Exponent®

OCCUPATIONAL EXPOSURE ASSESSMENT IN THE WORLD OF TSCA – THE IMPACT ON IH PROFESSIONALS

YPSW – January 23, 2026

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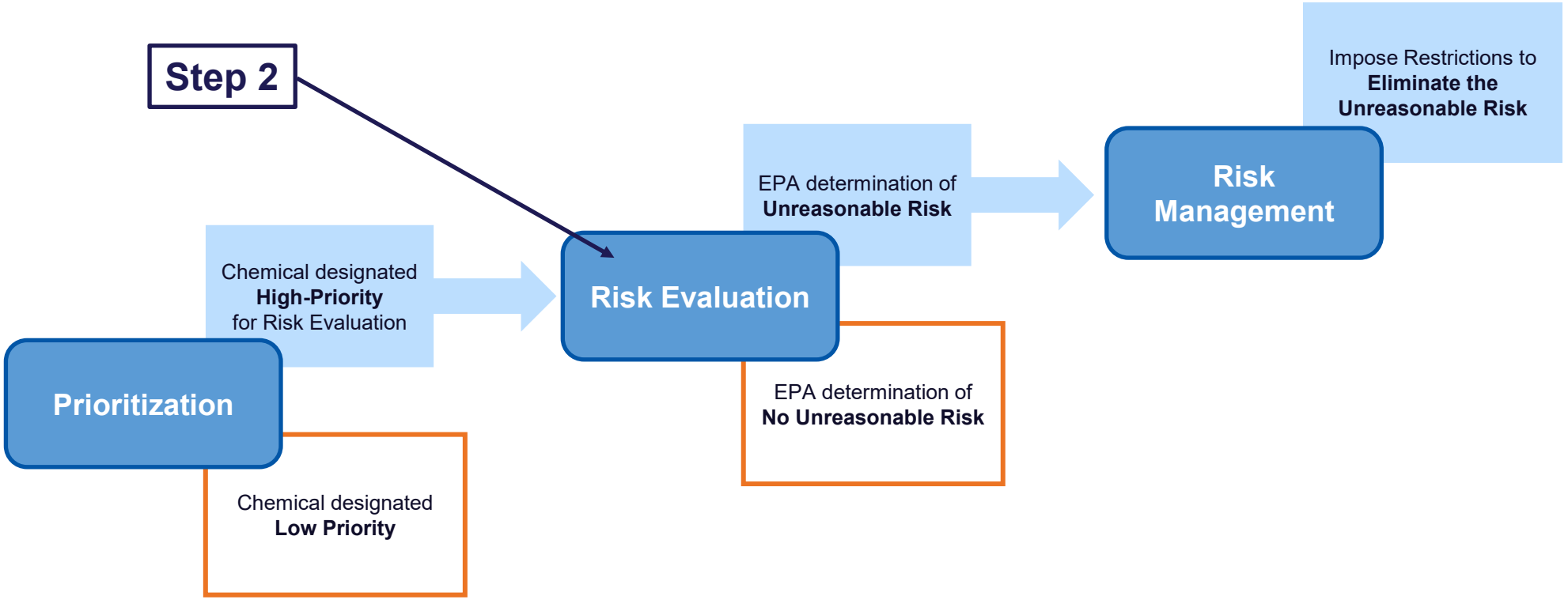
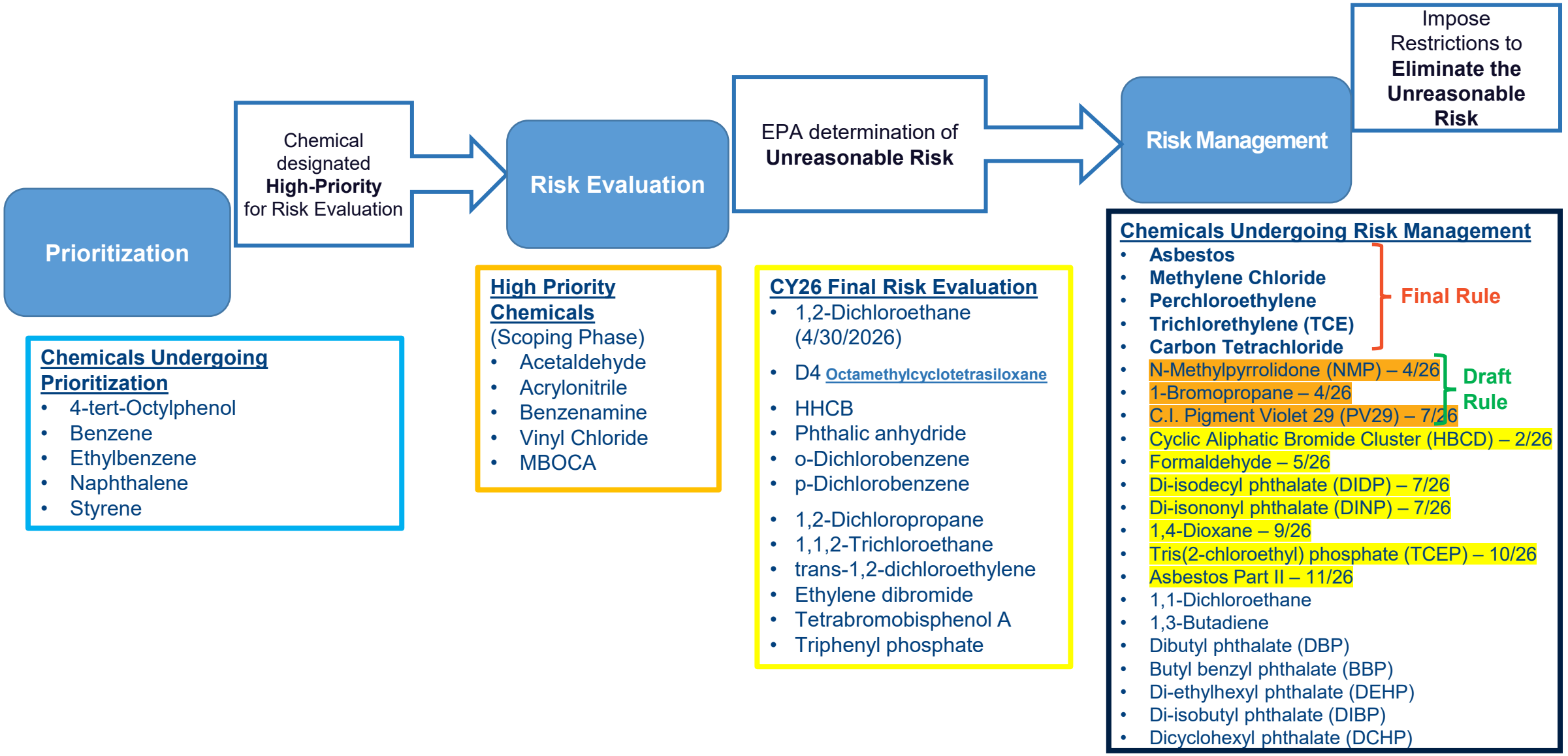
HOW EPA EVALUATES EXISTING CHEMICALS

- The Toxic Substances Control Act (TSCA) requires EPA to evaluate the safety of existing chemicals via a three-stage process:



https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca


Prioritization
Chemical designated **High-Priority** for Risk Evaluation
Risk Evaluation
EPA determination of **Unreasonable Risk**
Risk Management
Impose Restrictions to **Eliminate the Unreasonable Risk**
Chemicals Undergoing Prioritization
4-tert-Octylphenol
Benzene
Ethylbenzene
Naphthalene
Styrene
High Priority Chemicals
(Scoping Phase)
Acetaldehyde
Acrylonitrile
Benzenamine
Vinyl Chloride
MBOCA
CY26 Final Risk Evaluation
1,2-Dichloroethane (4/30/2026)
D4 Octamethylcyclotetrasiloxane
HHCB
Phthalic anhydride
o-Dichlorobenzene
p-Dichlorobenzene
1,2-Dichloropropane
1,1,2-Trichloroethane
trans-1,2-dichloroethylene
Ethylene dibromide
Tetrabromobisphenol A
Triphenyl phosphate
Chemicals Undergoing Risk Management
Asbestos
Methylene Chloride
Perchloroethylene
Trichlorethylene (TCE)
Carbon Tetrachloride
Final Rule
N-Methylpyrrolidone (NMP) – 4/26
1-Bromopropane – 4/26
C.I. Pigment Violet 29 (PV29) – 7/26
Draft Rule
Cyclic Aliphatic Bromide Cluster (HBCD) – 2/26
Formaldehyde – 5/26
Di-isodecyl phthalate (DIDP) – 7/26
Di-isononyl phthalate (DINP) – 7/26
1,4-Dioxane – 9/26
Tris(2-chloroethyl) phosphate (TCEP) – 10/26
Asbestos Part II – 11/26
1,1-Dichloroethane
1,3-Butadiene
Dibutyl phthalate (DBP)
Butyl benzyl phthalate (BBP)
Di-ethylhexyl phthalate (DEHP)
Di-isobutyl phthalate (DIBP)
Dicyclohexyl phthalate (DCHP)

