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Office of Chemical Safety and
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Draft Indoor Air Exposure Assessment for Formaldehyde

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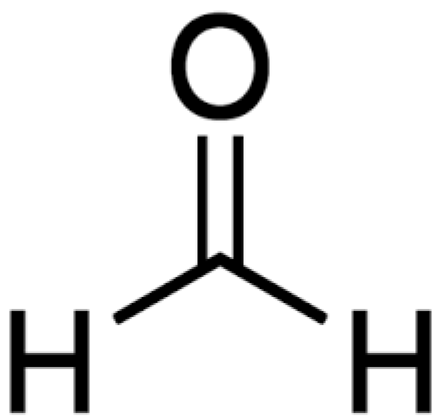

March 2024

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Key Points: Indoor Air Exposure Assessment for Formaldehyde

The draft indoor environment includes commercial settings, new homes, mobile homes, and automobiles, which are a major source of formaldehyde exposure to humans. This exposure is the result of ubiquitous use of formaldehyde in the manufacturing of consumer products (*e.g.*, rubber mats, plastic chairs, hardwood floors used in numerous products and articles). Formaldehyde may also be present in the indoor environment due to the use of candles, fireplaces, and gas stoves, all of which are non-TSCA sources of formaldehyde. The number of potential sources of formaldehyde to consider makes an indoor air assessment of formaldehyde highly complex. Adding to that complexity is the inability to apportion formaldehyde concentrations to a TSCA vs non-TSCA source, based on the currently available data.
EPA identified four conditions of use (COUs) under the Toxic Substances Control Act (TSCA) as significant formaldehyde contributors to commercial, automotive, and residential indoor air environments. The Agency estimated 1-year formaldehyde air concentrations for several residential, commercial, and automobile scenarios using the Consumer Exposure Model (CEM) and product-specific emission rates and fluxes. The following bullet summarizes the key point of this indoor air exposure assessment:

Modeled estimated concentrations ranged from 4.01 to 423.47 $\mu g/m^3$. The highest TSCA COU contributor to the residential indoor air environment was residential building wood products (hardwood floors). For non-TSCA sources of formaldehyde in indoor air, simulated 50th percentile room concentrations ranged from 12.3 to 44.2 $\mu g/m^3$ individually for candles, incense, cooking, wood combustion, and air cleaning devices, and up to 152.2 $\mu g/m^3$ for ethanol fireplaces.
EPA also evaluated available formaldehyde indoor air monitoring data from within residential homes, automotives, offices, and other buildings.

Model estimated formaldehyde concentrations (1 year) were within the same order of magnitude as measured concentration data (*e.g.*, reported in the American Healthy Homes Survey II), suggesting the identified TSCA COUs are important contributors to real-world concentrations of formaldehyde in indoor air. Formaldehyde concentrations are expected to be highest for

- New formaldehyde-based materials introduced to homes or automobiles; and
- Construction of new residences and automobiles using formaldehyde-based materials.

EXECUTIVE SUMMARY

Formaldehyde is a chemical ingredient in many commercial and consumer products, some of which are significant contributors to its chronic indoor air concentrations. As such, EPA evaluated and presents 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 and/or long-term (chronic) sources of formaldehyde in indoor air.

EPA used the CEM to estimate formaldehyde residential indoor air concentrations from specific consumer article categories by incorporating relevant emission rates extracted from the literature. EPA also considered monitoring data from commercial, residential, and automobile environments in its assessment of formaldehyde in indoor air.

Modeled and measured concentration values were generally within the same order of magnitude. Generally, residential homes are expected to represent the most health-protective ("conservative") indoor air scenario as they have lower room volumes and air exchange rates than commercial buildings.

EPA also evaluated measured indoor air concentrations of formaldehyde in homes, automobiles, and other buildings—including the American Healthy Homes Survey II, which included a nationally representative, indoor air monitoring study of formaldehyde administered by EPA and the U.S. Department of Housing and Urban Development (HUD).

Based on consideration of the weight of scientific evidence, EPA has medium confidence in the overall findings for the indoor air exposure assessment, primarily as a result of CEM's inability to consider chemical-half-life, although emission fluxes and rates from quality product emission studies were used to refine the model as much as possible for increased comparability with measured concentrations from the American Healthy Homes Survey II.

1 INTRODUCTION

Formaldehyde is a naturally occurring aldehyde produced during combustion, the decomposition of organic matter, and in the human body as a normal part of metabolism. Formaldehyde is also used extensively in construction, furniture manufacturing, and in consumer products. As such, formaldehyde is ubiquitous in indoor and outdoor environments. Formaldehyde is a gas that is distributed in solution as formalin or in a solid as paraformaldehyde.

Formaldehyde is a high priority chemical undergoing the Toxic Substances Control Act (TSCA) risk evaluation process for existing chemicals following passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016. It is concurrently undergoing a risk assessment under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and EPA's Integrated Risk Information System (IRIS) programs. This document presents a formaldehyde indoor air exposure assessment of TSCA conditions of use (COUs), as defined by the TSCA section 3(2) definition of "chemical substance." This TSCA-specific assessment serves to support risk management needs by EPA's Office of Pollution Prevention and Toxics (OPPT) and is one of many documents included within the Draft Formaldehyde Risk Evaluation.

1.1 Risk Evaluation Scope

The TSCA risk evaluation of formaldehyde comprises several human health and environmental assessment modules and two risk assessment documents—the environmental risk assessment and the human health risk assessment. A basic diagram showing the layout of these modular assessments and their relationships is provided in Figure 1-1. This draft indoor air exposure assessment is shaded blue. In some cases, individual assessments were completed jointly under TSCA and FIFRA. These modules are shown in dark gray.

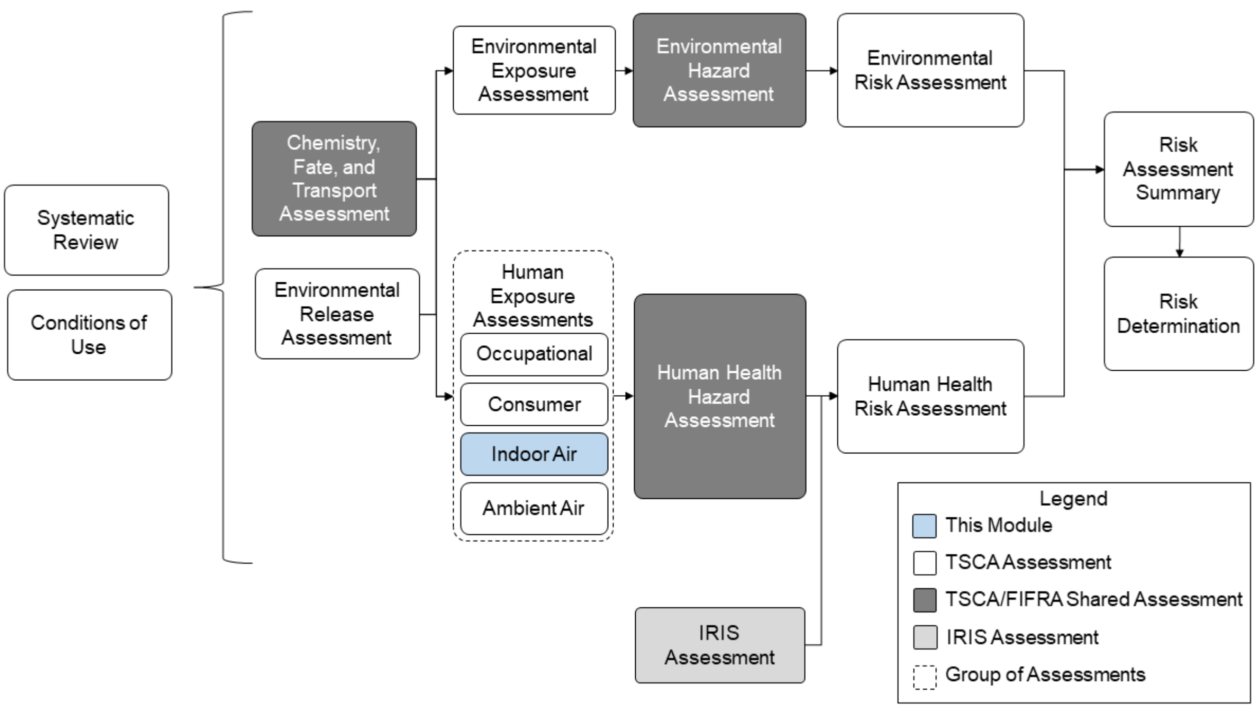

Figure 1-1. Risk Evaluation Document Summary Map

1.1.1 Indoor Air Exposure Assessment Scope

Prior publications indicate that the indoor air environment is a significant source of formaldehyde exposure (IPCS, 2002; ATSDR, 1999). EPA considered all reasonably available data regarding TSCA conditions of use (COUs), including consumer products[1] and articles[2] with high emission rates in the indoor air environment. Among the TSCA sources of formaldehyde indoor air exposure, wood products are expected to be the primary contributors (EPA, 2016) in addition to textiles and wallpaper due to their relatively high emission rates of formaldehyde and abundance in indoor environments (IPCS, 2002; ATSDR, 1999). EPA acknowledges that while 15-minute peak and other short term formaldehyde exposures can occur via product uses (*e.g.*, car wax and polish products), the primary focus of the indoor air assessment is on potential exposures from articles (*e.g.*, wood, wallpaper, seat covers, etc.). This is because those uses are generally more prevalent in typical residences and since articles are generally emit formaldehyde slowly over the span of several weeks, months, or years depending on the article and the applicable surface area within the rooms of use. This also allows for better comparability with mean monitoring concentrations, per Section 2.1.2.

EPA only considered products that are currently available on the consumer market. The assessed wood products (*i.e.*, hardwood floor and wood furniture) are unlikely to be compliant with the TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products given the wood product emission rates identified are from literature published from 2009 and prior (40 CFR Part 770). EPA utilized emission limits set for hardwood plywood (HWPW), medium density fiber board (MDF), and particle board (PB) to estimate potential indoor air exposures using weight fractions identified for wood products as presented in the Consumer Exposure Module (EPA, 2024c). However, due to uncertainties related to whether the assessed wood products are made entirely of HWPW, MDF, or PB, whether the identified products are compliant with the relevant emission standards, and whether the approach to estimating emission rates from the set emission limits, sufficiently represent products on the consumer market. there was a low confidence in such analysis which is qualitatively detailed in Appendix D. For a complete list of all formaldehyde COUs and relevant scenarios quantified, see the *Formaldehyde and Paraformaldehyde Use Report* (EPA, 2020b) and the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA, 2020a).

Formaldehyde is also used for personal care products, embalming and taxidermy; however, estimated exposures from these uses were not included in this indoor air exposure assessment because they are excluded from the chemical substance definition under TSCA section 3(2)(B)(vi) (pertaining to cosmetics as defined under the Federal Food, Drug, and Cosmetic Act) and (ii) (pertaining to pesticides as defined under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]), respectively.

The formaldehyde indoor air exposure assessment does not focus on byproduct or secondary formations of formaldehyde such as the generation of formaldehyde as a combustion byproduct (*e.g.*, cigarette smoking, fireplaces, wood stoves) because these are not TSCA COUs. However, because such sources are expected to contribute to long-term indoor air concentrations of formaldehyde, they are included in indoor air monitoring data where source apportionment cannot be performed.

Lastly, individuals may be exposed to formaldehyde in indoor air wherever certain non-TSCA consumer products or articles, such as wood burning fireplaces, wood stoves, or cigarettes, are used (ATSDR,

[1] Products are generally consumable liquids, aerosols, or semi-solids that are used a given number of times before they are exhausted (EPA, 2019).
[2] Articles are generally solids, polymers, metals, or woods, which are always present within indoor environments for the duration of their useful life, which may be several years (EPA, 2019).

1999). These sources of exposure are beyond the scope of this TSCA chemical risk evaluation; however, EPA acknowledges that these sources may contribute to the total formaldehyde exposure to which an individual may be exposed.

1.2 Summary of the Chemistry, Fate, and Transport Assessment

Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor. As described in the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde* (EPA, 2024b), while formaldehyde is subject to transformation processes in outdoor air, it is not expected to be subject to transformation and degradation processes in the indoor air environment (Salthammer et al., 2010). Thus, formaldehyde is expected persist in indoor environments.

Long-term formaldehyde concentrations in the indoor environment are driven by dissipation and adsorption. The major route of dissipation of formaldehyde in the indoor environments is by mechanical removal via introduction of fresh air. See Section 2.1.2 for a presentation of monitoring data regarding formaldehyde dissipation in indoor air.

Adsorption of formaldehyde to surfaces can occur based on the surface composition; however, because formaldehyde may re-emit at warmer temperatures (Plaisance et al., 2013; Cousins, 2012; Traynor et al., 1982), adsorption is not expected to be a source of dissipation. Additionally (see also Section 3.1.1.1), due to improved insulation in American homes built after 1990, temperature control and energy efficiency has generally improved such that formaldehyde might persist longer in such homes compared to older homes as a result of reduced indoor-outdoor air exchange.

Depending on the article, COU-specific formaldehyde emissions may last multiple years; although the emissions are expected to decrease over time and follow a first-order exponential process (EPA, 2016). For example, according to chamber studies of formaldehyde emissions from pressed wood products over time, emissions half-life for such products ranged from 1.5 to 2 years. Furthermore, with an emissions half-life of 1.5 years, the emission rate of pressed wood products after 10 years was estimated to be approximately 1 percent of the initial emission rate (EPA, 2016). Such emissions may vary by product formulations, chemical or product-specific properties, usage patterns, environmental conditions (*e.g.*, humidity, sun exposure).

1.3 Conceptual Exposure Model

EPA considered reasonably available information including physical and chemical properties of formaldehyde based on its specific forms in relevant products, as well as public comments received on the draft scope document for formaldehyde in finalizing the exposure pathways, exposure routes, and hazards subject to this assessment. Figure 1-2 is a graphical depiction of the actual or predicted relationships of a subset of TSCA COUs, exposure pathways, exposure routes, hazards, and exposed groups throughout the consumer life cycle of formaldehyde in indoor air. Since formaldehyde indoor air exposures are expected to occur over extended periods, this indoor air exposure assessment was performed in the context of long-term exposures over the span of 1 year. For example, a person who drives an automobile nearly every day (*i.e.*, over a period of 300 days) may be exposed to formaldehyde through inhalation as a result of formaldehyde offgassing to air from seat covers within the automobile. Similarly, uses of consumer products such as wood, furniture seat covers, and wallpaper contribute to indoor air concentrations that lead to exposures to formaldehyde.

