EPA Formaldehyde TSCA Risk Evaluation

AHFA Regulatory Summit

Date: August 20, 2025

Location: Colfax, NC

American Chemistry Council

Agenda

FORMALDEHYDE PANEL

ESSENTIAL CHEMICAL BUILDING BLOCK

EPA TSCA RISK EVALUATION

STAKEHOLDER ENGAGEMENT

About ACC Formaldehyde Panel

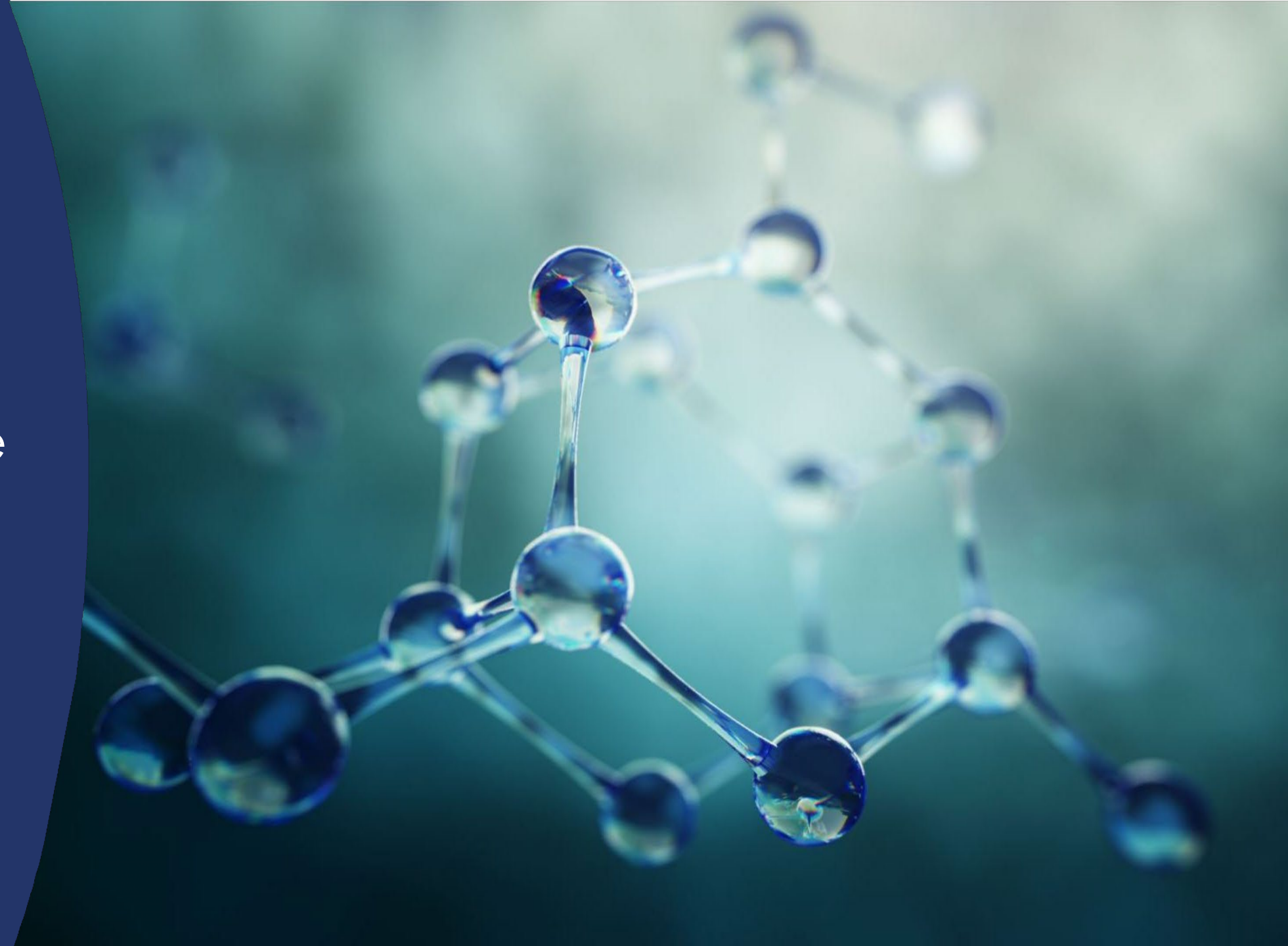
- The ACC Formaldehyde Panel **represents producers, suppliers, and users of formaldehyde and formaldehyde products**, as well as trade associations representing key formaldehyde applications.

