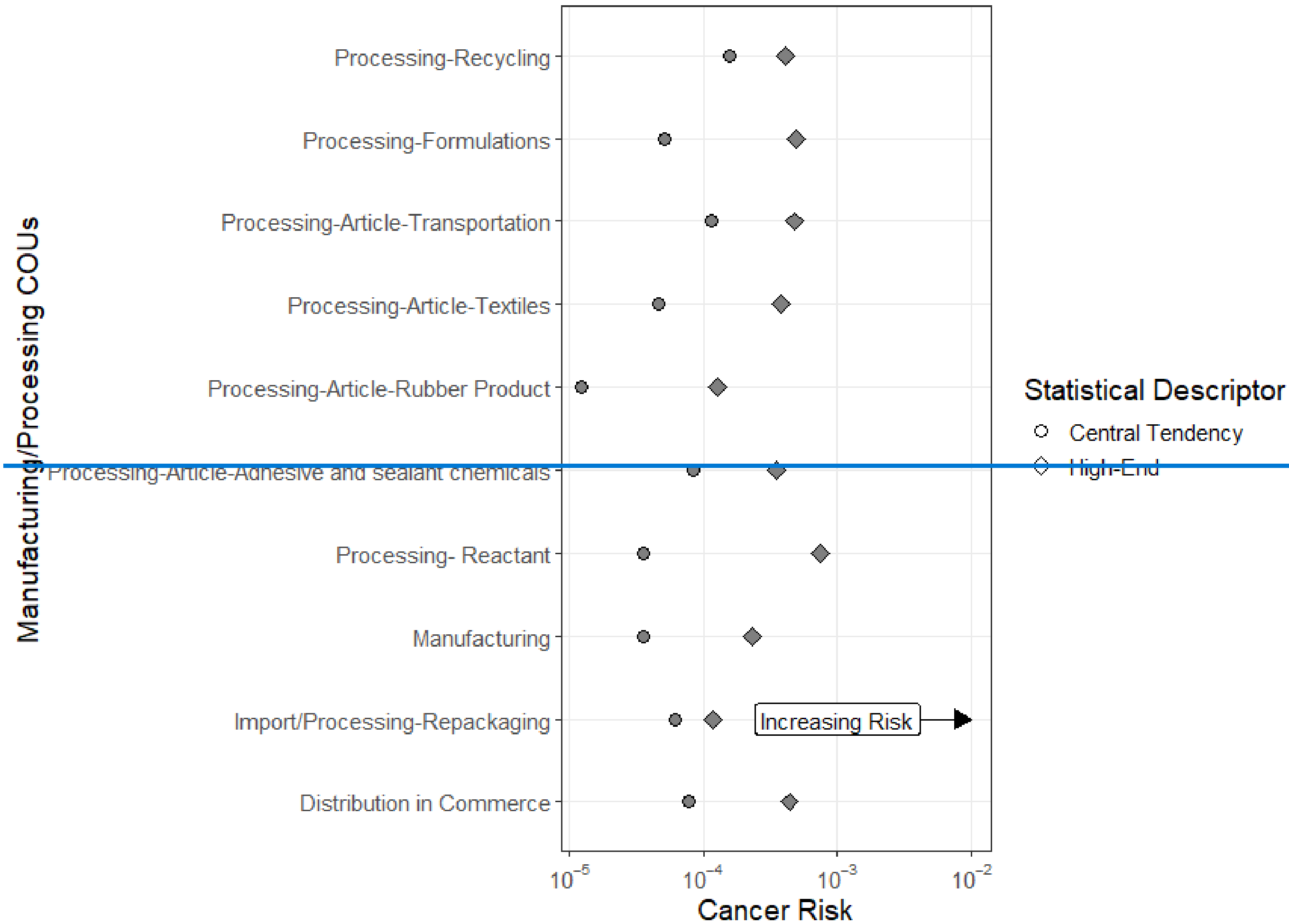


Figure 4-3. Chronic Cancer Occupational Inhalation Risk by TSCA Manufacturing/Processing COUs

As shown in Figure 4-3, the COUs under the manufacturing or processing lifecycle indicate increased cancer risk above the 50th percentile of exposure data. The central tendency risk estimates are generally between 1 in 100,000 and 1 in 10,000 increased cancer risks. The high-end risk estimates are generally between 1 in 10,000 and 1,000 increased cancer risks. For Processing- Incorporation into an Article-Additive in Rubber Product Manufacturing, the current available information indicates that most workers fall below 1.0×10^{-4} cancer risks but some individuals will be exposed to levels that indicate cancer risks at 1.28×10^{-4}. Based on the underlying monitoring data, workers whose job duties included calendaring, extruding, and weighing of the resins and other raw materials contributed to the high-end risk estimates.

For the COU with the highest high-end estimates, EPA has medium to high confidence in the risk estimates for Processing as a Reactant. The underlying occupational exposure scenario covers, in general, processes that use formaldehyde as a reactant for a variety of downstream products. This scenario integrates data from a variety of sources (*e.g.*, industry submissions, OSHA CEHD data) for a total of 202 8-hr TWA samples. Limitations within the monitoring data is a lack of additional details on worker activities for the individual samples. There is some uncertainty on the representativeness of the 50th and 95th percentiles towards the true distribution for the exposed population for this scenario.

Two COUs, Manufacturing-Import and Processing- Repackaging, are based on one exposure scenario of sites expected to be repackaging formalin or some other formaldehyde containing product. These generally include chemical wholesalers who sell a variety of chemicals in different container sizes for downstream users. EPA initially estimated the cancer risks using full-shift exposure data that were measured on workers for a majority of their day (>330 minutes). As shown in Figure 4-4, the cancer risks are estimated to be close to the 1 in 10,000 using this initial estimate based on the 7 full-shift estimates identified. However, this scenario had short-term exposure data that indicated higher 8-hour time weighted average if considered. EPA calculated an 8-hour time weighted average based on all of the relevant monitoring data for the scenario as EPA expects that industrial hygienists may not have measured full days if the worker rotated to repackaging other chemicals during their day. By adjusting these values to assume all unsampled time is zero, this calculates minimum 8-hr TWA from these workers. Figure 4-4 shows the cancer risk estimate considering the full set of data for repackaging adjusted to an 8-hour time weighted average where the unsampled time was set to 0.

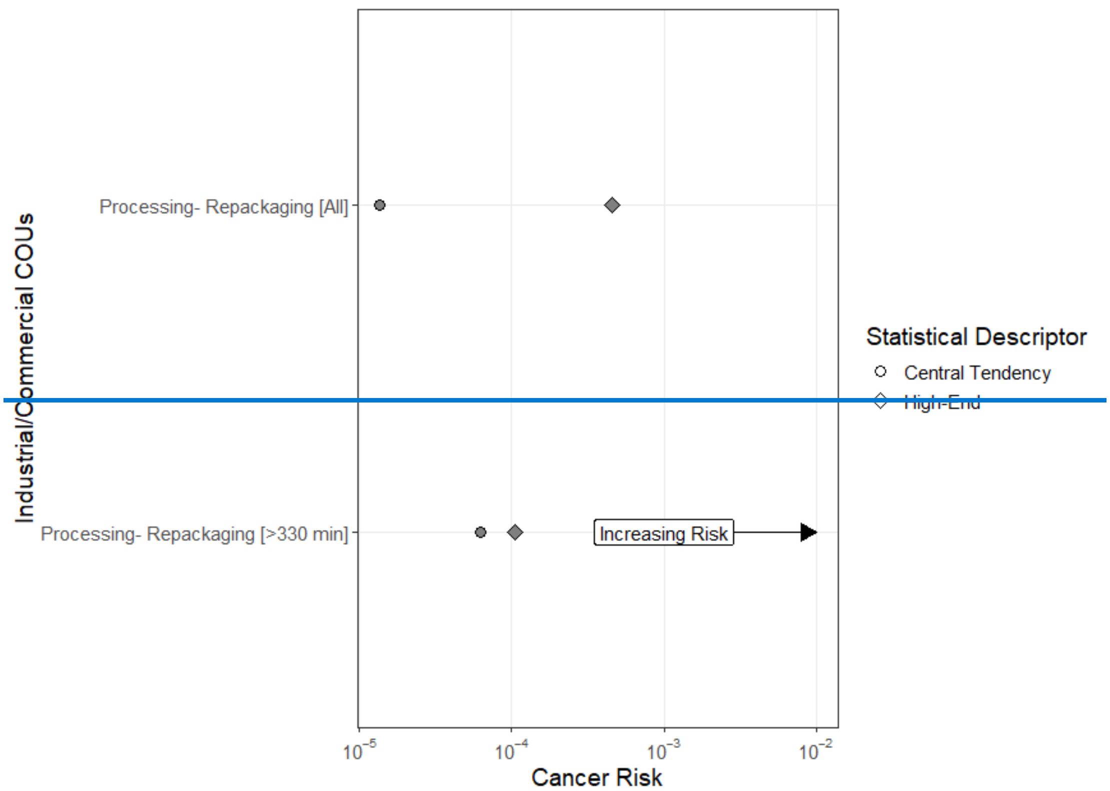


Figure 4-4. Cancer Risk for Manufacturing- Import and Processing – Repackaging

Figure 4-5 illustrates the cancer risks for COUs under the industrial or commercial use lifecycle stage. EPA identified 6 COUs where cancer risks at the high-end are below 1.0×10^{-4} :

- Industrial Use- Non-incorporative activities- Process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing;
- Industrial Use- Non-incorporative activities- Oxidizing/reducing agent; processing aids, not otherwise listed;
- Commercial Use – Chemical substances in packaging, paper, plastic, hobby products- Paper products; Plastic and rubber products; Toys, playground, and sporting equipment;
- Commercial Use- Chemical substances in agriculture use products- Lawn and garden products;
- Commercial Use – Chemical substances in treatment/care products- Laundry and dishwashing products;
- Commercial Use- Chemical substances in outdoor use products- Explosives materials; and
- Disposal

For the Commercial Use – Water Treatment Products, the calculated cancer risk for high-end estimates is slightly above the 1 in 10,000 benchmark. EPA modeled using the Tank Truck and Railcar Loading and Unloading Release and Inhalation Exposure Model. For this condition of use, EPA concluded the weight of scientific evidence is slight to moderate and, given that the model assumes use of vapor balance system and does not cover other activities that could occur which may underestimate exposures. In addition, EPA found limited use information for TSCA regulated activities of formaldehyde used for water treatment (*i.e.*, non-biocidal uses).

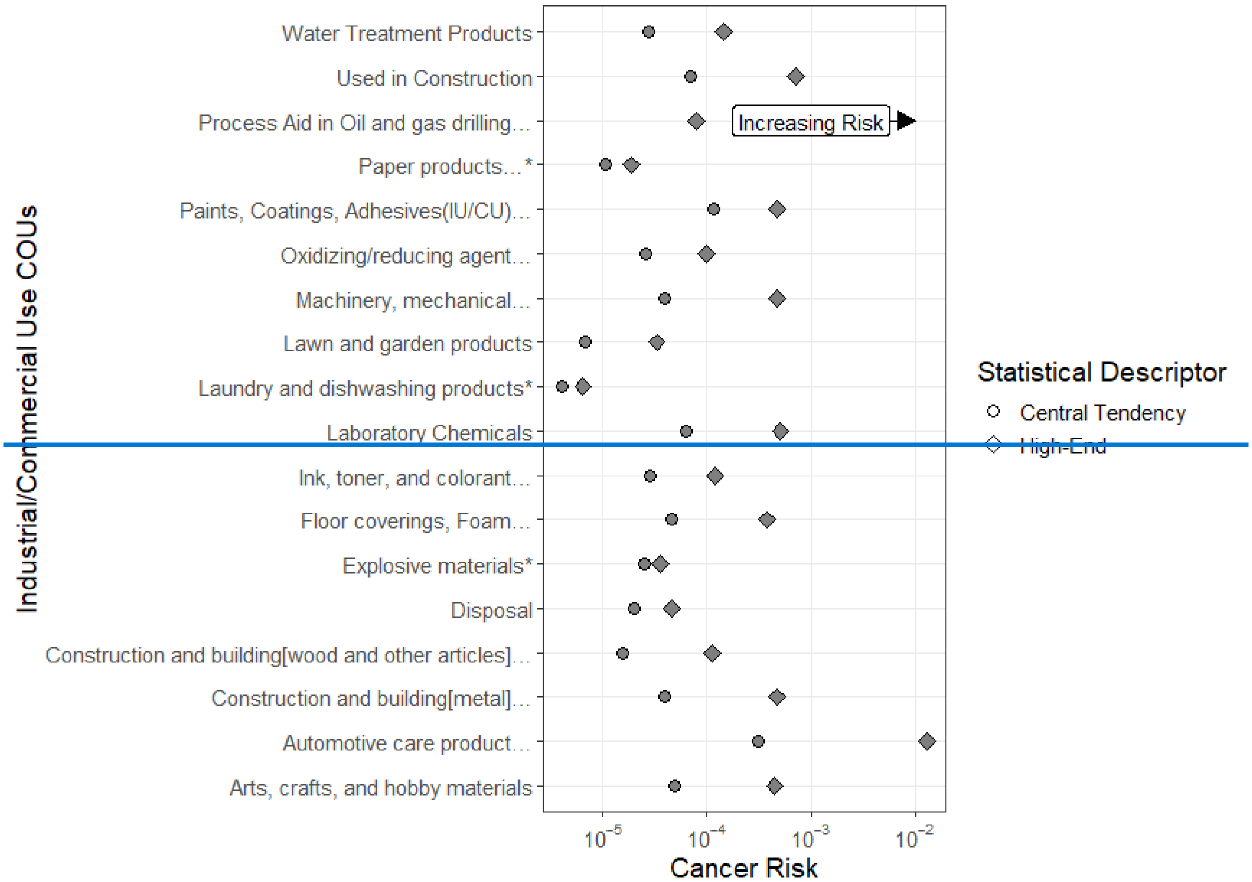


Figure 4-5. Chronic Cancer Occupational Inhalation Risk by TSCA Industrial/Commercial COUs

Note: Commercial Use- Chemical substances in treatment/care products-Laundry and dishwashing products, Commercial Use- Chemical substances in packaging, paper, plastic, hobby products- Paper products; Plastic and rubber products; Toys, playground, and sporting equipment, and Commercial Use- Chemical substances in outdoor use products- Explosive materials all have a slight weight of scientific evidence. For Process Aid in Oil and gas drilling, the central tendency is 6.7×10^{-6} which is not shown on the graph.

Four COUs were based on limited monitoring data:

- Commercial Use – Chemical substances in treatment/care products- Laundry and dishwashing products;
- Commercial Use – Chemical substances in packaging, paper, plastic, hobby products- Paper products; Plastic and rubber products; Toys, playground, and sporting equipment;
- Commercial Use- Chemical substances in outdoor use products- Explosives materials; and
- Disposal

For these COUs, the assessed exposure levels are less likely to be representative of worker exposure across the entire job category or industry. Ideally, EPA will present 50th and 95th percentiles for each exposed population. For COUs with less than 6 data points identified, EPA used the mean or midpoint of the range to serve as a substitute for the 50th percentile of the actual distributions. Similarly, the highest value of a range may serve as a substitute for the 95th percentile of the actual distribution. However, these substitutes are uncertain. The effects of these uncertainties on the occupational exposure assessment are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distribution of formaldehyde air concentrations and the variability of work practices among different sites. Although the weight of scientific evidence is low, EPA has concluded that the underlying data still provide plausible estimates of exposures for all COUs.

EPA has slight confidence for three of these COUs based on a slight weight of scientific evidence. For the laundry and dishwashing products, EPA identified 12 data points at one dry cleaner where formaldehyde was indicated to be present in a solvent. EPA did not identify exposure data at industrial or institutional laundries, which is a major limitation in the exposure estimate. For the Commercial Use – Chemical substances in packaging, paper, plastic, hobby products- Paper products; Plastic and rubber products; Toys, playground, and sporting equipment, EPA received two monitoring data points from a retail store that EPA assumes may sell paper and other hobby products. In addition to the low number of data points, the potential of overlap with other sources of formaldehyde at such a site was considered. Lastly for explosive materials, EPA did identify sufficient monitoring data from ammunitions centers and military bases, although there is uncertainty that the sampled formaldehyde may have come from other sources. These uncertainties may result in either overestimation or underestimation of exposures depending on the actual distribution of formaldehyde air concentrations for the specific COU.

4.2.1.3 Risk Estimates for Dermal Exposures

Acute non-cancer risk estimates for dermal exposure range from 3.40×10^{-3} to 19 (benchmark MOE of 10) for central tendency exposures and high-end exposures (see Figure 4-3). Risk estimates are greatest for TSCA COUs: Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products; and TSCA COUs: Processing – incorporation into an article – paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace); Industrial use – paints and coatings; adhesives and sealants; lubricants; commercial use – chemical substances in construction, paint, electrical, and metal products – adhesives and sealants; paint and coatings. Both OESs assumed an immersive dermal loading on the skin during the exposure scenario.

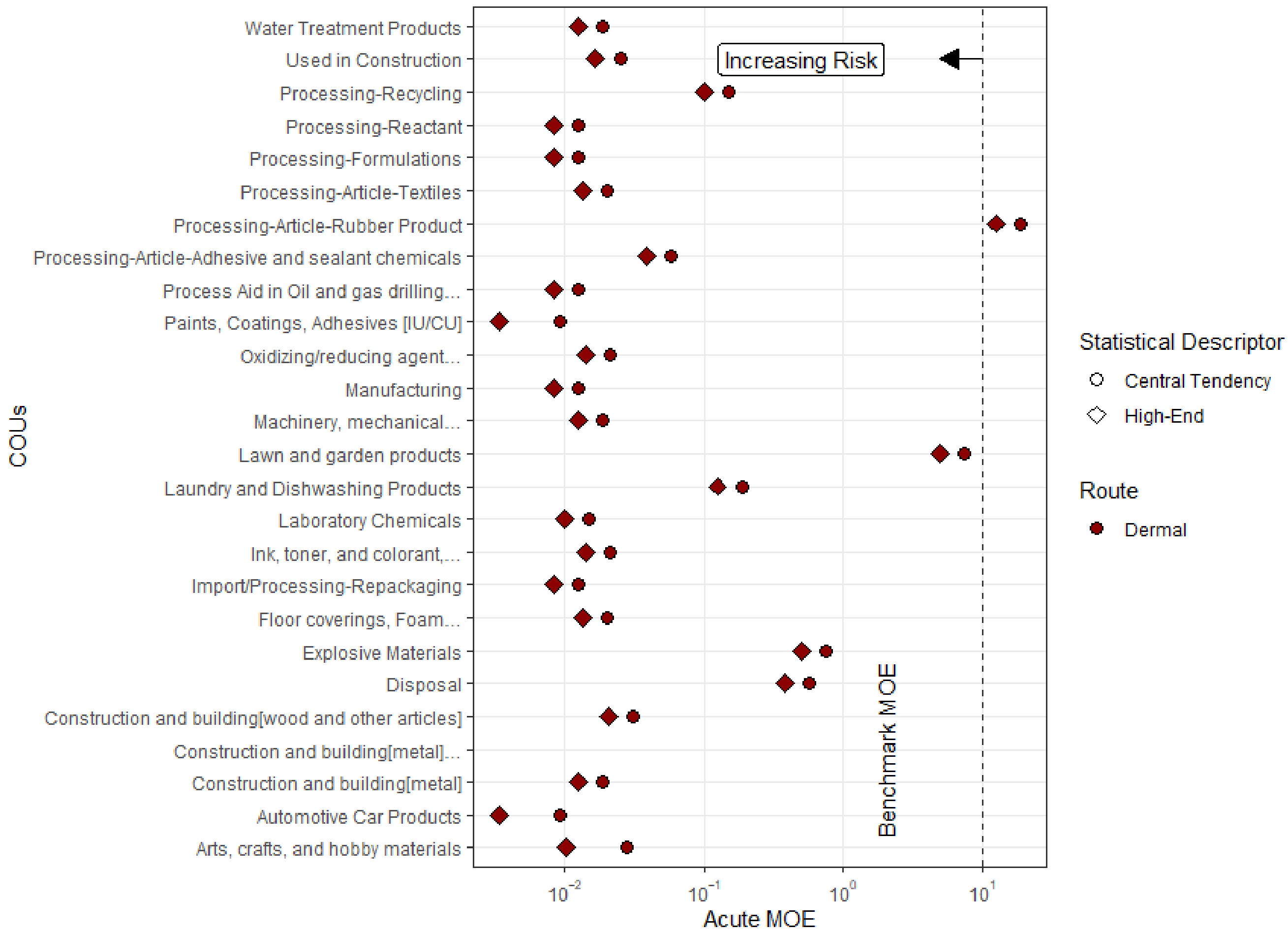


Figure 4-34-6. Acute Occupational Dermal Risks by TSCA COUs

Dermal risk estimates were not provided for Distribution in commerce and commercial use – packaging, paper, and hobby products COUs. These COUs involve the handling of solid articles with low concentrations of formaldehyde in which the dermal modeling approaches were not suitable. EPA expects the primary concern for these products is inhalation exposures from formaldehyde off-gassing.

Overall confidence in risk estimates via dermal exposure is medium. As described in Section 3.2, overall confidence in the dermal hazard value is high. As described in Section 2.5.1, overall confidence in dermal occupational exposures is medium based on a moderate weight of scientific evidence for all scenarios assessed. All scenarios used a modified version of the EPA Dermal Exposure to Liquids Model, which reduced to two parameters: an activity-based dermal loading and a maximum weight concentration of formaldehyde in the formulations handled. For many scenarios, maximum concentration information from sources such as the 2020 CDR (U.S. EPA, 2020b) have overall data quality determinations of either high or medium from EPA's systematic review process. However, some scenarios lacked sufficient information on the maximum concentrations expected and industry-specific or surrogate scenarios were used to inform calculations. There is some uncertainty on the range of concentrations of formaldehyde within certain processes and products whose impact is unknown and may either result in an overestimation or underestimation of exposures.

4.2.2 Risk Estimates for Consumers

EPA estimated short-term risks for exposure to formaldehyde resulting from exposure to formaldehyde in consumer products. For this analysis, EPA relied on the consumer exposure estimates modeled in the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d) and summarized in Section 2.2.

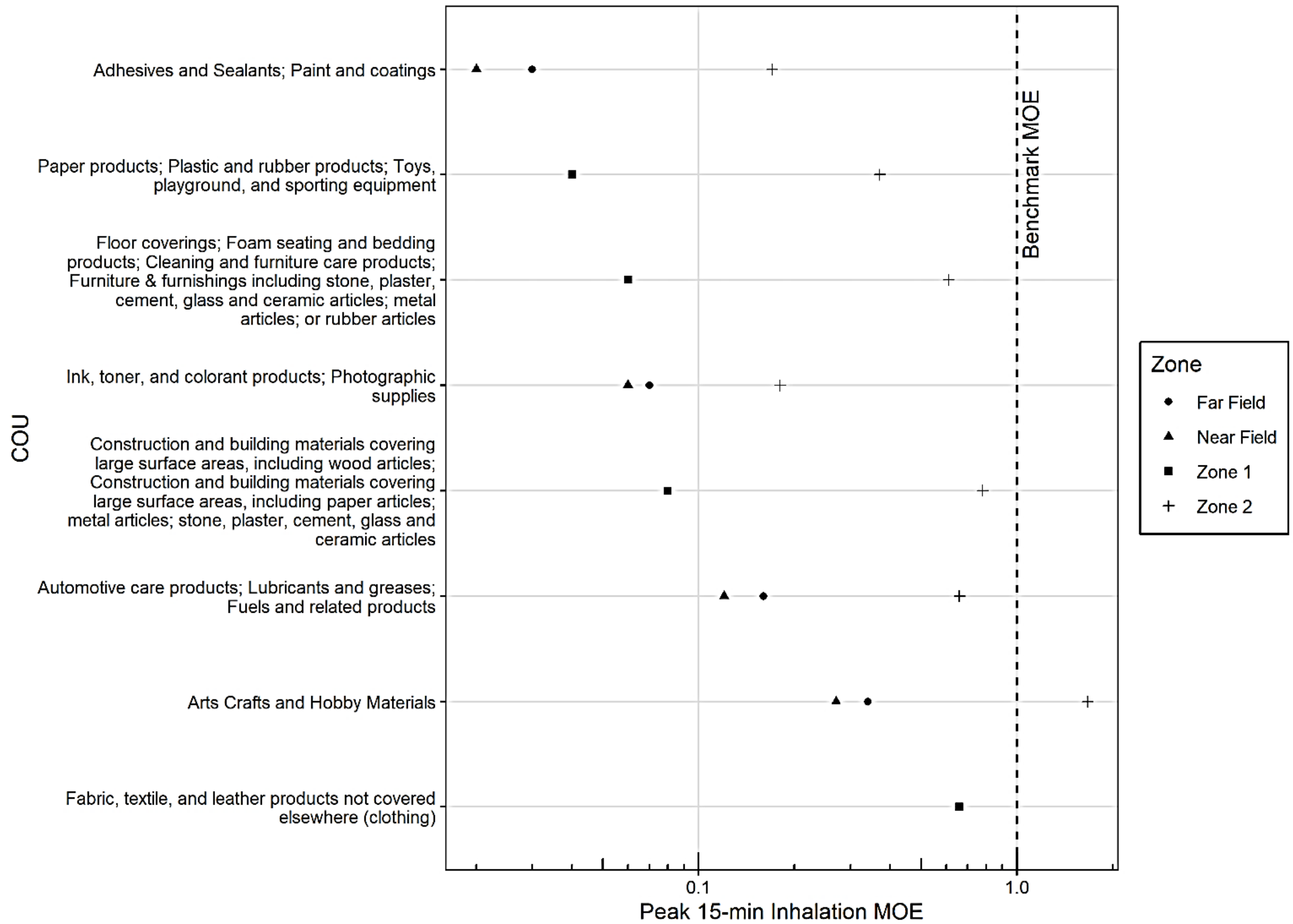
4.2.2.1 Risk Estimates for Inhalation Exposure to Formaldehyde in Consumer Products

In the final RE, EPA concluded that estimated risks to consumers were below the benchmark for all COUs. The Agency characterized risk for acute inhalation and dermal sensitization for consumers who use products and articles containing formaldehyde. This section outlines the results from the final RE and the draft risk calculations for acute inhalation.