The conceptual model in Figure 1-2 presents the exposure pathways, exposure routes and hazards to exposed groups from emitters of formaldehyde in indoor air. It should be noted that exposed groups include potentially exposed susceptible subpopulations (PESS) defined by TSCA section 3(12) to be a group of individuals within the general population identified by EPA who, due to either greater susceptibility or exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture. PESS includes infants, children, pregnant women, workers, the elderly, or overburdened communities whose exposure to formaldehyde in indoor air, including commercial settings (*e.g.*, schools, libraries, offices), might be more significant relative to others from the general population. Therefore, in addition to the modeled consumer exposures presented in Figure 1-2, monitoring concentrations in public spaces accessible to the general public are also presented.

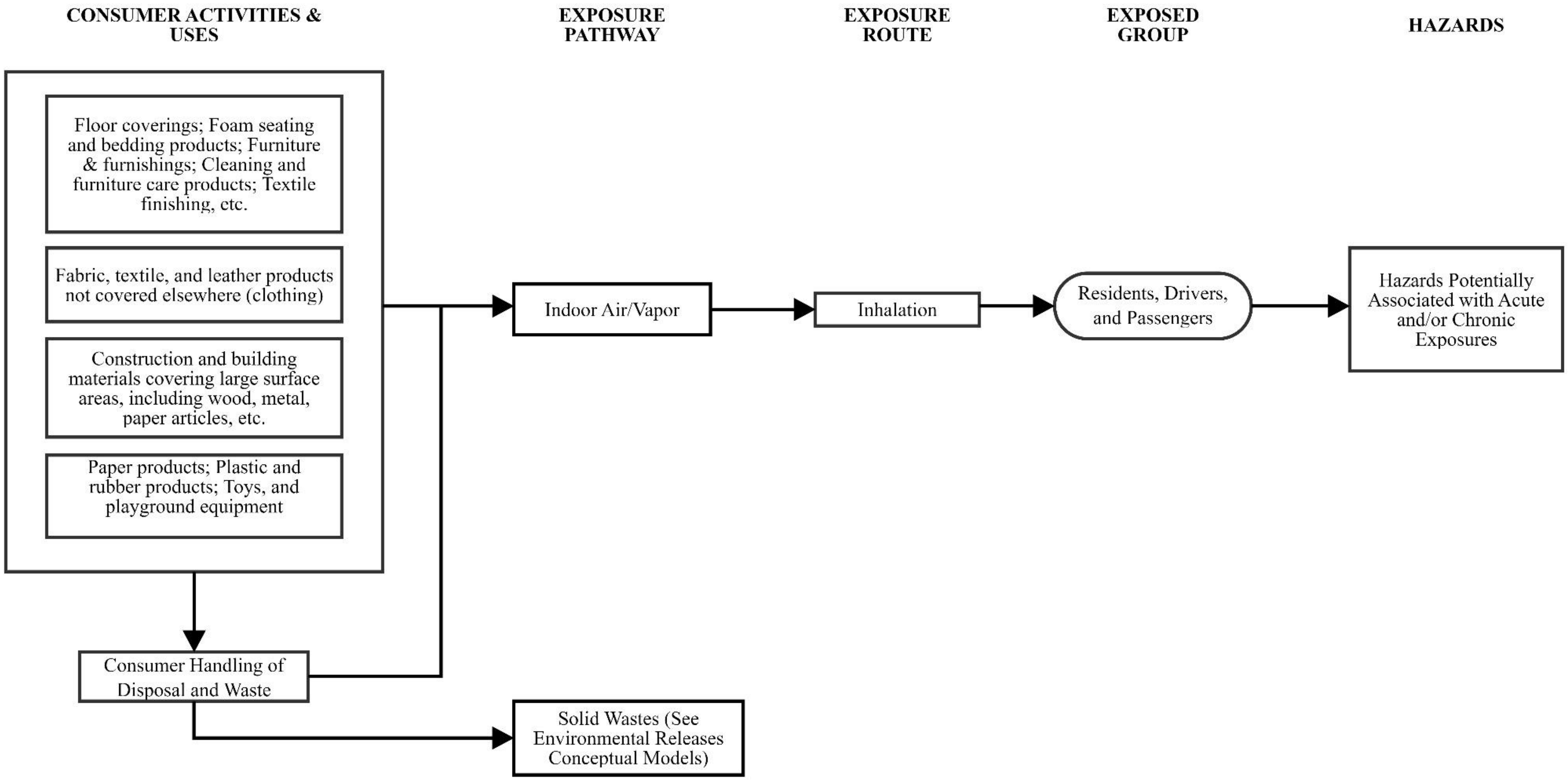

Figure 1-2. Formaldehyde Conceptual Model for Consumer Activities and Uses in Indoor Air: Consumer Exposures and Hazards

While the identified COUs are also reflective of consumer COUs and assessed as such in the *Draft Consumer Exposure Assessment for Formaldehyde* (EPA, 2024c), the indoor air assessment of formaldehyde is a refined assessment of these COUs due to their expected persistence and relatively high emissions of formaldehyde per room of use.

2 APPROACH AND METHODOLOGY

2.1 Indoor Air

EPA considered both modeled chronic average daily indoor air concentrations of formaldehyde over a 1-year period, as well as measured formaldehyde residential, commercial, and automobile indoor air concentration data from indoor air monitoring studies. Given the complexities of the exposure assessment of formaldehyde in indoor air, multiple lines of evidence were considered to understand the indoor air concentrations of formaldehyde resulting from formaldehyde TSCA COUs. These different data sources are described in the following sections.

2.1.1 Modeling

2.1.1.1 Consumer Exposure Model

Formaldehyde indoor air concentrations from TSCA COUs were estimated using the Consumer Exposure Model (CEM). Because CEM estimates air concentrations from a specific product or article, it is an ideal modeling tool for this indoor air exposure assessment. CEM is a longstanding model used by OPPT in several previous TSCA new and existing chemical risk evaluations to model consumer and bystander exposures from products and articles. The model has been updated based on feedback on both the performance and ease of use of the tool through beta testing and peer review (EPA, 2019).

The scenarios, chemicals, and defaults currently included in CEM are based on available data and professional judgment and allow the use of all parts of the model without requiring the model user to determine all inputs for each model run. At any time, defaults, chemicals, or use scenarios can be deleted, added, or refined based on newly available information. In addition, generic (blank) scenarios are available that can be populated with user-defined inputs (*e.g.*, article-specific emission rates) (EPA, 2019).

CEM retains 6 existing models from EPA's EPA's Exposure and Fate Assessment Screening Tool (E-FAST) model and adds 15 additional models, including 6 emission models and 3 inhalation models. All CEM models are used to estimate chemical concentrations in exposure media, including indoor air, airborne particles, settled dust, etc. (EPA, 2019). The consumer exposure assessment (and Section 3.1.2 and Appendix A) contains a detailed description of the CEM modeling approach and methodology (EPA, 2024c).

2.1.1.1.1 Model Output Time Period

While intermittent or short-term product and article uses contribute to indoor concentrations of formaldehyde, the indoor air assessment focused on the persistent sources of exposure that typically come from article emissions and off-gassing. Articles of most concern (*e.g.*, wood products) continually emit formaldehyde over time according to carrying emission rates.

For this assessment, CEM was used to estimate formaldehyde indoor chronic average daily air concentrations over a period of 1 year in automobiles and homes based on TSCA COUs.

2.1.1.1.2 Scenario Selection

After considering rates of emissions from all 12 formaldehyde TSCA COUs based on the literature and professional judgement, EPA identified four COUs along with 8 scenarios deemed to be significant and long-term to the indoor air assessment (EPA, 2016). The exposure scenarios, as defined in CEM (EPA, 2019), represent the COUs under which a product or article and relevant pathway of exposure (*i.e.*, means through which an individual is exposed to a chemical) fit within the lifecycle diagram provided in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA, 2020a).

Generally, an individual may be exposed to a chemical such as formaldehyde through multiple use scenarios, including using formaldehyde-emitting seat covers set on automobile car seats vs. using formaldehyde-emitting seat covers set on a living room sofa. In these examples, the surface area of the articles uses, size of room of use, and interzonal ventilation rate are important inputs that have a major impact on the modeled indoor air concentration and assumed exposure for the user of the formaldehyde-emitting article. A description of the room or use and the CEM has predefined scenarios with default parameters that can be adjusted by the user (*e.g.*, article-specific emission rates) (EPA, 2019). In certain cases, the modeler uses a generic product or article scenario if the scenario of interest does not fit CEM's pre-built options. For this indoor air assessment, EPA utilized pre-built CEM scenarios to model article-specific formaldehyde indoor air concentrations. EPA assumed that the formaldehyde indoor air exposure would occur according to the activity patterns of the individual. The individual was assumed to be someone who goes to work or school for most of the day and spends 1 hour in a vehicle, 2 hours in a living room and 10 hours in a bedroom every day.

The four indoor air TSCA COUs and the relevant scenarios are described in Table 2-1. Note that CEM identifies foam insulation under the exposure scenario heading of Plastic Articles: Foam Insulation.

Table 2-1. Formaldehyde Indoor Air Conditions of Use and Relevant Exposure Scenarios

Condition(s) of Use	CEM Exposure Scenarios
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)
Fabric, textile, and leather products not covered elsewhere	Seat Covers (automobile)
	Furniture Seat Covers (residential)[b]
	Fabrics: Clothing (residential)
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)
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Paper-Based Wall Paper (residential)

Because there may be multiple scenarios per COU, once results were generated, EPA selected a representative scenario according to the highest estimated concentration per duration and route of exposure. EPA assumes this approach is protective of most consumers within a given COU and allows the Agency to regulate according to the overall condition of use as it is mandated to do under TSCA. However, associated uncertainties with this approach include (1) the identified representative scenario according to highest estimated concentration may not necessarily be the most common, and (2) one individual may be exposed to formaldehyde through multiple scenarios within a single COU.

2.1.1.1.3 Chemical-Specific Input Parameters

To model formaldehyde indoor air concentrations, EPA modeled indoor air concentrations by identifying

1. The chemical of interest with a name (*i.e.*, formaldehyde) and physical chemical properties (*e.g.*, vapor pressure).
2. The emission models of interest.
    a. In this assessment, article-specific information used the E5 model (for products placed in room) instead of E6 (for articles placed in room), even though the COUs identified are articles since CEM does not allow the user to model chemical emissions from articles with specific emission rates with E6. Despite different underlying assumptions, a few trial runs without user-defined emission rates using the E5 and E6 model did not yield considerably different results. Thus, E5 was deemed as a worthy surrogate for E6.
3. The room of use (*e.g.*, automobile), zones/field of exposure (*i.e.*, near field or far field), and exposed individuals (*e.g.*, adults, youth, infants).
    a. Note: Near-field exposures typically correspond to the immediate area of product or article use and will typically have the highest amount of exposure. This space is assumed to represent consumer exposures. Far-field exposures typically correspond to the areas beyond where the product or article is being used, such as the area opposite of the room of use or another room beyond the room of use.
4. The weight fraction of the chemical in the product or article.
    a. While CEM provides a default value, this is typically identified via a search of safety data sheets (SDSs) from products currently on the consumer market, as was done for this exposure assessment.
5. Product or article properties (*e.g.*, density of product, surface area of article, frequency of use, duration of use, mass of product used, emission rates)
    a. While defaults are typically based on the Westat (1987) survey and EPA's *Exposure Factors Handbook* (EPA, 2021a), among other sources, the modeler has the ability to edit these parameters as they see fit; thus, the indoor air model was refined by incorporating formaldehyde emission rates from articles identified in the literature. Only emission rates for relevant TSCA COUs were utilized. Emission rates for non-TSCA COUs were irrelevant to this assessment and CEM cannot be used to model such sources (i.e., smoking and other sources of formaldehye by-product production).
        i. Emission rates (presented in Table 2-2) were gathered from the literature (Maddalena et al., 2009; Kelly et al., 1999; Yu and Crump, 1998; Matthews et al., 1984; Pickrell et al., 1984; Pickrell et al., 1983). Emission rates were commonly reported in ranges. Therefore, the midpoint of such ranges was calculated for each product identified in the literature to estimate the typical emissions of formaldehyde in a residential or automobile indoor air environment.
        ii. To estimate the most common emission rates per COU category for comparison with nationally representative indoor air monitoring data from the American Healthy Home Survey II, a central tendency of emission rates was estimated using an average of the median emission rates for all products identified per COU category. However, indoor air exposures for PESS are expected to be sufficiently addressed via an aggregate assessment of indoor air exposure from multiple TSCA COUs.
        iii. From the identified PECO relevant sources, emission rates were reported ranges except for a few studies where a single value was reported per product (Table 2-2). Although the list of identified sources do not represent all relevant sources

of data, these sources were deemed to be sufficiently representative of article-specific emission rate data per the systematic review process (EPA, 2021b). In instances where the true emission rate was less than a given value (*e.g.*, <0.1), this value was assumed to be the minimum (*i.e.*, 0.1). Non-detects (ND) were assumed to be 0. The median of ranges was used to approximate the 50th percentile or central tendency. The average of medians were calculated to generate a central tendency across products based on COU.

iv. See **Error! Reference source not found.** for a detailed description of a fit-for-purpose approach implemented to identify article-specific formaldehyde emission rates amongst other data including relevant monitoring data from literature.

6. The relevant environmental inputs for the relevant exposure scenarios (*e.g.*, building volume, use environment volume, air exchange rates, etc.)
7. Exposure factors (*e.g.*, inhalation rate)(EPA, 2021a)
8. The activity pattern that identifies the start time of exposure during a product or article use day and the general expected movement from room to room throughout over time.