- The Formaldehyde Panel's primary activities are **scientific research, regulatory and legislative advocacy, and outreach**.

- The Panel is also committed to **informing and educating** regulators, policymakers, the value chain, and the media on the weight of the scientific evidence surrounding formaldehyde exposure and safety.

- **Panel website**: www.americanchemistry.com/formaldehyde

Formaldehyde Applications



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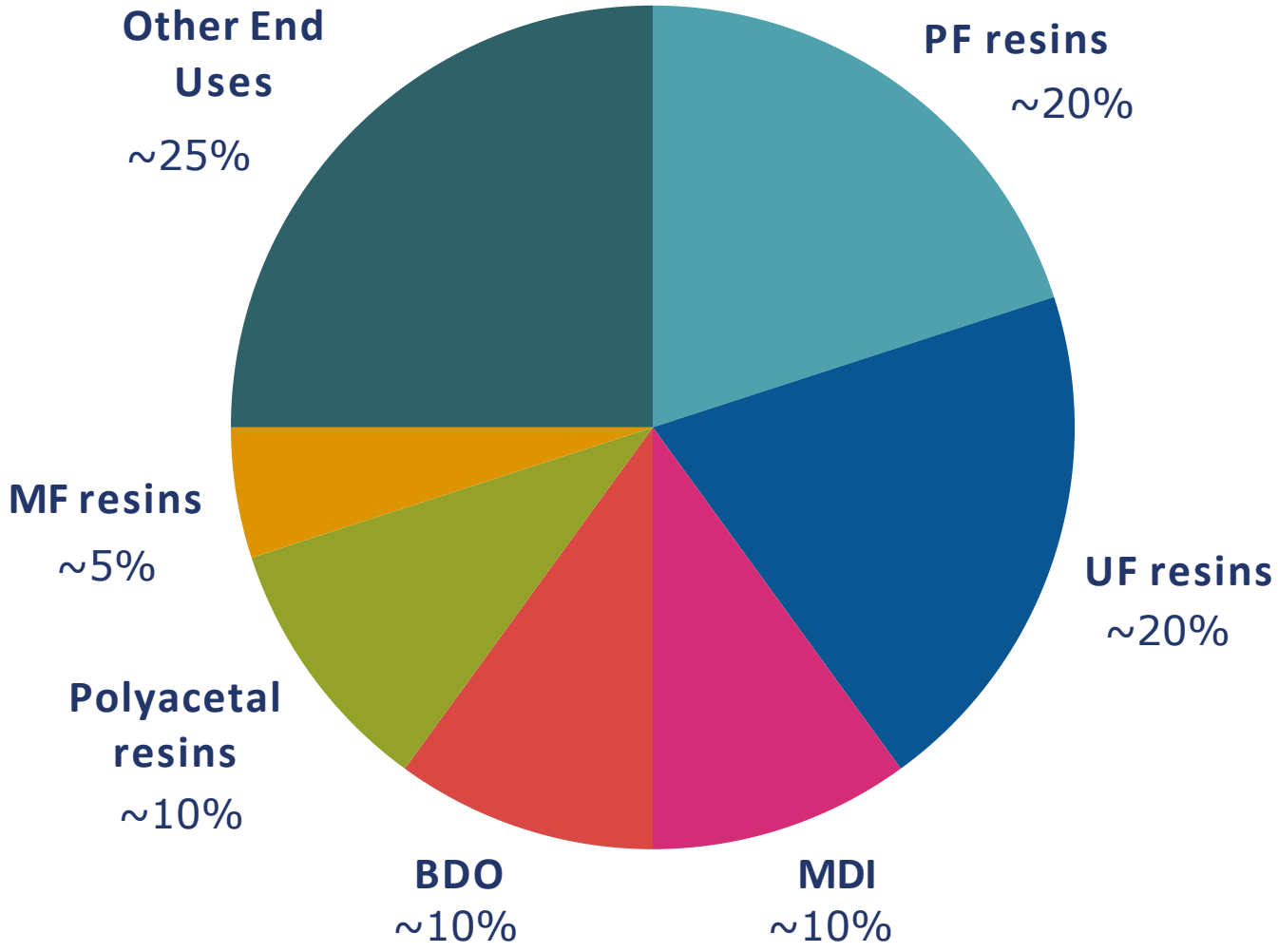
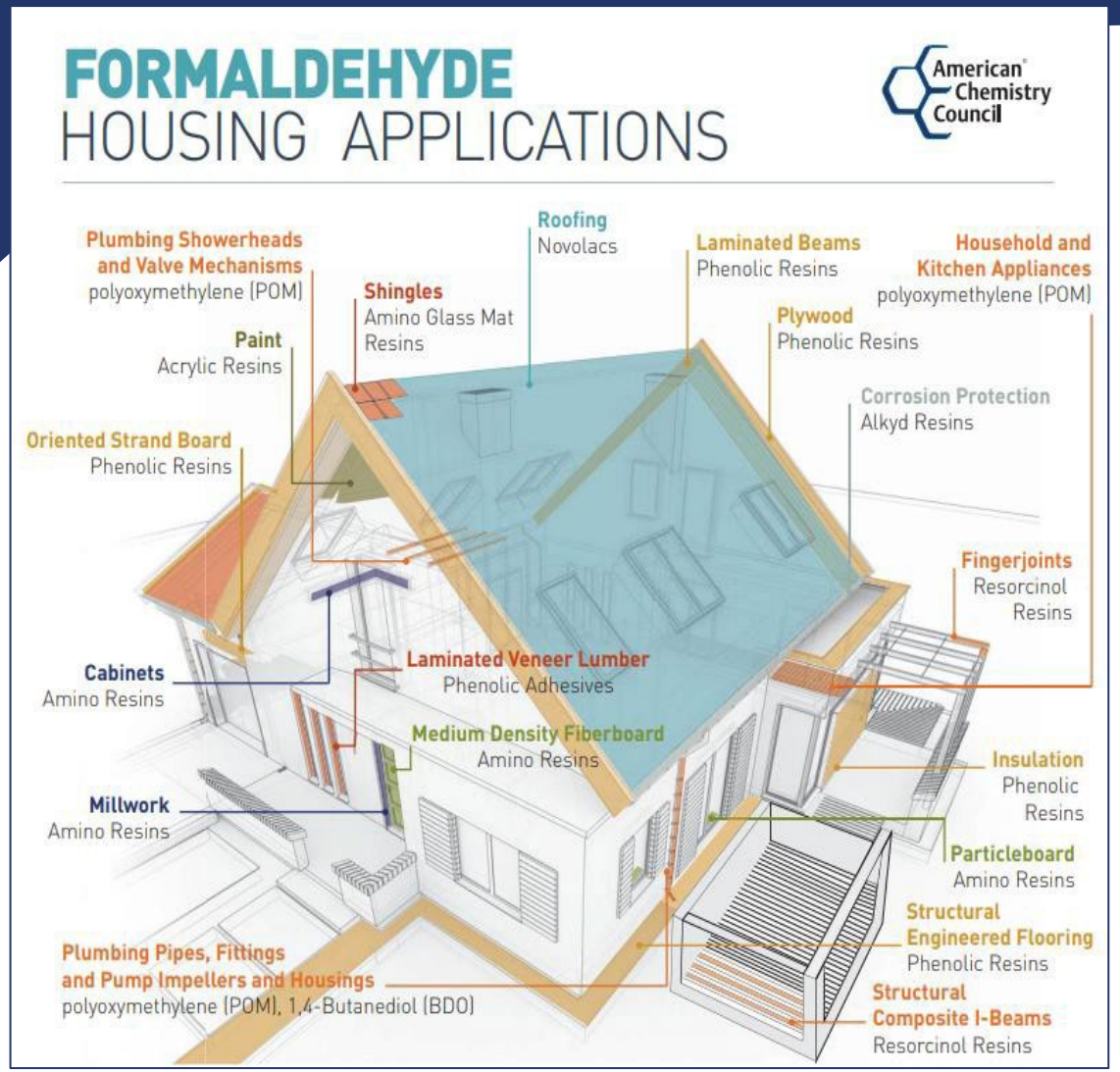
Consumption of Formaldehyde By End-Use



Source: ACC analysis based on data from Chemical Market Analytics by OPIS; data include ACC estimates.