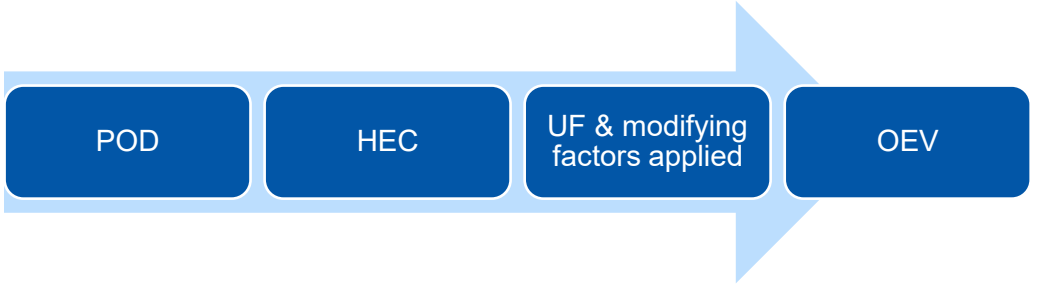
HAZARD ASSESSMENT – IT'S ONE OF THE PRIMARY REASONS OUR PROFESSION IS EVOLVING

EXAMPLES OF TLVS AND TSCA CHEMICAL EXPOSURE VALUES

Chemical	TLV 8 hr TWA	TLV basis	TSCA value (OEV/ECEL)
Perchloroethylene	**25 ppm**	**Eye irritation and central nervous system symptoms**	**0.14 ppm**
Methylene chloride	**50 ppm**	**Minimize potential for elevation of carboxyhemoglobin and CNS depression**	**2 ppm**
Trichloroethylene	**10 ppm**	**CNS effects and renal toxicity and cancer**	**0.2 ppm**
Carbon tetrachloride	**0.1 ppm**	**Liver damage**	**0.033 ppm**
Diisononyl phthalate	NA	NA	0.081 ppm
1,4-dioxane	20 ppm	Liver and kidney toxicity and eye & respiratory tract irritation	0.055 ppm
1,1- dichloroethane	100 ppm	Eye and upper respiratory tract irritation and possible liver and kidney injury	0.044 ppm
1,3-butadiene	2 ppm	Cancer A-2 suspected human carcinogen	0.11 ppm
Formaldehyde	0.1 ppm	Upper respiratory tract and eye irritation	0.01 → 0.11 → 0.3 ppm

WHAT IS A TSCA OEV VS. ECEL?

- OEV is used in the Risk Evaluation as "the level below which the EPA would not expect any (appreciable)* adverse health effects for a worker assuming exposure to the chemical substances for a working lifetime without controls (PPE)."
  - Also used to guide the needed LOD for acceptable data sets
  - Appears to be based on an acceptable risk level of 1 x 10^{-4} for carcinogens and a hazard benchmark of 1 for non-carcinogens
- ECEL is promulgated by EPA as part of Section 6 Risk Management
- ECEL often the same as the OEV
  - 8 hour or STEL
- EPA may require ECELs as an interim control prior to or as part of a Workplace Chemical Protection Program (WCPP)



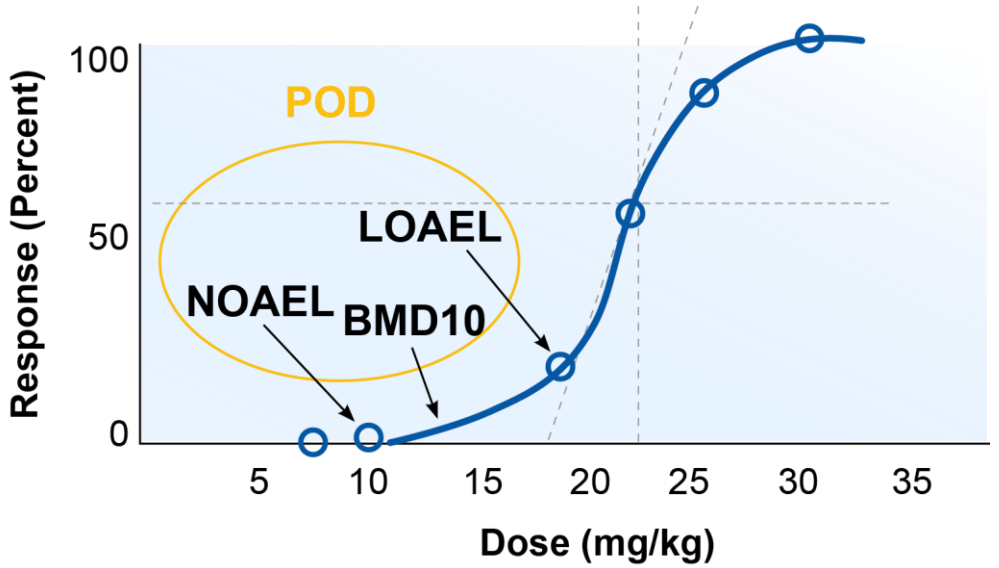
OEV and ECEL defined in the *Compliance Guide for the Workplace Chemical Protection Program Under TSCA (January 2025)*
** document states "appropriate" we believe EPA means appreciable*

KEY REASONS FOR TSCA DIFFERENCES

- Target organs of concern
  - i.e., eye irritation versus specific neurologic effects vs. carcinogenic effect
- Updated interpretation of studies
  - Effects reported at lower dose levels
  - However, debate in the selection of appropriate studies/endpoints and data quality
- Updated dose-response modeling methods (BMD analysis)
- Linear no threshold dose cancer modeling
- EPA evaluates non-cancer and cancer effects separately

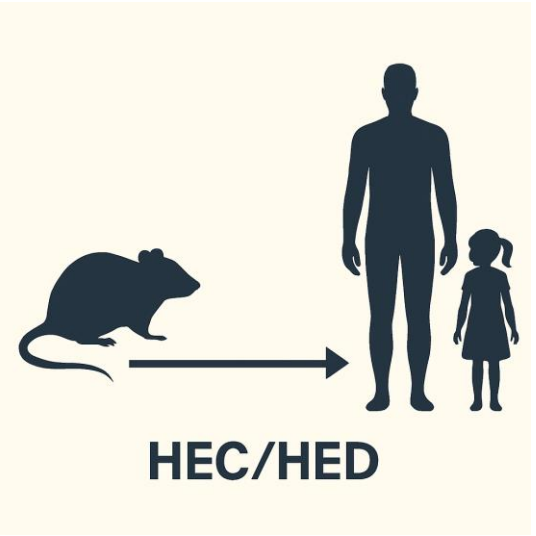
EPA NON-CANCER HAZARD ASSESSMENTS

- Point of departure (POD) = endpoint for assessment (mg/kg; mg/kg-day)
  - Toxicological dose-response curve from animal data or observational data corresponding to either:
    - low observable adverse effect level (LOAEL)
    - no observable adverse effect level (NOAEL)
    - benchmark dose (BMD)
- BMD is becoming EPA and other agency preferred approach as it reflects shape of curve, doesn't rely on testing doses
    - Requires larger data set and statistical modeling