Table 2-2. Formaldehyde Emission Rates by TSCA Condition of Use (COU)

Condition(s) of Use	Exposure Scenario	Identified Product Types in Literature	Source (HERO ID)	Reported Emission Rates, per Surface Area ($\mu g/m^2$-hr)[a]	Median Emission Rates per Identified Product, within a COU, per Surface Area ($\mu g/m^2$-hr)	Average Emission Flux per Exposure Scenario ($\mu g/m^2$-hr)	Expected Room of Use	Expected Surface Area of Article in Room of Use (m^2)	Average Emission Rates, per COU, and Room of Use (mg-hr)
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	Wood Articles: Hardwood Floors	Pressed wood products (concentration : 0.05 ppm)	(Matthews et al., 1984)	10[b]	10	454.5	Residence-Living Room	27.87	12.67
		Pressed wood products (concentration : 0.10 ppm)	(Matthews et al., 1984)	40[b]	40				
		Pressed wood products (concentration : 0.20 ppm)	(Matthews et al., 1984)	70[b]	70				
		Pressed wood products (concentration : 0.40 ppm)	(Matthews et al., 1984)	120[b]	120				
		Pressed wood products	(Pickrell et al., 1983)	ND (assuming "0")−1,500	750				
		Bare urea-formaldehyde wood products (¼– ¾")	(Kelly et al., 1999)	8.6−1,580[c]	794.3				
		Coated urea-formaldehyde wood products	(Kelly et al., 1999)	<2.7−460[c]	231.35				
		Bare phenol-formaldehyde wood products	(Kelly et al., 1999)	4.1−9.2[c]	6.65				
		Particle board	(Pickrell et al., 1984)	1,500−2,167[d]	1833.5				

Condition(s) of Use	Exposure Scenario	Identified Product Types in Literature	Source (HERO ID)	Reported Emission Rates, per Surface Area (µg/m²-hr)[a]	Median Emission Rates per Identified Product, within a COU, per Surface Area (µg/m²-hr)	Average Emission Flux per Exposure Scenario (µg/m²-hr)	Expected Room of Use	Expected Surface Area of Article in Room of Use (m²)	Average Emission Rates, per COU, and Room of Use (mg-hr)
		Plywood	(Pickrell et al., 1984)	1,292−1,375[d]	1333.5				
		Cabinet (including end cabinet)	(Maddalena et al., 2009)	5.21-419	212.105				
		Door (including cabinet door)	(Maddalena et al., 2009)	14.3-91.8	53.05				
Fabric, textile, and leather products not covered elsewhere	Furniture Covers, Car Seat Covers, Tablecloths	Curtain	(Maddalena et al., 2009)	14.4-323	168.7	118.8	Automobile (Furniture Seat Covers)	1	0.12
		Permanent press fabric	(Kelly et al., 1999)	42−215[c]	128.5				
		Cushion	(Maddalena et al., 2009)	69.2-410	239.6		Residence – Living Room (Furniture Seat Covers)	1	0.12
		Carpet	(Maddalena et al., 2009)	42.4-57.6	50				
		Fabrics	(Pickrell et al., 1983)	ND(assuming "0")−14.58	7.29				
	Fabrics: Clothing	New clothing	(Pickrell et al., 1983)	0.63−31.25	15.94	15.9	Residence – Bedroom (Clothing)	1.18	0.02
Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal	Wood Articles: Furniture	Bed Deck	(Maddalena et al., 2009)	4.1-136	70.05	116.6	Residence – Living Room	27.87	3.25
		Bench/Seat Bottom	(Maddalena et al., 2009)	33.3-293	163.15				

Condition(s) of Use	Exposure Scenario	Identified Product Types in Literature	Source (HERO ID)	Reported Emission Rates, per Surface Area (µg/m²-hr)[a]	Median Emission Rates per Identified Product, within a COU, per Surface Area (µg/m²-hr)	Average Emission Flux per Exposure Scenario (µg/m²-hr)	Expected Room of Use	Expected Surface Area of Article in Room of Use (m²)	Average Emission Rates, per COU, and Room of Use (mg-hr)
articles; or rubber articles									
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Paper products	Paper-based wallpaper	(Kelly et al., 1999)	27	27	27.0	Residence-Living Room (Drywall area used as surrogate for wall paper area)	20	0.54

[a] Emission rates were reported ranges with the exception of a few cases where a single value could be found per product. In instances where the true emission rate was less than a given value, say <0.1, this value was assumed to be the minimum (*e.g.*, 0.1). Non-detects (ND) were assumed to be 0. The median of ranges were taken to approximate a 50% percentile value, median or central tendency. The average of medians were calculated to generate a 50% percentile or central tendency values across products per COU.
[b] At 23 °C, 50% relative humidity, CH20 ER data interpolated to fixed CH20 concentrations from 0.05–0.40 ppm. This portrays the range of ERs according to range of concentrations.
[c] Emission rates represent typical conditions, defined as 70 °F, 50% relative humidity, and 1 air change per hour.
[d] Range indicates different test conditions in temperature and relative humidity.

2.1.2 Monitoring

Interpreting available indoor air monitoring data may result in uncertainties in estimating actual formaldehyde concentrations resulting in exposures from TSCA COUs. Several challenges are listed below and include:

- Samples may have been collected at exposure times or for exposure durations not expected to be consistent with a presumed hazard based on a specified exposure time or duration.
- Samples may have been collected at a time or location when there are multiple sources of formaldehyde present that are not TSCA COUs.
- Measured concentrations reflect total formaldehyde concentrations that may include sources of formaldehyde that are the result of non-TSCA uses or cannot be tied specifically to a COU.
- Activity patterns may differ according to demographic categories (*e.g.*, stay at home/work from home individual vs. an office worker), which can impact exposures specially to articles that continually emit a chemical of interest.
- Some indoor environments may have more ventilation than others, which may change across seasons.

Over 800 monitoring studies were identified for formaldehyde's TSCA risk evaluation, 290 of which are specific to the indoor air environment and associated with the 20 total TSCA COUs subject to this draft risk evaluation. Thus, indoor air monitoring exposures of formaldehyde has been extensively studied. This assessment does not attempt to present results from every study that has been identified from systematic review. Instead, EPA considered and incorporated several indoor air monitoring studies into this assessment (see Section 3.1.2). Among the presented monitoring studies, EPA focused its review and analysis efforts on a nationally representative formaldehyde indoor air monitoring data from the American Healthy Homes Survey II (AHHS II) as it is the most current and first nationally representative residential indoor air study of formaldehyde(QuanTech, 2021).

In addition, the term "background" indoor air concentration has often been used in reference to indoor air chemical assessments. This term may be generally used to define the typical measured concentrations of a chemical in media (*i.e.*, indoor air). It can also be used to describe the naturally occuring concentration of a chemical. For the formaldehyde indoor air exposure assessment, background formaldehyde indoor air concentration may contribute to an aggregate indoor concentration of formaldehyde over time in addition to combinations of TSCA and non-TSCA products that may vary across homes or automobiles. Formaldehyde indoor air monitoring concentrations presented were not combined in any way with modeling indoor air concentrations due to potential risk of double counting exposures that may already be aggregated in indoor air monitoring values.

3 RESULTS

3.1 Indoor Air Exposure Results

3.1.1 CEM Indoor Air Modeling

Since CEM does not consider chemical half-life over time (EPA, 2019), COU-specific estimates represent formaldehyde air concentrations from new articles introduced to a home or automobile, while the total estimates represent formaldehyde air concentrations from a newly built home or automobile based on the COUs assessed. For all modeled scenarios, there is an initial peak concentration of formaldehyde that reduces logarithmically overtime. The chronic average daily concentrations for 1 year of exposure are typically towards the bottom of the logarithmic curve for all scenarios modeled. It should also be noted that while all age groups were considered there were no differences observed in formaldehyde concentrations per room of use across age groups.

Modeling results for inhalation exposures estimated with CEM are summarized and presented in Table 3-1 and Figure 3-1, according to COU. Table 3-1 and Figure 3-1, presents the various TSCA sources of formaldehyde indoor air contribution in residential indoor air environments. The highest contributors to the chronic average daily air for one year concentration of formaldehyde to a typical home are building wood products (423.47 $\mu g/m^3$). The lowest contributors to formaldehyde air concentrations were furniture seat covers (4.01 $\mu g/m^3$) and clothing (5.19 $\mu g/m^3$). Estimated air concentrations were driven by the final emission rate per surface area in the expected room of use, which is dependent on the emission rates taken from literature and the anticipated surface area of the product in the assumed room of use. The modeled formaldehyde aggregate concentrations from articles contribute an estimated total of 26.05 $\mu g/m^3$ to automobile indoor air and an estimated total of 916.29 $\mu g/m^3$ to residential indoor air. Formaldehyde concentrations are expected to decrease over time U.S. EPA, 2016, 11181057}.CEM accounts for some dissipation over time via air exchanges between room of use and rest of home and between the home and outdoor air. Though, modeling results likely represent new articles added to a home since CEM does not account for chemical half-life.

3.1.1.1 Formaldehyde Residential Indoor Air Half-Life

Residential indoor air formaldehyde concentrations are generally expected to decrease over time following a first-order exponential process as the reservoir of formaldehyde from products and articles are depleted over time (EPA, 2016). This means that a new home with new formaldehyde-based products (*e.g.*, hardwood floors, furniture, clothing, etc.) is expected to have a high initial contribution of formaldehyde off-gassing to the indoor air environment. This is followed by a gradual decrease in formaldehyde off-gassing as formaldehyde sources are gradually depleted over time; then, a tapering off effect over an extended period, if no new formaldehyde-based products are added to the home (EPA, 2016). In a study by (Gammage and Hawthorne, 1985), newer mobile homes had significantly higher mean concentrations of formaldehyde compared to older mobile homes—1,032 µg $\mu g/m^3$ and 308 $\mu g/m^3$ respectively. These highest reported concentrations are slightly higher than the aggregated modeled concentrations from TSCA COUs representing new products added to a home. It should also be noted that in addition to new materials added to a home, other activities that may affect indoor concentrations of formaldehyde include ripping out drywall, fixtures, and using various sources of combustion indoors (*e.g.*, cigarette smoking).

According to the *2016 Formaldehyde Exposure Assessment Report TSCA Title VI Final Rule* (EPA, 2016), the half-life of formaldehyde in indoor air (*i.e.*, the amount of time for formaldehyde concentrations be decrease by half) is expected to be approximately between 1.5 and 3 years. From a cross-sectional study of homes with varying ages, authors noted that, if new formaldehyde-emitting products and articles were being added over time within the homes assessed, an estimated half-life would be close to 2.92 years. The latter is assumed to be an upper bound estimate for formaldehyde's half-life in residential indoor air. Instead, according to an analysis of various chamber studies of pressed wood products as they aged, the authors expect that the residential indoor air half-life of formaldehyde should be approximately 1.5 years in most cases (EPA, 2016).

In newer homes built after 1990, due to improved insulation and relatively less air circulation in certain homes, formaldehyde indoor air concentrations may persist longer (Persily et al., 2010). However, formaldehyde concentrations in remodeled or newly built homes, especially in wooden-framed homes, were found to decrease to mean levels comparable to older homes levels within 2 years (Park and Ikeda, 2006). This is likely because formaldehyde found in newer products is mostly released within that time frame (Park and Ikeda, 2006). Unfortunately, although CEM could not be adjusted to incorporate potential half-life over time, use of interzonal and indoor-outdoor air exchanges over time does account for some dissipation over time.

Table 3-1. Estimated Chronic Average Daily Formaldehyde Indoor Air Concentrations (According to CEM)

COU Subcategory	Scenario	Environment	CEM Calculated Chronic Average Daily Concentration ($\mu g/m^3$)
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)**	Living Room	**4.23E02**
Fabric, textile, and leather products not covered elsewhere	Seat Covers (Automobile)	Automobile	7.10E00
Fabric, textile, and leather products not covered elsewhere	Furniture Seat Covers (Residential)	Living Room	4.01E00
Fabric, textile, and leather products not covered elsewhere	**Fabrics: Clothing (Residential)**	Bedroom	**5.19E00**
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	**1.09E02**
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	**Paper-Based Wallpaper**	Living Room	**1.80E01**

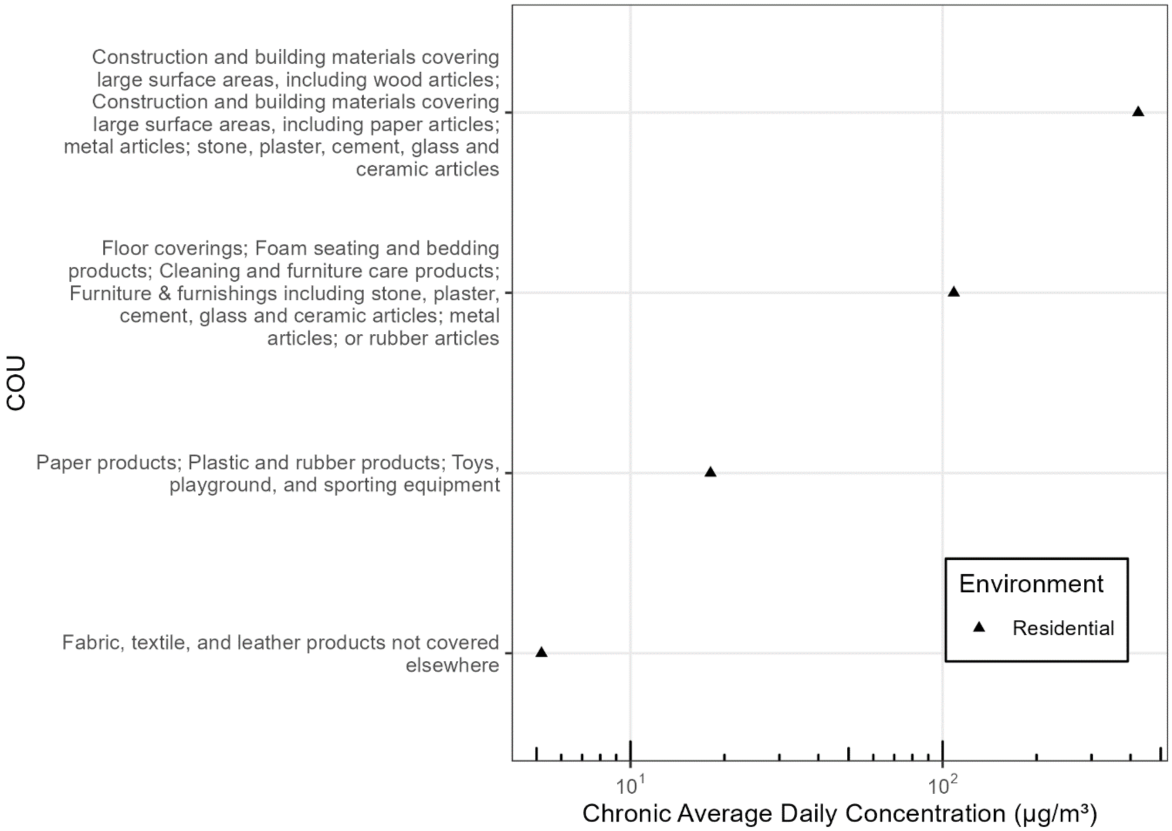

Figure 3-1. Estimated Chronic Average Daily Formaldehyde Indoor Air Concentrations (According to CEM)

3.1.2 Monitoring Data

EPA presents a supplemental summary of formaldehyde concentrations identified from several well-established residential (Table 3-2) and nonresidential (Table 3-3) indoor air monitoring studies to provide additional context to the TSCA formaldehyde indoor air exposure assessment. These monitoring data do not differentiate between TSCA and non-TSCA sources of formaldehyde. This means that EPA is unable to determine what portion of the reported indoor air concentrations are from TSCA vs non-TSCA Sources.