Essential Chemical Building Block

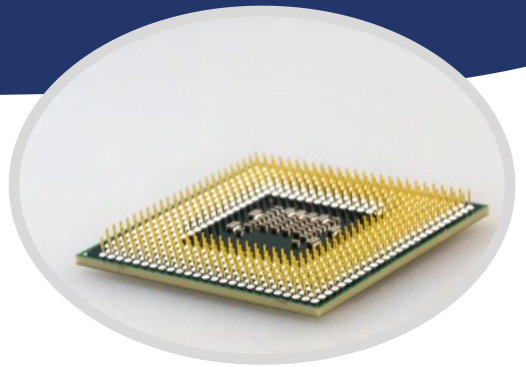


www.americanchemistry.com/formaldehyde

Essential Chemical Building Block

National Security

Aerospace



Semiconductors

Aquaculture

Building & Construction

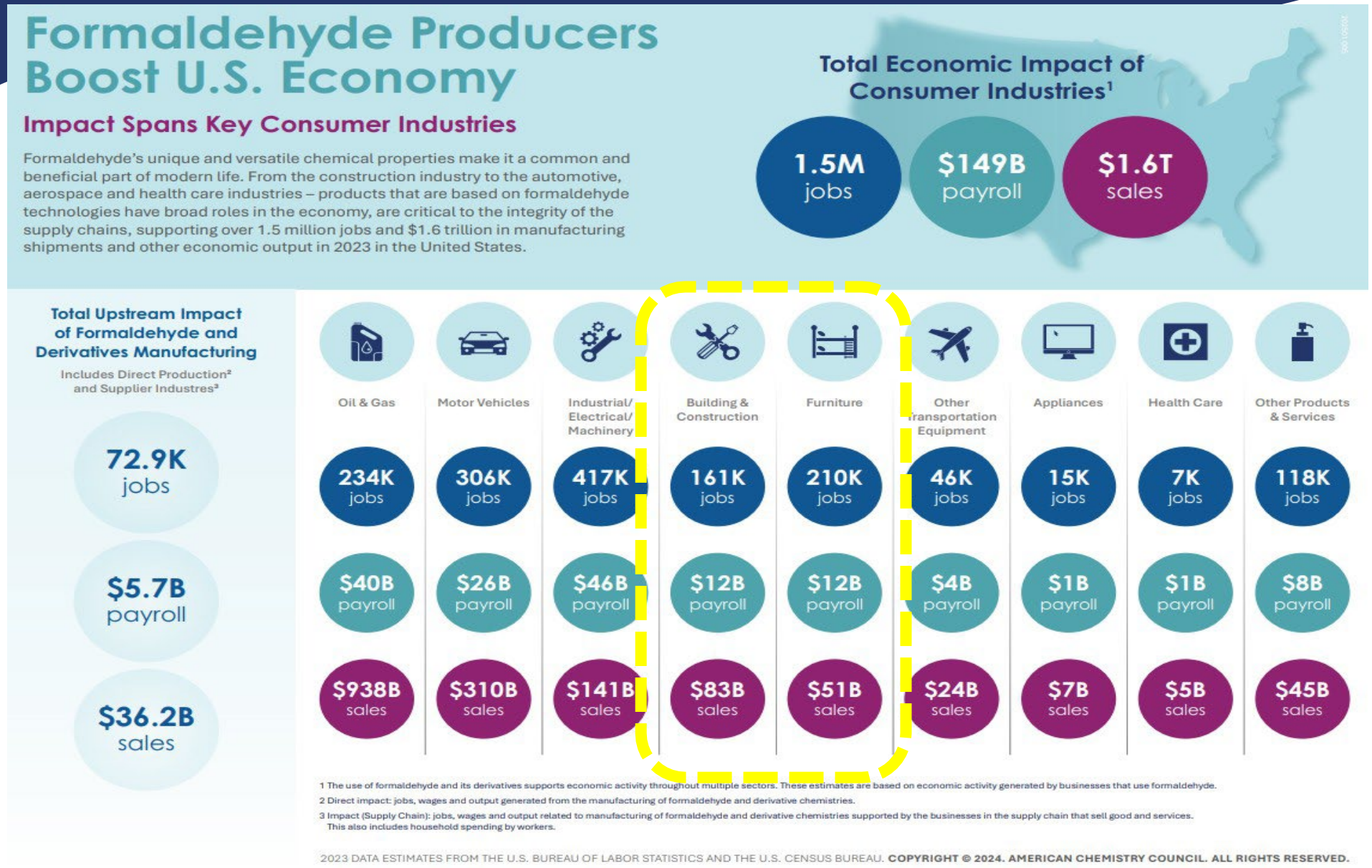
Automobiles

Healthcare Applications

Funeral Services

Agriculture

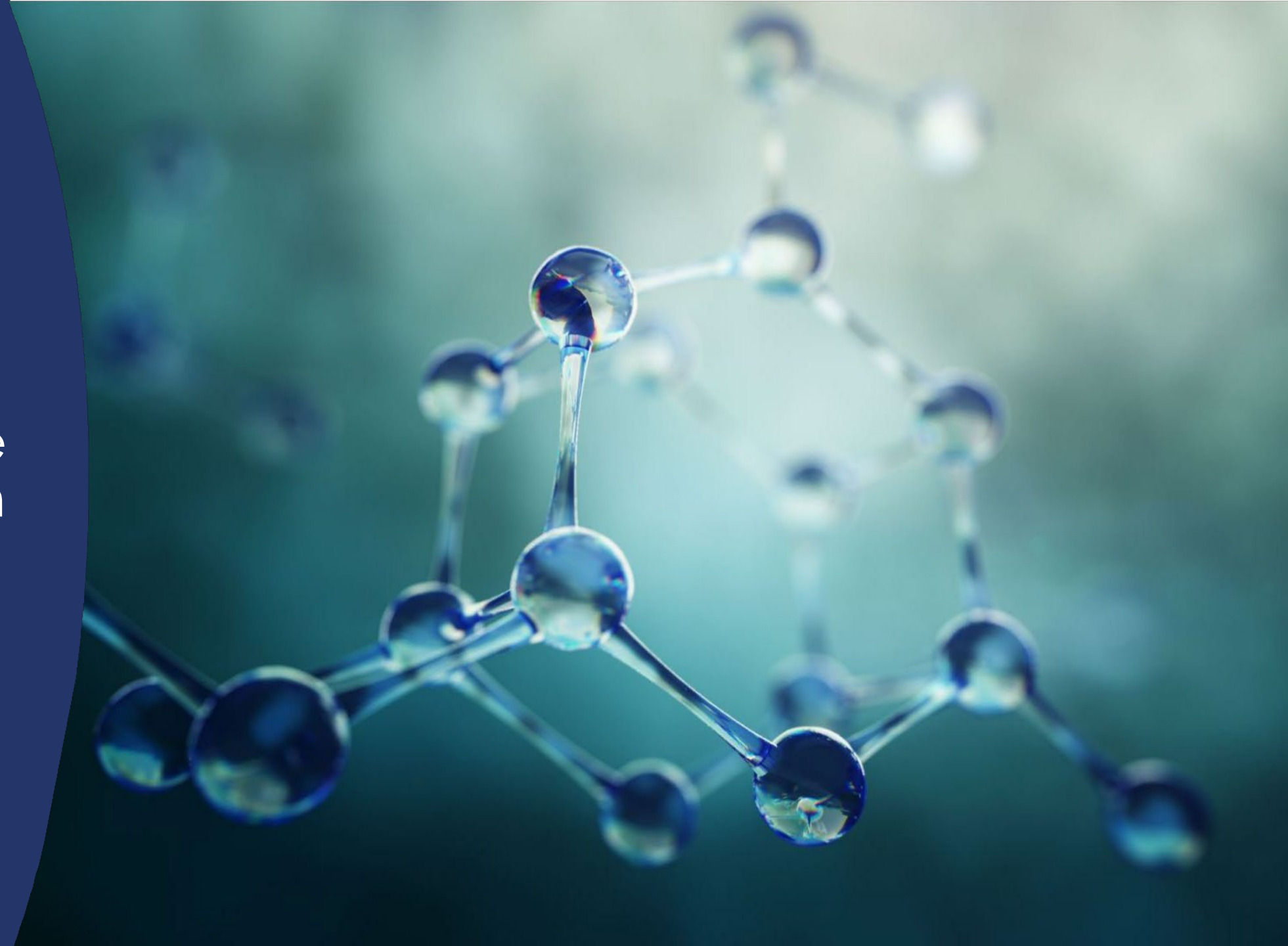
Formaldehyde Products Support the Economy