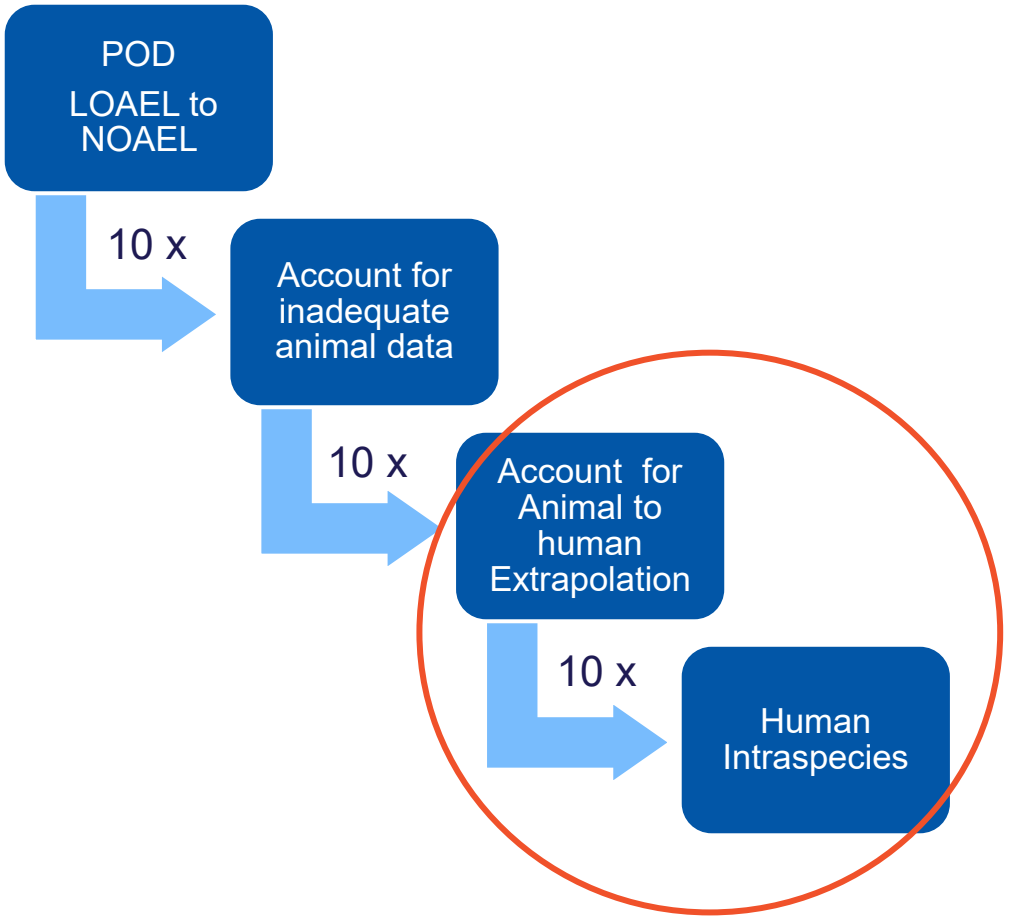


EPA NON-CANCER HAZARD ASSESSMENTS

- HED – human equivalent dose (mg/kg-day)
  - Converts animal to human equivalent dose based on body weight scaling
- HEC – human equivalent concentration (mg/m^3)
  - Converts animal study inhalation concentrations to human concentrations
  - Extrapolates based on an equivalent concentration using body weight and breathing rates and other pulmonary interspecies parameters
  - Or calculated directly by using models (i.e., physiologically based pharmacokinetic models (PBPK) or others)
- Advantage of HEC/HED modeling
  - often reduces Uncertainty Factor (UF) from 100 to 30 (typically)



USE OF UNCERTAINTY FACTORS (UF)



- Most common is a Total UF of 100 x for:
  - Animal → Human
  - Human → Human
- Total UF can be increased or decreased
  - LOAEL to NOAEL (BMD may help here)
  - Toxicokinetic (HEC calculation)
  - Lack of chronic duration studies
  - Human studies

USE OF UNCERTAINTY FACTORS (BENCHMARK MOE)

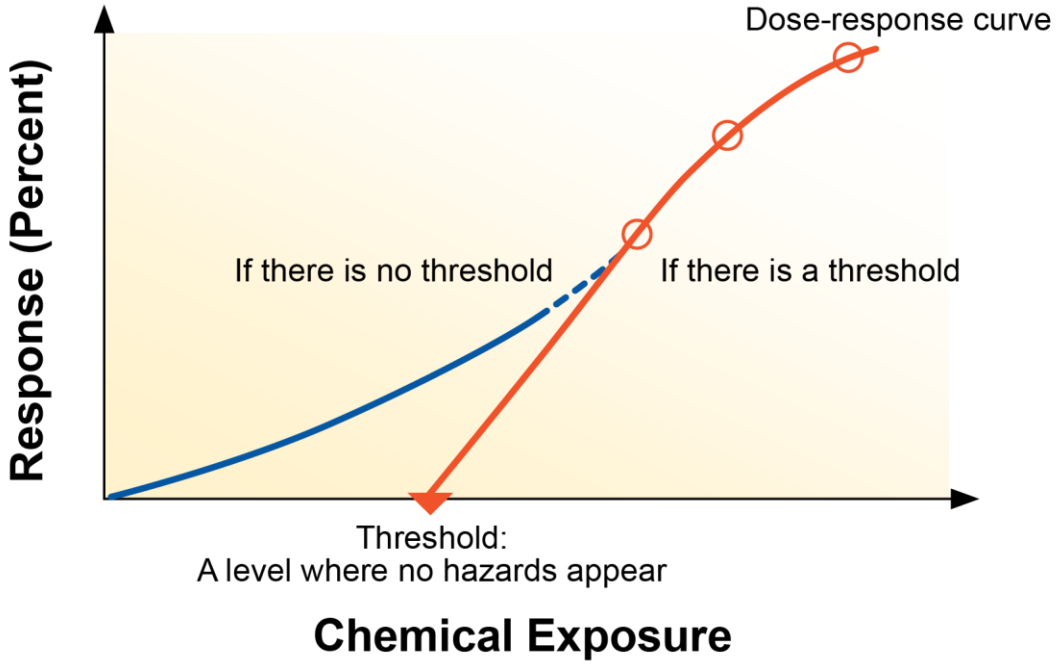
- Option 1: Applied to POD
  - POD ÷ UFs = "acceptable air concentration" for comparison to exposure
    - Example: Refence Concentration (RfC) = estimate of a continuous inhalation exposure to a human population including sensitive subgroups likely to be without an appreciable risk of deleterious effects during lifetime (mg/m^3)
      - Can be adjusted to worker scenario (ex. 8/24 hours 250/365 days)
      - However, original basis of study findings may not be relevant to worker populations! (e.g. formaldehyde)
    - Approach used to develop TSCA worker "acceptable air concentrations" [ECEL/OEV]
- Option 2: Margin of Exposure (MOE)
  - POD ÷ exposure = MOE for comparison to benchmark MOE
    - Where benchmark MOE = uncertainty factors
  - Approach used in TSCA Risk Evaluations to determine "unreasonable risk"

$$\frac{POD}{Exposure} = MOE$$

If MOE >Benchmark MOE (Total UF) then acceptable risk
If MOE < Benchmark MOE (Total UF) then unreasonable risk

EPA CANCER HAZARD ASSESSMENTS

- No threshold – linear modeling
- Modeling derives an inhalation unit risk value (IUR) $(ug/m^3)^{-1}$ that quantifies the excess lifetime cancer risk from continuous inhalation to 1 $\mu g/m^3$ of that chemical concentration



PERCHLOROETHYLENE – OCCUPATIONAL EXPOSURE LEVELS (ALL HUMAN STUDIES)

ACGIH

- Eye irritation and CNS effects reported at 10-100 ppm
- TWA = 25 ppm **(170 mg/m^3)**

ECHA

- CNS depression in human volunteer studies with NOAEC of 106 ppm
- Derived No Effect Level (DNEL) for 8 hr Worker Inhalation: **138 mg/m^3**

EPA RfC

- Cognitive and reaction time changes
- 0.04 mg/m^3 is the midpoint of the LOAELs with 1000 UF (IRIS | US EPA)
- 0.052 ppm **(0.36 mg/m^3)** as **RfC for continuous residential exposure (100 UF and different HEC calculations than IRIS)**

EPA ECEL

- Same midpoint as above (0.04 mg/m^3) was chosen
- Adjusted for occupational exposure, adjusted for breathing rate (i.e., 8/24 hour, 5/7 days)
- 0.14 ppm **(0.98 mg/m^3)** for occupational exposure

1 ppm = 6.79 mg/m^3

ECHA – European Chemical Agency

FORMALDEHYDE – OCCUPATIONAL EXPOSURE LEVELS

ACGIH

- 0.1 ppm (0.12 mg/m^3) based on sensory irritation in humans

ECHA

- 0.3 ppm (375 µg/m^3) local long-term effects based on sensory irritation in humans
- Protective of cancer risk based on animal studies using a non-linear approach showing an exponential increase in excess risk: the additional theoretical cancer risk of a non-smoker following a continuous (80 years) inhalation exposure of 0.1 mg/m^3 is assumed to be 3 x 10^{-7} ECHA (2019)

EPA

- Draft TSCA risk evaluation 2023 – 0.01 ppm
- Final TSCA risk evaluation Dec 2024 – 0.11 ppm (200 µg/m^3) for chronic based on nasopharyngeal cancer
- Revised TSCA evaluation Dec 2025 – 0.3 ppm
- Protective against irritation and **all other potential hazards, including cancer**