Table 3-2. Indoor Air Monitoring Concentrations for Formaldehyde

Reference	Monitoring Study Description	Formaldehyde Concentrations (µg/m³)	
		Central Value	**Range/Percentiles**
American Healthy Home Survey (QuanTech, 2021)	Nationally representative sample of 688 U.S. homes of various ages, types, conditions, and climates	Mean: 23.2	Range (lower/upper 95% tiles of mean): 21.4–5.0
(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

Reference	Monitoring Study Description	Formaldehyde Concentrations (μg/m^3)	
		Central Value	Range/Percentiles
(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)

The average measured formaldehyde concentrations range between 20 and 40 μg/m^3 in European homes (ECHA, 2019) and 30 to 40 μg/m^3 in Canadian homes (Canada, 2005). These values were derived from a variety of homes representing a range of factors that influence indoor formaldehyde concentrations including but not limited to the age of the home and ventilation. The ranges reported by the European Chemicals Agency (ECHA) and Health Canada are similar to that reported by the American Healthy Home Survey (QuanTech, 2021) (Table 3-2).

Table 3-3. Formaldehyde Monitored in Commercial Buildings in the United States

References	Monitoring Study Description	Formaldehyde Concentrations (µg/m³)	Descriptor
(Ceballos and Burr, 2012)	Office space indoor air monitoring for formaldehyde in a commercial building	24.56	Average
(EPA, 2023d)	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 U.S. school buildings	17.69	Median

3.1.2.1 Commercial and Other Buildings

EPA identified monitoring studies investigating indoor air in commercial and other buildings that can expose office workers, students, and the general population. These environments may have high formaldehyde levels from the off gassing of building materials and other products. The exposure to formaldehyde could stem from multiple COUs (*e.g.*, composite wood products; coatings, paints, adhesives, sealants; formaldehyde-based furnishings; and building materials).

Ceballos and Burr (2012) evaluated formaldehyde indoor air exposures in an office located in a two-story commercial building. The office contained cubicles separated by fabric-covered dividers and most of the office was carpeted. Over the 2-day sampling period inside the office, area concentrations remained at 25 µg/m³. Dodson et al. (2007) conducted personal breathing zone (PBZ) sampling of teachers in primary and secondary schools, as well as office workers. The median of these personal samples was 18 µg/m³.

Additionally, EPA identified studies measuring formaldehyde exposure in office environments outside of the United States Hanazato et al. (2018) measured area concentrations in a newly constructed commercial bank in Japan, and the formaldehyde concentrations in the samples ranged from 1.5 to 3.2 µg/m³. Samples were collected in the lobby, office space, seminar room, and outdoor space. Another study in Japan measured area formaldehyde concentrations across 17 office buildings with concentrations ranging from 3.4 to 21 µg/m³ in the winter and 12 to 45.2 µg/m³ in the summer (Azuma et al., 2017).

In Sweden, the PBZ of 79 participants across 8 office buildings was measured (Glas et al., 2004). The PBZ samples ranged from 2 to 18 µg/m³, with an average of 9 µg/m³. Another study measured the PBZ of office workers in Sweden and Finland, with geometric means of 7.6 µg/m³ and 8.1 µg/m³, respectively (Glas et al., 2014). Dingle et al. (2000) measured the area concentrations of formaldehyde across 18 conventional offices and 20 portable office buildings located on a university campus in Australia. The concentrations in the conventional office buildings ranged from 12 to 90 µg/m³, and the concentrations in the portable office buildings ranged from 516 to 2,592 µg/m³. The elevated formaldehyde concentrations in the portable office buildings were believed to be from the particleboard and plywood present in those buildings (Dingle et al., 2000).

In general, higher formaldehyde indoor air concentration had been reported in the past. EPA identified two studies from office environments in the United States in the 1990s with area concentrations ranging from less than 12 to 2,456 µg/m^3 (Hedge et al., 1995; Kaiser and Sylvain, 1994). Additionally, EPA identified three studies spanning multiple office buildings in Canada with individuals exposed to formaldehyde (Haghighat and Donnini, 1999; Allaire et al., 1997; Menzies et al., 1996). Menzies et al. (1996) measured formaldehyde concentrations in the air ranging from 15 to 59 µg/m^3 in two office buildings. Between the other two studies, concentrations ranged from less than 2 to 2,590 µg/m^3, and most of the office buildings were carpeted (Haghighat and Donnini, 1999; Allaire et al., 1997). A study conducted in 29 office buildings in northern Sweden measured air concentrations of formaldehyde ranging from 11 to 59 µg/m^3 (Sundell et al., 1993).

3.1.2.2 New Homes

According to (Hodgson et al., 2000), the lowest and highest indoor air concentrations of formaldehyde among four newly manufactured homes in East and Southeastern United States ranged from 25.79 to 57.73 µg/m^3 after a period of 2 to 9.5 months. Among seven new site-built homes in eastern and southeastern United States, formaldehyde indoor air concentrations ranged from 17.20 to 71.24 µg/m^3 from 1 to 2 months after completion. All homes were located in hot and humid climates that generally increase emissions of formaldehyde. Also, several site-built homes have relatively poor ventilation rates per the American Society of Heating, Refrigerating and Air-Conditioning Engineers. According to the authors, plywood flooring, latex paint, and sheet vinyl flooring were major sources of formaldehyde identified in that study.

(Offermann et al., 2008) also assessed formaldehyde indoor air concentrations in newly constructed homes. In this study, authors assessed 108 newly constructed homes in California. The measured indoor air concentration of formaldehyde ranged from 4.67 to 143.33 µg/m^3. Given that a primary focus of this study was on the effect of ventilation on indoor air formaldehyde concentrations, through their research, the authors determined that because new single-family homes in California are built relatively air-tight, and because the windows and doors were kept shut during the duration of the study—the indoor-outdoor air exchange rates were generally low (*i.e.*, 0.2 air exchanges per hour). This resulted in significantly elevated indoor air concentrations of formaldehyde.

3.1.2.3 Trailer Studies

(LBNL, 2008) measured formaldehyde indoor air concentrations within four Federal Emergency Management Agency (FEMA) camper trailers with concentrations ranging from 330.39 to 924.85 µg/m^3. According to (LBNL, 2008), relatively high concentrations of formaldehyde measured in FEMA temporary housing units are likely due to the very high composite wood surface area relative to room volume in addition to low ventilation rates—specifically for low area-specific fresh air flow rates in relation to the internal surface area in the assessed temporary housing units. Notably, the authors noted indicated that results from this study were not representative of all FEMA temporary housing unit conditions given only four such units were assessed. It is, however, representative of other temporary housing unit indoor air conditions with similar materials and low air flow conditions.

According to a similar study by (Murphy et al., 2013) with a sample of 519 FEMA-supplied trailers, including travel trailers, park models, and mobile homes, peak formaldehyde indoor air concentrations ranged from 196.52 to 724.65 µg/m^3 according to trailer type. The geometric mean concentration of formaldehyde in such homes were higher than levels found in traditional homes, as also presented in the (Murphy et al., 2013) study. (Murphy et al., 2013), noted that low air flow (especially closed windows more so than air conditioning) was a key reason for the relatively high concentrations of formaldehyde found in trailers. Increased indoor air temperate and relative humidity also correlated with increased formaldehyde concentrations in trailer indoor air. Although the authors did not investigate the impact of material type and trailer material composition on measured formaldehyde indoor air concentrations, all trailer brands had some trailers with formaldehyde concentrations exceeding 123 µg/m^3.

3.1.2.4 Japan Study

In 1996, Japan's National Institute of Health Sciences administered the first national survey of formaldehyde in approximately 230 homes with an arithmetic mean concentration of approximately 74.92 µg/m^3. After repeating this monitoring study with 1,181 homes in 2005, the arithmetic mean of formaldehyde across Japanese homes decreased to approximately 29.98 µg/m^3 (Osawa and Hayashi, 2007; Azuma et al., 2005). As reported by the World Health Organization, this reduction in average formaldehyde concentration in Japanese homes from 1996 to 2005 was likely due to an amendment of the national building codes and, more specifically, a restriction of materials that emit formaldehyde in interior finishing (WHO, 2010).

3.1.2.5 American Healthy Homes Survey II (AHHS II)

Although EPA considered all reasonably available air monitoring article relevant to the formaldehyde indoor air assessment, the Agency identified the AHHS II formaldehyde residential indoor air monitoring survey as the most recent and relevant high-quality American residential indoor dataset for formaldehyde. The AHHS II was the first nationally representative study of formaldehyde concentrations in indoor air from U.S. homes. The AHHS II survey was sponsored by the U.S. Department of Housing and Urban Development (HUD) along with EPA, and was conducted by QuanTech, Inc. (QuanTech, 2021).

The AHHS II was conducted from March 2018 through June 2019 and measured household levels of lead, lead-based paint hazards, pesticides, formaldehyde, and mold in American homes. The survey was conducted in 78 cities and counties across 37 states. Approximately 800 homes were randomly selected in these areas to participate in the survey. The final sample size for formaldehyde-specific indoor air sampling was 688 homes and represented homes that were lived in permanently, rather than temporary dwellings (QuanTech, 2021). For a summary of the AHHS II data collection methodology see Appendix B.

The AHHS II U.S. indoor air measured concentrations of formaldehyde are presented in Table 3-4 and illustrated in Figure 3-2. Indoor air concentrations of formaldehyde in the AHHS II study ranged from 0.27 to 124 µg/m^3 (3.5-hour time-weighted average [TWA]). These samples represent the indoor air concentration of formaldehyde in the most used room in the home. Statistical weights reported in the AHHS II data are applied here to reduce sampling bias and provide a more nationally representative distribution of monitored values.

Table 3-4. Range and Weighted Quantiles of AHHS II Residential Indoor Air Formaldehyde Concentrations (μg/m^3)

Minimum	10th Percentile	Median	90th Percentile	Maximum
0.27	7.54	19.8	41.8	124.2

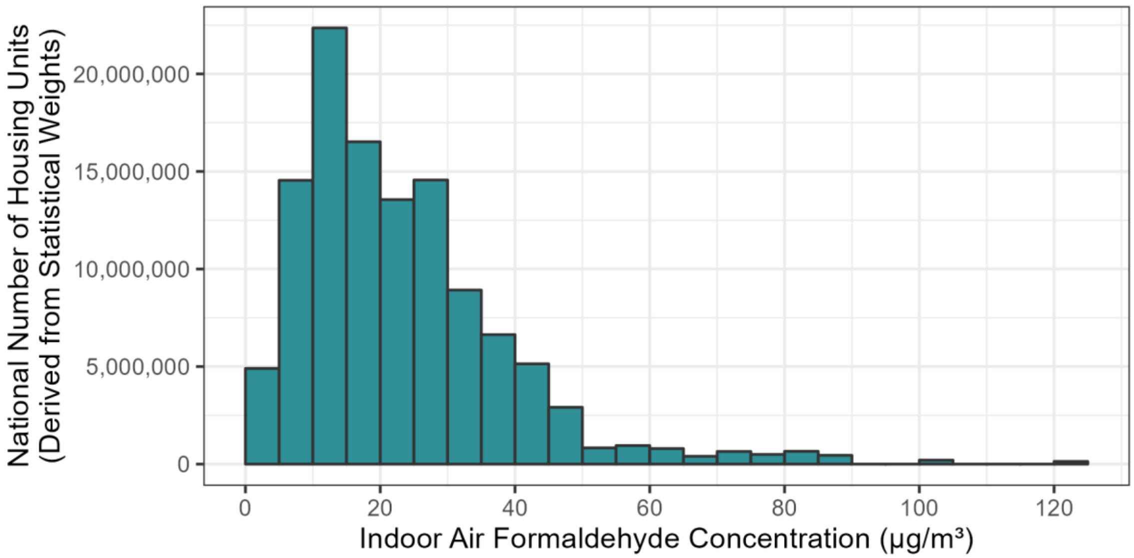

Figure 3-2. Histogram of Formaldehyde Indoor Air Sampling Results from AHHS II with Statistical Weights Applied

Although these measured concentrations cannot be linked to a specific TSCA COU, they represent total formaldehyde concentrations in homes across the United States.

3.2 Integration and Exposure Conclusions

3.2.1 Weight of Scientific Evidence

3.2.1.1 Indoor Air Exposure

The weight of scientific evidence (Table 3-5) for the indoor air exposure assessment of formaldehyde is primarily dependent upon studies that include product and article specific emission rates (Table 2-2). Based on the exposure systematic review standard operating procedures (EPA, 2021b), only studies and datasets with data deemed useful in generating a quantitative assessment (*e.g.*, via modeling) progress from data evaluation to data extraction. In the case of the formaldehyde pool of studies, there were several COU-specific studies that did not report any concentrations of formaldehyde but provided emission rates; those are labeled as “supplemental studies” in Table 2-2. Because emission rate data for the COUs assessed were generally scarce, from the exposure systematic review pool of studies, emission rates from supplemental studies were used in addition to those from low- and high-rated studies (EPA, 2023c).

A combination of nine experimental studies were rated medium per the exposure systematic review criteria (EPA, 2021b) and used to compile COU-specific emission rates used to apply user-defined, COU-specific emission rates to model formaldehyde indoor air concentrations using CEM—a peer-reviewed, high-tier model that has been used in previous TSCA risk assessments. Central tendency estimates were generated as discussed in Section 2.1.1.1.3 for comparability with the AHHS II data and to estimate typical indoor air concentration for most American households. A total of 16 studies indoor air monitoring studies were used to compare measured formaldehyde concentrations against modeled concentrations from TSCA COUs. Because these were not incorporated into any exposure calculations or modeling, EPA determined that an exposure systematic review rating was not necessary. However, all supporting monitoring studies were relevant and of good quality. Altogether, these 25 monitoring studies provided an overall confidence rating of high as presented in Table 3-5. The indoor air exposure assessment also relies upon a review of several monitoring studies; some of which are presented in Section 3.1.2. This includes a robust nationally representative monitoring study of formaldehyde in indoor air via the AHHS II, jointly sponsored by EPA and HUD.

From the COUs identified as significant contributors to the indoor air environment, the CEM modeling results presented in Figure 3-1 highlight COU-specific contributions of formaldehyde to indoor air likely driven primarily by the reported emission rates in literature along with the expected surface area of the article(s) in the home. Higher emission rates and surface areas corresponded with higher air concentrations. Central tendency product-specific emission rates (within a COU category) were used for the CEM modeling to represent emission rates in the typical American home or automobile. Therefore, it is conceivable that the estimated formaldehyde air concentrations would be lower if the lowest emission rates were used or higher if the highest reported emission rates were used.