The Agency used the Consumer Exposure Model (CEM) to estimate formaldehyde concentrations in consumer products. The exposure concentration estimates derived from CEM were based on safety data sheets (SDS) identified in the Use Report for Formaldehyde (CAS RN 50-00-0) and Paraformaldehyde (CAS RN 30525-89-4) with updated Information from the following: Chemical Data Reporting (2016–2019), Toxics Release Inventory (2020), and Clean Water Act permit discharges (2021). Additional searches were also conducted to identify and refine the chemical concentration of formaldehyde in consumer products and articles for the assessed COUs. These estimates are all presented in the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

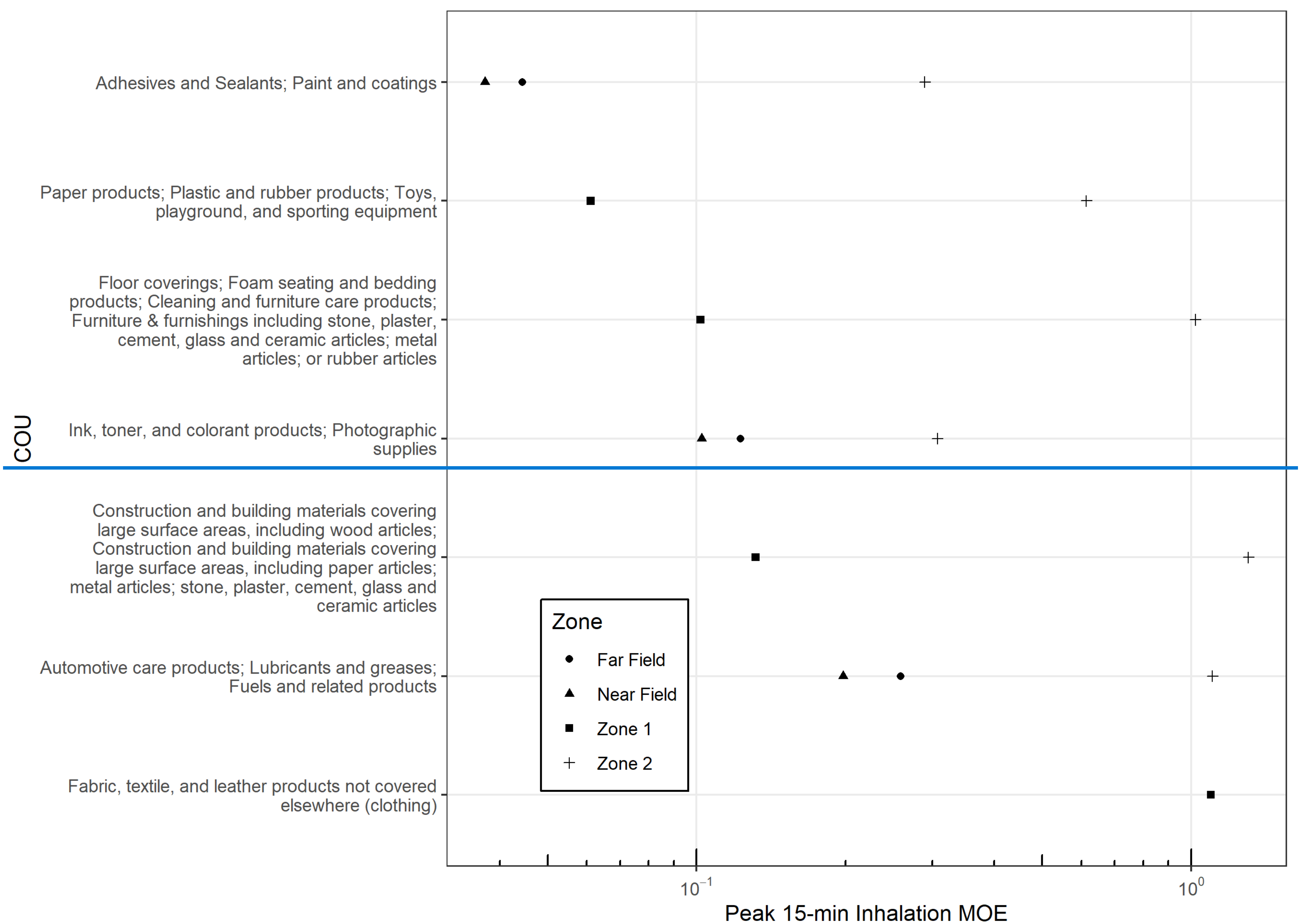
Risk estimates for consumer exposures for all TSCA COUs are based on a 15-minute peak concentration of formaldehyde in air from active use of associated consumer products and articles. In the final RE, exposure concentrations from COUs ranged from 220 to 16,450 μg/m^3 (1.8×10^{-1} to 1.3 ppm). The highest modeled exposure concentrations attributable to TSCA COUs came from Adhesives and sealants; paint and coatings.

With the POD of 0.3 ppm, the acute MOEs range from 0.02 to 1.67 for consumer users of products and articles (Revised Figure 4-4). Most consumer COUs are below the benchmark MOE of 1, but as mentioned previously, these estimates do not change the conclusions of the final RE.



Revised Figure 4-4. Acute Inhalation MOE for Consumer COUs for Formaldehyde

~~Acute inhalation risk estimates range from 4.0×10^{-2} to 8.9×10^{+2} across all exposure scenarios. See Figure 4-7 for a summary of the estimated risks associated with the TSCA COU representative scenarios. These acute risk estimates are calculated using high-end air concentrations modeled for a 15-minute period based a set of high-end model input assumptions and TSCA COU-specific assumptions about exposure frequency and duration. Acute non-cancer risk estimates are based on high-end consumer and bystander exposure estimates and the acute POD for sensory irritation reported in controlled human exposure studies in healthy adult volunteers. Acute risk estimates below 3 indicate that exposure is greater than the level of exposure associated with benchmark MOE. Lower MOE values indicate greater risks. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*.~~



~~**Figure 4-7. Peak 15-Minute Inhalation Risk by COUs in Consumer Products**~~
~~Results are presented according to COUs.~~

For some products, air concentrations were modeled for near-field and far-field (generally describing differences in exposure within the same room) while for other products concentrations were modeled for zones 1 and 2 (generally describing different rooms). Risks from near-field and zone 1 exposures generally represent risks from direct exposures to consumer users while far-field and zone 2 tend to represent risks to consumer bystanders. For instance, an individual applying floor coverings: Varnishes and floor finishes in a living room can be described as a consumer of that product in zone 1 or near-field of the application area. On the other hand, while the product is being applied there may be someone else either also in the room of use and assumed to be away from the immediate application area (or in the far-field), or in a completely different room from where the product is being applied (also known as zone 2). The x-axis presents the 15-minute peak inhalation non-cancer concentration, and the y-axis presents the modeled TSCA COUs.

EPA has medium confidence in the consumer inhalation risk estimates based on SACC peer-reviewed modeling and input data, including TSCA COU-specific product weight fractions identified from SDS of consumer products currently on the market, the quality and applicability of the CEM for the assessment of realistic consumer exposure scenarios that are representative of COUs, common consumer use patterns (*e.g.*, TSCA COU-specific amount used, duration and frequency of use (U.S. EPA, 2019)) according to the EPA *Exposure Factors Handbook* (U.S. EPA, 2011) and the 1987 Westat survey (Westat, 1987) and applicable to most population groups. Though the 1987 Westat survey (Westat, 1987) is the best available source of consumer user patterns, its reported use patterns may have changed for some products and articles over time and may not be representative of today's consumer use patterns. EPA also has medium confidence in the quality and representativeness of air monitoring data regarding consumer exposures. As described in Section 3.2, EPA has high confidence in the acute inhalation POD based on evidence in healthy adult volunteers in controlled exposure conditions.

4.2.2.2 Risk Estimates for Dermal Exposure to Formaldehyde in Consumer Products

EPA estimated non-cancer risks for acute dermal exposure to formaldehyde in consumer products.

Dermal risk estimates were calculated for low, central tendency and high-end exposure estimates using the POD based on skin sensitization responses observed in adults. The estimated dermal risks based on high-end exposures range from 3.24×10^{-3} to $1.08\times10^{+1}$ and are presented in Figure 4-5. Acute risk estimates below 10 indicate that exposure is greater than the level of exposure associated with benchmark MOE. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*.

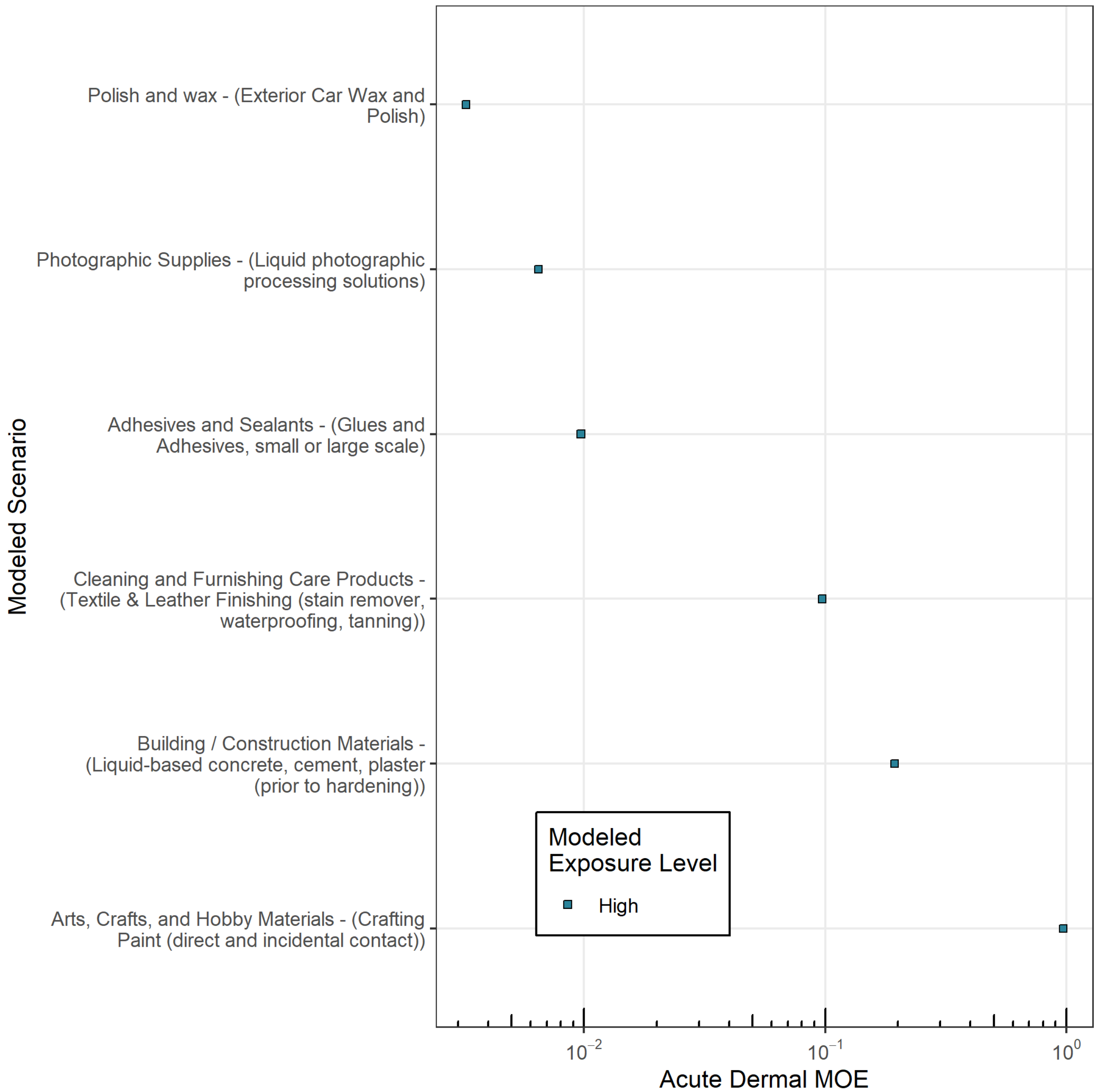


Figure 4-54-8. Acute Dermal Loading Risk by High-End Exposure Scenarios in Consumer Products

The y-axis presents the modeled scenarios written as TSCA COU followed by relevant exposure scenario.

EPA has medium confidence in the dermal risk assessment for consumers. As detailed in Section 3.2.1 of the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), EPA has medium confidence in the Thin Film Model, which EPA used to estimate dermal loading from spray and liquid consumer products, and in default model input values used in the dermal exposure assessment of realistic consumer exposure scenarios, which are representative of COUs, common consumer use patterns, and applicable to most population groups. EPA has high confidence in the TSCA COU-specific product weight fractions identified from SDSs of consumer products currently on the market and medium confidence in the applied quantity remaining on skin Q_u constant. Although a Q_u of 10.3 mg/cm^2 (most protective value for consumers using oil-based products (U.S. EPA, 1992)) is assumed to be realistic and protective of most liquid product consumer dermal exposures to formaldehyde, it is conceivable that a lower Q_u may be applicable for some consumer exposure scenarios (*e.g.*, consumer uses liquid product with PPE that prevents development of thin film of formaldehyde on the skin). This information in addition to the dermal loading identified in the literature (U.S. EPA, 1992) were used to parameterize the Thin Film model which has been peer reviewed by the SACC and used in previous OPPT existing chemical risk evaluations based on TSCA uses and OPP's formaldehyde risk evaluation based on pesticidal uses. No monitoring data are available on dermal exposures for consumers. As described in Section 3.2, overall confidence in the dermal hazard value is medium.

4.2.3 Risk Estimates for Indoor Air

EPA considered, residential and nonresidential monitoring data for its evaluation of formaldehyde indoor air concentrations since it allows the agency to characterize realistic ongoing formaldehyde indoor air exposures among Americans. However, these monitoring data do not differentiate between TSCA and other sources of formaldehyde, which means that EPA was unable to perform any exposure source attribution, including determining what portion of the reported indoor air concentrations are from TSCA COUs versus other sources.

Monitoring data are also not expected to represent peak exposures since the air monitoring reported, often occurs some period long after articles have been installed in a home. Instead, EPA expects the indoor air monitoring data to be more representative of long-term exposures to formaldehyde. Therefore, the Agency used a combination of monitoring and modeling data to best characterize formaldehyde indoor air exposures while considering the relative contributions of TSCA COUs to the indoor air environment. EPA evaluated its findings for exposures resulting from the use of consumer articles containing formaldehyde, under TSCA, and assessed indoor air exposures for four COUs expected to be significant sources of formaldehyde in indoor air.

EPA used CEM as a tier 1 modeling tool to estimate 1-year average formaldehyde residential indoor air exposures, and refined its formaldehyde indoor air exposure modeling results using IECCU, a tier 2 modeling tool, to estimate 15-minute peak, 3-month average and 1-year average formaldehyde residential indoor air concentrations from specific consumer article categories by incorporating relevant low-, median-, and high-end emission factors and surface areas of articles expected in a room of use, according to the literature.

The following subsections provide a summary of potential acute, chronic non-cancer, and cancer risks according to the indoor air exposure monitoring data and relevant modeling of significant TSCA COU contributors to indoor air exposures.

4.2.3.1 Risk Estimates Based on Indoor Air Monitoring Data

Monitoring data provide information about actual concentrations of total formaldehyde in indoor air, but the data reflect aggregate concentrations from all TSCA and other sources present. Monitoring data are therefore a good indication of aggregate formaldehyde exposures and risks in a range of indoor environments, but do not provide information about the relative contributions of each source.

EPA estimated chronic risks based on levels of formaldehyde detected in indoor air in monitoring studies representing a range of indoor air environments. The American Healthy Home Survey II is a survey published in 2021 that is representative of residential indoor air conditions across a wide range of American households. It is the most current nationally representative survey of formaldehyde in indoor air in American homes and is likely the best representation of the current range of aggregate exposures and risks from all sources of formaldehyde in indoor air. Other monitoring datasets considered in this analysis generally target indoor environments that typically have higher formaldehyde concentrations, such as trailers and mobile homes. Available indoor air monitoring datasets, for some indoor air environments, may not represent current conditions in indoor air following Title VI regulation of wood products. Figure 4-6 summarizes chronic non-cancer risk estimates, ~~while Figure 4-10 summarizes chronic cancer risk estimates based on indoor air monitoring data~~, relying on the assumption that these monitored concentrations could represent average exposures in indoor air and that exposure to these concentrations may be experienced continuously over time. This may be a snapshot of risks as indoor air concentrations may change over time, and people typically live in multiple homes over the course of their lives and may add new articles in the home at varying frequencies.

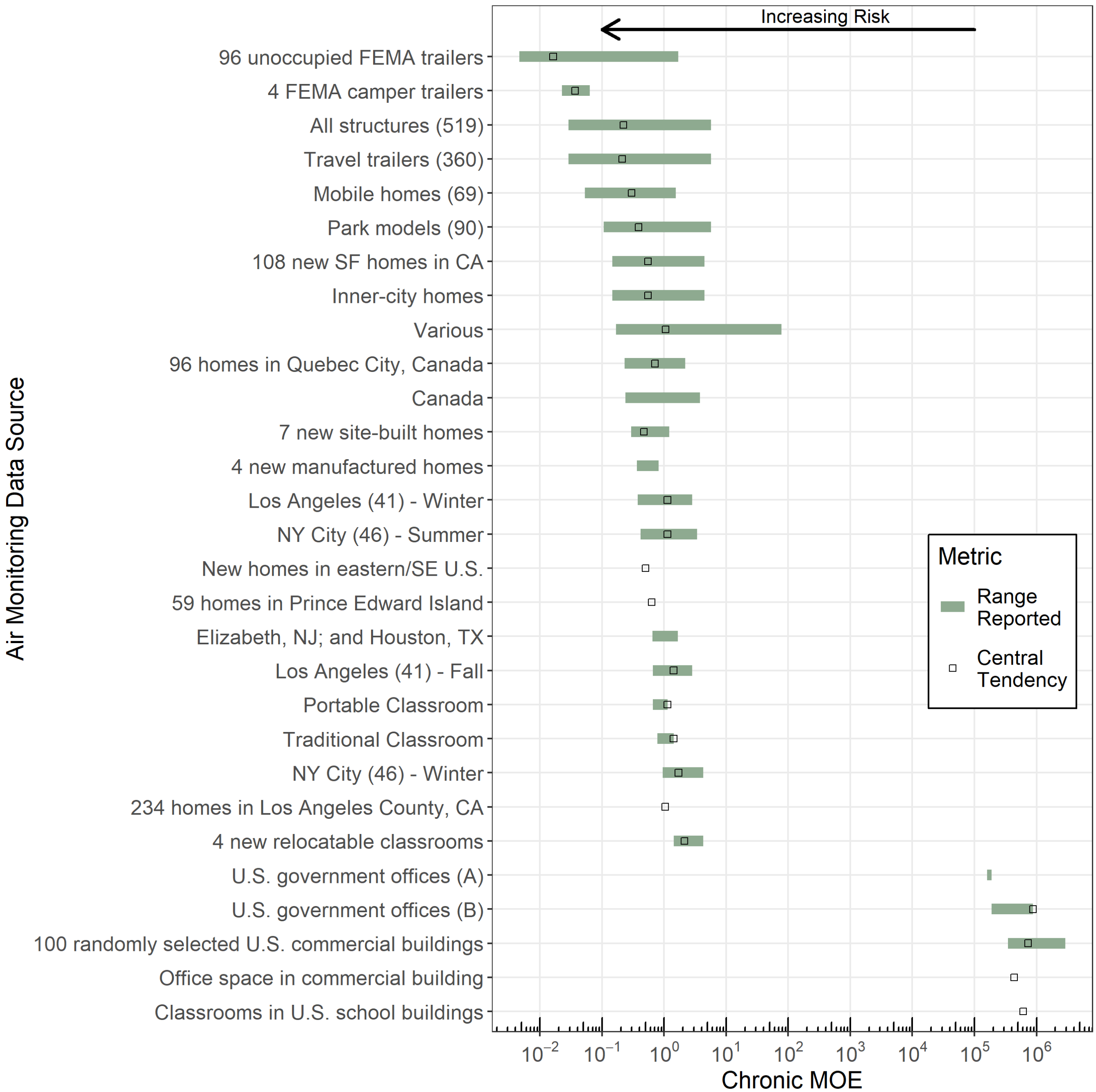


Figure 4-6. Chronic Non-Cancer Inhalation Risk by Indoor Air Monitoring Data Source
Air monitoring data sources listed on the y-axis are described in more detail in the *Indoor Air Assessment for Formaldehyde*.

Chronic non-cancer risk estimates presented in Figure 4-6 are calculated using exposures estimates based on available monitoring data and the chronic POD based on respiratory effects. Among all residence types and commercial environments, chronic non-cancer risk estimates based on indoor air monitoring data ranged from 4.6×10^{-3} to $7.8\times10^{+1}$. Chronic non-cancer risk estimates below 3 indicate that exposure is greater than the level of exposures associated with the benchmark MOE.

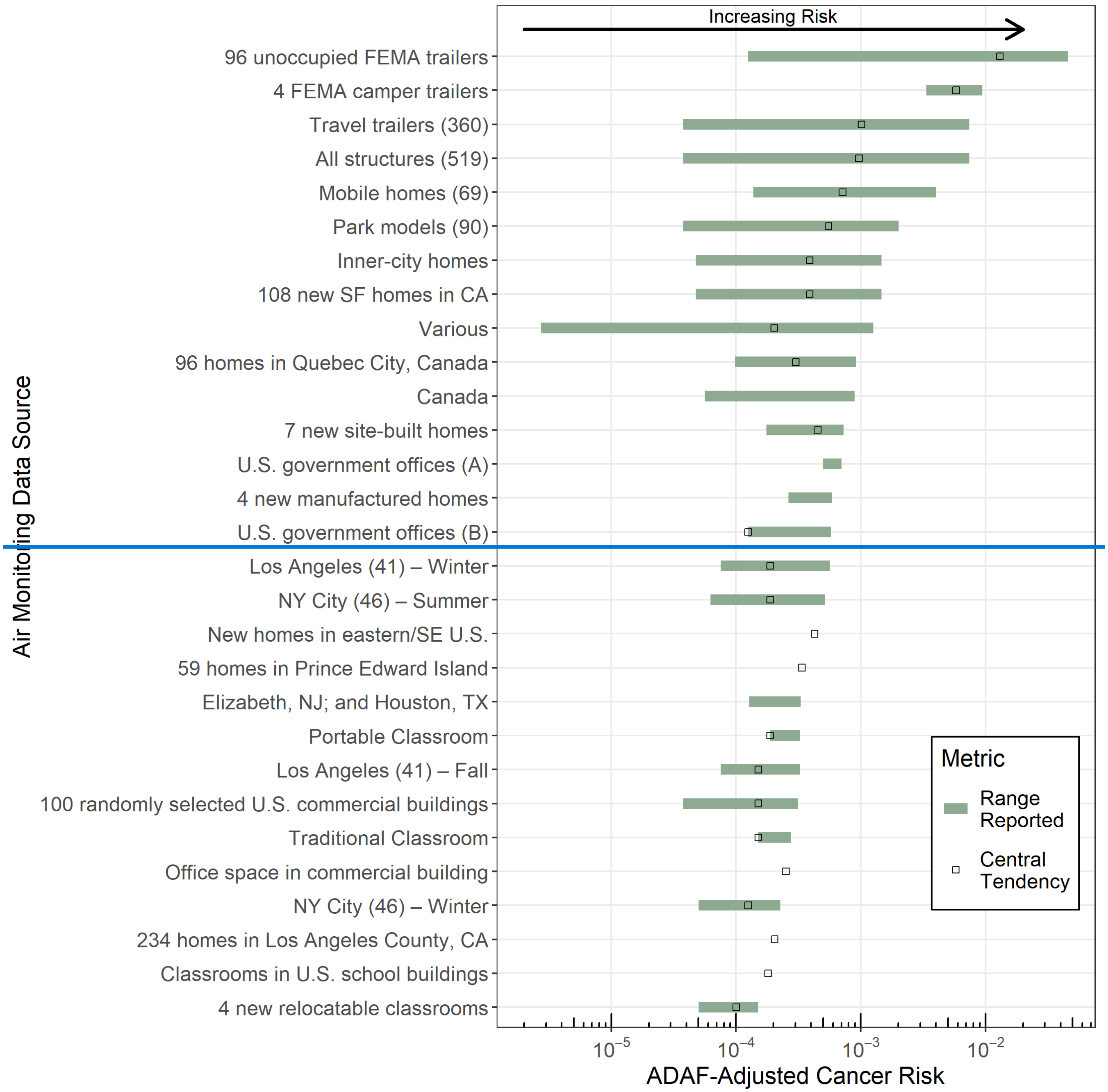


Figure 4-10. Cancer Inhalation Risk by Indoor Air Monitoring Data Source

Air monitoring data sources listed on the y-axis are described in more detail in the *Indoor Air Assessment for Formaldehyde*.

Cancer risk estimates presented in Figure 4-10 range from 2.74×10^{-6} to 4.60×10^{-2}. These ranges of risk estimates correspond to measured minimum concentrations of 3.7×10^{0} ppm from a study of 96 unoccupied FEMA trailers (ATSDR, 2007), and a measured maximum concentration of 2.2×10^{-4} ppm from the American Healthy Home Survey II (QuanTech, 2021). All calculated monitoring indoor air cancer risks were greater than 1 in 1,000,000. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*.

4.2.3.1.1 Monitoring Information in Consideration of Aggregate Risk

Given the ubiquity of formaldehyde in indoor environments, risks from individual sources rarely occur in isolation. EPA has therefore also considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air.

As previously noted, the AHHS II is the most current nationally representative survey of formaldehyde in indoor air in American homes. Therefore, among all monitoring sources, it is likely the most appropriate source for the estimation of aggregate risks in American residential indoor air across all households, including old and new homes. Using the maximum estimated monitoring indoor air estimate for formaldehyde in AHHS II (including contributions from both TSCA and other sources), it may be assumed that indoor air aggregate chronic non-cancer risks are as low as 1.68×10^{-1}. Chronic non-cancer risk estimates below 3 indicate that exposure is greater than the benchmark MOE identified for exposures based on sensory irritation reported in controlled human exposure studies in healthy adult volunteers. Lower MOE values indicate greater risks. Based on AHHS II monitoring data, Aggregate cancer risks are as high as 1.27×10^{-3} in typical U.S homes. All calculated AHHS II monitoring indoor air cancer risks were greater than 1 in 1,000,000. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*. The same can be inferred from mobile home, classroom, and other monitoring indoor air risk estimates.