FORMALDEHYDE OCCUPATIONAL EXPOSURE VALUE

- DRAFT Risk Evaluation – proposed 0.011 ppm!
- 2024 Risk Evaluation – 0.11 ppm

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

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

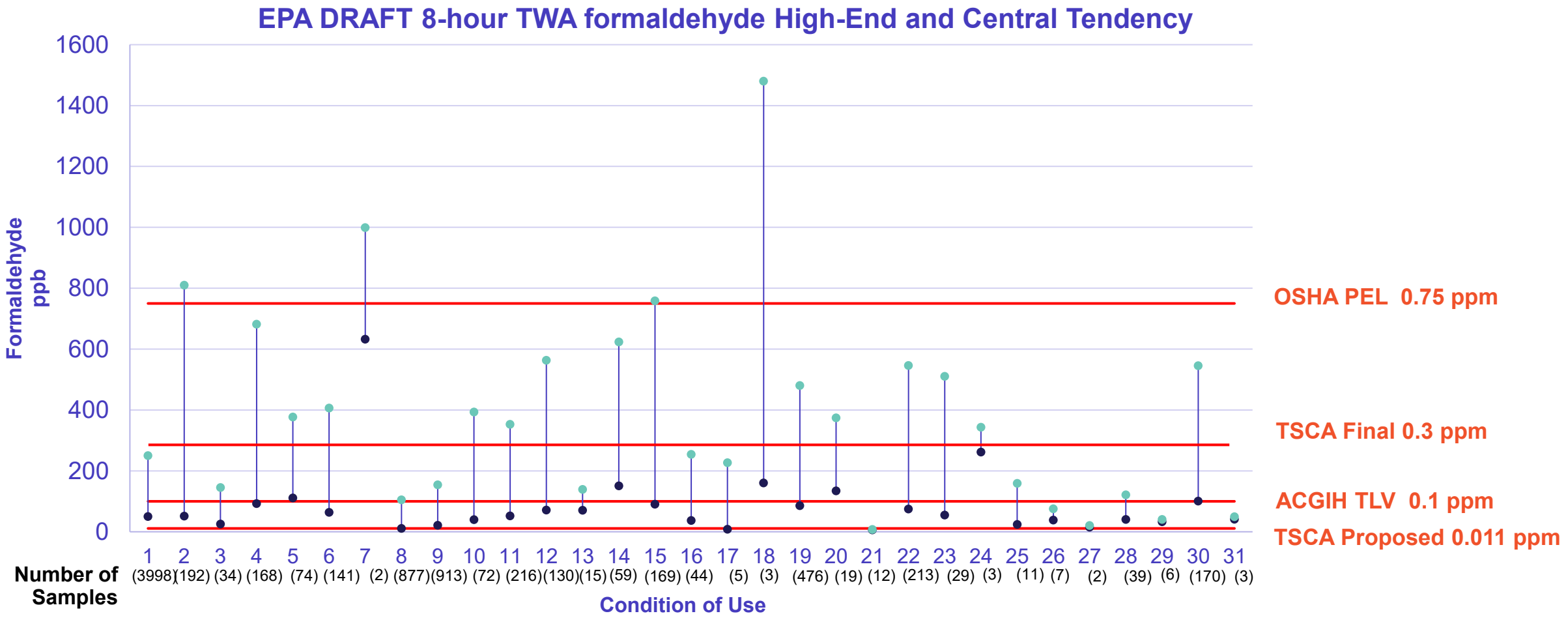
$$= \frac{1X10^{-4}}{7.90 \times 10^{-3}\ per\ ppm} * \frac{24\frac{h}{d} * \frac{365d}{y} * 78y}{8\frac{h}{d} * \frac{250d}{y} * 40y} * \frac{1.25\ \text{m}^3/hr}{1.25\ \text{m}^3/hr} =$$

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

- 2025 Risk Evaluation – 0.3 ppm

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

WHY THIS MATTERS



Note: Background residential indoor air 0.01-0.03 ppm

EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION APPROACH

HIERARCHY OF OCCUPATIONAL EXPOSURE ASSESSMENT APPROACHES

Monitoring data for the chemical of interest

- Personal exposure monitoring data (direct exposures)
- Area monitoring data (indirect exposures)

Surrogate data from other chemicals

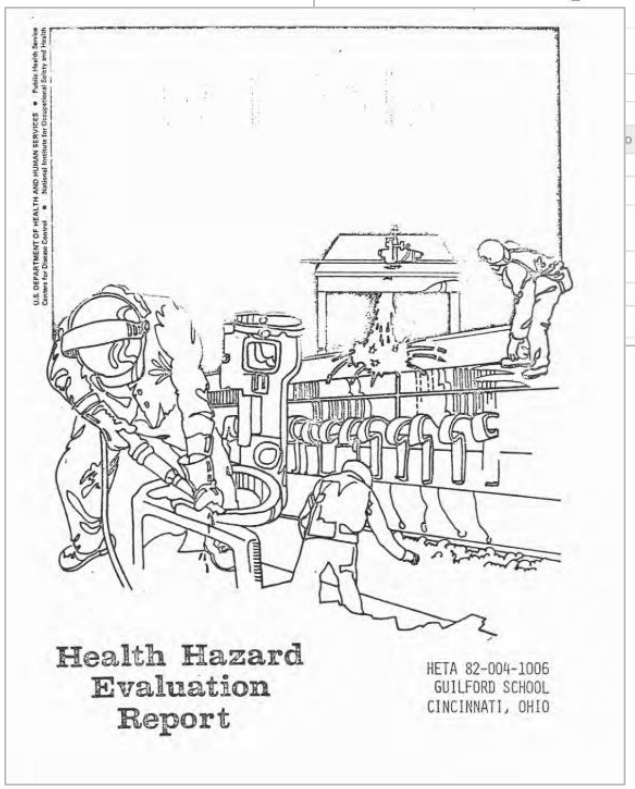
- With similar uses, volatility, and physical and chemical properties

Exposure modeling

- For COUs or OESs where data are limited
- Apply existing models to specific COUs or OESs
- Use available data to develop or adapt models for a particular scenario

SOURCES OF OCCUPATIONAL MONITORING DATA

- Data collected by government agencies
  - OSHA CEHD
  - NIOSH HHEs
- Industry Submissions
  - Monitoring data reported in published literature
- Company- or consortia-provided industrial hygiene studies
  - Raw data
  - Data summaries and analyses
  - EPA required Test Order submissions



TEST ORDERS

TSCA Section 4 Test Order Background

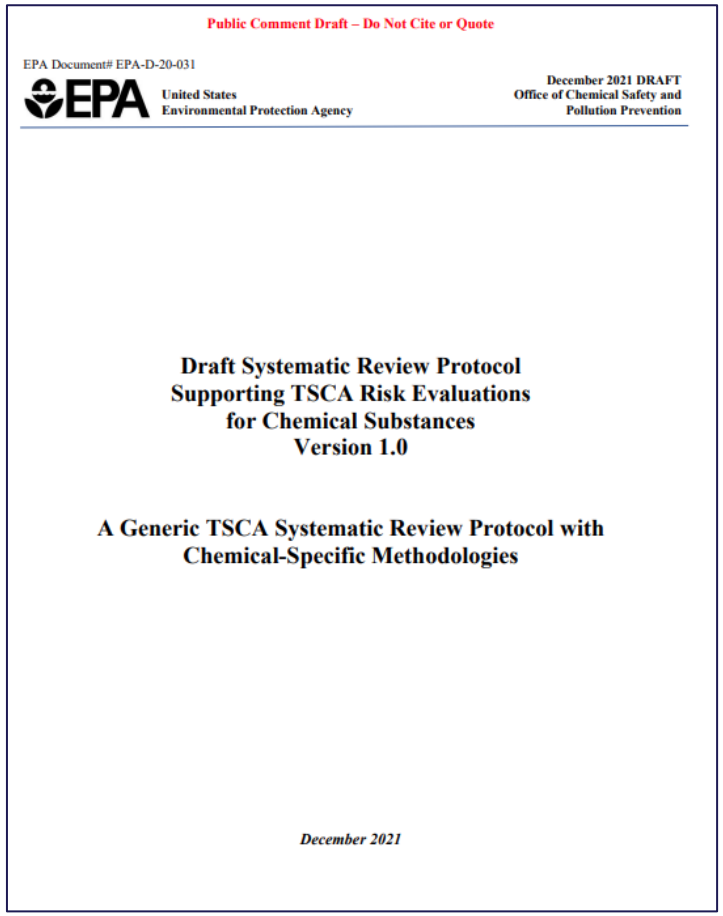
- **Authority**: Under **TSCA Section 4**, EPA has authority to require the generation of new information by chemical manufacturers (including importers) and processors:
  - TSCA Section 4(a)(1), where insufficient information exists, testing is necessary to get that information, and:
    - (i) the chemical substance may present unreasonable risk, or
    - (ii) the chemical substance is produced in substantial quantities and may cause substantial or significant exposures to the environment or humans
  - TSCA Section 4(a)(2), supports certain activities undertaken to specific provisions of TSCA and other federal law

https://www.epa.gov/system/files/documents/2022-01/r2-test-order-presentation-final.pdf

Testing Types:

- Physical-chemical properties
- Environmental Hazards
- Environmental Fate
- Health Effects
- ***Occupational Exposure***
  - ***To date 10 Test Orders Issued***
- Consumer Exposure