Best Available Science

- **No causal association between inhaled formaldehyde and myeloid leukemia** is supported by current evidence or biological plausibility
- Formaldehyde exhibits a **threshold dose-response mode of action**, below which no adverse effects, including cancer are expected
- **Sensory irritation is the most sensitive endpoint** that is protective of all effects (acute, chronic, non-cancer, chronic cancer)
- **Controlled chamber studies have a preferred study design and greater scientific rigor** than observational epidemiological studies
- **Uncertainty factors are not necessary** when using sensory irritation as the point of departure, as it reflects a conservative lower boundary for adversity
- **Duration adjustments are not necessary** because formaldehyde does not follow Haber's Law, meaning concentration, not duration, is the driver of whether effects will be seen

Formaldehyde Risk Evaluation



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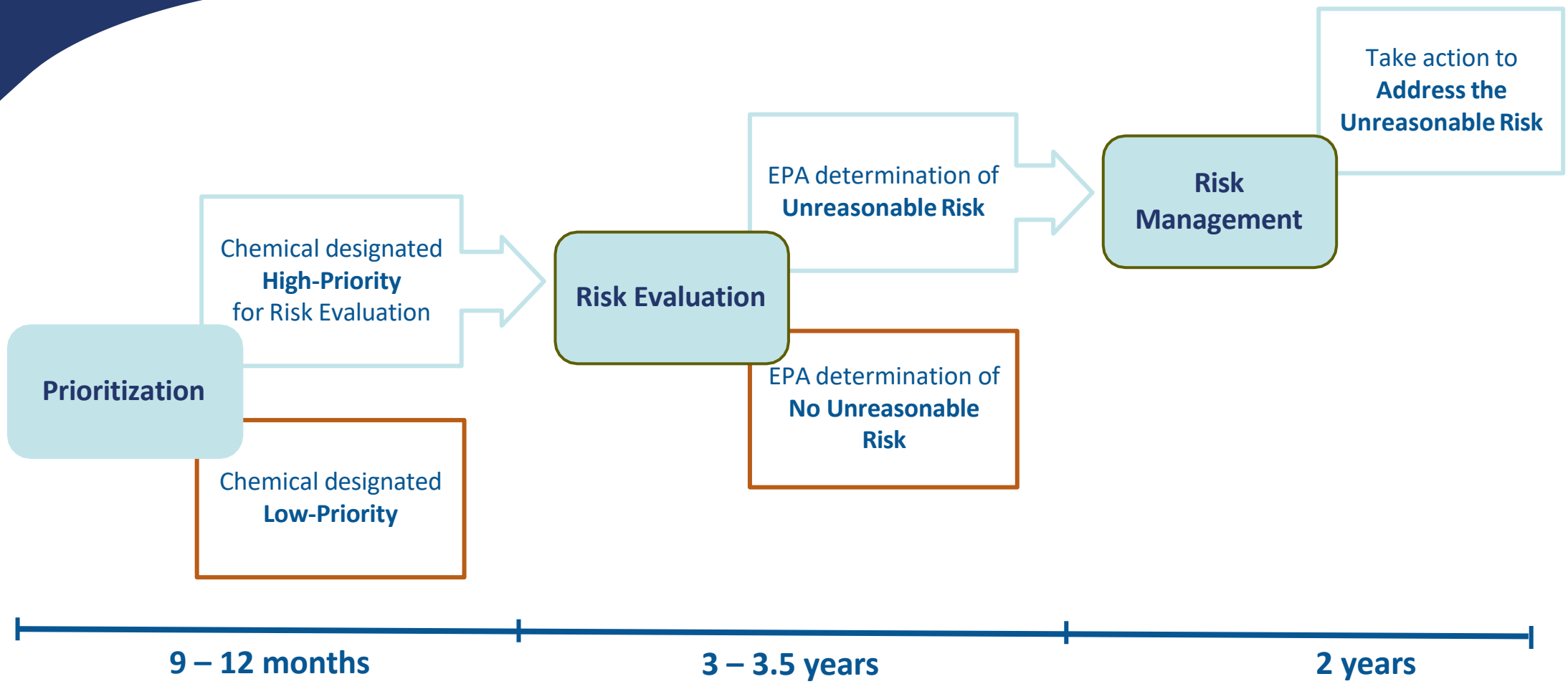
EPA TSCA Risk Evaluation Process