Again, it should be noted that CEM does not allow the user to adjust the model according to a chemical-half-life. This was a key source of uncertainty in the indoor air analysis of formaldehyde. Thus, the presented modeling results likely represent new constructions or new materials introduced to a home. If aggregated, the total formaldehyde residential concentration may be approximately 916 $\mu g/m^3$, which is comparable to monitoring results for new mobile homes where a concentration of 1,032 $\mu g/m^3$ was reported (Gammage and Hawthorne, 1985). However, in general, it is unclear whether the modeling results are reflective of most indoor air home environments in American residences. As a result, EPA has medium confidence in the applicability of the modeling results used to assess indoor air exposures to formaldehyde.

Please see Appendix C for additional information of the formaldehyde indoor air assessment.

Table 3-5. Weight of Scientific Evidence Conclusions for the Indoor Air Exposure Assessments

Consumer Route (Assessment)	Confidence in Model Used[a]	Confidence in Model Default Values[b]	Confidence in User-Selected Varied Inputs[c]				Number of Indoor Air Monitoring Data (Confidence Rating)[h]	Weight of Scientific Evidence Conclusion[h]
			Mass Used[d]	Use Duration[e]	Weight Fraction[f]	Room of Use[g]		
Inhalation (Indoor Air)	Medium	Medium	Medium	Medium	Medium	Medium	9 studies incorporated into modeling (Medium); 16 studies used to compare to modeling (High)	Medium

[a] "Confidence in Model Used" considers whether model has been peer reviewed, as well as whether it is being applied in a manner appropriate to its design and objective. CEM has been peer reviewed, is publicly available, and has been applied in a manner intended; that is, to exposures associated with uses of household products. CEM was the best available tool to assess indoor air exposure for formaldehyde.

[b] "Confidence in Model Default Values" considers default value data source(s) such as building and room volumes, interzonal ventilation rates, and air exchange rates in CEM. These CEM default values are all central tendency values (*i.e.*, mean or median values) sourced from EPA's *Exposure Factors Handbook* (EPA, 2021a).

[c] "Confidence in User-Selected Varied Inputs" considers the quality of their data sources, as well as relevance of the inputs for the selected consumer condition of use.

[d] "Mass Used" is primarily sourced from high quality studies used to develop CEM's COU-specific default mass of products used (EPA, 2019), which have been applied in previous agency assessments.

[e] "Use Duration" is primarily sourced from high quality studies used to develop CEM's COU-specific default mass of products used (EPA, 2019), which have been applied in previous agency assessments.

[f] "Weight Fraction" of formaldehyde in products is sourced from product Safety Data Sheets (SDSs), which were not reviewed as part of systematic review but were taken as authoritative sources on a product's ingredients.

[g] "Room of Use" is informed by responses in the Westat (1987) survey, which received a high-quality rating during data evaluation, although professional judgment is also applied for some scenarios. The reasonableness of these judgements is considered in the reported confidence ratings.

[h] In addition, while emission rates from nine studies were extracted from systematic review and incorporated into CEM modeling, over a dozen others were used to characterize the indoor air concentrations of formaldehyde in homes and automobiles.

[h] See the Systematic Review Protocol for a detailed description of weight of scientific evidence ratings (EPA, 2023a).

3.2.2 Indoor Air Exposure Conclusions

The presented results will be used in the draft human health risk assessment of indoor air aggregate exposures to formaldehyde to characterize overall risk impacts of formaldehyde from multiple TSCA COUs in indoor air.

3.2.2.1 Residential

3.2.2.1.1 Monitoring and Modeling Results

In general, the range of modeled formaldehyde residential indoor air concentrations were within an order of magnitude of the range of monitoring values (4 to 423 µg/m^3 compared to 0.3 to 124.2 µg/m^3, respectively) from a nationally representative studies of formaldehyde in residential indoor air, via the AHHS II residential indoor monitoring study (Figure 3-3). Also, some homes with at least one source of combustion had at least double the concentration of formaldehyde compared to homes with no reported sources of combustion.

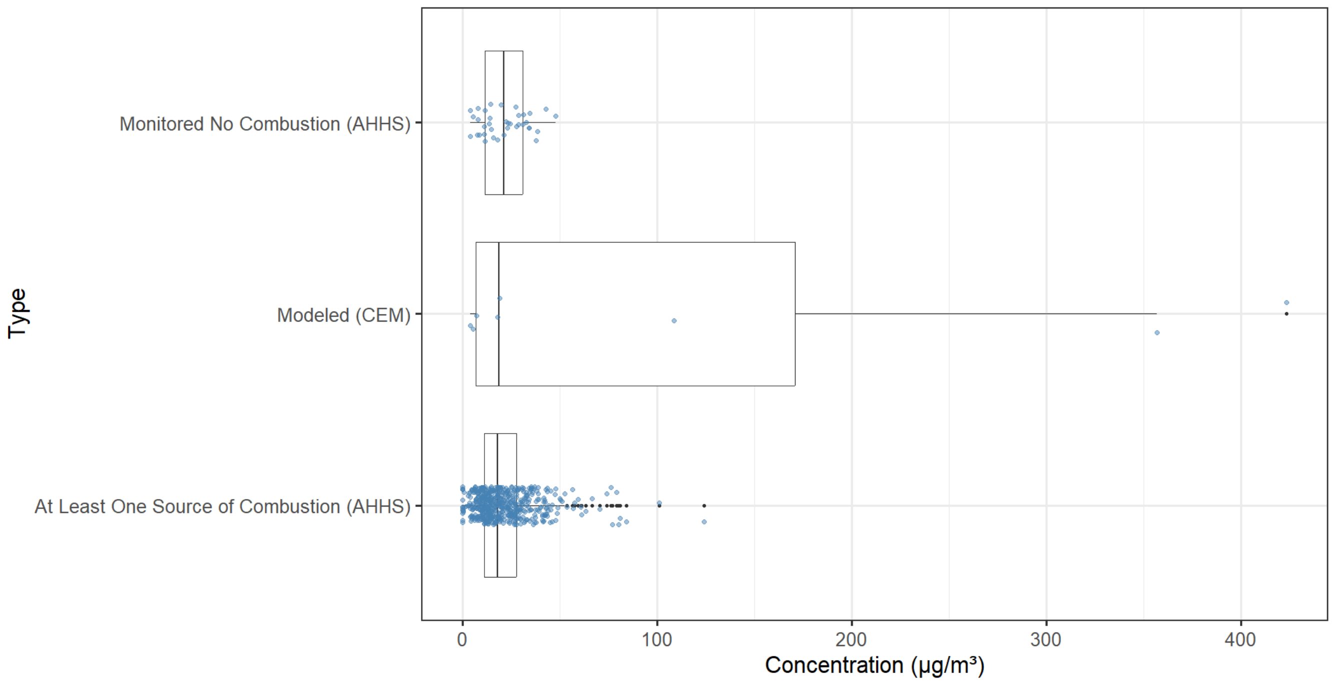

Figure 3-3. Comparison of AHHS II Monitoring to Modeling Estimates of Indoor Air Concentrations

Note: The highest measured formaldehyde concentration (124.2 µg/m^3) is not displayed as it is out of scale relative to the data points where most of the data are found.

Of note, mobile homes appeared to have generally higher concentrations of formaldehyde in indoor air (Murphy et al., 2013; LBNL, 2008). According to (Murphy et al., 2013), although formaldehyde concentrations varied by trailer type, formaldehyde indoor air concentrations exceeded 123 µg/m^3 for at least one of each tested trailer type. From an indoor air study of four FEMA campers, the highest measured concentration was 925 µg/m^3 (LBNL, 2008), which is significantly higher than 124 µg/m^3 reported by AHHS II for American homes.

The reported AHHS II U.S. indoor air measured concentrations of formaldehyde is expected to reflect the typical reduction of formaldehyde concentrations over time (Table 3-4). Potential additional factors that might have impacted the AHHS II monitoring results include temperature and humidity (seasonality), and ventilation. For some products, (*e.g.*, particle boards), an increase in temperature and humidity may increase formaldehyde off-gassing rate (Pickrell et al., 1984); and indoor environments with poor ventilation can lead to higher concentrations of measured formaldehyde in indoor air (EPA, 2016).

AHHS II monitoring results, presented in $\mu g/m^3$, cannot be apportioned according to TSCA COUs. From a nationally representative sample of 688 homes, the measured concentration of formaldehyde in American homes ranged from 0.27 to 124 $\mu g/m^3$, with 19.77 $\mu g/m^3$ as the 50th percentile. Per Figure 3-2, most homes had a formaldehyde air concentration that was 40 $\mu g/m^3$ or less.

The AHHS II air sampling was not performed throughout the entire home, and across multiple seasons. It should also be reiterated that formaldehyde emission rates decrease over time. Generally, it is expected that after the installation of formaldehyde-bearing materials in a home, there is an initial rise of formaldehyde concentration, followed by a leveling-off period that may be as brief as 30 days or less, which is followed by a longer gradual decline of formaldehyde concentration over time (EPA, 2016; Park and Ikeda, 2006).

Therefore, although CEM-estimated air concentrations from residential articles and AHHS II are individually informative about the potential indoor air concentrations of formaldehyde—especially if the home is new or if new products are introduced to the home—caution should be exercised when comparing the results from these two sources as there are some unique aspects to each, presented above. CEM results allow for an understanding of the potential relative formaldehyde indoor air concentrations for four COUs identified to be significant contributors in that environment. AHHS II results provide the real-world concentrations of formaldehyde in residential indoor air at the time of sampling, among American households.

A source of potential uncertainty from the CEM assessment is that the reported emission rates from the literature oftentimes had orders of magnitude differences that may be due to a number of factors, including study design, age, type and quality of the material assessed. Yet, it is possible that with more data such patterns may continue to be observed due to these factors. Therefore, it is unclear whether additional emission rate data would significantly improve the precision of the modeled outputs.

3.2.2.1.2 Relative Contributions of Formaldehyde Sources in Residential Indoor Air

Monitoring data from the American Healthy Homes Survey suggests that concentrations of formaldehyde may range from 0.27 to 124.2 $\mu g/m^3$ for all homes, with 95 percent of homes having concentrations below 47 $\mu g/m^3$ (QuanTech, 2021). Those data include formaldehyde produced from both TSCA sources (Section 3.1.1 of this module and Section 3.1.1 the Consumer Exposure Module (EPA, 2024c)) and non-TSCA sources of formaldehyde such as tobacco smoke or the use of fireplaces, gas-burning appliances, candles, and air purifiers (QuanTech, 2021). These non-TSCA sources do not contain formaldehyde but rather lead to the formation of formaldehyde during use.

For non-TSCA sources of formaldehyde in indoor air, simulated 50th percentile room concentrations ranged from 12.3 to 44.2 $\mu g/m^3$ individually for candles, incense, cooking, wood combustion, and air cleaning devices, and up to 152.2 $\mu g/m^3$ for ethanol fireplaces (ECHA, 2019). Air cleaning devices such as photocatalytic air purifiers can produce formaldehyde from irradiation of air contaminants, leading to increased indoor air concentrations of formaldehyde (Salthammer, 2019). Formaldehyde production associated with cooking depends on many factors, including cooking temperature and type of oil and variety of food being cooked. Select gas-oven cooking tests involving a variety of cooking parameters resulted in formaldehyde concentrations ranging from 36.5 to 417.3 µg/m^3 (Salthammer, 2019). **Error! Reference source not found.**Tobacco smoke is also known to be a contributor to formaldehyde concentrations within all indoor air environments (EPA, 2016; Girman et al., 1982), although according to the World Health Organization tobacco smoke primarily increases formaldehyde concentrations in indoor air environments where the rates of smoking are high with minimal ventilation (IPCS, 2002).

Many of these non-TSCA 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 non-TSCA sources to the indoor air. Combined, the many factors that may contribute to overall indoor air concentrations and relative concentrations from TSCA and non-TSCA uses introduce a significant source of uncertainty in the indoor air exposure assessment.

Although there are uncertainties in estimating indoor air concentrations of formaldehyde, EPA expects that generally a larger number of formaldehyde sources will lead to higher concentrations of formaldehyde in the indoor air (EPA, 2016; IPCS, 2002; ATSDR, 1999; Girman et al., 1982). Further, EPA expects that it is unlikely that all or most of the factors that increase formaldehyde concentrations will co-occur in a given home, so aggregation of exposures across all of the TSCA and non-TSCA sources of formaldehyde in indoor air would not be representative of actual exposures.

As previously noted, there is insufficient data to quantify the relative contributions of the modeled TSCA COUs to the AHHS II monitored concentrations of formaldehyde in American residential indoor air with certainty. However, modeled concentrations of formaldehyde were within the same order of magnitude as reported in the AHHS II study. Therefore, it is reasonable to conclude these results support the hypothesis that the identified TSCA COUs are key contributors to real-world concentrations of formaldehyde in residential indoor air. See Appendix C for a supplementary analysis of formaldehyde indoor air monitoring.

3.2.2.2 Automobile

The estimated formaldehyde concentrations from the two key automobile COU-based scenarios identified was 5.72 µg/m^3. By comparison, from a study of automobile formaldehyde concentration in the New York City Metropolitan Area, the measured average concentration of formaldehyde during commutes was approximately 300 µg/m^3 (Lawryk and Weisel, 1996; Lawryk et al., 1995). The two automobiles used in this study were a 1988 Chevrolet Celebrity and a 1987 Plymouth Horizon (Lawryk and Weisel, 1996). It is possible the materials used in these two older automobiles were relatively strong and persistent off-gassers of formaldehyde being manufactured in the late-1980s to the mid-1990s. While this is a well-executed study, it is relatively dated.

It would be useful to compare the CEM-estimated results with an updated study with more and relatively recent automobiles on a national scale. Vehicular air circulation systems and the materials used to build the indoor cabin of automobiles have likely changed significantly since the publication of this study in 1996. However, newer studies of this type were not identified through the systematic review of formaldehyde exposure literature (EPA, 2023b).
Nonetheless, comparatively, the estimated indoor air automobile concentrations of formaldehyde from the two articles assessed represent approximately 4 percent of the total measured concentrations of formaldehyde in the identified study. Thus, there may have been many more non-TSCA sources of

formaldehyde that contributed to the total concentration of formaldehyde in automobile indoor air specifically from the identified study.