In general, EPA has high confidence in the estimation of chronic non-cancer and cancer risk estimates based on the indoor air monitoring data as it relies on actual formaldehyde concentrations from various American indoor air settings. As discussed in Section 2.3.1, such data are expected to be representative of long-term aggregate exposures and are expected to include TSCA and other sources. As described in Section 3.2, EPA has high confidence in the chronic POD based on respiratory effects and medium confidence in the cancer IUR.

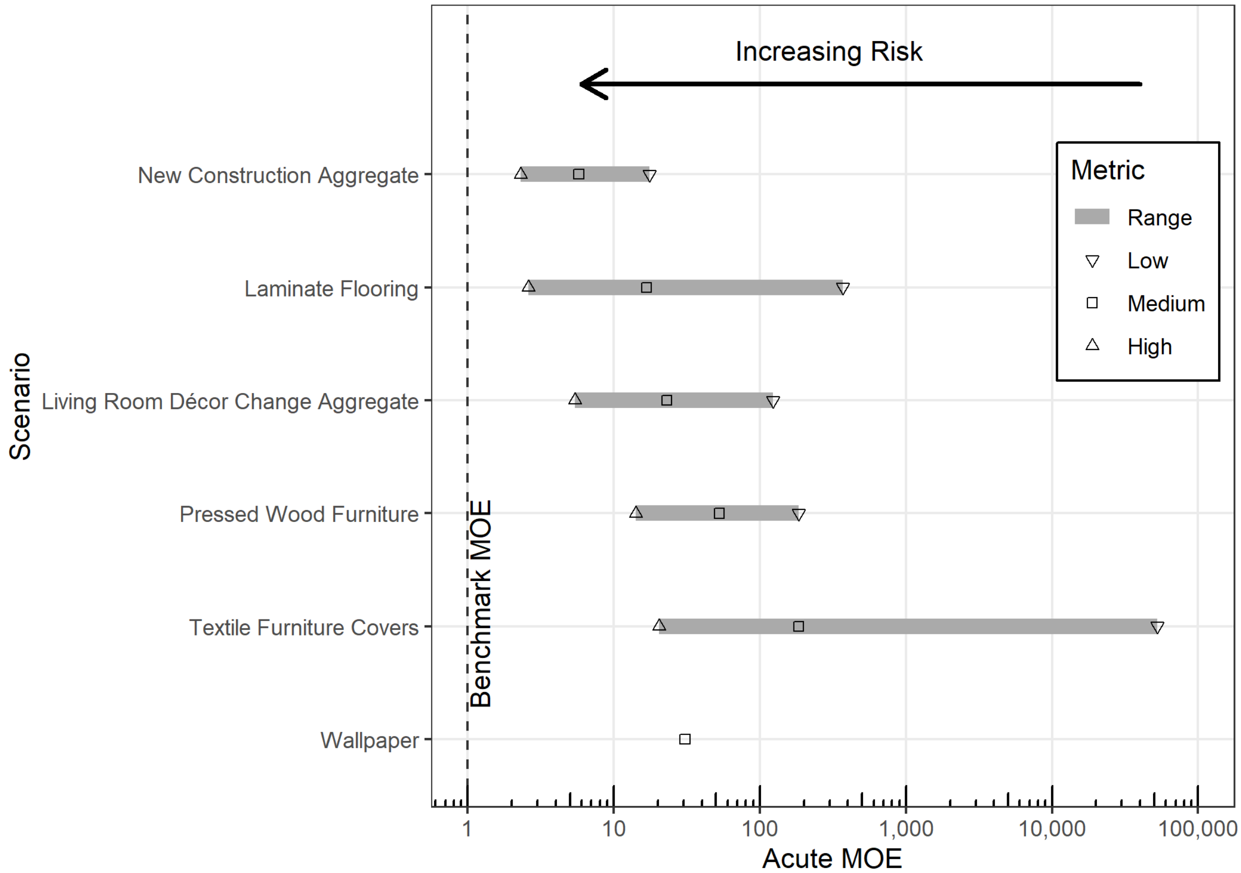
4.2.3.2 CEM Indoor Air Modeling Risk Estimates

There are no appreciable changes to the overall assessment conclusion using a POD of 0.3 ppm for indoor air scenarios. However, for completeness, EPA is providing risk estimates using the POD of 0.3 ppm (370 μg/m^3) and a benchmark MOE of 1.

The Agency used CEM and Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) to estimate formaldehyde concentrations in the indoor environment. The exposure concentration estimates derived from CEM were based on safety data sheets (SDSs) identified in the Use Report for Formaldehyde (CAS RN 50-00-0) and Paraformaldehyde (CAS RN 30525-89-4) with updated Information from: Chemical Data Reporting (2016–2019), Toxics Release Inventory (2020), and Clean Water Act permit discharges (2021). Additional searches were also conducted to identify and refine the chemical concentration of formaldehyde in article formulation for the assessed COUs. In contrast, formaldehyde concentration estimates derived from IECCU are based on emission factors identified through readily available literature as explained in the *Risk Evaluation for Formaldehyde – Systematic Review Protocol* (U.S. EPA, 2024f). All indoor air exposure concentration estimates can be found in the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d).

Acute risk estimates for indoor air exposures are based on 15-minute peak formaldehyde concentrations from passive use of consumer articles. These exposures ranged from 5.4×10^{-5} to 1.2×10^{-1} ppm (0.007–142 μg/m^3). The highest modeled (non-aggregate) exposures are reported for the following COUs: Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; Metal articles; and Stone, plaster, cement, glass and ceramic articles.

These concentrations are lower than the acute inhalation POD of 0.3 ppm (370 µg/m^3) with MOEs ranging from 2.6 to 52,638 for indoor residential settings (Revised Figure 4-7). Consequently, no risk estimates fall below the benchmark MOE.



Revised Figure 4-74. Acute Inhalation MOE for Indoor Air

~~Indoor air concentrations modeled for specific COUs provide an indication of the contributions of individual COUs to formaldehyde exposure and risk. EPA estimated chronic non-cancer risks based on formaldehyde concentrations modeled based on long-term emissions associated with specific COUs, as described in 2.3.1. The modeled air concentrations used as the basis for chronic risk estimates for indoor air were designed to estimate concentrations at the central tendency. As described in the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j), there is substantial uncertainty related to the degree of dissipation of formaldehyde over time and how exposures from specific products change over the course several years. For this reason, EPA has low confidence in exposure estimates modeled over longer than a year for specific TSCA COUs contributing to formaldehyde in indoor air. EPA therefore did not calculate cancer risk based on chronic indoor air exposures resulting from specific TSCA COUs. Figure 4-11 summarizes chronic non-cancer risk estimates and Figure 4-12 summarizes cancer risk estimates based on modeled average indoor air concentrations estimated to result from specific TSCA COUs over the course of the first year of product use.~~

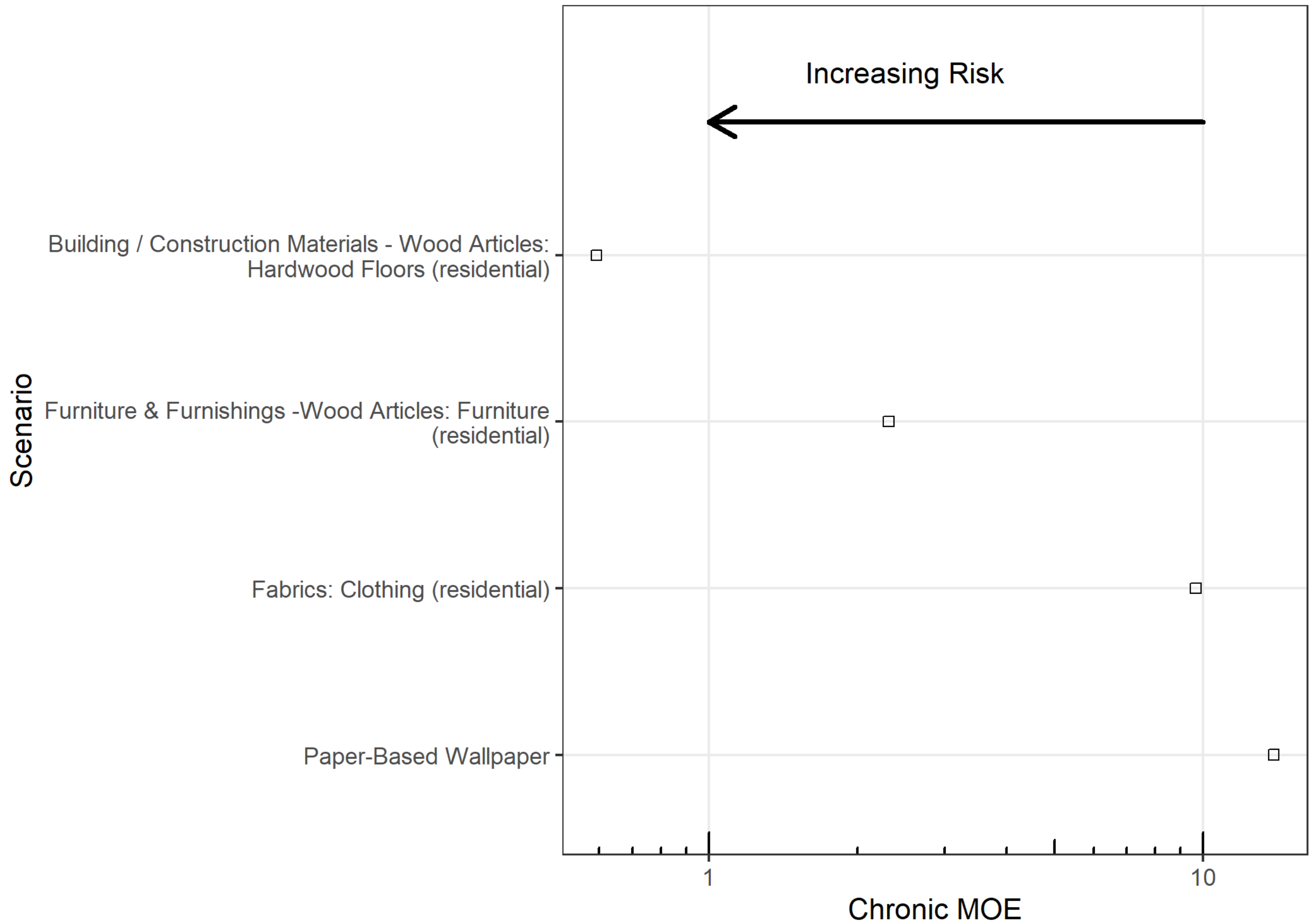


Figure 4-8. Chronic Non-cancer Inhalation Risk Based on CEM-Modeled Air Concentrations for Specific TSCA COUs

Chronic non-cancer risk estimates for TSCA COU representative scenarios presented in Figure 4-8 are calculated using exposures estimates based on CEM modeling and the chronic POD based on respiratory effects. Based on indoor air concentrations modeled for specific COUs, non-cancer risk estimates range from 5.92×10^{-1} to $1.39\times10^{+1}$ across all scenarios. Hardwood floors and wood furniture estimated chronic non-cancer risk risks were below 3 which indicate that exposure is greater than the level of exposure associated with the benchmark MOE. Lower MOE values indicate greater risks.

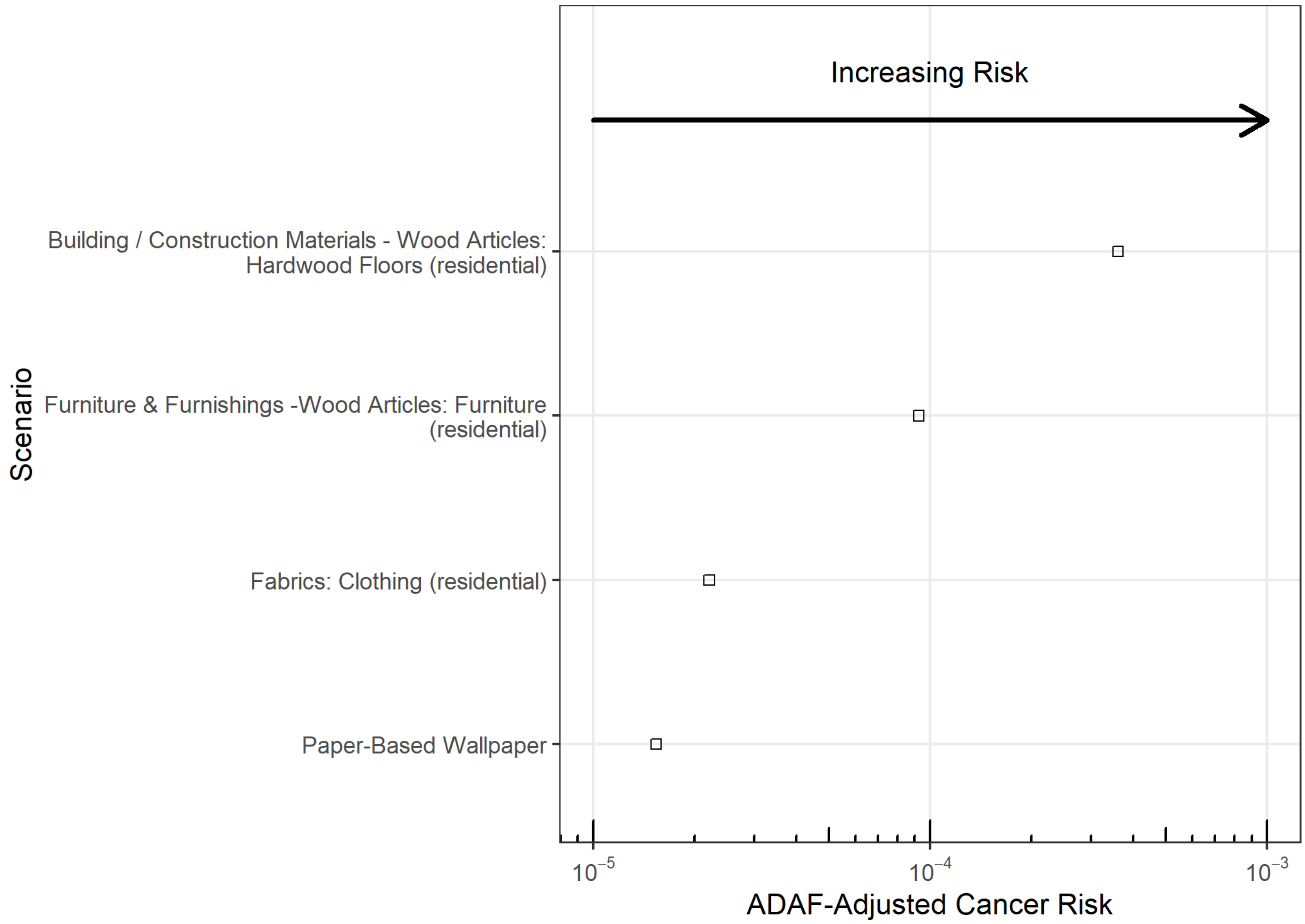


Figure 4-9. Cancer Inhalation Risk Based on CEM-Modeled Air Concentrations for Specific TSCA COUs

Cancer risk estimates are presented in Figure 4-9 for representative scenarios. Cancer risk estimates range from 1.54×10^{-5} to 3.61×10^{-4} across all scenarios. All modeled TSCA COUs', including wood articles, furniture covers and paper-based wallpaper, indoor air cancer risks were greater than 1 in 1,000,000 across all exposure scenarios. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*. These risk estimates account for dissipation that occurs over time due to the depletion of formaldehyde from the article and air exchange but do not account for the half-life of formaldehyde.

In general, EPA has medium confidence in IECCU's ability to assess formaldehyde chronic non-cancer ~~and cancer~~ risks in indoor air. Medium quality studies were used to incorporate TSCA COU-specific emission rates in IECCU. EPA used high quality CEM modeling data inputs to generate TSCA COU-specific indoor air concentrations, and comparability between modeled outputs and residential indoor air monitoring data. The inability to account for a first-order decay decreased confidence in overall inhalation risk estimates for indoor air. For this reason, risk estimates using CEM may be conservative relative to IECCU. Therefore, it is unclear whether the modeling results are reflective of most indoor air home environments in American residences. As described in Section 3.2, EPA has high confidence in the chronic POD based on respiratory effects ~~and medium confidence in the cancer IUR~~.

4.2.3.3 IECCU Indoor Air Risk Estimates

EPA used IECCU to estimate acute (15-minute peak), intermediate (3-month average), and chronic non-cancer (1-year average)~~, and cancer (lifetime)~~ risks for exposure to formaldehyde in indoor air associated with specific TSCA COUs, as described in 2.3.1. Through IECCU modeling, EPA considered decay rate of formaldehyde and the estimated concentrations are within the same order of magnitude as the AHHS II monitoring data. Below are the IECCU indoor air modeling risk estimates for acute (Section 4.2.3.4), intermediate (Section 4.2.3.5), chronic non-cancer and cancer (Section 4.2.3.6).

4.2.3.4 IECCU Indoor Air Acute Risk Estimates

EPA estimated acute (15-minute peak), risks for exposure to formaldehyde in indoor air. For this analysis, indoor air concentrations modeled for specific COUs provide an indication of the contributions of individual COUs to formaldehyde exposure and risk within 15 minutes of installing an article into the home. Figure 4-10 summarizes acute indoor air risk estimates for formaldehyde according to TSCA COUs.

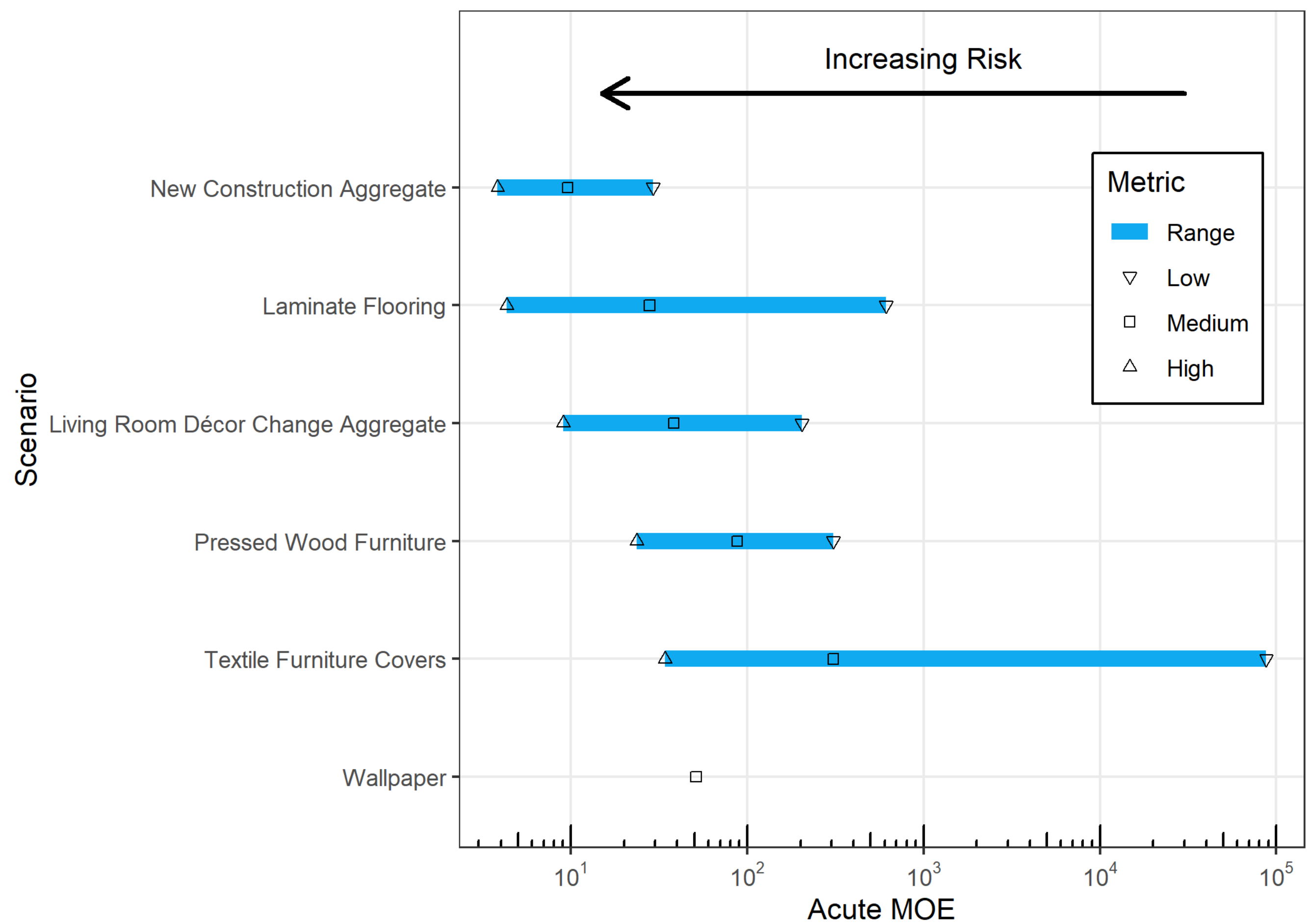


Figure 4-10. Acute Inhalation Risk Based on IECCU Modeled Air Concentrations for Specific TSCA COUs

Acute non-cancer risk estimates for TSCA COU representative exposure scenarios, presented in Figure 4-10, are based on air concentrations modeled in IECCU and the acute POD for sensory irritation reported in controlled human exposure studies in healthy adult volunteers. Acute risk estimates based on indoor air concentrations of all modeled individual scenarios range from 4.3 to 87,730 and from 3.8 to

204.7 for aggregate scenarios (as described in Table 2-5 of the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j)). Acute risk estimates below 3 indicate that exposure is greater than the level of exposure associated with benchmark MOE. Lower MOE values indicate greater risks.

In general, EPA has high confidence in IECCU's ability to assess formaldehyde acute risks in indoor air. Medium quality studies were used to incorporate TSCA COU-specific emission rates in IECCU. EPA used high quality IECCU modeling data inputs (*i.e.*, article-specific emission rates and building environmental inputs including building volumes, ventilation rates, and interzonal air flows from CEM for improved comparability with CEM results) to generate TSCA COU-specific indoor air concentrations, and comparability between modeled outputs and residential indoor air monitoring data. As described in Section 3.2, EPA has high confidence in the acute inhalation POD based on evidence in healthy adult volunteers in controlled exposure conditions.

4.2.3.5 IECCU Indoor Air Intermediate Risk Estimates

EPA estimated intermediate (3-month average) risks for exposure to formaldehyde in indoor air. For this analysis, indoor air concentrations modeled for specific COUs provide an indication of the contributions of individual COUs to formaldehyde exposure and risk within 3-months of installing an article into the home. Figure 4-11 summarizes intermediate indoor air risk estimates for formaldehyde according to TSCA COUs.

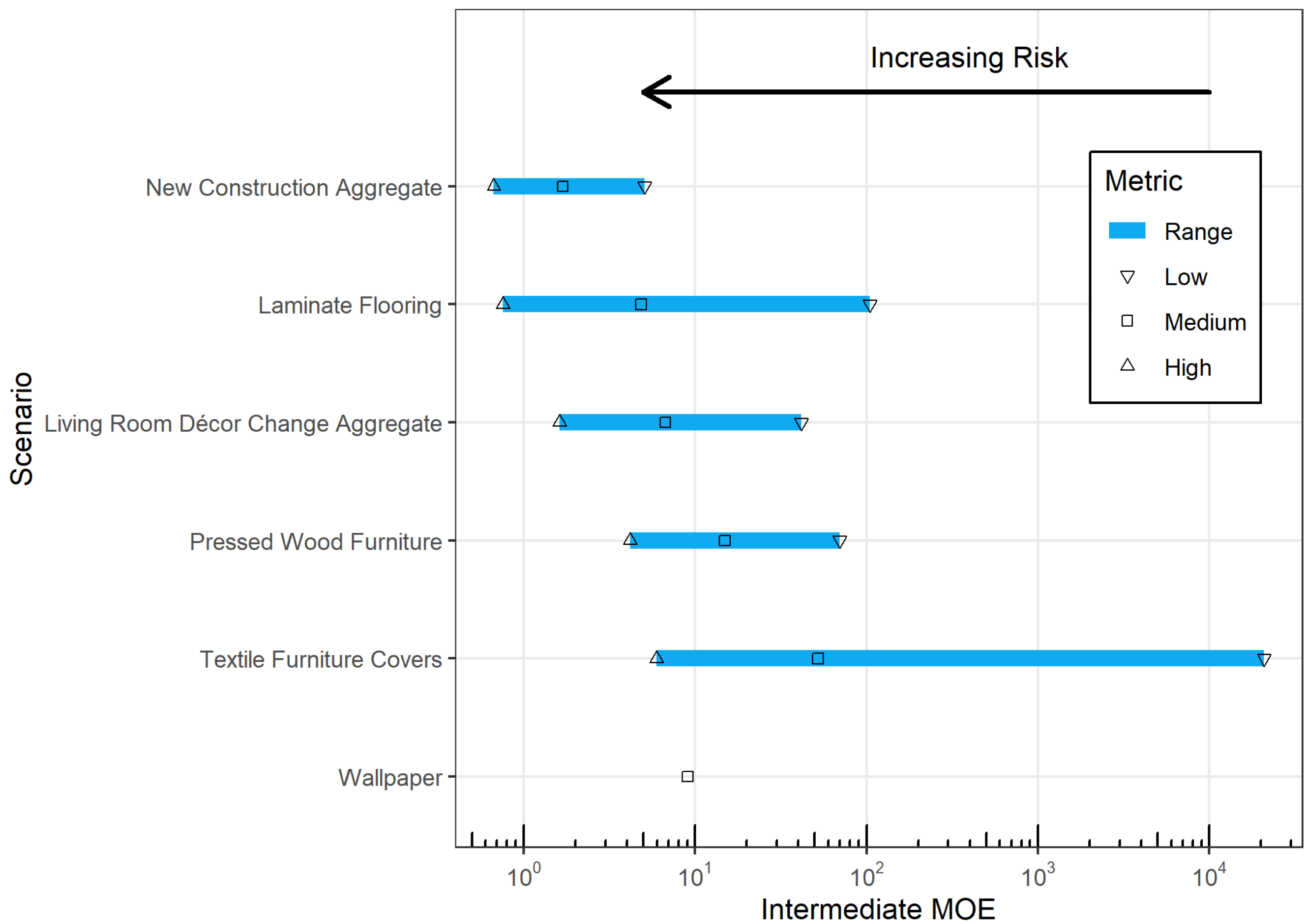


Figure 4-11. Intermediate Non-cancer Inhalation Risk Based on IECCU-Modeled Air Concentrations for Specific TSCA COUs

Intermediate non-cancer risk estimates for all representative exposure scenarios, presented in Figure 4-11, are calculated using exposures estimates based on IECCU modeling and the chronic non-cancer POD based on respiratory effects. Intermediate non-cancer risk estimates range from 6.7×10^{-1} to $2.1\times10^{+4}$ across all individual scenarios, and from 0.7 to 41.8 for aggregate scenarios. Intermediate risk estimates below 3 indicate that exposure is greater than the level of exposure associated with the benchmark MOE . Lower MOE values indicate greater risks. These risk estimates account for dissipation that occurs over time due to the depletion of formaldehyde from the article and air exchange and account for the exponential decay of formaldehyde.