DATA QUALITY EVALUATION



Public Comment Draft – Do Not Cite or Quote

EPA Document# EPA-D-20-031

EPA United States Environmental Protection Agency

December 2021 DRAFT
Office of Chemical Safety and Pollution Prevention

Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0

A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies

December 2021

Table_Apx M-4. Metric Ranking and the Range Metric Ranking for Ranking the Quality of Environmental Release and Occupational Exposure Data

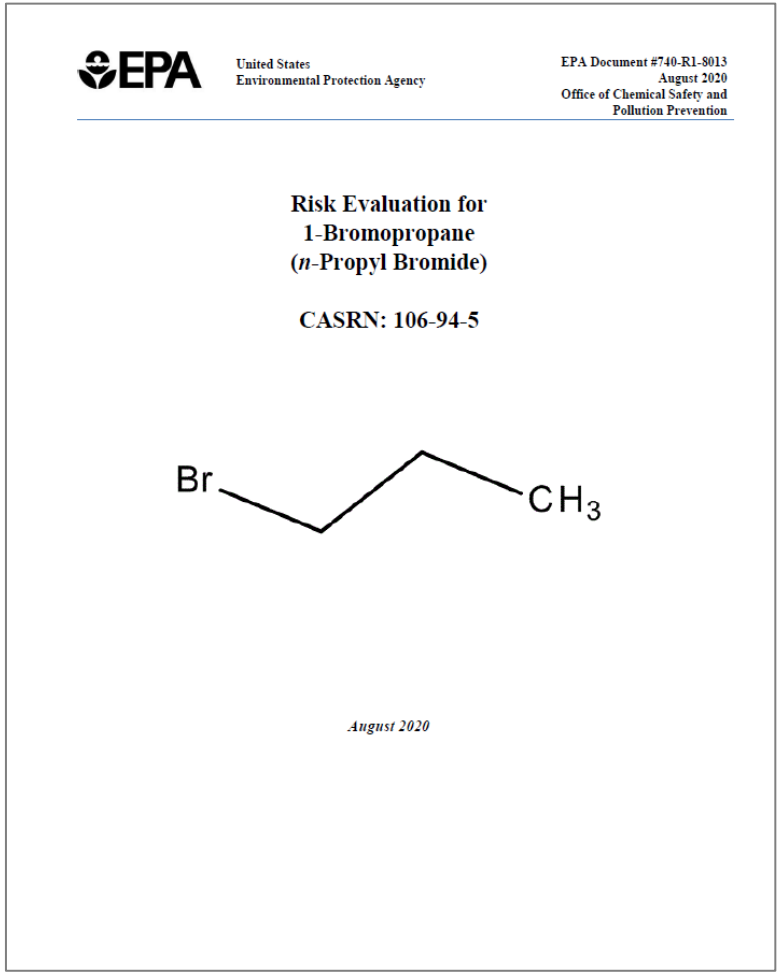
Domain	Metric	Metric Ranking (range of possible values)
Reliability	Methodology	1 to 3
Representativeness	Applicability	1 to 3
	Geographic scope	1 to 3
	Temporal representativeness	1 to 3
	Sample size	1 to 3
Accessibility/clarity	Metadata completeness	1 to 3
Variability and uncertainty	Metadata vompleteness	1 to 3
Sum (if all metrics included)[a]		7 to 21
Range of overall ranking, where overall ranking = ∑(metric ranking) / ∑(metric factors)		**7/7=1; 21/7=3 Range of overall ranking = low to high**
High	Medium	Low

[a] The sum of all metric ranking will differ if some metrics are not ranked (not applicable).

1 – BROMO PROPANE

Table 2-5. Data Evaluation of Sources Containing Occupational Exposure Data

Source Reference	Data Type	Confidence Rating	Condition of Use
(OSHA, 2013a)	PBZ Monitoring	High	Manufacture
(Enviro Tech International, 2020)	PBZ Monitoring	High	Processing -- Incorporation into Formulation
(Reh and Nemhauser, 2001)	PBZ Monitoring	High	Batch Vapor Degreaser
(Miller, 2019)	PBZ Monitoring	High	Batch Vapor Degreaser
(OSHA, 2013b)	PBZ Monitoring	High	Batch Vapor Degreaser, Spot Cleaner, Adhesive Chemicals (Spray Adhesive), Cold Cleaner
(OSHA, 2019)	PBZ Monitoring	High	Batch Vapor Degreaser, Spot Cleaner
(U.S. EPA, 2006b)	PBZ Monitoring	Medium	Batch Vapor Degreaser, Aerosol Spray Degreaser/Cleaner
(Eisenberg and Ramsey, 2010)	PBZ Monitoring	High	Dry Cleaning
(Blando et al., 2010)	PBZ Monitoring	High	Dry Cleaning
(NIOSH, 2002b)	PBZ Monitoring	High	Adhesive Chemicals (Spray Adhesive)
(Reh et al., 2002)	PBZ Monitoring	High	Adhesive Chemicals (Spray Adhesive)
(NIOSH, 2003b)	PBZ Monitoring	High	Adhesive Chemicals (Spray Adhesive)



EPA United States Environmental Protection Agency

EPA Document #740-R1-8013
August 2020
Office of Chemical Safety and Pollution Prevention

Risk Evaluation for 1-Bromopropane (*n*-Propyl Bromide)

CASRN: 106-94-5

August 2020

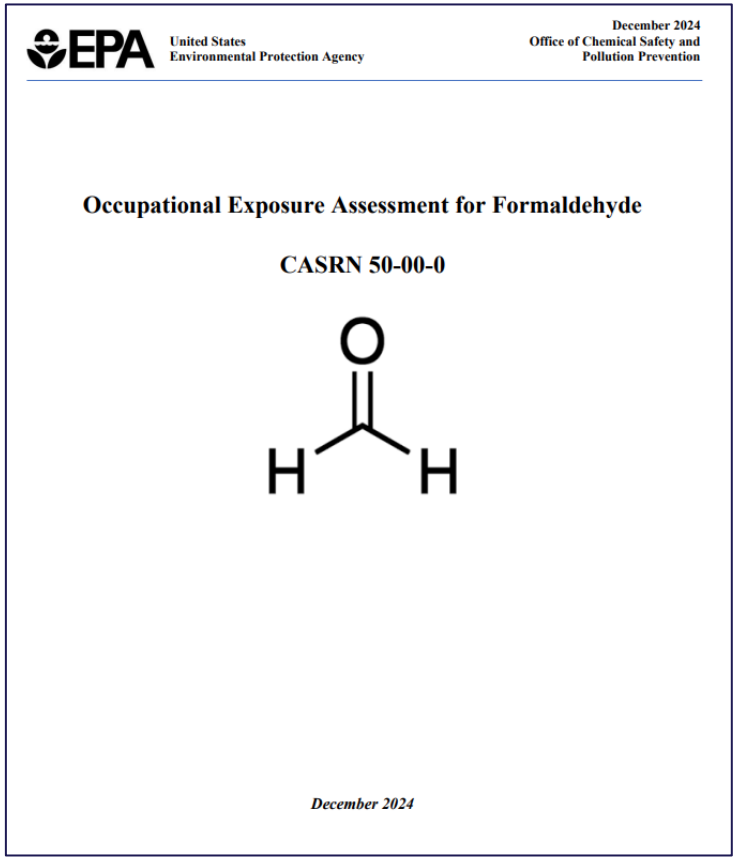
LET’S LOOK AT SOME EXAMPLES

GENERAL APPROACH

- For each occupational COU/OES:
  - Step 1: Describe processes and worker activities (literature search)
  - Step 2: Develop estimates of inhalation and dermal exposure
    - Central tendency (50th percentile) and high-end (95th percentile) estimates
    - Inhalation: full-shift and short-term concentrations
    - Dermal: dermal loading using exposure models
  - Step 3: Calculate exposure concentrations
    - Acute and chronic exposures (adjusted to consider averaging period)
  - Step 4: Calculate risk estimates
    - Non-cancer: margin of exposure (MOE) approach
    - Cancer: inhalation cancer risk

FORMALDEHYDE RISK EVALUATION

- Final risk evaluation released in December 2024
  - Assessed 63 conditions of use
- Revised December 2025
  - Updated draft risk calculations
- EPA determined that there is unreasonable risk to workers due to non-cancer and cancer effects



EXAMPLE COU: PROCESSING AS A REACTANT

Table 1-1. Crosswalk of COU Subcategories to Occupational Exposure Scenarios Assessed in the Risk Evaluation