3.2.2.3 Commercial and Other Buildings

Generally, reported formaldehyde indoor air concentrations in commercial and other buildings such as offices, schools, and other commercial businesses in recent studies have been below 61 μg/m^3. This was similar or lower than monitored concentrations in residential and automobile spaces. In addition, commercial and other buildings tend to cover larger spaces and have higher air exchange rates than in residential homes. Therefore, EPA did not model indoor air concentrations of commercial buildings as residential homes were considered a more protective indoor air scenario.

3.2.2.4 Comparing Indoor to Outdoor Air

EPA investigated formaldehyde air concentrations in indoor and outdoor settings to see how formaldehyde concentrations compared between each setting. EPA used monitoring data described in Section 3.1.2 and presented in Table 3-2 for indoor air and monitoring data from EPA's Ambient Monitoring Technology Information Center (AMTIC) (2015 to 2020) (EPA, 2022) described in the Draft Ambient Air Exposure Assessment (EPA, 2024a) for outdoor air. A raw comparison of these two datasets is presented in Figure 3-4.

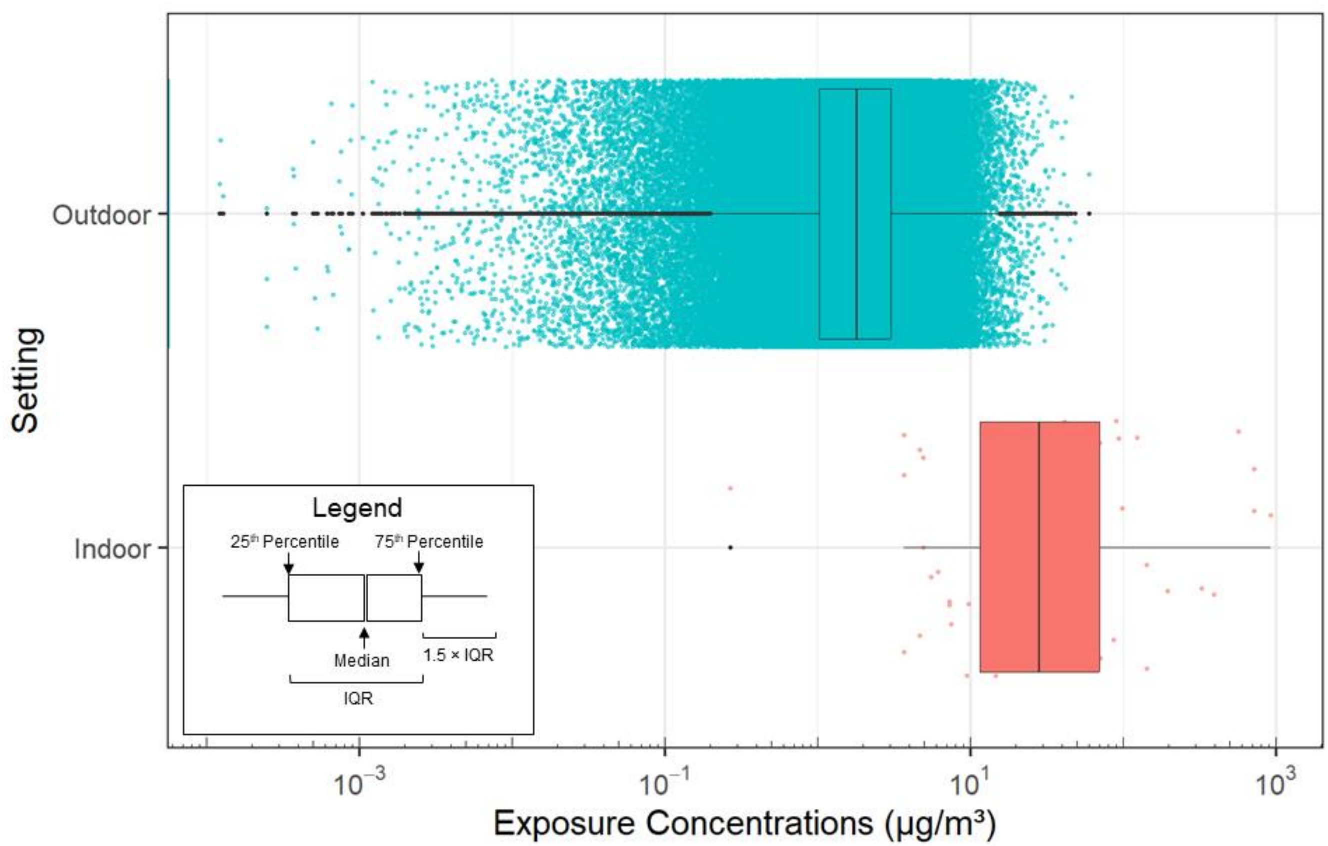

Figure 3-4. Monitoring Formaldehyde Concentrations in Indoor Compared to Outdoor Settings

EPA's comparison found formaldehyde concentrations measured in indoor air were generally higher than concentrations measured in the outdoor air (on average approximately an order of magnitude higher). These findings are consistent with previous investigations conducted by EPA which generally found indoor air concentrations of pollutants are two to five times greater than outdoor air. This is also consistent with other findings presented in published literature (ATSDR, 1999). From a study of concurrent 24-hour indoor and outdoor air of Canadian residences, average formaldehyde concentrations were an order of magnitude higher in indoor air in comparison to outdoor air—a finding that has also been reported in other countries (IPCS, 2002). It is expected that most indoor air environments contain more sources of formaldehyde per volume of air compared to outdoor air environments, and with improvements to building efficiency, especially in homes built after 1990 (Persily et al., 2010), less indoor-outdoor air ventilation is expected, which can lead to higher and persistent concentrations of formaldehyde in American homes (IPCS, 2002; ATSDR, 1999).

Considering the indoor and outdoor settings together, along with findings in published literature indicating individuals spend on average 87 percent of their day in homes or buildings (Klepeis et al., 2001), EPA expects exposure to formaldehyde in indoor air will be higher than exposure to formaldehyde in outdoor air. This is exacerbated by the presence of multiple sources of formaldehyde (both TSCA and non-TSCA), which can contribute to continuous formaldehyde concentrations within a home or residence whether it be exposure over an extended period of time to low concentrations of formaldehyde from off-gassing or short-term but repetitive use of products or appliances like gas-fired stoves, candles, and other products. Even products designed to clean/purify indoor air of certain pollutants can be a source of formaldehyde exposure (or other chemical exposures) in homes or residences.

Considering the entirety of potential sources of exposure to formaldehyde in indoor settings evaluating exposures and associated risks resulting from TSCA COUs in this setting is complex at best. As such, EPA's analysis of formaldehyde exposure in indoor air should be taken at face value, with recognition of multiple uncertainties in tying a particular exposure (and associated risks) to a TSCA COU. Furthermore, while exposures are higher in indoor environments, when trying to tie specific formaldehyde exposures to a TSCA COU via the indoor air pathway it is necessary for EPA to make certain assumptions that create a conservative exposure scenario and results in higher modeled concentrations than typically found in indoor air. EPA minimized this uncertainty by comparing modeled concentrations to monitored concentrations and found modeled concentrations for an individual TSCA COU typically falls within the range of monitored values and therefore are not unreasonable. However, considering most homes have more than one source contributing formaldehyde at different stages of useful life, and that monitored concentrations represent all sources of formaldehyde, when multiple individual TSCA COU contributions are added together, the total exposure quickly increases to modeled concentrations greater than monitored values. This supports EPA's recognition that most modeled concentrations are likely highly conservative in nature and may not be representative of actual exposures over extended periods of time.

This recognition is particularly important when considering off-gassing from various products (like building products, flooring, carpet, etc.) as typical dissipation curves associated with off-gassing show high concentrations immediately following installation, which typically peak within the first week but fall off logarithmically to much lower concentrations to which individuals are exposed over an extended period of time. Given that EPA does not have readily available data on the actual emissions from a particular product associated with a TSCA COU that has been installed in a home or residence, EPA is unable to capture the true emission rate to which individuals are exposed. As such, the Agency assumes and uses the monitored concentration from a building product measured following manufacturing as the initial concentration to which an individual is exposed when in their residence. This results in a highly conservative emission rate and exposure estimate via modeling since it is unlikely a newly manufactured product will be instantly installed in a home and individuals will immediately be exposed to those higher concentrations early in their exposure period. It is more likely that the actual emissions from any given product will be the rate following some period of storage time where initial off-gassing at those high-rates would have occurred prior to being installed in a residence. Therefore, the actual emission rate to which an individual is exposed over an extended period of time indoors would be logarithmically lower than the initial measured emission rate following manufacturing of the product. Nonetheless, the current assessment using CEM can be considered as a screening approach to ensure potential exposures to formaldehyde via the indoor air pathway are not missed and to provide a conservative exposure estimate that can be considered for characterizing exposures and associated risks while recognizing the uncertainty around such estimates. While EPA modeled a scenario using measured emission rates from manufactured products for this draft indoor air exposure assessment within CEM, the Agency is investigating other modeling approaches and emission rate values that may be available to consider and evaluate prior to finalizing its indoor air formaldehyde exposure assessment. Ideally, these models and emission rates will consider multiple factors like the rapid dissipation of off-gassing pollutants, and a more representative actual emission rate from off-gassing to model exposures.

A general residential dissipation curve of formaldehyde over time (in years) is presented in Figure_Apx F-1.

3.2.2.5 Aggregate Exposure

EPA defines aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." Theoretically, the reported formaldehyde concentrations from the monitoring data may represent aggregate formaldehyde indoor air concentrations in automobiles per the Lawryk et al. study (Lawryk and Weisel, 1996; Lawryk et al., 1995) and across U.S. households per the AHHS II study (QuanTech, 2021), assuming (1) at least a 3-hour TWA, or (2) the typical indoor air concentration of formaldehyde in these environments. An aggregate exposure to formaldehyde via the COUs assessed may occur in an automobile used routinely or in the home in which an individual resides. Risk estimates from the total modeled TSCA COU formaldehyde concentrations in automobile and residential indoor air concentrations (26.05 and 916.29 $\mu g/m^3$, respectively) may be aggregated for automobile and residential environments using a total margin of exposure (MOE_T) or aggregate risk index (ARI).

It is also conceivable that an individual may be exposed to formaldehyde via the indoor air of an automobile and home consecutively or during the same day, with an estimated COU-specific total indoor air concentration of 942.34 $\mu g/m^3$. Again, the MOE_T and ARI may be used to estimate the formaldehyde indoor air concentration risks across both environments. The latter aggregate risk calculation may best represent sentinel exposures and risks for individuals exposed to formaldehyde in both indoor air environments, whereas select TSCA COUs are expected to be significant contributors. Such an assessment would be assumed to be health protective to PESS populations.

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APPENDICES

Appendix A SYSTEMATIC REVIEW PRIORITIZATION FOR FORMALDEHYDE DATA

Summary of the Proposed Change to Systematic Review (SR) Approach for Exposure Discipline

OPPT plans to publish a final TSCA RE for formaldehyde by December 2024. This change allows for (1) the prioritization of high-quality, fit-for-purpose data that is critical for the formaldehyde exposure analyses; and (2) meets the current schedule for the development of exposure assessments in the draft TSCA risk evaluation.

To support this aspiration, a targeted approach was implemented to the systematic review of exposure studies for formaldehyde to address key data needs for the formaldehyde exposure assessment. This document is intended to memorialize the agreed upon process.

As of March 17, 2023, there were a total of 1,137 exposure studies; of which 1,029 studies had completed initial reviews (*i.e.*, primary evaluations performed by the contractor) and 388 studies had quality control (QC) assessments completed by EPA staff. A total of 135 had data evaluation issues pending resolution. Generally, after exposure studies undergo initial review QC, data relevant to the TSCA risk evaluation are extracted. Of all exposure studies, only about 30 percent were available for data extraction with a due date of June 30, 2023. To meet aforementioned deadlines and improve the quality and relevance of formaldehyde data incorporated into the relevant exposure assessments, the formaldehyde systematic review approach had to be improved to be more efficient and fit-for-purpose.

Prioritization Methodology

The data needs highlighted in Appendix A.1, according to exposure study type, emphasize the Formaldehyde Team's focus on the inhalation pathway. This is because through a review and discussion of the physical and chemical properties and exposure literature, the Formaldehyde Assessment Team determined that the inhalation pathway—especially in the indoor air environment—is likely a key risk driver for the formaldehyde risk evaluation. Thus, the team has taken a fit-for-purpose approach, not only with the exposure assessment of formaldehyde but with the systematic data approach that supports it. Through this fit-for-purpose systematic review, the Formaldehyde Assessment Team sought to identify studies that contained indoor air concentration and emission rate data that were product-, article-, and COU-specific. The extracted data would be from studies that have received an overall high study rating from the exposure systematic review process (EPA, 2021b)—assuming that such studies would be distinctly supportive to the formaldehyde exposure assessment, and despite the presence of studies rated medium or low, which might also provide some supporting data. Those medium- or low-rated studies could always be extracted as needed.

To identify the most relevant studies to the formaldehyde exposure assessment, the Formaldehyde Assessment Team performed a title and abstract screening (TiAB) using over 130 key words (see Appendix A.2) determined to be associated with formaldehyde COUs and indoor air parameters of interest, using a list of all existing formaldehyde exposure studies from Distiller that are PECO supplemental or PECO relevant and have primary data. A Boolean search criterion was applied, generally separating keywords by COU/product or article synonym using an *or* followed by an *and* with the air/emission criteria. For example: ((“paint” OR “vinyl wallpaper” OR “fiber glass” OR “fiberglass” OR “latex paint” OR “glue” OR “adhesive”) AND (“air” OR “indoor air” OR “ambient air” OR “air pollution” OR “air release” OR “emission*” OR “emission rate*” OR “emission flux” OR “flux” OR "inhalation" OR "atmosphere" OR "fume*" OR "fugitive" OR "gas*" OR "release*" OR "air release*"). Effectively, this creates a scenario where the Agency identified a paper with a product term such as "adhesive" in its title or abstract, but only when they appeared with an air/emission term.

Of 1,137 studies, approximately 290 were relevant to the exposure assessment of formaldehyde based on the aforementioned prioritization criteria. Of the 290 relevant studies, 185 had outstanding QCs that have been completed. In addition, 41 articles out of the 290 prioritized studies were rated high according to the Exposure discipline data evaluation metrics and proceeded through data extraction for incorporation into the exposure assessment as needed. A visual representation of the formaldehyde exposure SR prioritization scheme is included in Appendix A.3 of this document.