EPA Formaldehyde TSCA Risk Evaluation
Key Dates (2024 and Beyond)

Mar 2024
Draft Risk Evaluation

May 2024
60-Day Comment Deadline

May 2024
SACC Peer Review

Aug 2024
SACC Final Report

Aug 2024
Final IRIS Assessment

Jan 2025
Final Risk Evaluation

Sept 2025
Small Business Advocacy Review Panel
***Aug 22nd Nominations Deadline**

2026
Proposed Risk Management Rule

2027
Final Risk Management Rule

2027-2032
Mandatory Compliance Dates for Identified Restrictions
***within 5 years**

Note: EPA revisions to Procedures for Chemical Risk Evaluations Under TSCA expected soon for public comment.

Why is The IRIS Assessment Important

- The **IRIS assessment** is being used by other EPA regulatory programs as a **baseline for future regulation** on formaldehyde
- IRIS has **never been authorized** by Congress, and its current approach is **at odds with** Congressional requirements for the Agency to use the best available science under TSCA and other laws.
- Despite wide criticisms by the scientific community for its deficiencies and inadequate standards for scientific rigor and impartiality, **EPA is deferring to the IRIS assessment for formaldehyde for the TSCA Risk Evaluation**.
- EPA, states, other agencies may use these conclusions to justify permitting, enforcement, monitoring and regulatory changes for other activities; unreasonable risk determinations may also drive product or facility litigation.

2024 Final IRIS Assessment

Formaldehyde	1990/1991 IRIS	2024 Final IRIS
Non-Cancer Reference Concentration (RfC)*	No RfC	Based on respiratory-related effects **0.007 mg/m^3 = 6 ppb**
Cancer Inhalation Unit Risk (IUR)**	Based only on NPC "Probable human carcinogen, based on limited evidence in humans, and sufficient evidence in animals" IUR = 1.3 x 10^{-2} per mg/m^3	Based only on NPC "Carcinogenic to humans" (strongest conclusion available in EPA guidelines) **IUR =1.1 x 10^{-2} per mg/m^3**

* RfC = level of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

** IUR = the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/m^3 in air.

Formaldehyde Risk Evaluation
Unreasonable Risk Determination

- EPA determined that formaldehyde **presents an unreasonable risk of injury to human health** under the conditions of use.
- EPA **did not identify risk of injury to the environment** via water, land, or dietary pathways that would contribute to the unreasonable risk determination for formaldehyde.
- **General population exposures do not significantly contribute** to the unreasonable risk.
- Unreasonable risk determination:
  - Driven by **inhalation and dermal exposure routes in workers and consumers**
  - Made assuming the **use of no PPE**
- EPA **reconsidering TSCA framework rule**: single vs. whole chemical approach, consideration of PPE, regulatory definitions, etc.