Condition of Use (COU)			Occupational Exposure Scenario (OES) Mapped to COU
Life Cycle Stage	**Category**	**Subcategory**	
Manufacturing	Domestic Manufacturing	Domestic manufacturing	Manufacturing of Formaldehyde
	Importing[a]	Importing	Import and/or Repackaging of Formaldehyde
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; basic organic chemical manufacturing	
Processing	Reactant	Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; chemical product and preparation manufacturing; Paper manufacturing; Paint and coating manufacturing; Plastic products manufacturing; Synthetic rubber manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting	Processing as a Reactant
Processing	Reactant	Functional fluid in: Oil and gas drilling, extraction, and support activities	
Processing	Reactant	Processing aids, specific to petroleum production in all other basic chemical manufacturing	
Processing	Reactant	Bleaching agent in wood product manufacturing	
Processing	Reactant	Agricultural chemicals in agriculture, forestry, fishing, and hunting	
Processing	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	Textile Finishing

https://www.epa.gov/system/files/documents/2025-01/14.-formaldehyde-.-occupational-exposure-assessment-.-public-release-.-hero-.-dec-2024.pdf

EXAMPLE COU: PROCESSING AS A REACTANT

INHALATION EXPOSURE DATA SOURCES

Table 3-7. Processing as a Reactant Inhalation Exposure Data Evaluation

Worker Activity or Sampling Location	Data Type	Number of Samples	Overall Data Quality Determination	Source(s)
Various activities during resin manufacturing such as operator of impregnation machine and resin sample analysis	PBZ monitoring data	2	High	(Viegas et al., 2013)
Various activities such as operator, lab operator, and control room board operator	PBZ monitoring data	50	High	(Celanese Corp, 2022)
Drumming finished products and changing filters, pulling process samples, unknown worker activities during resin manufacturing	PBZ monitoring data	25	Medium to High	(Dow Chemical, 2019a, b, c, 2017a, c, d)
Unloading railcar, sampling, and operators	PBZ monitoring data	32	High	(Dow Chemical, 2024)
Operator, assistant operator, power house operator, mechanic, insulator and E/I technician	PBZ monitoring data	57	High	(Analytics Corporation, 2020a, b, 2019a, b, 2018a, b, 2017b, 2016a, b)
Operator during blending operators	PBZ monitoring data	5	High	(FRM Risk, 2019)
Exchanging drums of formalin, Lab technician	PBZ monitoring data	3	High	(AECOM, 2019)
Environmental health and safety, quality control/quality assurance, logistics, maintenance, and operators	PBZ monitoring data	92	High	(Stantec ChemRisk, 2023)
Unknown	PBZ monitoring data	293	Medium	(OSHA, 2019)

FORMALDEHDYE

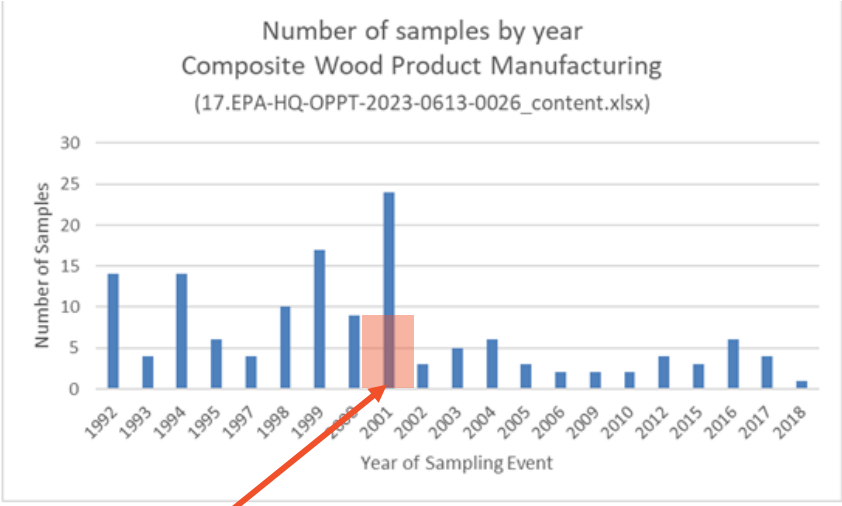


Figure 1. Number of Samples by Year for Composite Wood Product Manufacturing OES

Table 4-19. Composite Wood Product Manufacturing Inhalation Exposure Data Evaluation

Worker Activity or Sampling Location	Data Type	Number of Samples	Overall Data Quality Determination	Source
Foreman, cleaner, press operator, lab technician, and resin operator	PBZ monitoring data	7	Medium	(Lavoue et al., 2005)
Finishing area during plywood manufacturing	PBZ monitoring data	1	High	(Fransman et al., 2003)
Press operator during fiberboard manufacturing	PBZ monitoring data	3	High	(Sussell, 1995)
Unknown	PBZ monitoring data	261	Medium	(OSHA, 2019)

EXAMPLE COU: PROCESSING AS A REACTANT

INHALATION EXPOSURE ESTIMATES

Table 3-8. Summary of Inhalation Exposure Monitoring Data for Processing as a Reactant

	Exposure Concentration Type	Worker Exposures		Number of Worker Samples	ONU Exposures		Number of ONU Samples	Data Quality Rating of Air Concentration Data
		Central Tendency (ppm)	High-End (ppm)		Central Tendency (ppm)	High-End (ppm)		
Full shift	8-hour TWA Exposure Concentration	0.05	0.81	202	0.01	0.03	41	Medium to High
	12-hour TWA Exposure Concentration	0.02	0.15	33	0.02		0	High
Shorter term	15-minute	0.15	3.13	96	EPA did not identify short-term data for ONUs			Medium to High
	>15 to <330 minute	0.10	1.80	184				Medium to High
	>14 to <60 minute	0.15	3.27	134				Medium to High

EXAMPLE COU: PROCESSING AS A REACTANT

INHALATION EXPOSURE ESTIMATES

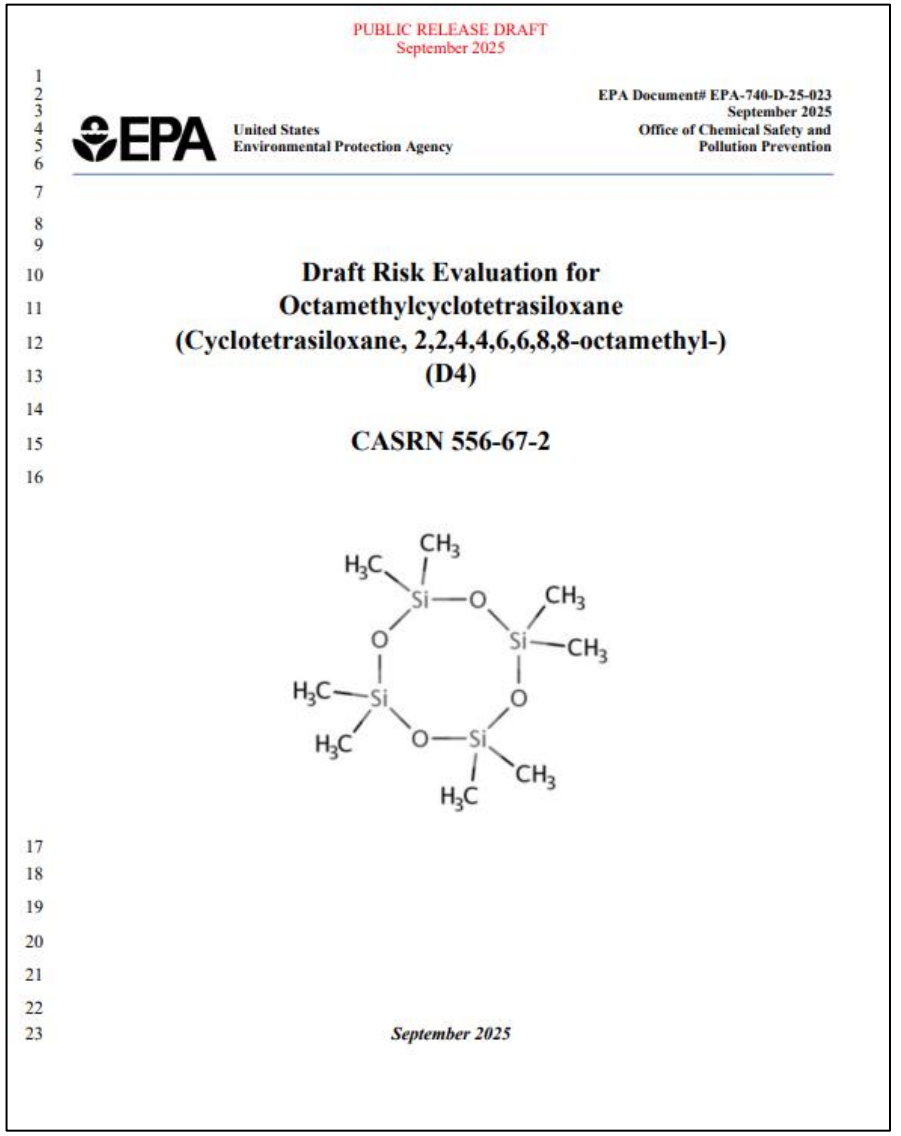
- 8-hour TWA data used to develop other estimates by applying modifiers [frequency (days/year) and duration (years/lifetime)]
- Average Daily concentrations (ADC) – evaluate chronic non-cancer risks
- Lifetime Average Daily Concentrations (LADC) – evaluate chronic cancer risks