Impacts

The expected extracted data provides a high-level of confidence in the supporting data that is available for formaldehyde's exposure analysis, while improving the efficiency of the systematic review of formaldehyde exposure studies and data. This required the reassignment of EPA and contractors to the formaldehyde systematic review project, as necessary. This proposal has facilitated the ability to meet the necessary deadlines to complete the draft formaldehyde exposure assessments.

Actions

EPA and contractors assigned appropriate staff to support the proposed approach to review and extract formaldehyde data of interest. As directed, for the review of formaldehyde data, EPA and the contractor prioritized the evaluation and extraction of COU-specific air concentration and emission rate (and other supporting exposure modeling parameters) data.

A.1 Formaldehyde Data Needs

Within the Exposure study pool are six key study types: monitoring, experimental, modeling, completed assessment, database, and survey.

- *Monitoring:* The Formaldehyde Assessment Team determined that measured indoor and ambient air data associated with formaldehyde COUs from the monitoring study type are most relevant to the formaldehyde exposure assessment. This is because the primary media of exposure for formaldehyde is air. Some monitoring studies contain air concentration data that may be used to compare with formaldehyde exposure modeling results. In addition, modeling parameters such as room ventilation rates, may also be useful for the refinement of models such as the CEM or the execution of higher tier models like the Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model. This monitoring data has been identified as the top priority for formaldehyde. This data has been identified as important to extract.
- *Completed Assessments:* Completed assessments may contain completed risk evaluations of formaldehyde, this study type can be informational and may be referred to for contextual information (*e.g.*, methodologies, conclusions, and other information). Some completed assessment studies contain modeling parameters which may be used for the formaldehyde exposure analysis—namely, product-specific formaldehyde emission rates (and room ventilation rates, if available) useful in CEM modeling refinements or higher tier models like the IECCU model. Under the current systematic review protocol for Exposure, completed assessments are extracted as monitoring or modeling studies. Completed assessments typically make use of secondary data that are not extracted for any study type. However, if completed assessments have been deemed to use primary monitoring data that are COU-specific, extract this data. However, do not extract any other data for this study type as it is not a critical need for the formaldehyde exposure assessment.

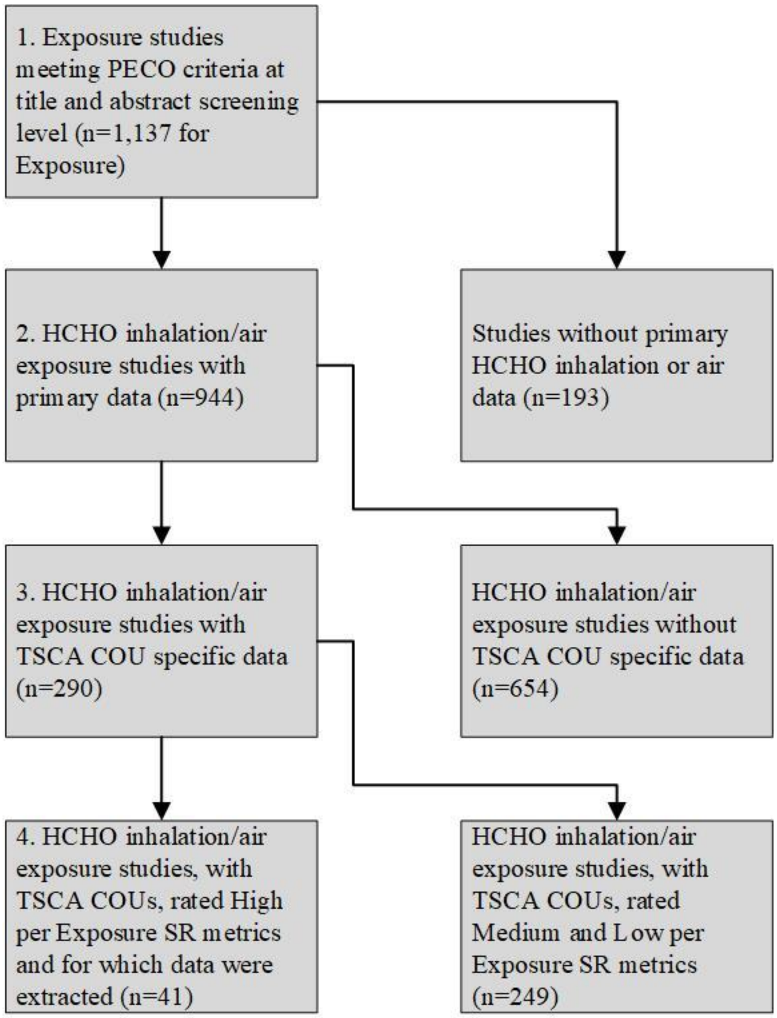
- *Databases:* Databases may provide quantitative or supplementary information often useful for exposure analyses. These may include datasets that contain air or water concentration data (*e.g.*, monitoring data) such as the Water Quality Portal (WQP). Data from such source streams may be referenced or potentially used for comparison to EPA modeled concentrations in its evaluation of formaldehyde exposures. Key datasets of need including the Toxics Release Inventory, Discharge Monitoring Report (which contain data from the WQP), and National Emissions Inventory and other datasets which provide direct inputs to EPA modeling efforts for formaldehyde have already been extracted and provided by ECRAD engineers per the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (EPA, 2021b). Thus, there is currently no need for any other datasets for the formaldehyde exposure assessment. Relevant data evaluation, QC, and extraction for databases which may contain monitoring data relevant to the ambient air, indoor air, and water pathways relevant to formaldehyde COUs has been completed.
- *Experimental:* Modeling parameters typically found in experimental studies such as permeability coefficients, absorption fractions, have already been identified through other disciplines' systematic reviews for formaldehyde. However, COU-specific emission rates, room ventilation rates and others, via chamber studies, for instance, are typically found in experimental study types. Such modeling parameters are useful in CEM modeling refinements or higher tier models like the IECCU model. This experimental data has been identified as the top priority for formaldehyde and such data has been extracted as needed, to support the formaldehyde exposure assessment.
- *Modeling:* Similar to experimental studies, modeling studies are needed for the draft formaldehyde risk evaluation. Because such COU-specific-modeling parameters (*e.g.*, emission rates) typically found in these study types have been identified as essential to the refinement of CEM modeling of consumer products or the execution of the IECCU model for the formaldehyde exposure assessment. This modeling data has been identified as a top priority for formaldehyde and such data has been extracted as appropriate, to support the formaldehyde exposure assessment.
- *Survey:* No survey data specific to formaldehyde were identified.

A.2 Boolean Search Terms

The following is a list of search terms derived from the formaldehyde TSCA COUs presented in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (U.S. EPA, 2020):

Fertilizer, paint, vinyl wallpaper, fiber glass wallpaper, fiberglass, latex paint, glue, building, wood, hardwood floor, furniture, pressed wood products, particle board, plywood, bare urea-formaldehyde wood product, coated urea-formaldehyde wood product, bare phenol-formaldehyde wood product, adhesive, caulk, sealant, vinyl covering, concrete, cement, plaster, PVC foam wallpaper, PVC wall covering, vapor barriers (bituminous tar), drain cleaner, toilet cleaner, multi-purpose cleaner, cleaner, stain remover, waterproofing agent, leather tanning, electronic, electronic appliance, furniture cover, car seat cover, tablecloth, textile wall, acoustic partitions, office chair, chair, textile, clothing, new clothing, fabric, permanent press fabric, varnish, floor finishes, floor coverings, decorative laminates, commercially applied urea-formaldehyde floor finish, foam insulation, insulation products, insulation, mineral wool insulation batt, glass wool fibrous insulation, insulant, PVC, liquid fuel, motor oil, oil, hardwood floor, furniture, chair, sofa, ink, toner, laundry detergent, dishwashing soap, soap, hand soap, liquid soap, liquid hand soap, lubricant, grease, paper, diaper, wipe, newspaper, magazine, paper towel, paper plates, paper cups, paper grocery bag, glues/adhesives (already noted above), fingernail hardener, photographic supplies, liquid photographic processing solutions, photographic processing solutions, photographic solutions, plastic, rubber, flooring, carpet, rubber mats, vinyl tiles, soft plastic flooring, cork floor tiles, plastic laminated board, black rubber trim, jointing, baby bottle nipple, pacifier, toy, car wax, polish, foam block, foam, tent, fish tank, water treatment product, drinking water treatment product, embalming, taxidermy [and] air, indoor air, ambient air, air pollution, air release, emission, emission rate, emission flux, flux, inhalation, atmosphere, fume, fugitive, gas, release, release rate.

A.3 Formaldehyde Data Prioritization Schematic



Figure_Apx A-1. Schematic of the Approach Used to Identify and Extract TSCA COU-Specific Data Pertinent to the Formaldehyde Exposure Assessment

Appendix B AHHS II SUMMARY OF DATA COLLECTION METHODOLOGY

To collect the data at each dwelling unit, a two-person team consisting of an interviewer and a technician was used. AHHS II data were captured using three form sets and a tablet survey: a Recruitment Questionnaire Form Set; a Resident Questionnaire Form Set and tablet Resident Questionnaire; and a Technician Form Set [Information Collection Review (ICR) Reference No: 201912-2539-001]. The Recruitment Questionnaire was used by the interviewer to determine whether the dwelling unit could be recruited into the survey. Once recruited, the interviewer used the tablet survey, supplemented by the Resident Questionnaire Form Set, to collect data on the unit. The Technician Form Set was used to collect data such as lead and formaldehyde. All data collected on paper forms were double keyed, reviewed, and entered into the datasets(QuanTech, 2021).

Residential indoor air samples of formaldehyde were collected in absorption tubes within SGS Galson air sampling pumps, in a frequently used location (commonly the living room). Samples ranged from 1 to 15 L of air at 0.03 to 1.5 L/minute. The air pump was run throughout the data collection home visit. Sampling time was not provided, and it likely varied between residences. However, the environmental sampling in AHHS II, while different in some respects from that of AHHS I, was expected to require a similar amount of time based on the AHHS II ICR [ICR Reference No: 201912-2539-001]. Per sampling times reported in AHHS I, the targeted sampling time for AHHS II was approximately 3.5 hours (QuanTech, 2021). As such, it may be reasonable to expect that the air sampling pump was typically on for 3.5 hours. This means that formaldehyde air monitoring air concentrations from the AHHS II were at least 3-hour TWAs. Formaldehyde air samples were then frozen and sent directly to SGS Galson, the provider of the sampling pumps, for analysis. Air samples were analyzed using modified NIOSH 2016 (HPLC – UV detection). The detection limit for formaldehyde air concentrations was 0.15 µg/m^3 for 3-hour sample at 1.5 L/min (which was at or near the maximum capability of the air sampling pump) (Table_Apx B-1). Detailed study methodology and results from the AHHS II are published in a series of reports available from the HUD Office of Healthy Homes and Lead Hazard Control (QuanTech, 2021).

Table_Apx B-1. Summary of Environmental Sampling and Analytical Method

Data Element	Description
ID[a]	T1
Information Captured or Target Analyte	Formaldehyde in air
Data Collection Method or Sampling Media	Absorption tube
Tests or Samples per Dwelling Unit	1 plus 1 blank/primary sampling unit (PSU)
Special Handling Requirements	Frozen after collection
Maximum Media Count	956
Sample Preparation	None
Analytical Method	Modified NIOSH 2016 (HPLC – UV detection)
Detection Limits	0.15 µg/m^3 for 3-hour sample at 1.5 LPM
Notes	Count includes 1 spiked QC/PSU

[a] Identifies the protocol containing detailed instructions for the tests or sample collection (QuanTech, 2021).

Appendix C SUPLEMENTARY INDOOR AIR ASSESSMENT

Because formaldehyde is a combustion byproduct(ATSDR, 1999), homes with various sources of combustion (*e.g.*, wood fireplace) are generally assumed to have higher concentrations of formaldehyde. However, combustion sources of formaldehyde, often referred as non-TSCA sources of exposure, are beyond the jurisdiction of TSCA. The purpose of this supplementary indoor air assessment is to contextualize modeled formaldehyde concentrations in the indoor environment and provide confidence in modeled concentrations while accounting for combustion sources of exposure.

C.1 Summary of Supplementary Indoor Air Assessment Methodology

EPA used the AHHS II dataset to identify homes with and without sources of combustion. EPA combined the AHHS2_Hazard and the ResidentQ datafiles from AHHS II, after sorting the data according to dwelling unit id (duid), to collate data on formaldehyde concentration and reported sources of combustion including the presence of smoking (including frequency of smoking events), combustion furnace, gas stove, wood fireplace, gas hot water heater, gas dryer, gas cool stove/oven, portable fuel-fired heater or other combustion sources. Presence or absence of combustion sources in each home was identified based according to yes or no resident response to the relevant question. The data was organized according to homes with at least one reported source of combustion and homes with no reported sources of combustion. Measured formaldehyde indoor air concentrations were analyzed according to this distinction.

CEM was used to modeled formaldehyde indoor air concentrations for new materials in a home; especially for articles (for the relevant TSCA COUs) that are identified as the biggest emitters of formaldehyde relative to others in the formaldehyde consumer exposure assessment. Such exposures were extrapolated to a year of exposure and further as a lifetime average daily concentration for the identified TSCA COUs

EPA generated box and whisker plots for a summary of all three sets of data including measured formaldehyde indoor air concentrations for homes with and without reported combustion sources, and estimated formaldehyde indoor air concentrations from TSCA COUs.