In general, EPA has high confidence in IECCU's ability to assess formaldehyde intermediate non-cancer risks in indoor air. Medium quality studies were used to incorporate TSCA COU-specific emission rates in IECCU. EPA used high quality IECCU modeling data inputs (*i.e.*, article-specific emission rates and building environmental inputs including building volumes, ventilation rates, and interzonal air flows from CEM for improved comparability with CEM results) to generate TSCA COU-specific indoor air concentrations, and comparability between modeled outputs and residential indoor air monitoring data. As described in Section 3.2, EPA has high confidence in the chronic POD based on respiratory effects.

4.2.3.6 IECCU Indoor Air Chronic Risk Estimates

EPA estimated chronic non-cancer (1-year average)~~, and cancer (lifetime)~~ risks for exposure to formaldehyde in indoor air. For this analysis, indoor air concentrations modeled for specific COUs provide an indication of the contributions of individual COUs to formaldehyde indoor air exposure and risks over one year or lifetime. Figure 4-12 summarizes chronic non-cancer indoor air risk estimates~~, while Figure 4-16 summarizes cancer indoor air risk estimates~~ for formaldehyde according to TSCA COUs.

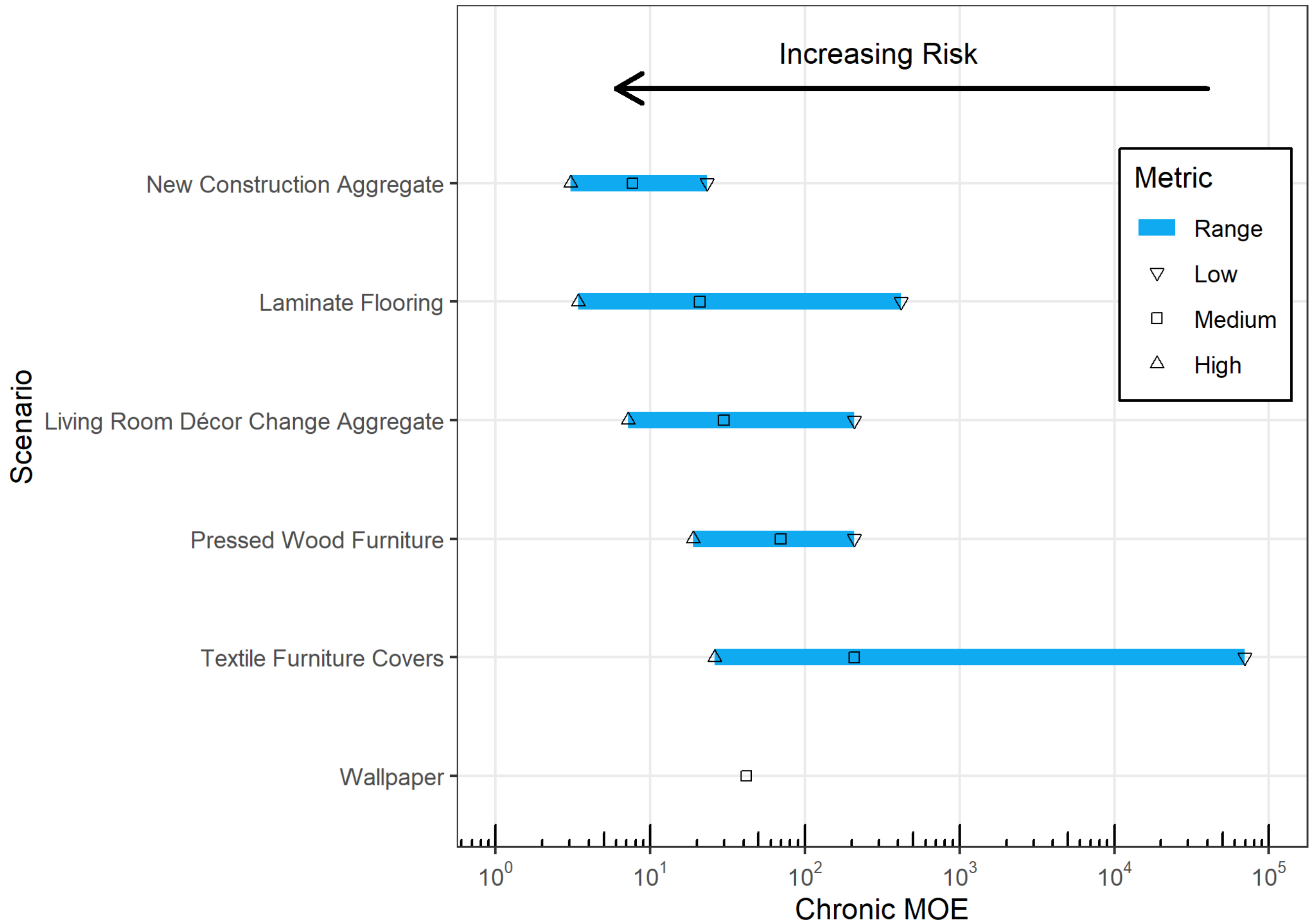


Figure 4-12. Chronic Non-cancer Inhalation Risk Based on IECCU-Modeled Air Concentrations for Specific TSCA COUs

Chronic non-cancer risk estimates for representative exposure scenarios, presented in Figure 4-12, are calculated using exposures estimates based on IECCU modeling and the chronic POD based on respiratory effects. Chronic non-cancer risk estimates range from 3.42×10^{0} to $6.96\times10^{+4}$ across all single scenarios, and $3.04\times10^{+0}$ to $2.09\times10^{+2}$ for aggregate scenarios. Chronic non-cancer risk estimates below 3 indicate that exposure is greater than the level of exposure associated with the benchmark MOE.

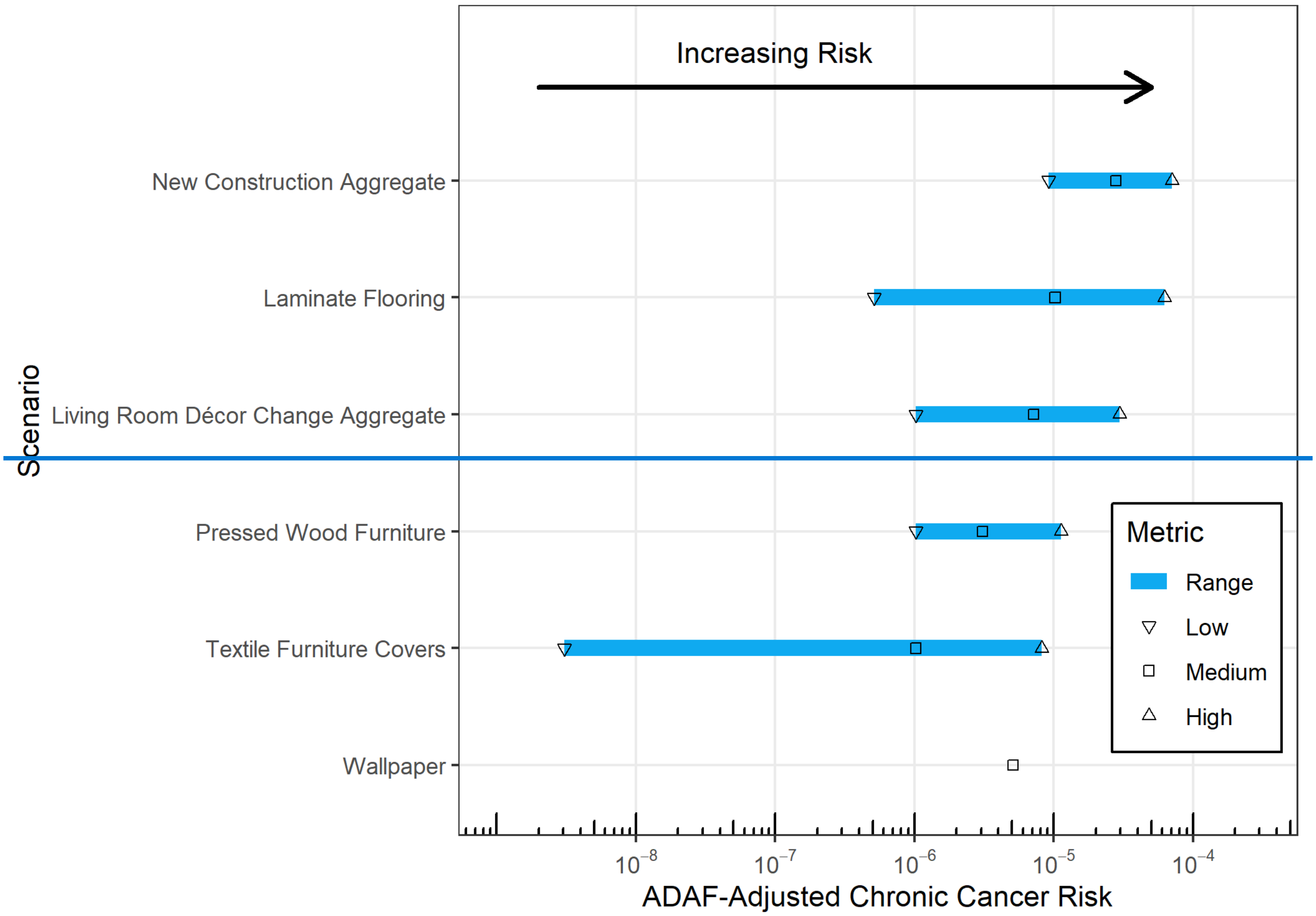


Figure 4-16. Cancer Inhalation Risk Based on IECCU-Modeled Air Concentrations for Specific TSCA COUs

Cancer risk estimates for representative exposure scenarios are presented in Figure 4-16. Cancer risks range from 3.07×10^{-9} to 6.24×10^{-5} across all individual scenarios, and 1.02×10^{-6} to 7.02×10^{-5} for aggregate scenarios. All medium and high-end modeled individual TSCA COUs', including wood articles, furniture covers and wallpaper, indoor air cancer risks were greater than 1 in 1,000,000. The indoor air cancer risks for both modeled aggregate scenarios, based on TSCA COUs, were greater than 1 in 1,000,000. All risk estimates including for all exposure scenarios evaluated are provided in the *Supplemental file: Consumer – Indoor Air Acute and Chronic Inhalation Risk Calculator*. These risk estimates account for dissipation that occurs over time due to the depletion of formaldehyde from the article and air exchange and account for the exponential decay of formaldehyde.

In general, EPA has medium confidence in IECCU's ability to assess formaldehyde chronic non-cancer and cancer risks in indoor air. Medium quality studies were used to incorporate TSCA COU-specific emission rates in IECCU. EPA used high quality IECCU modeling data inputs (*i.e.*, article-specific emission rates and building environmental inputs including building volumes, ventilation rates, and interzonal air flows from CEM for improved comparability with CEM results) to generate TSCA COU-specific indoor air concentrations, and comparability between modeled outputs and residential indoor air monitoring data. The ability to account for a first-order decay, as noted in the literature (Jung and Mahmoud, 2022), increased confidence in overall inhalation risk estimates for indoor air. However, EPA has medium confidence in the applicability of the modeling results used to assess long-term indoor air risks to formaldehyde because, similar to the CEM modeling, it is unclear whether the modeling results are reflective of most indoor air home environments in American residences. Chamber study data submitted from industry showed a biphasic emission profile (rapid emission of formaldehyde when the product is new followed by a much slower emission of formaldehyde) for laminated wood products that is not captured in the modeling results. This biphasic emission profile may also occur for other urea-formaldehyde based products; however, data are not available to confirm this. For this reason, it is possible that IECCU modeled estimates underestimated actual chronic risks in indoor air. ~~As described in Section 3.2, EPA has high confidence in the chronic POD based on respiratory effects and medium confidence in the cancer IUR.~~

4.2.4 Risk Estimates for Ambient Air

EPA evaluated short-term (acute) and long-term (chronic non-cancer~~ and cancer~~) risks resulting from human exposure to formaldehyde via the ambient air pathway, inhalation route using previously peer-reviewed methodologies and considering multiple lines of evidence. These methodologies and lines of evidence include evaluating releases from two separate databases (TRI and NEI) using several peer-reviewed models (IIOAC, HEM, AirToxScreen), and consideration of ambient monitoring data from EPA's AMTIC archive. summarizes the risk estimates based on all the results identified by EPA for several of these lines of evidence. A description of each line of evidence and the associated risk estimates included in is provided below.

EPA recognizes that the risk estimates from the various lines of evidence presented in are not directly comparable due to spatial and temporal differences, as described in Section 2.4.3 and the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). These risk estimates are conservative and have some uncertainties at the local scale as previously described. In summary, ambient air modeling for formaldehyde does not account atmospheric degradation (i.e. photolysis) and how local weather patterns may affect the presence of formaldehyde over time. Furthermore, the assumption that individuals reside in the same location for the duration of their life (i.e. 78 years) is conservative.

~~4.2.4.1 Risk Estimates Based on Ambient Air Monitoring~~

~~There is abundant monitoring data on formaldehyde in ambient air. As described in Section 2.4.1, monitoring data from EPA's AMTIC archive (U.S. EPA, 2022a) include a range of air monitoring data collected across the country under a variety of experimental designs and across heterogenous environments.~~

~~Considering the ubiquity of formaldehyde in the ambient air and the diversity of sources contributing to the monitored concentration at each monitoring site, EPA considers the AMTIC dataset reflective of the range of total aggregate formaldehyde concentrations in a variety of outdoor environments attributable to TSCA COUs and all other sources of formaldehyde (including biogenic sources and secondary formation). As such, the risk estimates based on the AMTIC data provide an indication of the total aggregate risk from all sources contributing to ambient air concentrations of formaldehyde which may be present in the real world. Additionally, EPA expects the monitoring data would be inclusive of all independent sources contributing to formaldehyde in the ambient air (*i.e.*, show the additive nature of each independent contributor to the total aggregate concentration of formaldehyde and associated risks).~~

~~EPA calculated chronic cancer risks based on air concentrations reported in AMTIC across 6 years and summarizes this data at the top of Figure 4-17. These risk estimates rely on the assumption that monitored concentrations represent a chronic exposure to a single individual over a lifetime. Since this monitoring data captures a snapshot of air concentrations at a single timepoint, there is uncertainty around the extent to which the available monitoring data are accurate representations of long-term~~

chronic exposures. Furthermore, this data set is not reflective of national emission standards recently enacted under the Clean Air Act for industrial manufacturing facilities (i.e. Hazardous Organic National Emission Standards for Hazardous Air Pollutants) or the updated multi-pollutant emission standards for light-duty and medium-duty vehicles.

The overall AMTIC dataset had risk estimates ranging from 0 to 6.11×10^{-4} with a median of 1.63×10^{-5} and a mean risk estimate of 2.1×10^{-5} [± 2.2 μg/m^3].

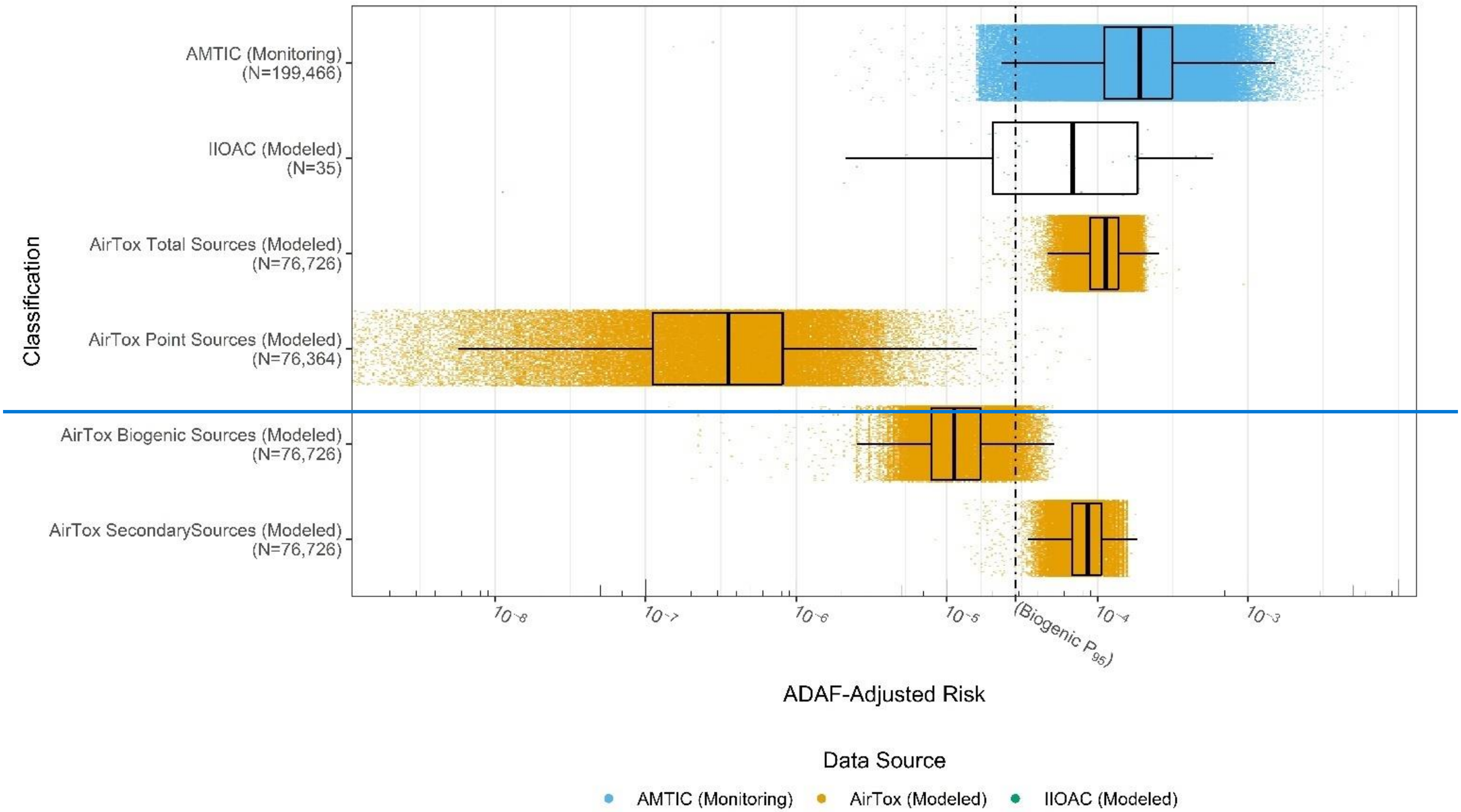


Figure 4-17. ADAF-Adjusted Cancer Risk for Monitoring and Modeling Ambient Air Data

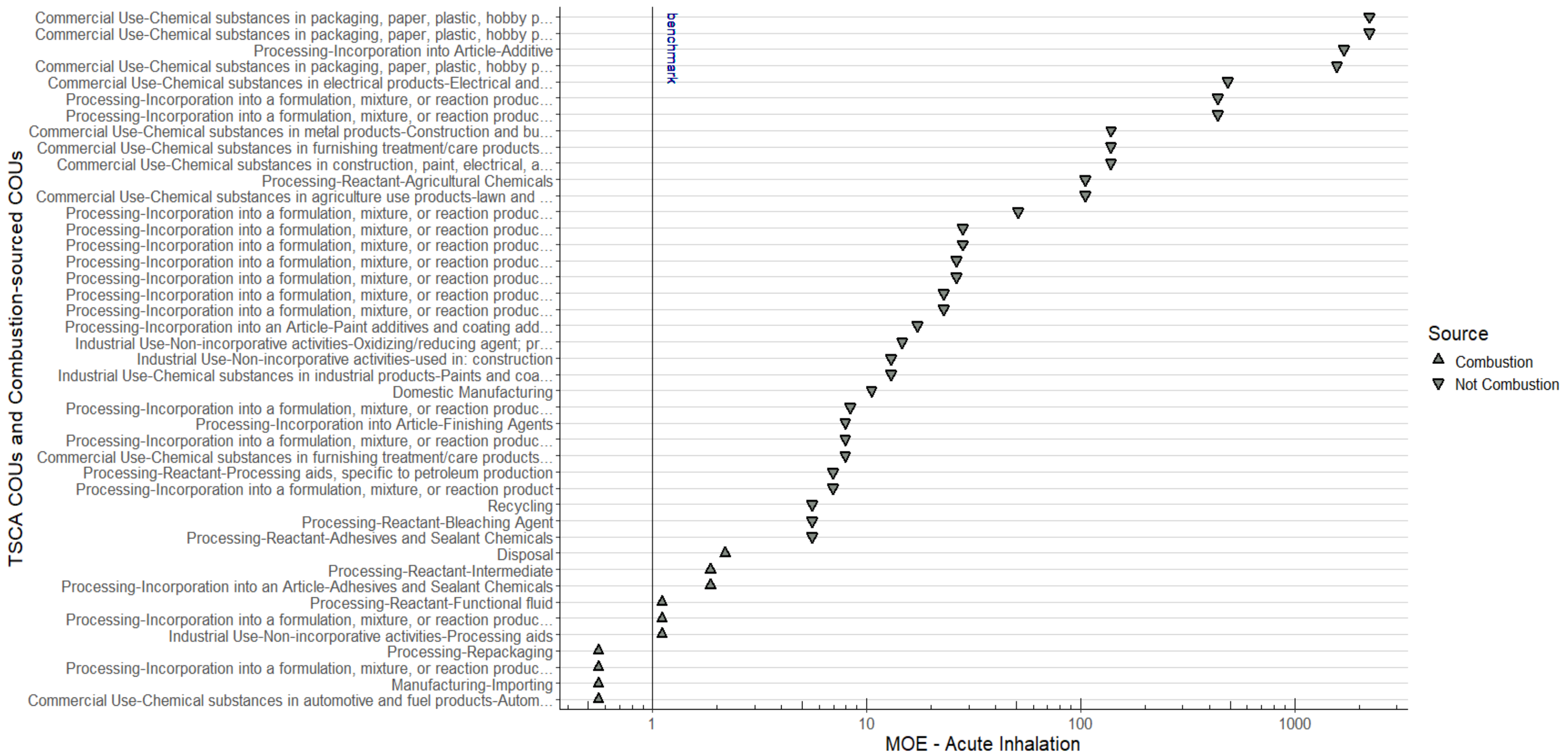
~~4.2.4.2~~4.2.4.1 Risk Estimates Based on Modeled Concentrations near Releasing Facilities

In the final RE, the Agency did not determine that acute exposure to formaldehyde in ambient air resulting from COUs would significantly contribute to the unreasonable risk of formaldehyde. As such, there are no appreciable changes to the overall assessment conclusions using a POD of 0.3 ppm. However, for transparency risk estimates using the POD of 0.3 ppm (370 μg/m^3) and a benchmark MOE of 1 are reported.

Acute risk estimates for ambient air for COUs and combustion are based on the maximum release scenarios and the 95th percentile of modeled daily average exposure concentrations 100 m from a releasing facility. The Agency uses these high-end, daily average modeled concentration as this period is the shortest time step modeled by the Integrated Indoor-Outdoor Air Calculator's (IIOAC) and used as a surrogate for a 15-minute exposure. EPA describes its assumptions associated with using daily average concentration as a surrogate for 15-minute exposure and possible over or underestimation of exposures and associated risks in the final RE. Ambient air concentrations ranged from 0.0004 to 66.2 μg/m^3 and 61 to 662 μg/m^3. The highest modeled daily average exposures attributable to COUs are associated with wood product manufacturing and paper manufacturing industry sectors. Daily average exposures primarily attributable to combustion sources, such as airplanes, on-site vehicles, process heaters, turbines, and reciprocating internal combustion engines (RICE) ranged from 2 to 662 μg/m^3. The highest of these concentrations were estimated for Wholesale and Retail Trade as well as the Oil and Gas Drilling, Extraction, and Support Activities industry sectors.

The acute risk estimates, utilizing an acute inhalation POD of 0.3 ppm (370 μg/m^3) and a benchmark MOE of 1 for COUs from non-combustion sources, range from 5.5 to 2,239 (Revised Figure 4-13). These risk estimates are above the benchmark of 1.

Risk estimates for combustion sources range from 0.6 to 2. MOEs for Industrial use – non-incorporative activities – processing aids, Processing – incorporation into an article – adhesives and sealant chemicals, and Processing – reactant – functional fluids COUs are no longer below the benchmark. Risk estimates for Commercial use – chemical substances in automotive and fuel products – automotive care products, lubricants and greases, fuels and related products; Manufacturing – importing; Processing – incorporation into a formulation, mixture, or reaction product – intermediate; and Processing – repackaging COUs are below the benchmark.