Exposure Outputs

Category	Exposure Level	Full-Shift (Eight- or Twelve-Hour) TWA Exposure	Acute Exposures	Chronic, Non-Cancer Exposures	Subchronic, Non-Cancer Exposures	Chronic, Cancer Exposures
		$C_{FA,\ 8\text{-hr TWA}}$ (ppm)	$C_{FA,\ Acute}$ (ppm)	$ADC_{FA,\ 24\text{-hr TWA}}$ (ppm)	$ADC_{FA,\ Subchronic}$ (ppm)	$LADC_{FA,\ 24\text{-hr TWA}}$ (ppm)
Worker	High End	0.8	3.1	0.4	0.4	9.48E-02
ONU		3.00E-02		1.40E-02	1.50E-02	3.51E-03
Worker	Central Tendency	5.10E-02	0.3	2.38E-02	2.54E-02	4.63E-03
ONU		7.07E-03		3.29E-03	3.53E-03	6.42E-04

DRAFT EVALUATION OF D4

- Draft risk evaluation released in September 2025
- EPA preliminarily determined that there is unreasonable risk to workers from inhalation and dermal exposure
  - 24 Occupational COUs identified
- EPA did not consider PPE use in making risk determinations
  - But included quantitative estimates of effect of PPE in risk worksheet



PUBLIC RELEASE DRAFT
September 2025

EPA Document# EPA-740-D-25-023
September 2025
Office of Chemical Safety and Pollution Prevention

EPA United States Environmental Protection Agency

Draft Risk Evaluation for Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) (D4)

CASRN 556-67-2

September 2025

D4 OCCUPATIONAL EXPOSURE ASSESSMENT

- To evaluate inhalation exposures in manufacturing/processing COUs, EPA used monitoring data submitted by industry consortium

Table 3-2. Summary of Estimated Inhalation Exposures for Manufacture of D4

OES	SEG	Exposure Scenario	TWA Exposures 8-, 10-, or 12-hr TWA (mg/m^3)		Acute Concentration (AC; mg/m^3)		Intermediate Average Daily Concentration, Non-Cancer (IADC; mg/m^3)		Chronic Average Daily Concentration, Non-Cancer Exposures (ADC; mg/m^3)		
			Central Tendency	High-End	Central Tendency	High-End	Central Tendency	High-End	Central Tendency	High-End	
Manufacturing	Administrative (ONU)	8-hr	3.0E−01		2.1E−01		1.5E−01		1.4E−01		N=1
	Chemical operator	8-hr	2.9	9.7	2.0	6.6	1.5	4.8	1.4	4.5	N=17
	Laboratory technician	8-hr	2.4E−01	4.7E01	1.7E−01	3.2E01	1.2E−01	2.3E01	1.1E−01	2.2E01	N=3
	Logistic technician	12-hr	3.3E−01	3.4	3.4E−01	3.5	2.5E−01	2.6	2.3E−01	2.4	
	Material handler	8-hr	1.6E−01	1.6E−01	1.1E−01	1.1E−01	7.9E−02	7.9E−02	7.3E−02	7.3E−02	
	Production operator	8-hr	5.1E−01	8.0	3.5E−01	5.5	2.5E−01	4.0	2.4E−01	3.8	
	Production operator	10-hr	9.1E−01	2.1	7.8E−01	1.8	5.7E−01	1.3	5.3E−01	1.2	
	Production operator	12-hr	1.8E−01	1.9	1.9E−01	1.9	1.4E−01	1.4	1.3E−01	1.3	

Note: EPA received inhalation monitoring data from SEHSC from manufacturing and processing facilities (SEHSC, 2019). This data contained both PBZ and area measurements. This data received a rating of medium from EPA's systematic review process. The distributions (*e.g.*, high-end and central tendency) were created based on the number of data points and used the process described in Section 2.4.2.

D4 ASSESSMENT – PPE CONSIDERATIONS

- Based on quantitative estimation of effect of PPE, EPA concluded: "*When applied, the use of PPE is found to mitigate the unreasonable risk to workers*"

Risk Estimation for Aggregate Exposures						
Risk Type	Exposure Level	Benchmark MOE (= Total UF)	Glove Protection Factor	No Respirator	Exposure Estimates: Worke Respira	
					10	25
Acute, Non-Cancer	High-End	30	No Gloves	7.5	13	14
			5	13	49	60
			10	15	75	104
			20	15	103	166
	Central Tendency	30	No Gloves	24	39	41
			5	43	151	182
			10	48	237	321
			20	51	329	519

PPE CONSIDERATIONS FOR RISK EVALUATIONS

- In September 2025, EPA announced proposed amendment to 40 C.F.R. § 702.39:
  - "In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment."

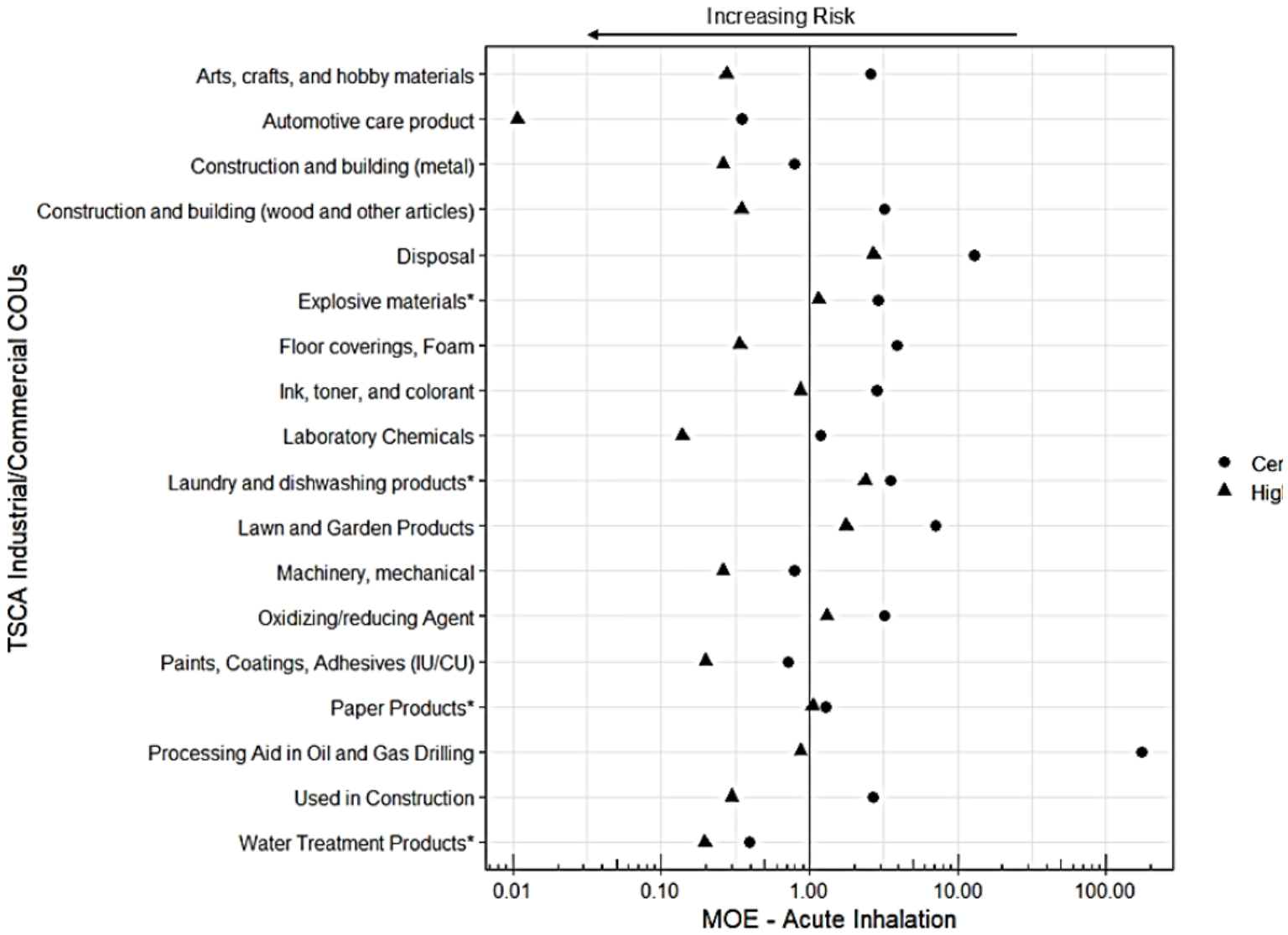
RISK CHARACTERIZATION- DETERMINATION OF “UNREASONABLE RISK”