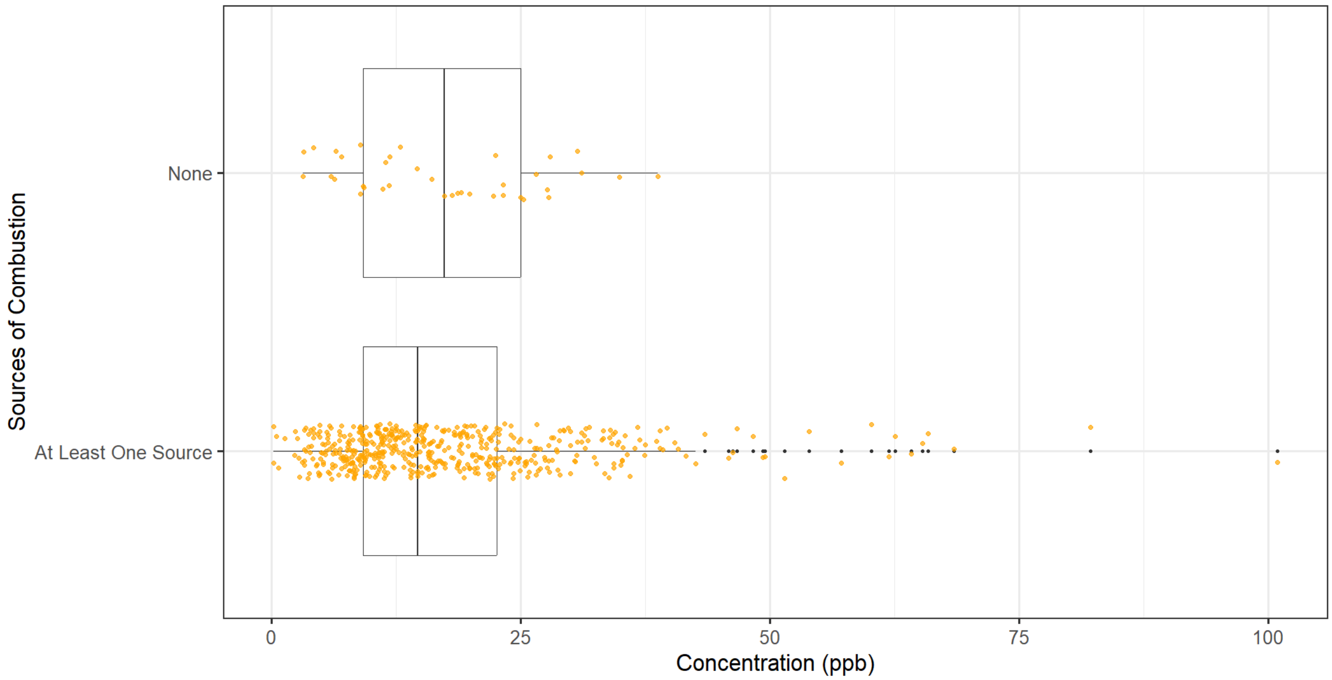
C.2 Comparison of Formaldehyde Indoor Air Estimates from CEM Modeling of TSCA COUs Relative to Homes with and without Reported Combustion Sources, According to AHHS II

Regarding the comparison of formaldehyde indoor air concentrations there are fundamental differences between the modeled and the monitoring data. Caution should be applied when comparing modeled to monitoring results, as this is not a 1:1 comparison, due to the following:

1. **Assumed total exposure –** The assessment of exposures in the indoor air environment is an aggregate assessment. By definition, this means that the measured indoor air of formaldehyde from AHHS II represent indoor air exposures from all formaldehyde sources across U.S. homes. This means that despite controlling for combustion sources for exposure, there may be other non-TSCA sources of exposure that could not be accounted for. On the other hand, through the indoor air exposure assessment of formaldehyde, EPA conducted a targeted assessment of the largest emitters of formaldehyde from TSCA-based sources of exposure. Therefore, the aggregated modeled indoor air concentrations of formaldehyde based on TSCA COUs, may not be a directly comparable to AHHS II concentrations of formaldehyde after removing homes without combustion sources.

2. **Dissipation over time** – While measured formaldehyde concentrations from AHHS II represent homes that have a combination of new and old materials that have off-gassed over time (and potentially several decades), CEM does not incorporate chemical half-life (EPA, 2019)
    a. COU-specific estimates represent formaldehyde air concentrations from new articles only
        i. Hence, total modeled estimates may represent formaldehyde air concentrations from a newly built home (or automobile), based on the TSCA COUs assessed.
3. **Room of use** – First, CEM models according to the most likely room of use for a given article per TSCA COU. CEM also assumes a typical home has a building volume of 492 m^3 and specific default room sizes (*e.g.*, 50 m^3 for a living room). AHHS II measured formaldehyde in the most frequently used room in each home, which differed from one to another. For instance, formaldehyde may have been measured a living room for one home and in a kitchen for another. Therefore, the measured monitoring concentration may be from a different room of use or an entire home type than CEM considered. Similarly, CEM also assumes specific interzone ventilation rates and air exchange rates in a residential area per hour, which may differ depending on the home type and size of the home. AHHSII considered homes of varying types (and, therefore, home of varying sizes) including detached single-family homes, mobile homes and apartments in buildings with five or more units. Thus, it may also be assumed that the interzonal ventilation rates and air exchange rates would differ between homes in the AHHS II survey and CEM defaults.
4. **Humidity and temperature** – Increased indoor air temperatures and humidity levels have been demonstrated to correlate with increased formaldehyde indoor air concentrations (Murphy et al., 2013). The degree to which humidity and temperature impacted the measured formaldehyde indoor air concentrations in AHHS II is unknown. However, CEM cannot yet account for or vary temperature and humidity but is an area of future improvement.
5. **Exposure duration** – CEM assumes durations of exposure specific to TSCA COUs assessed from which a lifetime average daily concentration is estimated. However, the measurement of formaldehyde indoor air concentrations in the AHHS II survey was according to a 3.5-hour TWA.

Within the AHHS II survey, some homes were reported to have sources of combustion ranging from tobacco smoke to wood fireplaces, which are known to produce formaldehyde as a byproduct. EPA analyzed the formaldehyde concentrations in AHHS II from homes with and without at least one combustion source of formaldehyde (Figure_Apx C-1). Some agreeance can be observed in the spread of the two datasets mostly in the lower quartiles of the figure. However, there were more homes in the upper quartile of formaldehyde indoor air concentrations where there was at least one source of combustion compared to when there were none. In addition, some homes with at least one reported combustion source had considerably higher measured formaldehyde indoor air concentrations compared to homes with no reported combustion sources.



Figure_Apx C-1. Comparing the Relative contributions of Homes with and without Sources of Combustion for Formaldehyde in AHHS II

Appendix D SUPLEMENTARY COMPOSITE WOOD PRODUCT ASSESSMENT

As noted in Section 1.1.1, EPA conducted a supplementary assessment of wood products focusing on estimating potential exposure levels based upon composite wood product emission limits set under TSCA Title VI.

D.1 Methods

This supplementary assessment was conducted using the following general steps:

1. Identify emission standards set for HWPW, MDF, and PD
2. Use the identified emission limits to estimate composite wood product-specific emission rates
    a. First, by converting the product-specific emission standards to air concentration (Table_Apx D-1)
    b. Then, using that estimated air concentration to generate emission rates using Equation_Apx D-1 (EPA, 2016) (Table_Apx D-2)

Equation_Apx D-1.

$$[CH_2O]_{SS} = \frac{\frac{b * Area}{PEX * VOL} + [CH_2O]_{out}}{D}$$

Where:

$[CH_2O]_{SS}$	= steady-state formaldehyde concentration inside the compartment (mg/m^3)
$[CH_2O]_{out}$	= steady-state formaldehyde concentration outside the compartment (mg/m^3)
b	= the emission rate at zero CH_2O concentration in the air (mg/m^2-hr)
$Area$	= Exposed surface area of the source (m^2)
PEX	= the compartment's air exchange rate with outdoors (hr^{-1}), assuming a mixing factor equal to unity
VOL	= the volume of the compartment (m^3)
D	$= 1 + \frac{m * Area}{PEX * VOL}$
m	= the mass transfer coefficient (m/hr)

Assuming that $[CH_2O]_{out}$ is zero, substituting for D in Equation_Apx D-1, and denoting $PEX * VOL$ as Q (*i.e.*, the airflow rate in/out of the chamber, in m3/hr), we can solve for be as follows:

Equation_Apx D-2

$$b = [CH_2O]_{SS} * \left(1 + m * \frac{Area}{Q}\right) * \left(\frac{Q}{Area}\right)$$

3. Model indoor air exposures using other key parameters highlighted in Section 2.1.1.1.3
    a. Of note, central tendency weight fractions for building wood products were used

Table_Apx D-1. Estimating Concentrations in mg/m^3 from Emission Standards in ppm

Pressed Wood Products	Emissions Standard (ppm)	Molecular Weight	Constant (volume of 1 mole at 1 atm)	Concentration (mg/m^3)
Hardwood plywood	0.05	30.03	24.45	0.061411043
Medium density fiberboard	0.11	30.03	24.45	0.135104294
Particleboard	0.09	30.03	24.45	0.110539877

Table_Apx D-2. Estimating Emission Rates from Product Specific Concentrations

Pressed Wood Products	Concentration (mg/m^3)	Assumed Slope or Mass Transfer Coefficient (m/hr)	Assumed Chamber Volume (m^3)	PEX[a]	Q (m^3/hr) [b]	Surface Area (m^2)	Emission Rate ($mg/m^2/hr$)
Hardwood Plywood	0.061411043	0.27	100	0.5	50	26	0.134679141
Medium Density Fiberboard	0.135104294	1.06	100	0.5	50	26	0.403026503
Particleboard	0.110539877	0.7	100	0.5	50	26	0.289954601

[a] PEX = compartment's air exchange rate with outdoors (per hour), assuming a mixing factor equal to unity
[b] Q = the airflow rate in/out of the chamber

The exposure scenario modeled was for an individual who spends two hours per day, every day, in a living room with flooring made with engineered wood flooring. Formaldehyde inhalation exposures are assumed to stem from emissions from HWPW, MDF, or PB.

D.2 Results

The estimated yearly average daily indoor air concentrations from pressed wood products were as high as 1.35×10^{-2} ppm.

Table_Apx D-3. CEM Estimated Average Daily Concentration over 1 Year

Condition of Use Subcategory	Scenario	Environment	CEM Calculated Average Daily Concentration (ppm)
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 Plywood (residential)	Residential (Living Room)	4.50E−03
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: Medium Density Fiberboard (residential)	Residential (Living Room)	1.35E−02
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: Particleboard (residential)	Residential (Living Room)	9.69E−03

D.3 Conclusion

EPA qualitatively assessed potential exposures from HWPW, MDF, and PB, according to the emission standards established under TSCA Title VI, using the best available information and tools. It is unknown the degree to which the estimated indoor air concentrations from the modeled composite wood products are reflective of real-world scenarios. Due to the following key uncertainties, EPA has a low confidence in this assessment:

- The identified emission standards were assumed to be equivalent to a product specific indoor air concentration, but it is unknown to what degree this is reflective of composite wood products currently on the market.
- Whether the assessed wood products are made entirely of HWPW, MDF, or PB.
  - Wood products on the market may be composed of a combination of composite wood layers.
- Whether the identified products are compliant with the relevant emission standards.
- Whether the approach to estimating emission rates from the set emission limits sufficiently represent products on the consumer market.

Appendix E MODELING ACTIVITY PATTERNS

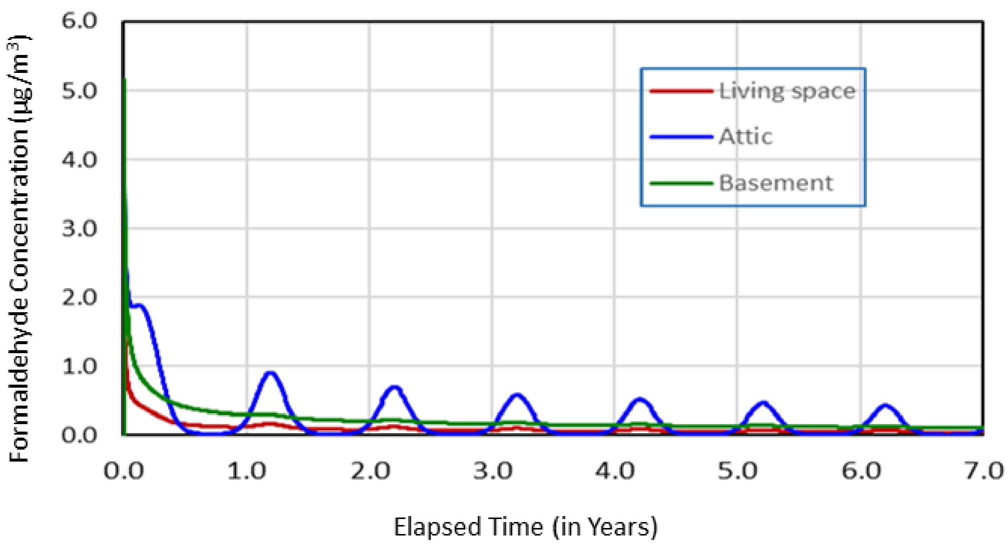
Activity pattern three was selected that assumes that a person goes to work or school for most of the day (Table_Apx E-1) (EPA, 2019). For modeled COUs an hour was assumed to be spent in an automobile, 10 hours in a bedroom and 2 hours in a living room.

Table_Apx E-1. Receptor Activity Patterns

Time	Activity Pattern 1: Person stays at home for most of the day	Activity Pattern 2: Person goes to school or work for part of the day	Activity Pattern 3: Person goes to school or work for most of the day
12:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
1:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
2:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
3:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
4:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
5:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
6:00 AM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
7:00 AM	Residence - Bathroom	Residence - Bathroom	Residence - Bathroom
8:00 AM	Automobile	Automobile	Automobile
9:00 AM	Work / School / COF	Work / School / COF	Work / School / COF
10:00 AM	Residence - Living Room	Work / School / COF	Work / School / COF
11:00 AM	Residence - Living Room	Work / School / COF	Work / School / COF
12:00 PM	Residence - Kitchen	Work / School / COF	Work / School / COF
1:00 PM	Outside	Outside	Work / School / COF
2:00 PM	Residence - Living Room	Residence - Living Room	Work / School / COF
3:00 PM	Residence - Living Room	Residence - Living Room	Work / School / COF
4:00 PM	Residence - Laundry/Utility/Garage	Residence - Laundry/Utility/Garage	Work / School / COF
5:00 PM	Outside	Outside	Outside
6:00 PM	Residence - Kitchen	Residence - Kitchen	Residence - Kitchen
7:00 PM	Residence - Living Room	Residence - Living Room	Residence - Living Room
8:00 PM	Residence - Living Room	Residence - Living Room	Residence - Living Room
9:00 PM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
10:00 PM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom
11:00 PM	Residence - Bedroom	Residence - Bedroom	Residence - Bedroom

Appendix F GENERAL FORMALDEHYDE DISSIPATION CURVE

Figure_Apx F-1 displays the general formaldehyde dissipation in residential indoor air. The figure shows an initial spike in concentration from off-gassing following initial installation of new articles. This is followed by a rapid decrease in concentrations over the first few months. In each building configuration, the living area has less fluctuations in concentrations after the initial concentration spike following installation compared to other areas. Similarly, the basement in the attic/living space/basement building configuration has less fluctuations in concentrations after the initial concentration spike following installation. The higher variability in concentrations seen in the attic of both building configurations and the crawlspace of the attic/living space/crawlspace building configuration reflect the sensitivity of off-gassing to temperature in unconditioned zones within the two building configurations.



Figure_Apx F-1. General Formaldehyde Dissipation in a Residence