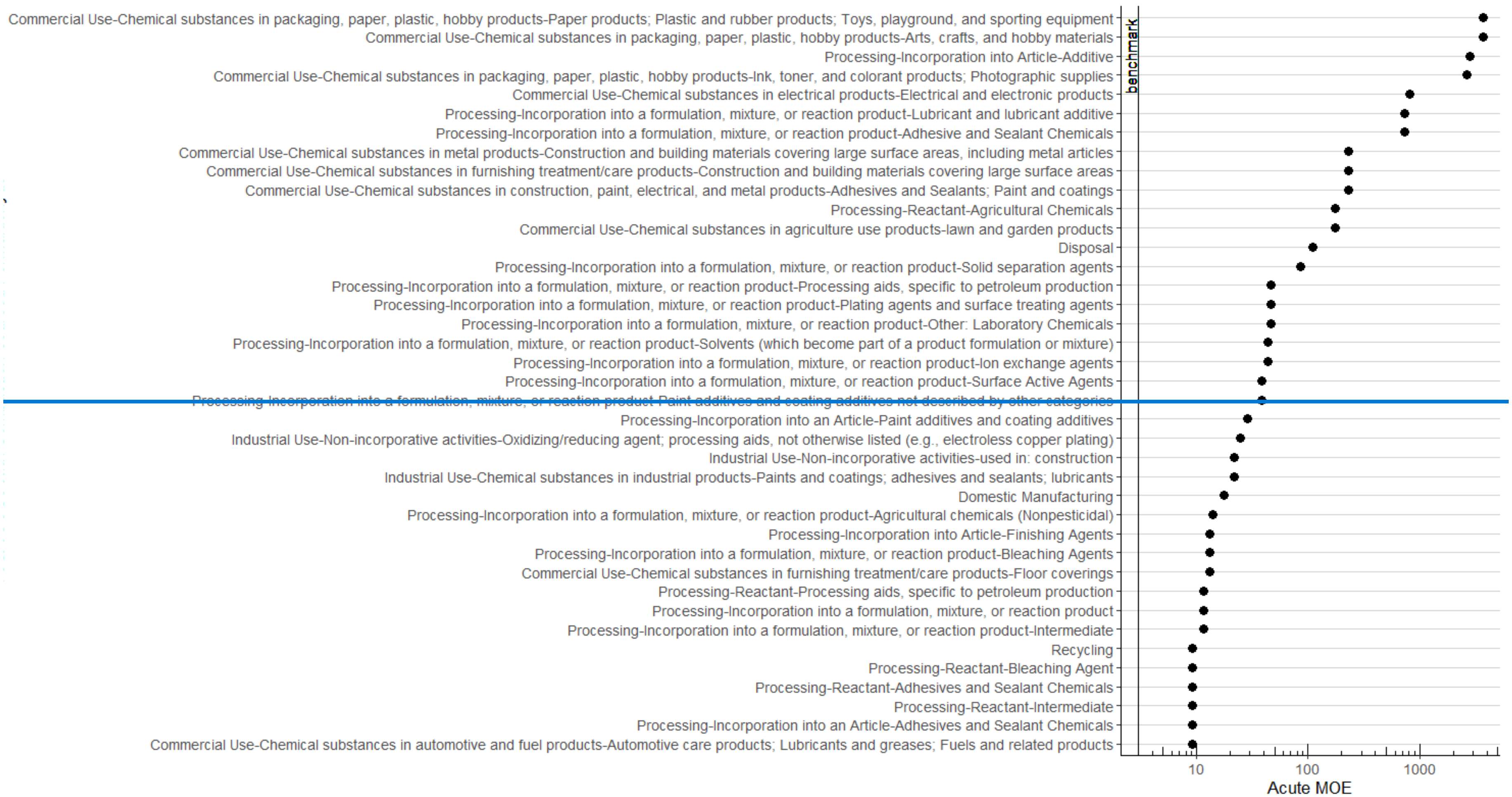
Revised Figure 4-13. Acute Inhalation MOE for Outdoor Air

4.2.4.3 Short-Term Risk Estimates for Ambient Air

Short-term risk estimates for ambient air in this assessment are based on the maximum release scenario and the 95th percentile modeled daily average exposure concentrations at 100 meters from a releasing facility as described in Section 2.4.2.1.1 and the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). EPA separately presents short-term risk estimates for exposures primarily attributable to the COUs and combustion in this assessment.

Short-term risk estimates based on IIOAC modeled results attributable to the COUs range from 9 to 3,732 and are presented in Figure 4-18. These values represent the highest risk estimates across all industry sectors cross-walked to the same COU. EPA found zero acute non-cancer risk estimates below the acute benchmark MOE of 3 for exposures primarily attributable to the COUs. The top five acute non-cancer risk estimates representing the highest risks which are linked to the COUs are provided in Table 4-2.

The first two columns in Table 4-2 include information on the industry sector and the industry sector crosswalk to TSCA COUs. The release dataset column notes the source of the reported data, either TRI or NEI. The fugitive and stack columns provide the industry reported source apportioned release values which were used as direct inputs to the IIOAC model. The acute risk estimate column presents the risk estimates derived from the sum of the modeled exposure results for fugitive and stack releases at 100 meters from a releasing facility.



~~**Figure 4-18. Acute Risk Estimates based on Estimated Daily Concentrations by TSCA COU for the Maximum Release Scenario and 95th Percentile Modeled Concentration at 100 m from Industrial Facilities Releasing Formaldehyde**~~

Table 4-2. Top Five Acute Non-cancer Risk Estimates Indicating the Highest Risks Attributable to TSCA COUs

Industry Sector	COUs	Maximum Release Value (kg/year)			Acute Risk Estimate
		Release Dataset	Fugitive	Stack	
Wood Product Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	NEI	9,774	157,547	9
	Processing-Incorporation into an Article-Adhesives and Sealant Chemicals				
	Processing-Reactant-Adhesives and Sealant Chemicals				
	Processing-Reactant-Bleaching Agent				
	Processing-Reactant-Intermediate				
	Recycling				
Paper Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	NEI	11,585	23,929	11
	Processing-Incorporation into an Article-Adhesives and Sealant Chemicals				
	Processing-Reactant-Intermediate				
	Recycling				
All Other Basic Organic	Commercial Use-Chemical substances in automotive and fuel products-Automotive care	NEI	11,036	9,053	12

Industry Sector	COUs	Maximum Release Value (kg/year)			Acute Risk Estimate
		Release Dataset	Fugitive	Stack	
Chemical Manufacturing	products; Lubricants and greases; Fuels and related products				
	Processing-Incorporation into a formulation, mixture, or reaction product				
	Processing-Incorporation into a formulation, mixture, or reaction product-Intermediate				
	Processing-Reactant-Adhesives and Sealant Chemicals				
	Processing-Reactant-Intermediate				
	Processing-Reactant-Processing aids, specific to petroleum production				
Textiles, Apparel, and Leather Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	TRI	9,347	18,644	14
	Commercial Use-Chemical substances in furnishing treatment/care products-Floor coverings; …				
	Processing-Incorporation into a formulation, mixture, or reaction product-Bleaching Agents				
	Processing-Incorporation into Article-Finishing Agents				
Pesticide, Fertilizer, and	Commercial Use-Chemical substances in automotive and fuel products-Automotive care	TRI	8,922	15,588	14

Industry Sector	COUs	Maximum Release Value (kg/year)			Acute Risk Estimate
		Release Dataset	Fugitive	Stack	
Other Agricultural Chemical Manufacturing	products; Lubricants and greases; Fuels and related products				
	Processing-Incorporation into a formulation, mixture, or reaction product-Agricultural chemicals (Nonpesticidal)				
	Processing-Reactant-Intermediate				

~~Short-term risk estimates based on IIOAC modeled results attributable to combustion range from 1 to 4 and are presented in Table 4-2. These values represent the risk estimates indicating the highest risk within each industry sector. EPA found two of the top five acute non-cancer risk estimates below the acute benchmark MOE of 3 for exposures primarily attributable to combustion.~~

~~The first three columns of Table 4-3 include information on the industry sector, site reporting the fugitive and stack releases, and the major process unit source(s) from which those releases came. The release dataset column notes the source of the reported data, either TRI or NEI. The fugitive and stack columns provide the industry reported source apportioned release values which were used as direct inputs to the IIOAC model. The acute risk estimate column presents the risk estimates derived from the sum of the modeled exposure results for fugitive and stack releases at 100 meters from a releasing facility.~~

~~As previously described in Section 2.4.2.1.1, the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and shown in Table 4-3, all the maximum releases within each of the top five industry sectors are from combustion sources like airplanes, on-site vehicles, process heaters, turbines, and RICE. The modeled concentrations used to derive the associated estimates are much higher than the highest concentrations found with the AMTIC, HEM, and 2019 AirToxScreen datasets. EPA's deeper dive into these high values showed that the highest 95th percentile releases evaluated for this assessment were at least 1 to 2 orders of magnitude lower than the maximum releases within the same industry sector. Based on the additional investigation/deeper dive into the highest maximum reported releases, EPA concludes these facilities are likely outliers within their respective industry sectors and not representative of national level releases within the respective industry sectors for TSCA purposes. Nonetheless, the risk estimates are provided for transparency and may inform other EPA programs.~~

Table 4-3. Top Five Acute Non-cancer Risk Estimates Indicating the Highest Risks Attributable to Combustion

Industry Sector	Facility (County, State)	Major Process Unit Source(s)	Maximum Release Value (kg/year)			Acute Risk Estimate
			Release Dataset	Fugitive	Stack	
Wholesale and Retail Trade	Columbus AF Base (Lowndes, MS)	Aircrafts	NEI	138,205		1
	Transcontinental Gas Pipeline Company, LLC (Henry, GA)	RICE, Turbines			95,159	
Oil and Gas Drilling, Extraction, and Support Activities	Chevron USA Inc. (Kern, CA)	Process heaters, RICE, Turbines	NEI	22,742		2
	Frenchie Draw Central Compressor Station (Fremont, WY)	RICE			1,412,023	
Non-Metallic Mineral Product Manufacturing	Cemex Black Mountain Quarry Plant (San Bernardino, CA)	On-Site Vehicles	NEI	41,190		3
	Thermafiber Inc (Wabash, IN)	Not reported			36,492	
Services	Pope Airforce Base (Cumberland, NC)	Aircrafts	NEI	34,155		4
	Seneca Energy LFGTE Facility (Seneca, NY)	RICE			63,483	
Utilities	Lorain County LFG Power Station (0247100968) (Lorain, OH)	RICE	NEI	10,108		10
	Basin Creek Power Services (Silver Bow, MT)	RICE			101,968	

~~4.2.4.4~~4.2.4.2 Long-Term Risk Estimates for Ambient Air

Long-term risk estimates for ambient air in this assessment are based on the 95th percentile release scenario and the 95th percentile modeled annual average exposure concentrations within the area distance of 100 to 1,000 meters from a releasing facility as described in Section 2.4.2.1.2 and the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). Long-term risk estimates are derived for both chronic non-cancer effects and cancer in this assessment.

Long-term risk estimates based on IIOAC modeled results for chronic non-cancer effects range from 4 to 10,180 and are presented in Figure 4-14. These values represent the highest risk estimates across all industry sectors cross-walked to the same COU. EPA found zero chronic non-cancer risk estimates below the chronic benchmark MOE of 3 for exposures primarily attributable to TSCA COUs. The top five chronic non-cancer risk estimates representing the highest risks which are linked to the COUs are provided in Table 4-2.

Figure 4-14. Chronic Non-cancer Risk based on Modeled Annual Average Air Concentrations Attributable to TSCA COUs

Table 4-2. Top Five Chronic Non-cancer Risk Estimates Indicating the Highest Risks Attributable to TSCA COUs

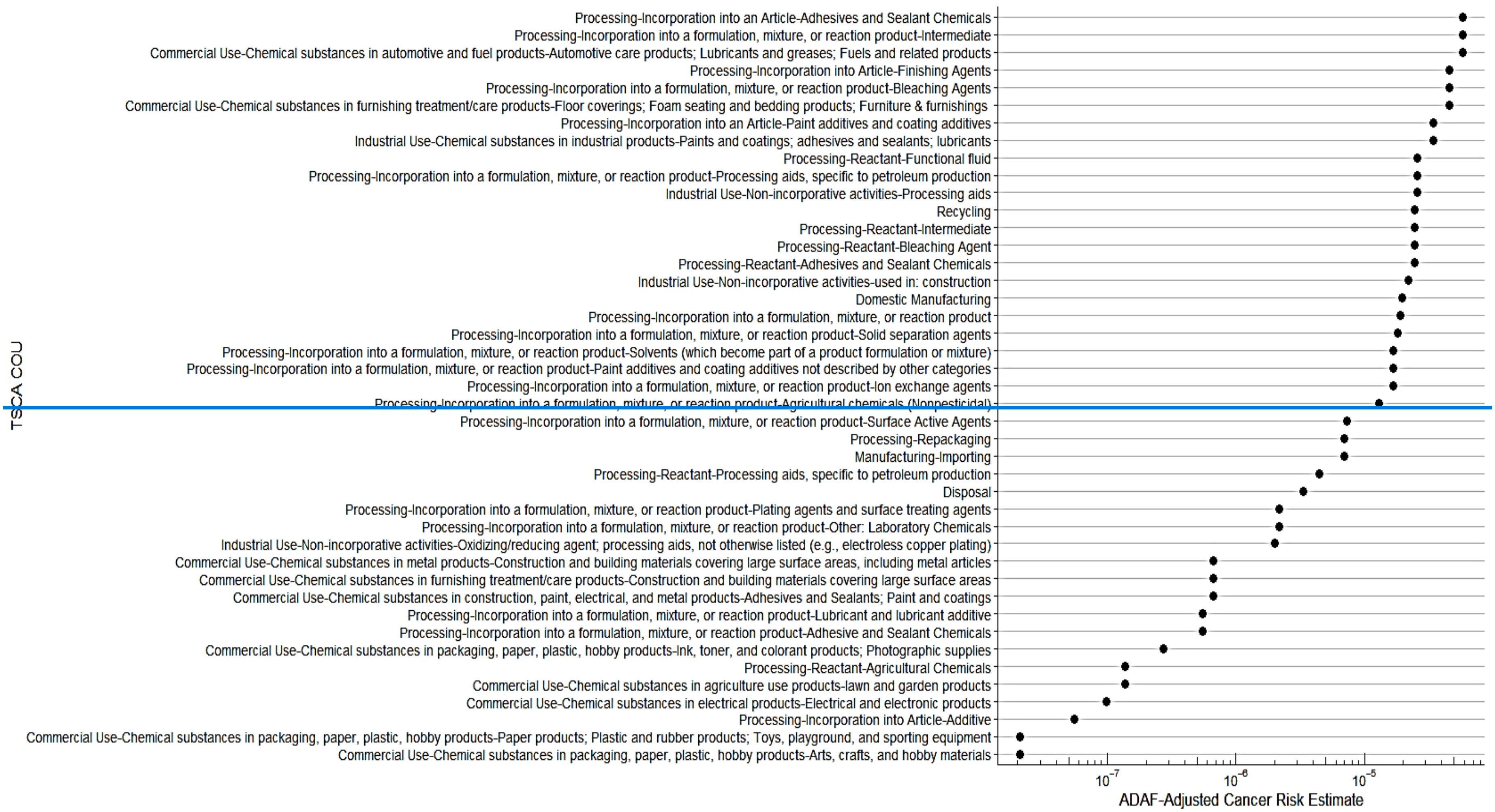
Industry Sector	COUs	Maximum Release Value (kg/year)			Chronic Risk Estimate
		Release Dataset	Fugitive	Stack	
Non-metallic Mineral Product Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	TRI	8,407	27,961	4
	Processing-Incorporation into a formulation, mixture, or reaction product-Intermediate				
	Processing-Incorporation into an Article-Adhesives and Sealant Chemicals				
	Processing-Reactant-Intermediate				
Textiles, Apparel, and Leather Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	TRI	8,042	3,315	5
	Commercial Use-Chemical substances in furnishing treatment/care products-Floor coverings; Foam seating and bedding products; Furniture & furnishings.				
	Processing-Incorporation into a formulation, mixture, or reaction product-Bleaching Agents				
	Processing-Incorporation into Article-Finishing Agents				
Transportation Equipment Manufaturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	TRI	3,146	40,823	6
	Industrial Use-Chemical substances in industrial products-Paints and coatings; adhesives and sealants; lubricants				
	Processing-Incorporation into an Article-Paint additives and coating additives				

Industry Sector	COUs	Maximum Release Value (kg/year)			Chronic Risk Estimate
		Release Dataset	Fugitive	Stack	
Oil and Gas Drilling, Extraction, and Support Activities	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	NEI	4,117	7,265	8
	Industrial Use-Non-incorporative activities-Processing aids				
	Processing-Incorporation into a formulation, mixture, or reaction product-Intermediate				
	Processing-Incorporation into a formulation, mixture, or reaction product-Processing aids, specific to petroleum production				
	Processing-Reactant-Functional fluid				
Wood Product Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products	NEI	3,807	7,9601	9
	Processing-Incorporation into an Article-Adhesives and Sealant Chemicals				
	Processing-Reactant-Adhesives and Sealant Chemicals				
	Processing-Reactant-Bleaching Agent				
	Processing-Reactant-Intermediate				
	Recycling				

Long-term risk estimates for cancer based on 95th percentile IIOAC modeled concentration results range from 2.1×10^{-8} to 5.9×10^{-5} and are presented in Figure 4-20. These values represent the highest risk estimates across all industry sectors cross-walked to the same COU. When comparing the derived risk estimates for cancer attributable to TSCA COUs to the three cancer benchmarks considered in this risk assessment, EPA found 31 TSCA COUs have cancer risk estimates greater than the cancer benchmark of 1×10^{-6}. EPA found 23 TSCA COUs with cancer risk estimates greater than the cancer benchmark of 1×10^{-5} and zero TSCA COUs with cancer risk estimates greater than the cancer benchmark of 1×10^{-4}. The top five cancer risk estimates representing the highest risks which are linked to the COUs are provided in Table 4-5.

Risk estimates derived from the 95th percentile IIOAC modeled concentrations fall within the lower range of the risk estimates derived from the AMTIC monitoring dataset. This is expected since the risk estimates derived from the 95th percentile IIOAC modeled concentrations represent localized impacts of industrial facilities associated with a TSCA COU while the risk estimates derived from the AMTIC monitoring dataset represent a total aggregate risk from all sources of ambient formaldehyde including TSCA COUs, secondary formation, biogenic sources, mobile sources, and other sources.

Overall, based on the results, the long-term risk estimates for cancer derived from the 95th percentile IIOAC modeled concentrations which are attributable to TSCA COUs, are generally representative of risks to individuals residing near industrial facilities releasing formaldehyde to the ambient air. This conclusion is supported by the comparison to the risk estimates derived from the AMTIC dataset. These conclusions assume individuals live within 1,000 meters of one or more industrial facilities releasing formaldehyde to the ambient air for a full 78-year lifetime.



~~Figure 4-20. Lifetime Risk Estimates for Cancer based on Modeled Annual Average Air Concentrations Attributable to TSCA COUs~~

Table 4-5. Top Five Cancer Risk Estimates Indicating the Highest Risks Attributable to TSCA COUs

Industry Sector	COUs	Maximum Release Value (kg/year)			Cancer Risk Estimate
		Release Dataset	Fugitive	Stack	
Non-metallic Mineral Product Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products Processing-Incorporation into a formulation, mixture, or reaction product-Intermediate Processing-Incorporation into an Article-Adhesives and Sealant Chemicals Processing-Reactant-Intermediate	TRI	8,407	27,961	5.9×10^{-5}
Textiles, Apparel, and Leather Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products Commercial Use-Chemical substances in furnishing treatment/care products-Floor coverings; Foam seating and bedding products; Furniture & furnishings. Processing-Incorporation into a formulation, mixture, or reaction product-Bleaching Agents Processing-Incorporation into Article-Finishing Agents	TRI	8,042	3,315	4.6×10^{-5}
Transportation Equipment Manufaturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products Industrial Use-Chemical substances in industrial products-Paints and coatings; adhesives and sealants; lubricants	TRI	3,146	40,823	3.5×10^{-5}

Industry Sector	COUs	Maximum Release Value (kg/year)			Cancer Risk Estimate
		Release Dataset	Fugitive	Stack	
Oil and Gas Drilling, Extraction, and Support Activities	Processing-Incorporation into an Article-Paint additives and coating additives Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products Industrial Use-Non-incorporative activities-Processing aids Processing-Incorporation into a formulation, mixture, or reaction product-Intermediate Processing-Incorporation into a formulation, mixture, or reaction product-Processing aids, specific to petroleum production Processing-Reactant-Functional fluid	NEI	4,117	7,265	2.6×10^{-5}
Wood Product Manufacturing	Commercial Use-Chemical substances in automotive and fuel products-Automotive care products; Lubricants and greases; Fuels and related products Processing-Incorporation into an Article-Adhesives and Sealant Chemicals Processing-Reactant-Adhesives and Sealant Chemicals Processing-Reactant-Bleaching Agent Processing-Reactant-Intermediate Recycling	NEI	3,807	7,9601	2.4×10^{-5}

4.2.4.5 Population Analysis for Cancer Risks using HEM

EPA used the HEM to help understand how modeled air concentrations (and associated risks) at the national level intersected with populated areas. The HEM is capable of estimating exposures to populations at one or more user-defined distance(s) from releasing facilities (out to 50,000 meters (approximately 31 miles)) and at the centroid of census blocks across the nation based on the most recent census data integrated into the HEM. When estimating exposures (in particular at the centroid of census blocks), the HEM results represent an aggregation of exposures from multiple nearby facilities (*e.g.*, facilities in proximity to others releasing formaldehyde to the ambient air).

EPA expands the population analysis to include the demographic characteristics of exposed populations who may be experiencing an increased cancer risk from industrial facilities releasing formaldehyde to the ambient air. This population and demographic analysis use the highest reported releases across six years of TRI data for each industrial facility reporting releases to TRI. EPA considers the same cancer benchmarks for this analysis as it does for the IIOAC modeling described in the previous section (see Section 4.2.4.4).

A full summary of estimated populations by level of risk estimate with stratification by demographics is presented in Table 4-6. For the demographic analysis, an individual is identified as one of five racial/ethnic categories: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category for these analyses. While population counts are summarized at the census block level, the demographic information is summarized by census block group, and applied to each census block within the census block group.

EPA's population analysis using HEM estimated a total population of 1,023,773 people experience a lifetime cancer risk of at least one in one million (1×10^{-6}). EPA's population analysis estimated 6,935 people were estimated to experience risk greater than 10 in 1 million (1×10^{-5}), and 19 were estimated to experience risk greater than 100 in 1 million (1×10^{-4}). No population was found with estimated risks exceeding 200 in 1 million.

Across the entire modeling domain, including census blocks within 50 km of any TRI facility reporting formaldehyde releases, the average risk to the entire population of 232,907,302 people was estimated to be 0.04 in 1 million. This average risk was slightly higher for the African American and Native American demographics included in the modeling, at an estimate of 0.06 in 1 million.

Table 4-6. Population Summary for Cancer Risk Estimates Derived from HEM Modeling of TRI Releases of Formaldehyde to Air

Range of Lifetime Individual Cancer Risk	Number of People within 50 km of any Facility in Different Ranges for Lifetime Cancer Risk					
	Total Population	White	African American	Native American	Other and Multiracial	Hispanic or Latino
< 1 in 1 million	232,907,302	140,083,682	30,322,675	881,180	21,243,988	40,375,778
1 to <5 in 1 million	1,023,773	665,609	171,444	7,929	54,384	124,408
5 to <10 in 1 million	40,652	26,742	5,429	542	2,884	5,055

Range of Lifetime Individual Cancer Risk	Number of People within 50 km of any Facility in Different Ranges for Lifetime Cancer Risk					
	Total Population	White	African American	Native American	Other and Multiracial	Hispanic or Latino
10 to <20 in 1 million	6,935	4,430	1,057	21	246	1,181
20 to <30 in 1 million	2,692	1,901	388	8	64	331
30 to <40 in 1 million	509	359	70	4	11	65
40 to <50 in 1 million	555	379	117	0	18	41
50 to <100 in 1 million	338	202	101	0	7	27
100 to <200 in 1 million	19	10	6	0	1	2
≥200 in 1 million	0	0	0	0	0	0
Total population within model domain	233,982,775	140,783,315	30,501,287	889,684	21,301,603	40,506,886
Average risk (chance in 1 million)	0.04	0.04	0.06	0.06	0.03	0.03

Further breakdown of relative population demographics compared to national averages is presented in Table 4-7. This summary of results shows that among the population with estimated cancer risk higher than (1×10^{-6}), some population groups are disproportionately represented as indicated by a higher percentage of a population group experiencing elevated risk than the overall nationwide percentage of the population representing that group. These groups include white, African American, and Native American demographics, as well as those with income below the poverty level and those aged over 25 years without a high school diploma.

Table 4-7. Demographic Details of Population with Estimated Cancer Risk Higher than or Equal to 1 in 1 Million, Compared with National Proportions

Demographic	Nationwide	Population with Cancer Risk Higher than or Equal to (1×10^{-6})
Total Population	329,824,950	1,075,473
Race and ethnicity by percent		
White	59.5%	65.1%
African American	12.1%	16.6%
Native American	0.6%	0.8%
Other and Multiracial	8.8%	5.4%
Hispanic or Latino	19.0%	12.2%
Income by percent		
Below Poverty Level	12.8%	15.7%

~~Above Poverty Level~~	~~87.2%~~	~~84.3%~~
~~Below Twice Poverty Level~~	~~30.2%~~	~~34.9%~~
~~Above Twice Poverty Level~~	~~69.8%~~	~~65.1%~~
~~Education by percent~~		
~~Over 25 and without a High School Diploma~~	~~11.6%~~	~~12.3%~~
~~Over 25 and with a High School Diploma~~	~~88.4%~~	~~87.7%~~
~~Linguistically isolated by percent~~		
~~Linguistically Isolated~~	~~5.2%~~	~~2.2%~~

~~Overall confidence in risk estimates based on modeled air concentrations from HEM is high because, as described in Section 2.4.2, HEM (and its underlying dispersion model AERMOD) are peer reviewed models which use industry reported releases across multiple years of data from two databases (TRI and NEI) as direct inputs to the HEM. Both databases have high-quality ratings under EPA's systematic review process. Additionally, the modeling approaches and methods used for this analysis have been peer reviewed and integrates recommendations by SACC from previous peer reviewed approaches and methods~~

~~As described in Section 3.2, overall confidence in the acute and chronic, non-cancer hazard POD used to derive risk estimates is high while overall confidence in the inhalation unit risk for formaldehyde used to derive cancer risk estimates is medium.~~

~~4.2.4.6~~4.2.4.3 Integration of Modeling and Monitoring Information

EPA evaluated and characterized exposures and risks to the general population from industrial releases of formaldehyde to the ambient air using actual reported releases and peer reviewed models to estimate exposures at select distances from releasing facilities. EPA also evaluated and characterized exposures and risks to the general population based on ambient monitoring data obtained from AMTIC.

Modeling and monitoring results show comparable exposures and risks to the general population from formaldehyde in the ambient air. However, direct comparisons between modeled and monitored concentrations and associated risks should be made with caution because of spatial and temporal differences among the various lines of evidence. Additionally, individually each line of evidence represents different contributions to the overall exposures and associated risks used in this risk characterization. For example, EPA's modeling represents individual exposures to formaldehyde from industry reported releases specific to TSCA COUs at pre-defined distances from releasing facilities. The ambient monitoring data, on the other hand, represents total ambient concentrations of formaldehyde from all sources releasing formaldehyde to the ambient air (*e.g.*, biogenic sources, secondary formation, mobile sources, etc.) and cannot be readily associated with a TSCA COU. Furthermore, monitoring data is direct measured concentrations (rather than estimated concentrations) at many different distances and locations which may or may not be nearby industrial facilities releasing formaldehyde to the ambient air. While individual lines of evidence may not be directly comparable, taken together the data and results support EPA's use of IIOAC daily and annual average modeled concentrations to derive risk estimates and characterize risks.