RISK CHARACTERIZATION

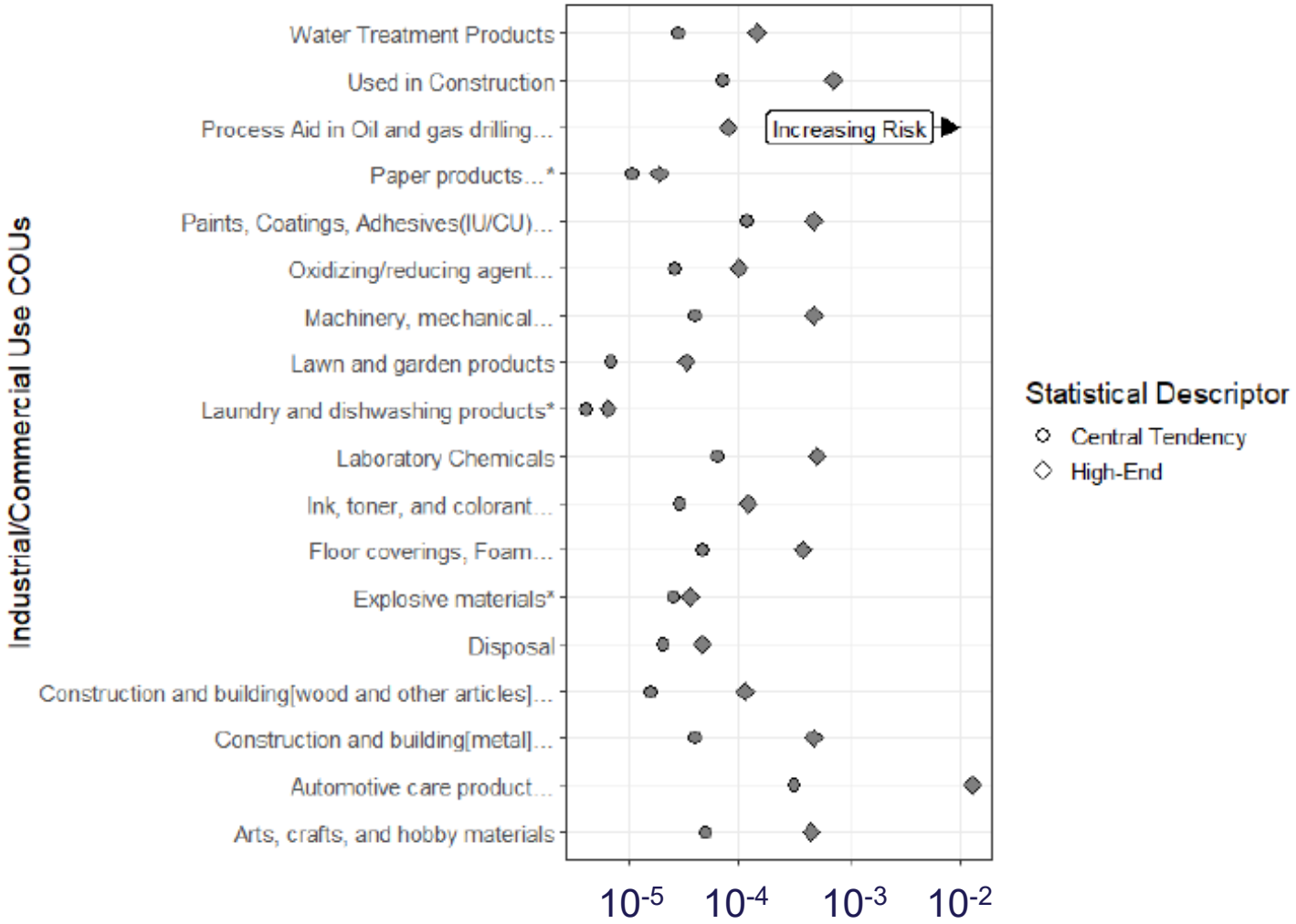
- EPA evaluates Non-cancer and Cancer effects separately
- Non-cancer
  - Chronic vs. acute effects
  - Early risk assessments characterized risks separately for different target endpoints (i.e., kidney, liver, CNS, reproductive toxicity)

Note: Dermal exposure is also considered with comparison to systemic dose (mg/kg-day)

FORMALDEHYDE ACUTE NON-CANCER RESULTS BY COU

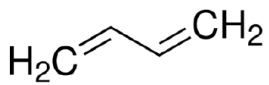


FORMALDEHYDE CANCER RISK CHARACTERIZATION BY COU



Risk Evaluation for 1,3-Butadiene

CASRN 106-99-0



Life Cycle Stage/ Category(ies)	Subcategory	Job Group/SEG	Exposure Route and Duration	Exposure Level	Risk Estimates for No PPE			PPE to Mitigate Risk (Max APF = 50) [e]		
					Intermediate Non-Cancer (Benchmark MOE = 30)	Chronic Non-Cancer (Benchmark MOE = 30)	Cancer (Benchmark = 1E−04)	Intermediate Non-Cancer (Benchmark MOE = 30)	Chronic Non-Cancer (Benchmark MOE = 30)	Cancer (Benchmark = 1E−04)
Disposal *(continued)*	Disposal *(continued)*	Worker [a] (Recyling task-length)	Inhalation 8-hour TWA	Central Tendency	295	316	1.2E−05	2,955 (APF 10)	3,163 (APF 10)	1.2E−06 (APF 10)
				High-End	52	56	9.1E−05	520 (APF 10)	557 (APF 10)	9.1E−06 (APF 10)
		ONU [c] (Recyling task-length)	Inhalation 8-hour TWA	Central Tendency	295	316	1.2E−05	–	–	–
				High-End	295	316	1.6E−05	–	–	–
		Worker [a] (Waste handling, treatment, and disposal [full shift])	Inhalation 8-hour TWA	Central Tendency	**22**	**23**	**1.7E−04**	218 (APF 10)	233 (APF 10)	1.7E−05 (APF 10)
				High-End	**3.9**	**4.1**	**1.2E−03**	39 (APF 10)	41 (APF 10)	4.9E−05 (APF 25)
		ONU [c] (Waste handling, treatment, and disposal [full shift])	Inhalation 8-hour TWA	Central Tendency	**22**	**23**	**1.7E−04**	–	–	–
				High-End	**22**	**23**	**2.2E−04**	–	–	–
		Worker [a] (Waste handling, treatment, and disposal [task-length])	Inhalation 8-hour TWA	Central Tendency	295	316	1.2E−05	2,955 (APF 10)	3,163 (APF 10)	1.2E−06 (APF 10)
				High-End	52	56	9.1E−05	520 (APF 10)	557 (APF 10)	9.1E−06 (APF 10)
		ONU [c] (Waste handling, treatment, and disposal [task-length])	Inhalation 8-hour TWA	Central Tendency	295	316	1.2E−05	–	–	–
				High-End	295	316	1.6E−05	–	–	–

Note: **bold** and gray-shaded text indicates that an MOE is below the MOE benchmark value of 30 or above a cancer risk of 1×10^{-4}.
APF = Assigned Protection Factor; MOE = margin of exposure; OES = occupational exposure scenario; PPE = personal protection equipment; SEG = similarly exposed group; TWA = time-weighted average

[a] According to Table 5-4, there is evidence that specific tasks associated with this job group always involve wearing of respirators for some facilities and COUs. However, a consistent level of respiratory protection cannot be assumed across a job group, and EPA does not have information to suggest that respirators are worn for the entirety of the work day for any job group/SEG.

[b] According to Table 5-4, there is evidence that specific tasks associated with this job group sometimes involve wearing of respirators. However, a consistent level of respiratory protection cannot be assumed across a job group, and EPA does not have information to suggest that respirators are worn for the entirety of the work day for any job group/SEG.

[c] Respirator use is not expected for occupational non-users (ONUs).

[d] There is insufficient information to determine respirator use for workers in this OES.

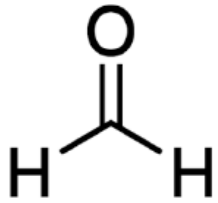
WHAT IS A TSCA “UNREASONABLE RISK”

United States
Environmental Protection Agency

EPA Document #EPA-740-R-24-015
December 2024
Office of Chemical Safety and
Pollution Prevention

Human Health Risk Assessment for Formaldehyde

CASRN 50-00-0



December 2024

"Risk estimates include inherent uncertainties and the overall confidence in specific risk estimates varies."

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

UNREASONABLE RISK

- Purposely not defined
- Various considerations for different chemicals
- Context driven
- But… is it basically exposures above the EPA ECEL?
  - Well…pretty much yes.

CONCLUSION: WHY TSCA IS CHALLENGING AND EXCITING