~~4.2.4.7~~4.2.4.4 Overall Confidence in Exposures, Risk Estimates, and Risk Characterizations for Ambient Air

There are many sources of formaldehyde which contribute to exposures to the general population. This ambient air exposure assessment for formaldehyde considers multiple lines of evidence including measured (monitored) and modeled formaldehyde concentrations to derive risk estimates and characterize risk. Overall, this human health risk assessment finds that the general population living near industrial facilities releasing formaldehyde to the ambient air experience both short-term and long-term inhalation exposure to formaldehyde attributable to TSCA COUs. While individual lines of evidence may not be directly comparable, taken together the data and results support EPA's use of IIOAC daily and annual average modeled concentrations to derive risk estimates and characterize risks.

EPA has medium confidence in the IIOAC modeled results used to derive risk estimates and characterize risks. Several inputs used for the IIOAC model are generally conservative, including the maximum and 95th percentile releases modeled and relied upon for the exposure concentrations, stack parameters representing a low, slow moving, non-buoyant plume, and the meteorological station within IIOAC used for this assessment representing a high-end station which leads to higher overall estimated concentrations. However, there are uncertainties in model outputs due to assumptions made when choosing input parameters, including the use of annual average releases to calculate daily releases and the use default parameters used within IIOAC. There is additional uncertainty because IIOAC does not consider the location of residential areas relative to industrial facilities associated with TSCA COUs. Similarly, the assessment was conducted independent of the size of the facility footprint, the precise location of the release, and the relative location of residences.

Additional lines of evidence provide context for the use of IIOAC modelling results. Monitoring data from AMTIC represent the aggregate concentration of formaldehyde in the ambient air from all sources, while IIOAC modeled concentrations represent local exposures attributable to TSCA COUs at select distances near a releasing facility. AirToxScreen data provide further context for contributions from multiple sources including biogenic, secondary, TSCA COUs and other sources. HEM results provide additional context on the spatial variability of formaldehyde concentrations across the U.S. The additional population and demographic analysis conducted using EPA's HEM supports the presence of individuals within distances (centroids of census blocks) evaluated for this risk evaluation and the increased risk estimates for cancer at those locations. While the individual lines of evidence provide context, the individual datasets are not directly comparable to each other, due to spatial and temporal differences. Further, formaldehyde concentrations are highly variable based on geographic location (*e.g.*, HEM results show elevated concentrations in the Southeastern United States), nearby releases, and contributions from other sources of formaldehyde. Taken together, the totality of integrated data can and do allow for a characterization of general population risks but has some uncertainty.

For formaldehyde, the contribution of combustion activities to the high-end exposure and risk estimates observed with the maximum release scenario is apparent and remains an uncertainty. However, as described in the *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and Section 2.4.2.1, releases primarily attributable to combustion activities are limited to a handful of very high reported releases within the NEI dataset. When modeled, these releases result in modeled concentrations at least an order of magnitude greater than the highest monitored concentrations from the AMTIC dataset. Additionally, when compared to the 95th percentile release values these maximum releases appear to be outliers relative to the remaining reported releases within a given industry sector.

Use of the full facility release data (all facilities across a single industry sector) to develop the four release statistics modeled with IIOAC complicate singular TSCA COU estimates because reported releases at one site may include multiple sources under multiple COUs that include combustion sources and non-combustion sources. As such, for industrial COUs, EPA has a moderate to robust weight of scientific evidence as the databases have high data quality scores and are supported by numerous data points. EPA has a moderate weight of scientific evidence for the commercial COUs since certain assumptions around industrial releases getting cross-walked to commercial COUs may not be fully representative for a commercial release value.

Overall confidence in risk estimates based on air concentrations modeled near release sites is medium for non-cancer estimates and medium for cancer estimates based on the hazard values. As described in Section 3.2, overall confidence in the chronic, non-cancer hazard POD is high, while overall confidence in the inhalation unit risk for formaldehyde is medium..

4.2.5 Comparison of Non-cancer Effect Levels and Air Concentrations

Hazard and risk assessments often lack human data on the specific concentrations at which an effect occurs in people and risk estimates often incorporate a substantial amount of uncertainty. In the case of formaldehyde, a robust database of epidemiology studies provides information about the air concentrations of formaldehyde that have been associated with respiratory effects in people and supports hazard values with minimal uncertainty.

Figure 4-21 indicates that the respiratory effects of formaldehyde in people can occur within the range of air concentrations reported in monitoring studies. This comparison suggests that chronic exposure to some of the indoor and outdoor air concentrations captured in available monitoring data are at levels that may be expected to result in adverse health effects based on available human evidence.

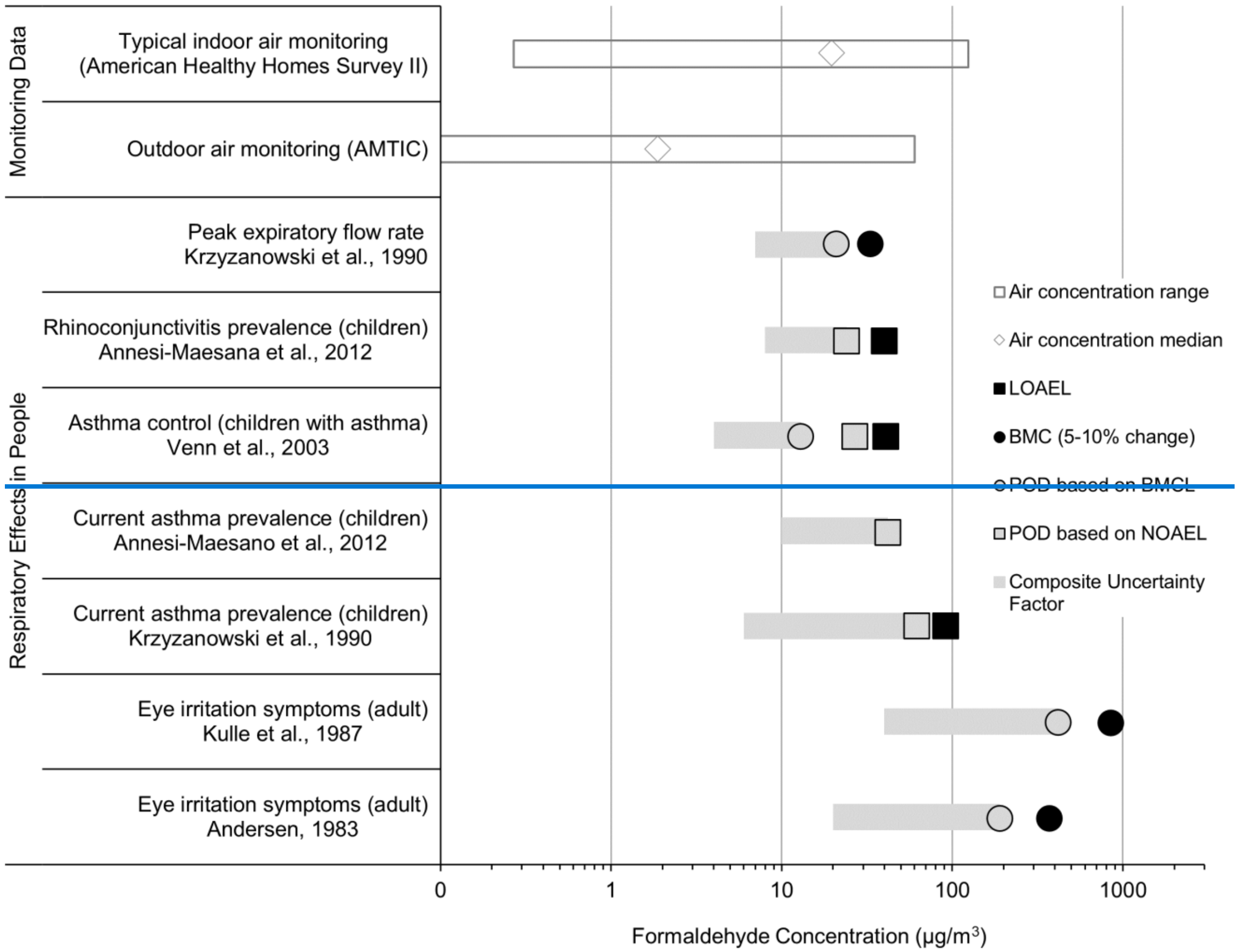


Figure 4-21. Comparison of Non-cancer Health Effect Levels Reported in People and Indoor and Outdoor Air Concentrations

Indoor air monitoring data summarized here are the American Healthy Homes Survey II data described in Section 2.3.3 and reflect the range of typical indoor air concentrations. Outdoor air monitoring data summarized here are the AMTIC dataset and include a diverse range of outdoor air monitoring sources. Black shapes indicate air concentrations at which adverse health effects were reported in epidemiology studies or controlled human exposure studies (LOAEL or BMC), grey circles and squares indicate concentrations at which no significant health effects were reported (NOAEL or BMCL), and grey bars indicate the total uncertainty factors identified for each study. Effect levels (LOAEL, BMC, NOAEL and BMCL) and composite uncertainty factors for each study are presented as reported in the IRIS assessment (U.S. EPA, 2024k).

4.2.64.2.5 Potentially Exposed or Susceptible Subpopulations

EPA considered PESS throughout the exposure and hazard assessments supporting this analysis. Table 4-3 summarizes how PESS were incorporated into the risk evaluation through consideration of increased exposures and/or increased biological susceptibility. The table also summarizes the remaining sources of uncertainty related to consideration of PESS. Appendix B provides additional details on PESS considerations for the formaldehyde risk evaluation.

The available data suggest that some groups or lifestages have greater exposure to formaldehyde. For example, people exposed to formaldehyde at work, those who frequently use consumer products containing high concentrations of formaldehyde, people living or working near facilities that emit formaldehyde, and people living in mobile homes and other indoor environments with high formaldehyde concentrations are expected to have greater exposures. In this assessment, EPA evaluated risks anticipated for a range of scenarios under TSCA COUs where exposures are expected to be greatest. In addition to high exposures associated with COUs, some people will have greater exposure to formaldehyde through sources that are not being assessed under TSCA. For example, those living near major roadways, people living in areas with frequent exposure to wildfire smoke, smokers, and people exposed to second-hand smoke, are expected to have greater exposures to formaldehyde. For these groups, higher exposures from other sources of formaldehyde may increase susceptibility to additional exposures from TSCA sources. As described in Section 4.3, EPA assessed risks from several aggregate exposure scenarios; however, the wide range of possible combinations of aggregate sources are expected to be highly variable across individuals and are a remaining source of uncertainty.

Some groups or lifestages may be more susceptible to the health effects of formaldehyde exposures. For example, children have developing respiratory systems and narrower airways that may make them more susceptible to the respiratory effects of formaldehyde. The chronic inhalation hazard value is derived in part based on dose-response information in children with asthma and is supported by dose-response information on lifestage-specific reproductive and developmental effects in humans and animals. The chronic inhalation hazard value incorporates information on several sensitive groups; therefore, EPA used a value of 3 for the UF_H to account for human variability.

Other factors that may increase susceptibility to formaldehyde include chronic disease, co-exposures, sex, lifestyle, sociodemographic status, and genetic factors. ~~People with chronic respiratory diseases (*e.g.*, asthma) may be more susceptible to the respiratory effects of formaldehyde.~~ Co-exposure to other chemical or non-chemical stressors that increase risk of asthma, reduced pulmonary function, reproductive and/or developmental toxicity, nasopharyngeal cancer or myeloid leukemia, may increase susceptibility to the effects of formaldehyde on the same health outcomes. ~~While these factors are not quantitatively accounted for in the hazard characterization, EPA used values of 3 or 10 for the human variability UF_H to account for increased susceptibility when quantifying risks from exposure to formaldehyde. The Risk Assessment Forum, in *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002), discusses some of the evidence for choosing the default factor of 10 when data are lacking—including toxicokinetic and toxicodynamic factors as well as greater susceptibility of children and elderly populations. U.S. EPA (2002), however, did not discuss many of the factors presented in Appendix C.~~

~~As described in Section 4.1.2 and in the IRIS assessment (U.S. EPA, 2024k), EPA applied ADAFs to lifetime cancer risk estimates to account for increased susceptibility to nasopharyngeal cancer following inhalation exposure during early life.~~

Table 4-34-8. Summary of PESS Considerations Incorporated throughout the Analysis and Remaining Sources of Uncertainty

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
Lifestage	EPA considered several scenarios in which lifestage may influence exposure. For air exposures, the impacts of lifestage differences were not able to be adequately quantified and so the air concentrations are used for all lifestages. Consumer exposure scenarios include lifestage-specific exposure factors for adults, children, and formula-fed infants (U.S. EPA, 2024d). Based on physical chemical properties and a lack of studies evaluating potential for accumulation in human milk following inhalation, dermal or oral exposures, EPA did not quantitatively evaluate the human milk pathway. This is a remaining source of uncertainty. In the consumer exposure assessment, EPA also considered potential oral exposure associated with mouthing behaviors in infants and young children (U.S. EPA, 2024d); however, EPA did not have sufficient information on this exposure route to quantify risks.	EPA identified potential sources of biological susceptibility to formaldehyde due to lifestage differences and developmental toxicity as described in the IRIS assessment (U.S. EPA, 2024k), the hazard value for chronic inhalation was informed in part by dose-response data on asthma in children, male reproductive toxicity, female reproductive effects and developmental toxicity and is expected to be protective of these endpoints. A 3× UF was applied for human variability. For oral, dermal, and acute inhalation hazard values, EPA did not identify quantitative information on lifestage differences in toxicity and this is a remaining source of uncertainty. A 10× UF was applied for human variability. EPA has concluded that a mutagenic mode of action is operative in formaldehyde-induced nasopharyngeal carcinogenicity. To account for increased cancer risks from early life inhalation exposures to formaldehyde, EPA applied an age dependent adjustment factor (ADAF) to cancer risk estimates to account for increased susceptibility to nasopharyngeal cancer following exposure during early life.
Pre-existing Disease	EPA did not identify health conditions that may influence exposure. The potential for pre-existing disease to influence exposure (due to altered metabolism, behaviors, or treatments related to the condition) is a source of uncertainty.	EPA identified the potential for pre-existing health conditions, such as asthma, allergies, nasal damage, or other respiratory conditions to contribute to susceptibility to formaldhyde. As described in the IRIS assessment (U.S. EPA, 2024k), EPA considered quantitative dose-response information in children with asthma in derivation of the chronic inhalation hazard value. A 3× UF was applied for human variability. For oral, dermal, and acute inhalation hazard values, the potential influence of pre-existing diseases on susceptibility to formaldehyde remains a source of uncertainty. A 3× or 10× UF was applied for human variability.
Lifestyle Activities	EPA identified smoking as an additional other source of exposure to formaldehyde that may increase aggregate exposure for smokers and people exposed to second-hand	EPA qualitatively described the potential for biological susceptibility resulting from smoking, alcohol consumption and physical activity but

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
	smoke. To some degree, formaldehyde exposure from smoking is indirectly accounted for in some indoor air monitoring data but it is not directly quantified.	did not identify quantitative evidence of increased susceptibility to formaldehyde. This is a remaining source of uncertainty.
Occupational Exposures	EPA evaluated risks for a range of occupational exposure scenarios that increase exposure to formaldehyde, including manufacturing, processing, and use of formulations containing formaldehyde. EPA evaluated risks for central tendency and high-end exposure estimates for each of these scenarios (Section 4.2.1). Firefighters are an occupational group expected to have increased exposure to formaldehyde associated with combustion and burning building materials but those exposures are beyond the scope of this assessment.	EPA did not identify occupational factors that increase biological susceptibility to formaldehyde. This is a remaining source of uncertainty.
Geographic Factors	EPA evaluated risks to communities in proximity to sites where formaldehyde is released to ambient air (Section 4.2.4). In the environmental release assessment, EPA mapped tribal lands in relation to air, surface water and ground water releases of formaldehyde to identify potential for increased exposures for tribes due to geographic proximity (U.S. EPA, 2024g). EPA also identified living near major roadways or in areas with frequent exposure to wildfire smoke as potential sources of increased exposure to formaldehyde for some populations. These other sources of exposure are a source of uncertainty that is not directly incorporated into risk estimates for outdoor air exposures.	EPA did not identify geographic factors that increase biological susceptibility to formaldehyde. This is a remaining source of uncertainty.
Socio-demographic Factors	EPA did not identify specific sociodemographic factors that influence exposure to formaldehyde. Income and other sociodemographic factors may be correlated with some of the exposure scenarios that result in greater exposure from both TSCA and other sources (*e.g.*, living near industrial release sites, or near roadways). This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to socioeconomic factors, ~~such as race or ethnicity and sex or gender,~~ but did not identify quantitative evidence of increased susceptibility to formaldehyde. This is a remaining source of uncertainty.

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
Nutrition	EPA did not identify nutritional factors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA did not identify nutritional factors that affect biological susceptibility to formaldehyde.
Genetics	EPA did not identify genetic factors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to genetic variants~~, which was accounted for applying a 10× UF for human variability~~. The specific magnitude of the impact of genetic variants is unknown and remains a source of uncertainty.
Unique Activities	EPA did not identify specific exposure scenarios that are unique to tribes or other groups that expected to increase exposure to formaldehyde. Potential sources of increased exposure to formaldehyde due to specific tribal lifeways or other unique activity patterns are a source of uncertainty.	EPA did not identify unique activities that influence susceptibility to formaldehyde. This is a remaining source of uncertainty.
Aggregate Exposures	EPA evaluated risk from multiple sources releasing to indoor or outdoor air and aggregate exposures across multiple exposure pathways or exposure scenarios. While EPA assessed risks from several aggregate exposure scenarios, the wide range of possible combinations of aggregate sources are expected to be highly variable across individuals and are a remaining source of uncertainty.	EPA does not identify ways that aggregate exposures would influence susceptibility to formaldehyde. This remains a source of uncertainty.
Other Chemical and Non-chemical Stressors	EPA did not identify chemical and nonchemical stressors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to chemical or nonchemical factors such as chemical co exposures but did not identify specific quantitative evidence regarding susceptibility to formaldhyde based on chemical and non-chemical stressors. This remains a source of uncertainty.

4.3 Aggregate and Sentinel Exposures

TSCA section 6(b)(4)(F)(ii) (15 USC 2605(b)(4)(F)(ii)) requires EPA, in conducting a risk evaluation, to describe whether aggregate or sentinel exposures under the COUs were considered and the basis for their consideration.

EPA considered how aggregate exposures to formaldehyde from multiple sources, across multiple routes, or across pathways may increase the overall risk for some people.

The relative contributions of each source of formaldehyde to overall exposure and risk varies across individuals, locations, and scenarios. For example, in communities living near industrial facilities with high releases, those point sources may be one of the greatest sources of exposure to formaldehyde in outdoor air. For people living near roadways, formaldehyde emitted from vehicles as a combustion byproduct may be a greater source of exposure. For people living in mobile homes or other indoor environments with high formaldehyde concentrations, indoor air in their homes may be the greatest source of exposure. Some people may be exposed to formaldehyde from multiple sources in indoor and outdoor air and through work or use of consumer products. For example, some people living near release sites may also be exposed at work and through high concentrations of formaldehyde in indoor air at home. Although there are too many possible combinations of exposures to evaluate all iterations, EPA considered a range of scenarios in which aggregate exposures within and across exposure pathways may increase total exposure and risk.

EPA qualitatively considered aggregate exposures and risks across inhalation, oral, and/or dermal routes of exposure. ~~For formaldehyde, cancer risk is only quantified for inhalation exposures and therefore cannot be quantitatively aggregated across multiple routes.~~ Non-cancer risks for formaldehyde are highly route-specific and each route-specific hazard value was based on effects that occur near the portal of entry. Because the non-cancer effects are specific to the route of exposure, EPA concluded that the non-cancer risks are not additive across routes. Similarly, because EPA determined that risks are not additive across routes, EPA did not aggregate exposure and risk across pathways for which exposure routes are not the same (*e.g.,* EPA did not aggregate inhalation exposure through outdoor air with dermal exposure associated through use of consumer products).

EPA considered the combined exposures that may result from multiple sources releasing formaldehyde to air in a particular indoor or outdoor environment. Monitoring data for formaldehyde is the best available indication of aggregate exposures that occur in indoor or outdoor air under a range of conditions. As described in Section 4.2.3 and Section 4.2.4, EPA considers the range of risk estimates based on monitoring data to provide an estimate of the range of risks from aggregate exposures in air. However, risk estimates based on monitoring do not provide information about the relative contribution of different sources. EPA therefore also used the HEM model to evaluate aggregate risks based on modeled air concentrations for multiple TSCA sources releasing formaldehyde to outdoor air (Section 4.2.4.1 and the *Ambient Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a)). As described in Section 2.3.1, the Agency considered aggregating air concentrations estimated for plausible combinations of TSCA COUs expected to co-occur in specific indoor air environments including "décor change", "new build" composite indoor air exposure scenarios, and an alternative aggregate indoor air exposure scenario whereby an individual was assumed to be exposed to the highest modeled concentration of formaldehyde from laminate flooring simultaneously with average residential indoor air monitoring concentrations reported from the AHHS II. However, EPA acknowledges that such aggregate scenarios may represent conservative, though realistic for some individuals, indoor air estimates according to TSCA COUs. ~~In Sections 4.2.3.4, 4.2.3.5, and 4.2.3.6 EPA presented acute,~~

~~intermediate, chronic non-cancer and cancer aggregate risk estimates respectively for the TSCA COU aggregate composite exposure scenarios.~~

EPA qualitatively considered the aggregate exposures individuals may experience from multiple exposure scenarios. For example, given the ubiquity of formaldehyde, individuals exposed to formaldehyde through work or through use of consumer products are expected to also have exposure to formaldehyde through indoor air at home. In many potential combinations of exposures scenarios, the exposures and risks from one scenario are much greater than from the other scenarios that may be aggregated with it (*e.g.*, occupational risks for a particular COU may be orders of magnitude greater than risks from formaldehyde in outdoor air). When this is the case, aggregate risk would be very similar to risk from the scenario with the highest risk. In cases where risks from two exposure scenarios are similar (*e.g*., occupational risks for some COU may be in the same range as risks from indoor air exposures as home based on AHHS II monitoring data), aggregate risks could be as much as double the risk from each pathway in isolation. These types of aggregate risks were not quantified for specific combinations of scenarios. Risks for individual exposure scenarios should be interpreted with an appreciation for potential aggregate exposures and risks.

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APPENDICES

Appendix A ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADAF	Age-dependent adjustment factor
ADC	Average daily concentrations
BMD	Benchmark dose
BMR	Benchmark response
CASRN	Chemical Abstracts Service Registry Number
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CNS	Central nervous system
DIY	Do it yourself
DMR	Discharge Monitoring Report
EPA	Environmental Protection Agency
ESD	Emission Scenario Document
FSHA	Federal Hazardous Substance Act
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HEC	Human Equivalent Concentration
HED	Human Equivalent Dose
HEM	Human Exposure Module
HERO	Health and Environmental Research Online (Database)
HUD	(U.S.) Department of Housing and Urban Development
IIOAC	Integrated Indoor-Outdoor Air Calculator (Model)
IRIS	Integrated Risk Information System
K_{OC}	Soil organic carbon: water partitioning coefficient
K_{OW}	Octanol: water partition coefficient
LADC	Lifetime average daily concentrations
LC50	Lethal concentration at which 50% of test organisms die
LD50	Lethal dose at which 50% of test organisms die
LOD	Limit of detection
Log K_{OC}	Logarithmic organic carbon: water partition coefficient
Log K_{OW}	Logarithmic octanol: water partition coefficient
MOA	Mode of action
NAICS	North American Industry Classification System
NASEM	National Academies of Sciences, Engineering, and Medicine
ND	Non-detect
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
OCSPP	Office of Chemical Safety and Pollution Prevention
OES	Occupational exposure scenario
ONU	Occupational non-user

OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulations
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
REL	Recommended Exposure Limit
SDS	Safety data sheet
STEL	Short-Term Exposure Limit
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total toxic organics
TWA	Time-weighted average
U.S.	United States
WWT	Wastewater treatment

~~Appendix B LIST OF DOCUMENTS AND SUPPLEMENTAL FILES~~

~~List of Documents and Corresponding Supplemental Files~~

~~1. *Conditions of Use for the Formaldehyde Risk Evaluation* (U.S. EPA, 2024c).~~

~~2. *Environmental Risk Assessment for Formaldehyde* (U.S. EPA, 2024h)~~

~~3. *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b).~~

~~4. *Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).~~
~~4.1. Supplemental Air Release Summary and Statistics for NEI and TRI for Formaldehyde.xlsx~~
~~4.2. Supplemental Land Release Summary for TRI for Formaldehyde.xlsx~~
~~4.3. Supplemental Water Release Summary for DMR and TRI for Formaldehyde.xlsx~~

~~5. *Environmental Exposure Assessment for Formaldehyde* (U.S. EPA, 2024e)~~
~~5.1. Supplemental Water Quality Portal Results for Formaldehyde.xlsx~~

~~6. *Environmental Hazard Assessment of Formaldehyde*, (U.S. EPA, 2024f)~~

~~7. *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024l)~~
~~7.1. Formaldehyde Occupational Exposure Modeling Parameter Summary.xlsx~~
~~7.2. Occupational Supplemental Formaldehyde Risk Calculator.xlsx~~
~~7.3. Supplemental Occupational Monitoring Data Summary.xlsx~~

~~8. *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d).~~
~~*8.1. Consumer Modeling, Supplemental A for Formaldehyde.xlsx*~~
~~*8.2. Consumer Acute Dermal Risk Calculator, Supplemental B for Formaldehyde.xlsm*~~
~~*8.3. Consumer - Indoor Air Acute and Chronic Inhalation Risk Calculator, Supplemental B for Formaldehyde.xlsm*~~

~~9. *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j).~~
~~9.1. Consumer Exposure Model Inputs for Formaldehyde.xlsx~~
~~9.2. Consumer Acute Dermal Risk Calculator for Formaldehyde Supplement B.xlsx~~
~~9.3. Acute and Chronic Inhalation Risk Calculator for Consumer and Indoor Air for Formaldehyde Supplement C.xlsx~~

~~10. *Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a)~~
~~10.1. IIOAC Assessment Results and Risk Calcs Supplement A for Ambient Air.xlsx~~
~~10.2. IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement B.xlsx~~
~~10.3. IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement C.xlsx~~

~~11. *Human Health Hazard Assessment for Formaldehyde* (U.S. EPA, 2024i).~~

~~12. *Risk Evaluation for Formaldehyde – Systematic Review Protocol* (U.S. EPA, 2024m)~~
~~12.1. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties* (U.S. EPA, 2024r)~~

12.2. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport* (U.S. EPA, 2024p)

12.3. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure* (U.S. EPA, 2024q)

12.4. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure.* (U.S. EPA, 2024s)

12.5. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Extraction Information for General Population, Consumer, and Environmental Exposure* (U.S. EPA, 2024o)

12.6. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Epidemiology* (U.S. EPA, 2024u)

12.7. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Animal Toxicology* (U.S. EPA, 2024t)

12.8. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Environmental Hazard* (U.S. EPA, 2024v)

12.9. *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology* (U.S. EPA, 2024n)

13. *Unreasonable Risk Determination for Formaldehyde*
14. *Non-technical Summary for Formaldehyde*
15. *Response to Public and SACC Comments for Formaldehyde*

~~Appendix C~~Appendix B DETAILED EVALUATION OF POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS

~~C.1~~B.1 PESS Based on Greater Exposure

In this section, EPA addresses potentially exposed populations expected to have greater exposure to formaldehyde. Table_Apx B-1 presents the quantitative data sources that were used in the PESS exposure analysis for incorporating increased background and COU-specific exposures.

Table_Apx B-1. PESS Based on Greater Exposure

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
Lifestage	Embryo/fetus	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased TSCACOU exposure anticipated for this lifestage.	• EPA did not quantify exposures specific to this lifestage.
	Pregnant ~~people~~ women	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased TSCA COU exposure anticipated for this lifestage.	• EPA did not quantify exposures specific to this lifestage
	Children (infants, toddlers)	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• For air exposures, the impacts of lifestage differences were not able to be adequately quantified and so the air concentrations are used for all lifestages. • Consumer exposure scenarios include lifestage-specific exposure factors for adults, children, and infants (U.S. EPA, 2024d) • Based on pchem properties and a lack of studies evaluating potential for accumulation in human milk following inhalation, dermal or oral exposures, EPA did not quantitatively evaluate the human milk pathway. This is a remaining source of uncertainty. • In the consumer exposure assessment, EPA also considered potential oral exposure associated with mouthing behaviors in infants and young children (U.S. EPA, 2024d), however EPA did not have sufficient information on this exposure route to quantify risks.	• Lifestage specific consumer exposure scenarios for infants, children, and adults are based on information from U.S. EPA (2005a)and U.S. EPA (2011).
	Older Adults	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased COU or pathway specific exposure for this lifestage.	• EPA did not quantify exposures specific to this lifestage.
Unique Activities	Subsistence Fishing	• EPA did not identify other sources of increased exposure associated with subsistence fishing or other exposure scenarios unique to tribes or other groups.	• EPA did not identify sources of increased COU or pathway specific exposure for subsistence fishing or other exposure pathways unique to tribes or other groups.	• EPA did not quantify exposures associated with subsistence fishing.

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
Lifestyle	Smoking	• EPA identified smoking as an additional other source of exposure to formaldehyde that may increase aggregate exposure for smokers and people exposed to second-hand smoke. To some degree, formaldehyde exposure from smoking is indirectly accounted for in some indoor air monitoring data described in Section 5.2.3.1, but it is not directly quantified.	• EPA did not identify sources of increased COU or pathway specific exposure for smoking or other lifestyle factors.	• EPA did not directly quantify exposures associated with smoking.
Geography	Living in proximity to sources of formaldehyde releases to outdoor air	• EPA identified living near major roadways or in areas with frequent exposure to wildfire smoke as potential sources of increased exposure to formaldehyde for some populations. To some degree, ambient air monitoring data may indirectly account for some of these sources but they are not directly quantified. These other sources of formaldehyde are a source of uncertainty that is not directly incorporated into risk estimates for outdoor air exposures.	• EPA evaluated risks to communities in proximity to sites where formaldehyde is released to ambient air (Section 5.2.4). In the environmental release assessment, EPA mapped tribal lands in relation to air, surface water and ground water releases of formaldehyde to identify potential for increased exposures for tribes due to geographic proximity (U.S. EPA, 2024g).	• EPA quantified exposures for communities in proximity to release sites using air concentrations modeled based on releases reported to TRI, as described in U.S. EPA (2024g) and Section 5.2.4 • EPA did not directly quantify exposures associated with living near roadways or other sources of formaldehyde in outdoor air.
Other chemical and non-chemical stressors	Built Environment	• EPA identified the built environment (including building materials and other products) as source of increased exposure to formaldehyde associated with other sources. Indoor air concentrations assessed in Section 4.2.3 incorporate both TSCA and other sources of formaldehyde in indoor air.	• EPA identified the built environment (including building materials and other products) as a source of increased exposure to formaldehyde associated with COUs. Indoor air concentrations assessed in Section 4.2.3 incorporate both TSCA and other sources of formaldehyde in indoor air.	• EPA quantified exposures associated with specific TSCA COUs based on 2016 and 2020 Chemical Data Reporting (U.S. EPA, 2020a, 2016a), the Formaldehyde and Paraformaldehyde Use Report (U.S. EPA, 2020d) and product weight fractions and densities reported in chemical safety data sheets (SDSs) identified through product-specific internet searches; EPA quantified exposures and risks associated with aggregate

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
				indoor air based on a range of monitoring data described in the Indoor Air Assessment (U.S. EPA, 2024j). • EPA did not directly quantify indoor air exposures associated with other sources.
Occupational	Workers and occupational non-users	• EPA identified firefighters as an occupational group with increased exposure to formaldehyde associated with combustion containing building materials with high concentrations to formaldehyde. While combustion exposures are beyond the scope of this assessment, this is a remaining source of uncertainty in characterizing aggregate exposures for some groups.	• EPA identified all occupational exposure scenarios as a potential source of exposure to formaldehyde. Those with higher frequency or higher duration exposures are expected to have the greatest exposures and risks. EPA evaluated risks for a range of occupational exposure scenarios that increase exposure to formaldehyde, including manufacturing, processing, and use of formulations containing formaldehyde. EPA evaluated risks for central tendency and high-end exposure estimates for each of these scenarios (Section 5.2.1).	• EPA quantified occupational exposures associated with TSCA COUs based on a range of COU-specific data, including monitoring data from OSHA and NIOSH and modeled air concentrations. Specific data sources are described in detail in the Draft Occupational Exposure Assessment (U.S. EPA, 2024l).
Consumer	High frequency consumers High duration consumers	• EPA identified dietary exposures through food, food packaging, drugs, and personal care products that contain formaldehyde as other sources that may contribute to total formaldehyde exposure. These exposures are beyond the scope of this assessment and are a source of uncertainty in characterizing aggregate exposures.	• Consumer products designed for children (*e.g.*, children's toys) may lead to elevated exposures for children and infants. • EPA identified all consumer exposure scenarios involving TSCA COUs as potential sources of exposure to formaldehyde. Those with higher frequency and/or higher duration exposures are expected to have the greatest exposures and risks.	• EPA quantified consumer exposure (U.S. EPA, 2024d) based on the Formaldehyde and Paraformaldehyde Use Report (U.S. EPA, 2020d) and the Exposure Factors Handbook (U.S. EPA, 2011) (Ch. 17).

~~C.2~~B.2 PESS Based on Greater Susceptibility

In this section, EPA addresses subpopulations and lifestages expected to be more susceptible to formaldehyde exposure than others. This discussion draws heavily from the recent summary of susceptible populations and lifestages included in the IRIS assessment (U.S. EPA, 2024k). Table_Apx B-2. presents the data sources that were used in the PESS analysis evaluating susceptible subpopulations and identifies whether and how the subpopulation was addressed quantitatively in the risk evaluation of formaldehyde.

Table_Apx B-2. Susceptibility Category, Factors, and Evidence for PESS susceptibility

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Lifestage	Embryos/ fetuses/infants	Direct quantitative human and animal evidence for developmental toxicity following inhalation exposure (*e.g.*, decreased fertility, increased spontaneous abortions and changes in brain structures).	Taskinen et al. (1999) John et al. (1994) Sarsilmaz et al. (2007) Aslan et al. (2006)	–	–	Hazard value for chronic inhalation is supported in part by dose-response information on female reproductive effects and developmental toxicity and is expected to be protective of these endpoints
	Infants and Children	In some studies, children appear to be more susceptible than adults to respiratory effects of formaldehyde. Early life exposures to chemicals with a mutagenic mode of action may increase cancer risk. EPA has concluded that the evidence is sufficient to conclude that a mutagenic mode of action of formaldehyde is operative in formaldehyde-induced nasopharyngeal carcinogenicity.	Bateson and Schwartz (2008) Venn et al. (2003) Annesi-Maesano et al. (2012) Krzyzanowski et al. (1990). U.S. EPA (2005b)	Developing lungs until age 6-8, narrower airways Different expression of enzymes responsible for metabolizing formaldehyde	Bateson and Schwartz (2008) Thompson et al. (2009)	Hazard value for chronic inhalation is based in part on dose-response information on asthma prevalence/asthma control in children. ~~ADAFs are applied to nasopharyngeal cancer risk estimates to account for increased susceptibility to cancer following exposure during early life.~~
	Pregnant women	No direct evidence identified	–	Pregnant women may have increased sensitivity to the development and exacerbation of atopic eczema following exposure to formaldehyde	Matsunaga et al. (2008)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Males of reproductive age	Direct quantitative evidence in for reduced fertility following inhalation exposure; IRIS assessment concludes "evidence indicates" formaldehyde "likely causes" male reproductive effects based on robust evidence in animals and slight evidence in people.	(U.S. EPA, 2024k)	Possible contributors to male reproductive effects/infertility (see also factors in other rows): • Enlarged veins of testes	CDC (2023b)	Hazard value for chronic inhalation is supported in part by dose-response information on male reproductive toxicity and is expected to be protective of these endpoints

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
				• Trauma to testes • Anabolic steroid or illicit drug use Cancer treatment		
	Older adults	No direct evidence identified	–	Older adults may have reduced metabolism and higher rates of chronic diseases that may increase susceptibility	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
Pre-existing disease or disorder	Health outcome/ target organs	A few epidemiological studies found that individuals with asthma and allergies were more susceptible to the deterioration of respiratory function after being exposed to formaldehyde than those without these conditions. Evidence from human and animal studies indicated that individuals with pre-existing nasal damage or a history of respiratory issues were more susceptible to developing formaldehyde induced nasal cancer.	Krzyzanowski et al. (1990) Kriebel et al. (1993) Woutersen et al. (1989) Appelman et al. (1988) Falk et al. (1994)	Individual variations in nasal anatomy and soluble factors in the upper respiratory tract can potentially influence the uptake of highly reactive gases like formaldehyde. This variability could possibly lead to differences in the distribution of inhaled formaldehyde and susceptibility to its health effects.	ICRP (1994) Santiago et al. (2001) Singh et al. (1998)	Acute inhalation hazard values are based in part on dose-response information in humans already identified as sensitive to formaldehyde in dermal patch test studies. No direct quantitative adjustment to chronic inhalation, oral or dermal hazard values or risk estimates; Use of UF_H
Lifestyle activities	Smoking	No direct evidence identified	–	Heavy smoking may increase susceptibility to formaldehyde toxicity. However, it is unclear if this	Fishbein (1992) CDC (2023a) CDC (2023b)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
				increased sensitivity is due to additional formaldehyde exposure or other chemicals in cigarette smoke.		
	Alcohol Consumption	No direct evidence identified	–	Chronic alcohol consumption may affect the susceptibility to reproductive and cancer related health outcomes.	CDC (2023a)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Physical Activity	Studies observed that prolonged physical activity increased an individual's susceptibility to formaldehyde induced respiratory impairments. These studies demonstrated that those who were exposed to formaldehyde after 15 minutes of exercise experienced more significant declines in lung function compared to those who had shorter exercise sessions or no exercise at all.	Green et al. (1987) Green et al. (1989)	Insufficient activity may increase susceptibility to multiple health outcomes Overly strenuous activity may also increase susceptibility.	CDC (2022)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
Sociodemo-graphic status	Race/ethnicity	An epidemiological study suggests a racial difference in susceptibility to formaldhyde toxicity, as nonwhite individuals were found to have higher mortality rates for nasopharyngeal cancer and multiple myeloma compared to their white counterparts.	Hayes et al. (1990)	–	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Socioeconomic status	No direct evidence identified	–	Individuals with lower socioeconomic status may experience adverse	ODPHP (2023b)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
				health outcomes due to unmet social needs, environmental factors, and limited access to healthcare services.		
	~~Sex/gender~~	~~A higher prevalence of burning or tearing eyes was observed among women compared to men, suggesting that women may be more sensitive to the irritant properties of formaldehyde on the eyes and upper respiratory tract.~~ ~~Several animal studies showed that males exhibit a higher incidence of lesions in the upper respiratory tract than females.~~ ~~Evidence from epidemiological studies and animal models indicates that formaldehyde exposure can lead to male reproductive impairments, reduced fertility, and increased risk of miscarriage in women~~	~~Liu et al. (1991)~~ ~~Woutersen et al. (1987)~~ ~~Zwart et al. (1988)~~ ~~Maronpot et al. (1986)~~ ~~Kerns et al. (1983)~~ ~~Taskinen et al. (1999)~~ ~~John et al. (1994)~~ ~~Wang et al. (2015)~~	~~–~~	~~–~~	~~Both acute and chronic inhalation hazard values are based in part on epidemiological studies include that include both male and female subjects,~~
Nutrition	Diet	No direct evidence identified	–	An antioxidant deficient diet may exacerbate inflammatory responses, primarily due to formaldehyde's well-known inflammatory properties.	CDC (2023a) CDC (2020) CDC (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
				Obesity can increase susceptibility to cancer.		
	Malnutrition	No direct evidence identified	–	Micronutrient malnutrition can result in various conditions, such as birth defects, maternal and infant mortality, preterm birth, low birth weight, poor fetal growth, childhood blindness, and undeveloped cognitive ability. Deficiencies in micronutrients may increase an individual's susceptibility to the adverse health effects of formaldehyde, particularly respiratory impairments. This is due to the critical role of micronutrients in maintaining robust immune function, potent antioxidant defenses, and the structural integrity of the respiratory system.	CDC (2021) CDC (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

<table>
<tr><th rowspan="2">Susceptibility Category</th><th rowspan="2">Specific Factors</th><th colspan="2">Direct Evidence this Factor Modifies Susceptibility to Formaldehyde</th><th colspan="2">Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde</th><th rowspan="2">Incorporation of Each Factor into the Risk Evaluation</th></tr>
<tr><th>Description of Interaction</th><th>Key Citations</th><th>Description of Interaction</th><th>Key Citations</th></tr>
<tr><td rowspan="2">Genetics/ epigenetics</td><td>Target organs</td><td>No direct evidence identified</td><td>--</td><td>Genetic disorders, such as Klinefelter's syndrome, Y-chromosome microdeletion, myotonic dystrophy can affect male reproduction/fertility</td><td>CDC (2023b)</td><td>No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H</td></tr>
<tr><td>Toxicokinetics</td><td>Studies suggested that certain genetic variants could impair the activity of ADH and ALDH enzyme. This potential impairment could reduce the clearance of formaldehyde, thereby increasing susceptibility to adverse health effects associated with formaldehyde exposure.

Studies have demonstrated that genetic variations in ADH3 and ALDH2 genes have been associated to higher susceptibility to asthma and CNS toxicity, while polymorphism in genes related to DNA repair, such as XRCC3, have been shown to impact susceptibility to formaldhyde induced genotoxicity.

Studies in experimental animals with genetically modified ALDH2 and ALDH5 genes, responsible for eliminating endogenous formaldhyde, suggested that variations in these genes could potentially increase susceptibility to genotoxicity.</td><td>Wu et al. (2007)

Hedberg et al. (2001)

Deltour et al. (1999)

Tan et al. (2018)

Nakamura et al. (2020)

Dingler et al. (2020)</td><td>–</td><td>–</td><td>No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H</td></tr>
</table>

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
		Although some studies have suggested that specific genetic variants may influence susceptibility to formaldehyde toxicity, their findings have not been conclusive.				
Other Chemical and Nonchemical stressors	Built environment	No direct evidence identified	–	Poor quality housing often contains environmental triggers of asthma such as pests, mold, dust, building materials that may exacerbate reduced asthma control associated with formaldehyde exposure	ODPHP (2023a)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Social environment	No direct evidence identified	–	Poverty, violence, as well as other social factors may make some populations more susceptible to the health effects associated with formaldehyde exposure.	CDC (2023d) ODPHP (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Chemical co-exposures	Several studies have demonstrated that co-exposure to formaldehyde and other substances, including environmental pollutants and dietary components, could potentially affect respiratory health, hypersensitivity reactions, or lung function.	Besaratinia et al. 2014 Fang et al. 2004 Gavriliu et al. 2013	–	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
		While studies have indicated that certain dietary components, such as methanol and caffeine can contribute to the endogenous production of formaldehyde in non-respiratory tissues, the extent to which this influences susceptibility to inhaled formaldehyde remains unclear. Environmental tobacco smoke exposure has been associated with an increased likelihood of hypersensitivity responses in individuals concurrently exposed to formaldehyde. Studies suggest that exposure to tobacco smoke may potentiate the effects of formaldehyde or even trigger such responses at lower formaldehyde concentrations, particularly in children and nonsmoking adults	Hohnloser et al. (1980) Riess et al. (2010) Summers et al. (2012) Krzyzanowski et al. (1990)			

~~Appendix D~~Appendix C AMBIENT AIR RISK ESTIMATES – COMMERCIAL USES

The ambient air exposure assessment for formaldehyde quantitatively evaluates exposures resulting from industrial releases of formaldehyde to ambient air. EPA expects that releases resulting from TSCA industrial COUs have larger point source emissions than the air emissions resulting from commercial uses.

As discussed in the Environmental Release Assessment (U.S. EPA, 2024g), where available, EPA used TRI and NEI to inform air releases from commercial COUs. However, facilities are only required to report to TRI if the facility has 10 or more full-time employees; is included in an applicable North American Industry Classification System (NAICS) code; and manufactures, processes, or uses the chemical in quantities greater than a certain threshold. Reporting to NEI depends on submissions voluntarily provided by state, local, and tribal agencies and is supplemented by data from other EPA programs. For NEI, the general threshold for major source is the potential to emit more than 10 tons per year for a single Hazardous Air Pollutant (HAP), or 25 tons/year for any combination of HAPs.

Due to these limitations, commercial sites that use formaldehyde and/or formaldehyde-containing products may not report to TRI or NEI and are therefore not included in these datasets.

EPA did not quantify releases and therefore ambient air risk estimates for the following COUs:

- Distribution in commerce
- Commercial use – chemical substances in treatment/care products – laundry and dishwashing products
- Commercial use – chemical substances in treatment products – water treatment products
- Commercial use – chemical substances in outdoor use products – explosive materials
- Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals; and
- Commercial use – chemical substances in automotive and fuel products- automotive care products; lubricants and greases; fuels and related products.[9]

EPA discusses the release potential for each COU in in the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g) based on the available information. In general, EPA expects industrial COUs to be the drivers of risk for ambient air from the TSCA COUs within the scope of this draft risk evaluation.

For the following commercial COUs

- Commercial use – chemical substances in furnishing treatment/care products- floor coverings; foam seating and bedding products; furniture and furnishings not covered elsewhere; cleaning and furniture care products; fabric, textile, and leather products not covered elsewhere-construction
- Commercial Use – chemical substances in construction, paint, electrical, and metal products-adhesives and sealants; paint and coatings

[9] Use of fuels may be associated with petroleum refinery and utilities, however, note formaldehyde from combustion sources is not assessed as an independent COU subcategory in this risk evaluation.

- Commercial Use – chemical substances in furnishing treatment/care products – building/construction materials – wood and engineered wood products; building/ construction materials not covered elsewhere

EPA expects emissions may be similar to the construction sector, which has cancer risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COUs

- Commercial use – chemical substances in electrical products – electrical and electronic products
- Commercial use – chemical substances in metal products – metal products not covered elsewhere

EPA expects emissions may be similar to the electrical equipment, appliance, and component manufacturing and fabricated metal product manufacturing sector, which has cancer risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COU, Commercial use – chemical substances in agriculture use products – lawn and garden products, EPA expects emissions may be similar to the agriculture, forestry, fishing, and hunting sector, which has risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COUs

- Commercial use – chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment
- Commercial use – chemical substances in packaging, paper, plastic, hobby products- arts, crafts, and hobby materials
- Commercial use – chemical substances in packaging, paper, plastic, hobby products- ink, toner, and colorant products; photographic supplies

EPA expects emissions may be similar to the Printing and Related Support Activities & Photographic Film Paper, Plate, and Chemical Manufacturing sector, which have risk estimates lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount. EPA does, however, note that printing operations that use printing ink, toner, or colorant products containing formaldehyde may occur at industrial sites such as those included in Paper Manufacturing, which has a cancer risk estimate of 1.24×10^{-5}.

~~Appendix E~~Appendix D OCCUPATIONAL EXPOSURE VALUE DERIVATION

EPA calculated an occupational exposure value for consideration of formaldehyde inhalation exposure in workplace settings (see Section D.1). This revised draft occupational exposure value derivation applies the 0.3 ppm POD and uncertainty factor of 1. This calculated value may be used to support risk management efforts for formaldehyde under TSCA section 6(a), 15 U.S.C. §2605.

EPA calculated an acute occupational exposure value of 0.3 ppm (614 μg/m^3) that is intended to protect workers and ONUs against sensory irritation effects resulting from acute occupational exposures. As noted in the human health hazard TSD for the risk evaluation for formaldehyde (U.S. EPA, 2024b), this sensory irritation effect appears to be more responsive to exposure concentration than duration. Therefore, the occupational exposure value (OEV) applies to all durations of exposure and serves as the short-term exposure value. Use of this OEV is health-protective against other effects, including cancer as described in the Federal Register Notice Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability.

Of the identified occupational monitoring data for formaldehyde, there have been measured workplace air concentrations below the calculated exposure values. A summary table of available monitoring methods from the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) is included below in Section B.D.2. The table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The calculated exposure values are above the limit of detection (LOD) and limit of quantification (LOQ) using at least one of the monitoring methods identified.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA for formaldehyde of 0.75 ppm in 1992 (https://www.osha.gov/annotated-pels), with an action level of 0.5 ppm. In addition, OSHA has set a short-term exposure limit (STEL) of 2 ppm. OSHA's PEL must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act. Other international regulatory bodies such as the European Union established an occupational exposure regulatory limit of 0.3 ppm (European Chemicals Agency, http://echa.europa.eu/).[10]

There are also recommended exposure limits established for formaldehyde by other governmental agencies and independent groups. The American Conference of Governmental Industrial Hygienists (ACGIH) set a Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL in 2017. This chemical also has a NIOSH Recommended Exposure Limit (REL) of 0.016 ppm TWA and 15-minute Ceiling limit of 0.1 ppm (https://www.cdc.gov/niosh/npg/).

~~EPA has calculated occupational exposure values for consideration of formaldehyde inhalation exposure in workplace settings (see Appendix E.1). EPA calculated occupational exposure values of 0.17 ppm (200 μg/m^3) based on the acute non-cancer hazard value for sensory irritation and 0.11 ppm (133μg/m^3) based on the chronic cancer IUR for nasopharyngeal cancer.~~

~~TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus these occupational exposure values represent risk-only numbers. In risk management rulemaking for formaldehyde following the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical~~

[10] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.002.

or essential uses. In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the occupational exposure values presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c).

The calculated values for formaldehyde are derived based on standard occupational scenario assumptions of 8 hours/day, 5 days/week exposures for a total of 250 days exposure per year, and a 40-year working life.

EPA expects that at the acute occupational exposure value of 0.17 ppm (200 µg/m^3), a worker or ONU would be protected against sensory irritation effects resulting from acute occupational exposures. The acute exposure limit is unchanged for all durations of a single exposure and also serves as the short-term exposure limit (STEL) to protect against 15-minute exposures. EPA expects that at the cancer occupational exposure value of 0.11 ppm (133µg/m^3) as an 8-hr TWA, a worker or ONU would be protected against excess risk of nasopharyngeal cancer above the 1×10^{-4} benchmark value resulting from occupational formaldehyde exposure.

Of the identified occupational monitoring data for formaldehyde, there have been measured workplace air concentrations below the calculated exposure values. A summary table of available monitoring methods from the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) is included in Appendix E.2. The table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The calculated exposure values are above the limit of detection (LOD) and limit of quantification (LOQ) using at least one of the monitoring methods identified.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA for formaldehyde of 0.75 ppm in 1992 (https://www.osha.gov/annotated-pels), with an action level of 0.5 ppm. In addition, OSHA has set a STEL of 2 ppm. OSHA's PEL must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act. EPA's calculated exposure values are based on newer information and analysis from this risk evaluation. Other international regulatory bodies such as the European Union established a regulatory limit of 0.3 ppm (European Chemicals Agency, http://echa.europa.eu/)[11].

There are also recommended exposure limits established for formaldehyde by other governmental agencies and independent groups. The American Conference of Governmental Industrial Hygienists (ACGIH) set a Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL in 2017. This chemical also has a NIOSH Recommended Exposure Limit (REL) of 0.016 ppm TWA and 15-minute Ceiling limit of 0.1 ppm (https://www.cdc.gov/niosh/npg/).

E.1D.1 Occupational Exposure Value Calculations

This appendix presents the calculations used to estimate occupational exposure values using inputs derived in this risk evaluation. The human health hazard value used in this equation is based on the acute inhalation hazard value identified in the Federal Register Notice.

[11] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.002

Occupational Exposure Value

The occupational exposure value (EV_{acute}) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx 1:

Equation_Apx 1.

$$EV_{acute} = \frac{Hazard\ Value_{acute}}{Benchmark\ MOE_{acute}} = \frac{0.3\ \text{ppm}}{1} = 0.3\ \text{ppm} = 368\ \frac{\mu\text{g}}{\text{m}^3}$$

Where:

Benchmark MOE $_{acute}$	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 1 selected in the FRN.
EV $_{acute}$	=	Exposure limit based on acute effects
Hazard Value $_{acute}$	=	Human hazard value for acute occupational exposure scenarios

Unit conversion:

1 ppm = 1,228 µg/m^3 (based on molecular weight of 30.026 g/mol for formaldehyde)

~~Summary of Air Sampling Analytical Methods Identified~~

~~EPA conducted a search to identify relevant NIOSH and OSHA analytical methods used to monitor for the presence of formaldehyde in air (see Table_Apx). This table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The sources used for the search included the following:~~

- ~~NIOSH Manual of Analytical Methods (NMAM), 5th Edition;~~
- ~~NIOSH NMAM 4th Edition; and~~
- ~~OSHA Index of Sampling and Analytical Methods.~~

~~Notably, the limit of detection provided is based on the recommended volume. The specific limit of detection may vary depending on the time sampled and flowrate used.~~

~~This appendix presents the calculations used to estimate occupational exposure values using inputs derived in this risk evaluation. Multiple values are presented below for hazard endpoints based on different exposure durations. The human health hazard values used in these equations are based on the inhalation non-cancer hazard values and the IUR summarized in Table 3-1.~~

~~Acute/Short-Term, Non-cancer Occupational Exposure Value~~

~~The acute occupational exposure value (EV_{acute}), equivalent to the 15-minute STEL, was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx E-1:~~

~~Equation_Apx E-1.~~

$$EV_{acute} = \frac{HEC_{acute}}{Benchmark\ MOE_{acute}} = \frac{0.5\ \text{ppm}}{3} = 0.167\ \text{ppm} = 0.2\ \frac{\text{mg}}{\text{m}^3}$$

~~Lifetime Cancer Occupational Exposure Value~~

The EV_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of 1×10^{-4}:

$$EV_{cancer} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} * \frac{IR_{input}}{IR_{workers}}$$

$$= \frac{1X10^{-4}}{7.90 \times 10^{-3}\ per\ ppm} * \frac{24\frac{h}{d} * \frac{365d}{y} * 78y}{8\frac{h}{d} * \frac{250d}{y} * 40y} * \frac{1.25\ \mathrm{m}^3/hr}{1.25\ \mathrm{m}^3/hr} =$$

$$= 0.108\ \mathrm{ppm} = 0.133\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

$AT_{HECrepeat}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, intermediate and chronic occupational risk, based on study conditions and/or any HEC adjustments (24 hr/day for 30 days) (see Section 4.2.2.1)
$AT_{HECacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (24 hr/day) (see Section 4.2.2.1)
AT_{IUR}	=	Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hr/day for 365 days/year) and averaged over a lifetime (78 years) (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B).
$Benchmark\ MOE_{acute}$	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 3 (see Table 3-7)
$Benchmark\ MOE_{repeat}$	=	Short term non-cancer benchmark margin of exposure, based on the total uncertainty factor of 100 (see Table 3-8)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk
EV_{acute}	=	Exposure limit based on acute effects
$EV_{intermediate}$	=	Existing chemical exposure limit (mg/m^3), based on non-cancer effects following repeat exposures
$EV_{chronic}$	=	Existing chemical exposure limit (mg/m^3), based on non-cancer effects following repeat exposures
EV_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hr/day) (see Table 3-8)
EF	=	Exposure frequency (250 days/yr), (see Section 4.2.2.1)
$HEC_{acute\ or\ repeat}$	=	Human equivalent concentration for acute or intermediate/chronic occupational exposure scenarios, respectively (see Tables 3-7 and 3-8)
IUR	=	Adult-based inhalation unit risk (per ppm) (see Table 3-6)
IR	=	Inhalation rate (default is 1.25 m^3/hr for workers and 0.6125 m^3/hr for general population at rest)
WY	=	Working years per lifetime at the 95th percentile (40 years (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B)

Unit conversion:

1 ppm = 1.23 mg/m^3 (based on molecular weight of 30.026 g/mol for formaldehyde)

~~E.2~~D.2 Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH and OSHA analytical methods used to monitor for the presence of formaldehyde in air (see Table_Apx D-1). This table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The sources used for the search included the following:

1. NIOSH Manual of Analytical Methods (NMAM), 5th Edition;
2. NIOSH NMAM 4th Edition; and
3. OSHA Index of Sampling and Analytical Methods.

Of note, the limit of detection provided is based on the recommended volume. The specific limit of detection may vary depending on the time sampled and flowrate used.

Table_Apx D-1. Limit of Detection (LOD) and Limit of Quantification (LOQ) Summary for Air Sampling Analytical Methods Identified

Air Sampling Analytical Methods[a]	Year Published	LOD[b]	LOQ	Notes	Source
NIOSH Method 2016	2016	0.012 ppm	N/A	Estimated LOD is 0.07 µg/sample. The working range is 0.012 to 2.0 ppm for a 15-L sample.	NIOSH Manual of Analytical Methods (NMAM 2016)
NIOSH Method 2541[c]	1994	0.24 ppm	N/A	Estimated LOD is 1 µg/sample. The working range is 0.24 to 16 ppm for a 10-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 2541)
NIOSH Method 3500[d]	1994	0.02 ppm	N/A	Estimated LOD is 0.5 µg/sample. The working range is 0.02 to 4 ppm for an 80-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 3500)
NIOSH Method 5700[e]	1994	0.0004 mg/m^3 (0.0003 ppm)	N/A	Estimated LOD is 0.08 µg/sample. The working range is 0.0004 to 3.8 mg/m^3 for a 1,050-L sample. Used for determination of formaldehyde in both textile and wood dusts.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 5700)
OSHA Method 52	1989	16 ppb	16 ppb	Detection limit and reliable quantification limit is 482 ng per sample (16 ppb for 24 L)	OSHA Index of Sampling and Analytical Methods (OSHA 52)
OSHA Method 1007[f] https://www.osha.gov/sites/default/files/methods/osha-1007.pdf	2005	0.56, 1.70, or 0.17 ppb (Sampler – ChemDisk-AL, UMEx 100, DSD-DNPH, respectively)	1.88, 5.68, or 0.58 ppb (Sampler – ChemDisk-AL, UMEx 100, DSD-DNPH, respectively)	Method reports LOD/LOQ of overall procedure as 0.56/1.88 ppb for ChemDisk-AL samplers, 1.70/5.68 ppb for UMEx 100 samplers, and 0.17/0.58 for DSD-DNPH samplers	OSHA Index of Sampling and Analytical Methods (OSHA 1007)

Air Sampling Analytical Methods[a]	Year Published	LOD[b]	LOQ	Notes	Source

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion
[a] EPA has additional air sampling methods targeted for measurement of ambient and indoor air, the methods listed in this table are air sampling for occupational exposures.
[b] These sources cover a range of LOD including both below and above the preliminary occupational exposure value.[c] The method is suitable for the simultaneous determinations of acrolein and formaldehyde.
[d] This is the most sensitive formaldehyde method in the NIOSH Manual of Analytical Methods and is able to measure ceiling levels as low as 0.1 ppm (1 5-L sample). It is best suited for the determination of formaldehyde in area samples.
[e] Results should be considered separately from vapor-phase formaldehyde exposure; Method measures both "released" and formaldehyde equivalents.
[f] Recommends use of OSHA Method 52 when monitoring exposures resulting from the use of formalin solutions.

~~Appendix F~~Appendix E DERMAL EXPOSURE APPROACH

The dermal load (Q_u) is the quantity of chemical on the skin after the dermal contact event. This value represents the quantity remaining after the bulk chemical formulation has fallen from the hand that cannot be removed by wiping the skin (*e.g.*, the film that remains on the skin). To estimate the dermal load for formaldehyde for occupational and consumer uses, EPA used dermal loading based on *A Laboratory Method to Determine the Retention of Liquids on the Surface of the Hands* (U.S. EPA, 1992) and formaldehyde weight concentrations relevant to the occupational use or consumer product. In addition, only acute exposures were quantitatively assessed given the identified dermal skin sensitization POD is likely only relevant to acute exposures (U.S. EPA, 2024i). The supporting study measured liquid retention on the surface of hands based on indirect (*i.e.*, contact with saturated object) contact and direct (*i.e.*, immersive) contact.

For consumer exposures, EPA assumes a pool of a liquid product was formed on the skin, or that a rag was used that reduced the evaporation of formaldehyde during use. A Qu of 10.3 mg/cm2 was used as the most protective value for consumers using oil-based products expected to have longer residence times on the skin relative to water-based products, as reported in (U.S. EPA, 1992). While this is the most protective value for consumer usage of oil-based products, it may overestimate exposures in some cases including when using water-based liquid products. Dermal exposures are only reasonably foreseen for consumers but not bystanders.

Owing to volatility and expected use patterns, dermal loading of formaldehyde from solid products is unlikely, except for certain textiles including clothing that are treated with formaldehyde in dyeing and wrinkle prevention step in the textile manufacturing process (Herrero et al., 2022). EPA could not identify supporting evidence for dermal loading exposures from the handling or wear of fabrics. The Agency also could not identify a diffusion coefficient of formaldehyde for clothing. Therefore, EPA had a low level of confidence in the estimation of dermal loading from textiles including clothing. Thus, a qualitative assessment is reported for this product type in the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d).

For occupational exposures, EPA uses the guidance in *Updating CEB's Method for Screening-Level Assessments of Dermal Exposure* (U.S. EPA, 2013) on selection of Q_u values. EPA assumes routine and incidental contact with liquids occur for workers during routine maintenance activities, manual cleaning of equipment, filling drums, connecting transfer lines, sampling, and bench-scale liquid transfers. For this event, the memorandum uses values of 0.7 to 2.1 mg/cm^2-event for routine liquid contact. EPA uses the maximum value of the range from the memorandum to estimate high-end dermal loads. EPA also included a central tendency liquid dermal loading values, EPA used the 50th percentile of the dermal loading results from the underlying study (U.S. EPA, 1992). The 50th percentile value was 1.4 mg/cm^2-event for routine/incidental contact with liquids.

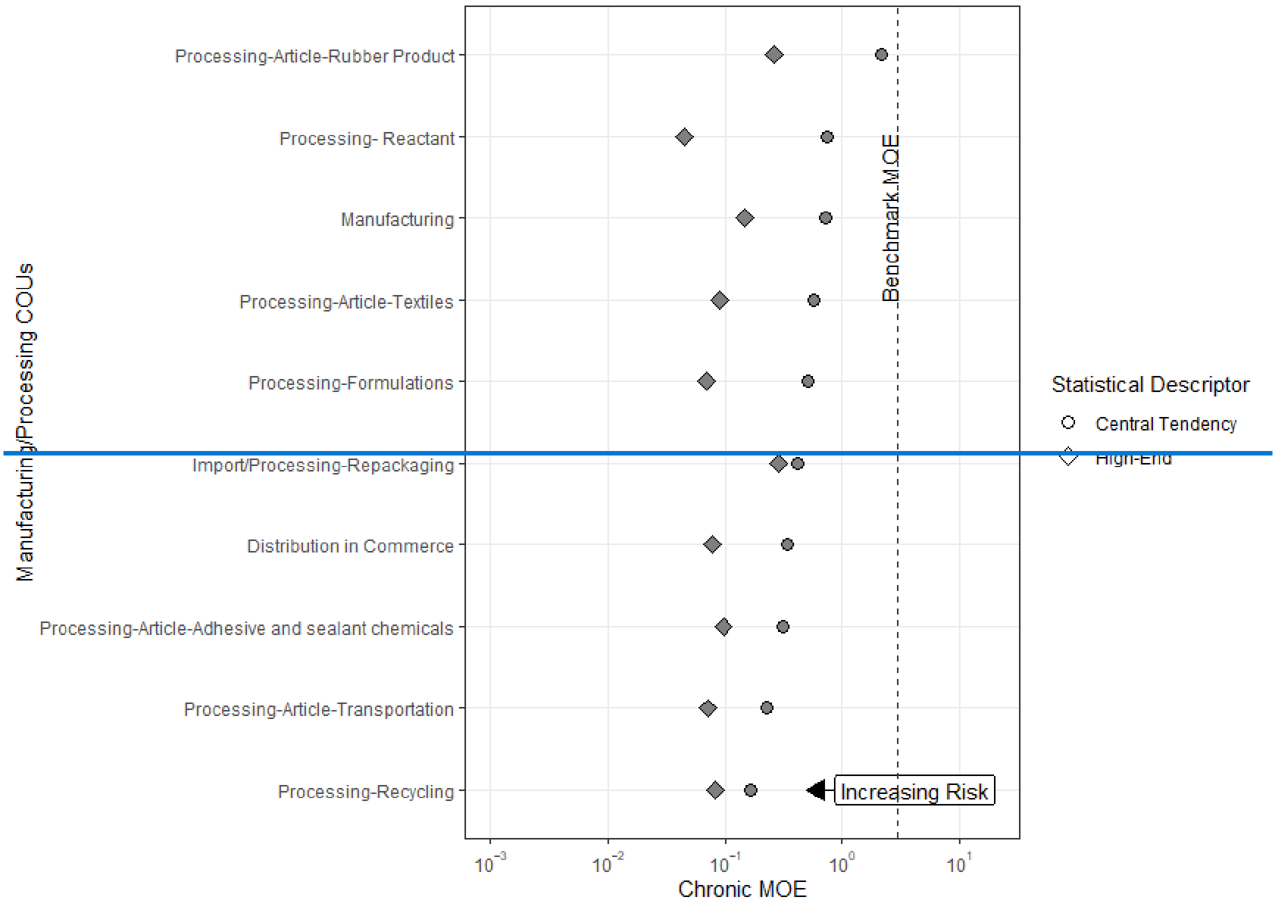
EPA assumes routine and immersive contact with liquids occur for workers during manual spray applications or contact with very wet surfaces. For this event, the memorandum uses values of 1.3 to 10.3 mg/cm^2-event for liquid contact. EPA uses the maximum value of the range from the memorandum to estimate high-end dermal loads. EPA also included a central tendency liquid dermal loading values, EPA used the 50th percentile of the dermal loading results from the underlying study (U.S. EPA, 1992). The 50th percentile value was 3.8 mg/cm^2-event for routine/incidental immersive contact with liquids. The dermal exposure estimates do not consider the use of gloves or other protective equipment.

Appendix G ADDITIONAL OCCUPATIONAL RISK CHARACTERIZATION

The following subsections provide a summary of potential chronic non-cancer risks associated with formaldehyde based on TSCA COUs during occupational COUs.

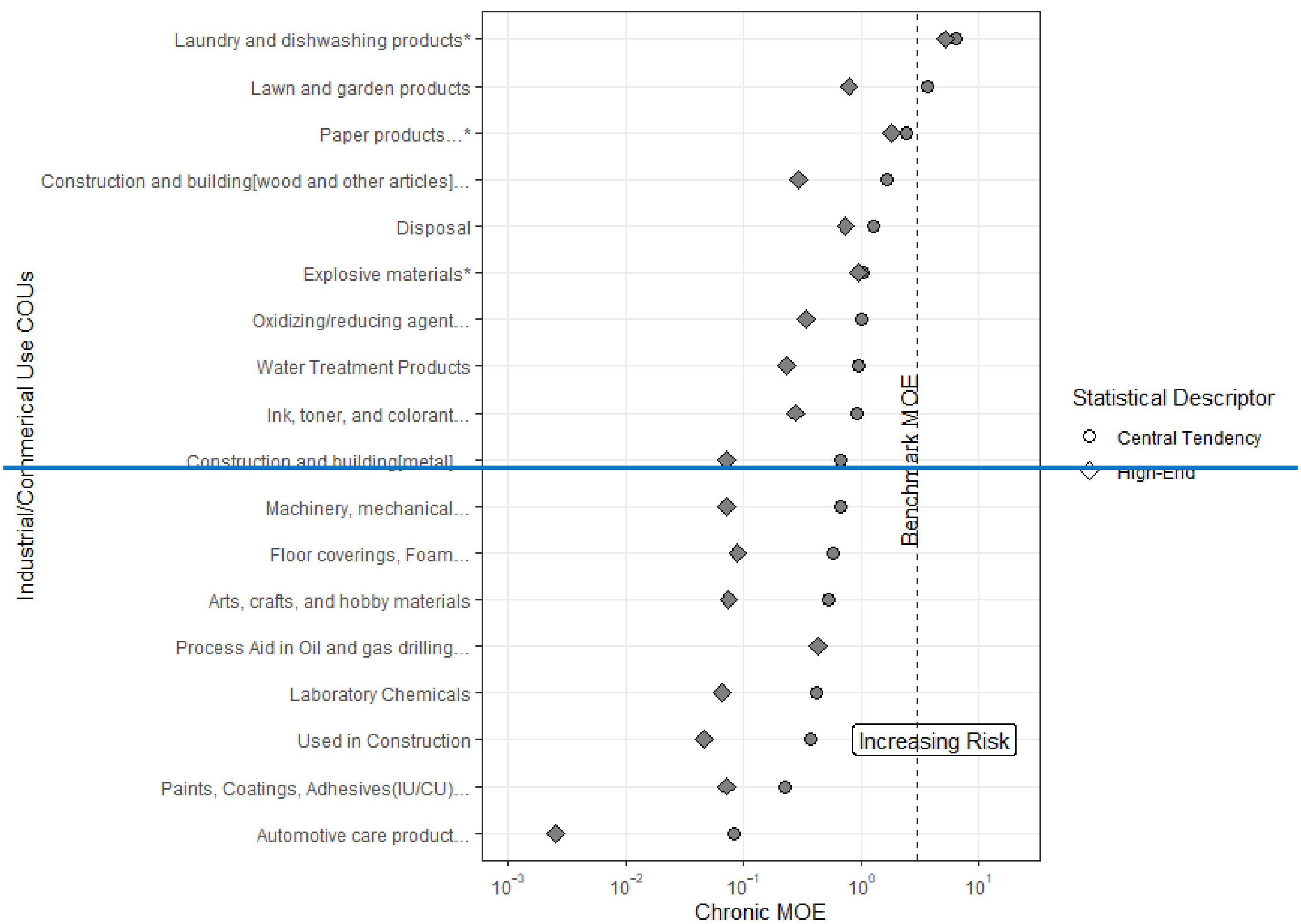
G.1 Chronic Non-cancer Risk Estimates

As shown in Figure_Apx H-1, chronic non-cancer risk estimates for worker inhalation exposure range from 2.59×10^{-3} to 3.91×10^{3} for both high-end and central tendency exposures. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated. While some healthy adult workers may be less susceptible to formaldehyde at concentrations below the benchmark MOE, Chronic non-cancer effects may be a concern for susceptible workers such as those with chronic respiratory disease or those with co-exposures that contribute to similar respiratory effects. Of the 50 TSCA COUs evaluated, 48 TSCA COUs have chronic risk estimates below an MOE of 3 based on their high-end and central tendency risk estimates, with 1 TSCA COUs whose chronic risk estimates was above an MOE of 3 for their central tendency risk estimate. Sub-chronic, non-cancer risk estimates follow a similar risk profile and are not separately illustrated, except Commercial Use- lawn and garden products which has central tendency and high-end estimates below the MOE of 3 for sub-chronic non-cancer risk estimates.



~~Figure_Apx H-1. Chronic Non-Cancer Occupational Inhalation Risks for Manufacturing/ Processing COUs~~

~~Non-cancer MOE risk estimates based on occupational exposure with lower MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated.~~



Figure_Apx H-2. Chronic Non-cancer Occupational Inhalation Risks for Industrial/Commercial Use COUs

Non-cancer MOE risk estimates based on occupational exposure with lower MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated.

For chronic inhalation risks, EPA has high confidence in the chronic, non-cancer hazard POD. The chronic, non-cancer hazard POD is supported by a robust database of evidence in humans and animals that demonstrates concordance in effect levels across multiple endpoints and it includes evidence in children with asthma and other sensitive groups. Generally, EPA has medium confidence in the exposure estimates for full-shift exposures but confidence for individual scenarios varies from low to high across the OESs assessed. For most exposure scenarios, EPA estimated full-shift exposures by integrating discrete data identified from peer-reviewed literature and other sources.

Appendix H ADDITIONAL CONSUMER RISK CHARACTERIZATION

The following subsections provide a summary of potential chronic exposures and risks associated with formaldehyde based TSCA COUs during consumer use.

H.1 Consumer Chronic Risk Estimates

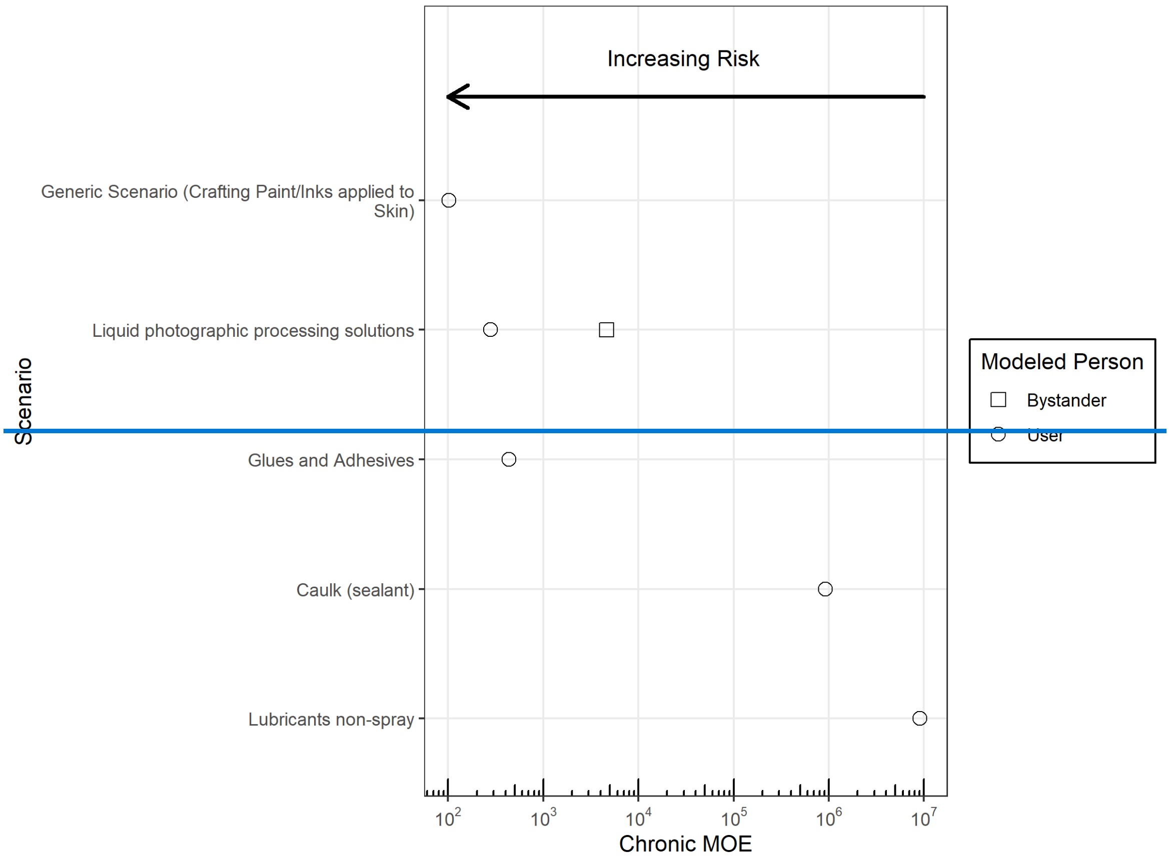
EPA estimated non-cancer risks for exposure to formaldehyde resulting from exposure to formaldehyde in consumer products. For this analysis, EPA relied on the consumer exposure estimates modeled in the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d) and summarized in Section 2.2.

EPA does not expect most consumer exposures to be chronic in nature because product use patterns generally tend to be infrequent with relatively short durations of use. Therefore, EPA did not estimate potential cancer risks for consumers.

H.1.1 Risk Estimates for Inhalation Exposure to Formaldehyde in Consumer Products

EPA estimated non-cancer risks to consumers and bystanders from inhalation of formaldehyde in consumer products.

Chronic non-cancer risk estimates for consumers based on modeled chronic inhalation exposures range from $1.02\times10^{+2}$ to $9.98\times10^{+6}$, with lower values indicating greater risks (Figure_Apx I-1). Non-cancer risk estimates below 1 indicate that exposure is greater than the hazard point of departure based on respiratory effects in sensitive groups, including children. The risk estimates for chronic exposures presented here are based on central tendency air concentrations modeled for a set of mid-range model input assumptions and TSCA COU-specific assumptions about exposure frequency and duration. Risk estimates presented here represent risks to consumers who frequently use products containing formaldehyde and are based on the consumer activity and use patterns described in the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d). For example, cancer risk estimates for the arts, crafts, and hobby material COU presented here are not representative of all arts and crafts products. They are based on an assumption of exposure to a specific set of products that contain 0.1 percent formaldehyde used an average of 15 minutes/day, 300 days each year, over a period of 57 years which are standard CEM temporal inputs primarily based upon the 1987 Westat survey of consumer activities and use patterns (U.S. EPA, 2021a, 2019; Westat, 1987).



Appendix I

Appendix J Figure_Apx I-1. Chronic Non-cancer Inhalation Risks for Consumer Products by COU

Appendix K Chronic risk estimates are based on consumer and bystander exposure estimates that rely on central tendency assumptions about product use duration and frequency. Non-cancer MOEs are based on modeled air exposure estimates and are interpreted relative to a benchmark MOE of 3. Lower MOE values indicate greater risks. The x-axis presents risk estimates for chronic inhalation exposure estimates, and the y-axis presents the modeled TSCA COUs.

Appendix L

Appendix M Overall confidence in inhalation risk estimates for consumer products is medium for chronic non-cancer risks. As described in Section 3.2.1 of the Consumer Exposure Module, the overall confidence in monitoring data used in the indoor air assessment is high due to reliance on 41 high quality formaldehyde air exposure studies relevant to TSCA COUs, and CEM modeling assumptions and inputs, which have been peer reviewed and used in previous existing chemical risk evaluations. While EPA relied on available survey data on product use patterns, there is uncertainty around the applicability of the generic survey data for current use patterns for specific product types. For example, for some inputs relied on the use and activity patterns reported in the Westat survey from 1987 (Westat, 1987). Although this is a robust dataset it may not be reflective of current use patterns for the specific product types assessed. As described in Section 3.2, overall confidence in the chronic, non-cancer hazard POD is high because it is supported by a robust database of evidence in humans and animals that demonstrates concordance in effect levels across multiple endpoints and it includes evidence in children with asthma and other sensitive groups.

Appendix N