Lifecycle Diagram of Formaldehyde

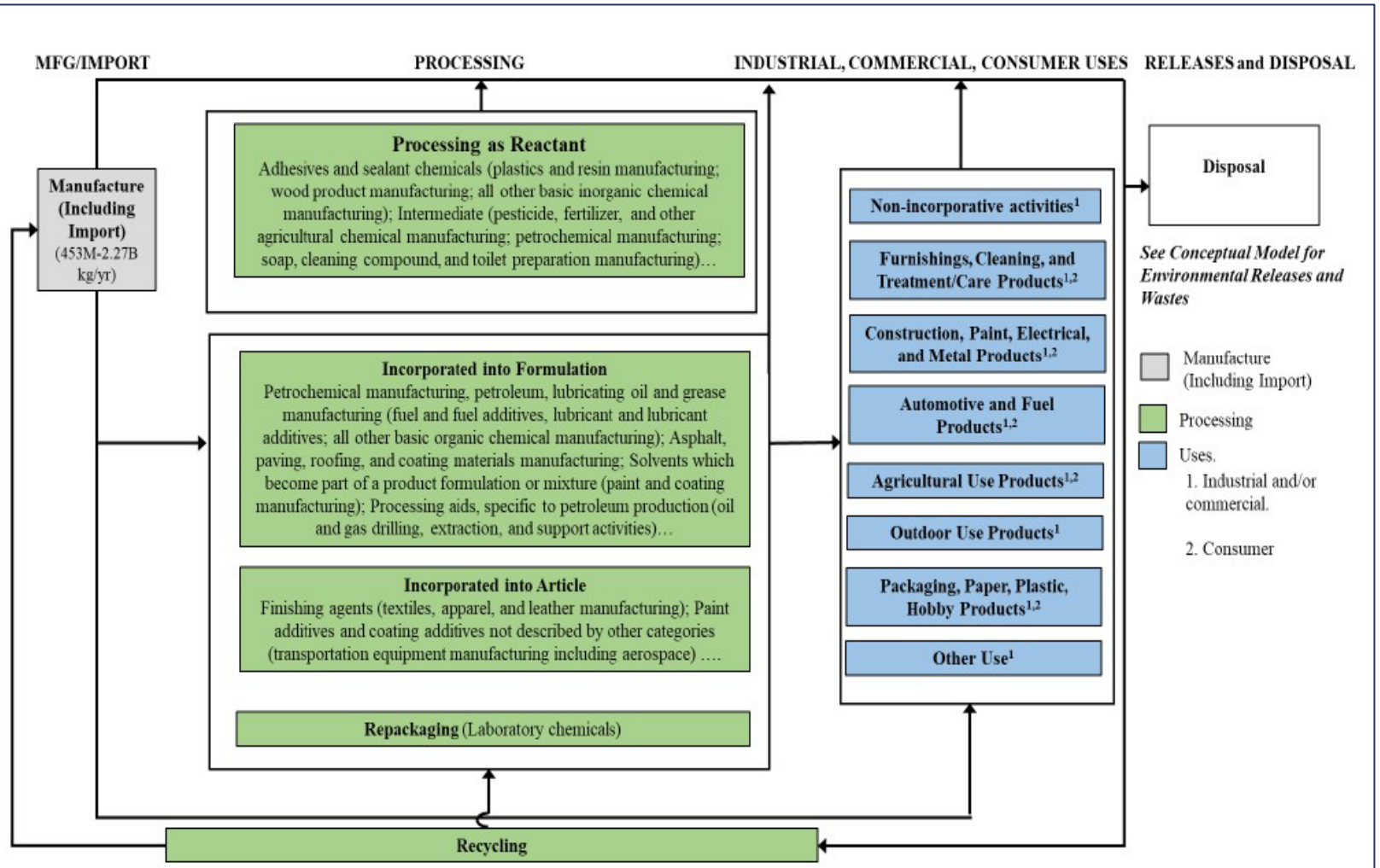


Figure 1-2. Lifecycle Diagram of Formaldehyde

Conditions of Use (COUs)

- **58 out of 63 TSCA COUs** significantly contribute to the unreasonable risk
- **5 COUs** do not contribute to the unreasonable risk.
- **Examples of COUs considered:**
  - Manufacturing of formaldehyde (domestic and import)
  - Processing- Reactant: wood product manufacturing; bleaching agent in wood product manufacturing
  - Processing - Reactant: Intermediate in paper manufacturing; wood product manufacturing; construction
  - Processing – Incorporation into an Article: adhesives and sealant chemicals in wood product manufacturing; paper manufacturing
  - Regulated composite wood products under TSCA Title VI include included in 4 COUs:
    - Commercial and Consumer Use In : construction and building materials covering large surface areas, including wood articles
    - Commercial and Consumer Use In: Floor coverings; furniture and furnishings

See: Risk Evaluation for Formaldehyde: Conditions of Use (pdf)

TSCA Title VI Considerations

- EPA **evolving position** on including composite wood products regulated under TSCA Title VI in the scope of the risk evaluation
- 2020 Final Scope excluded TSCA Title VI products
- 2024 Risk Evaluation included TSCA Title VI products
- EPA determined that excluding TSCA Title VI regulated composite wood products from the Risk Evaluation would reduce the comprehensiveness of the evaluation
- **The Agency has determined that composite wood products regulated under Title VI do not significantly contribute to the unreasonable risk of formaldehyde due to acute inhalation effects for consumers.**

Uses Excluded from Evaluation

- **Not all sources are evaluated**, for instance because they occur naturally or because they are excluded from the TSCA "chemical substance" definition.
    - Biogenic sources (like trees and wood chips); forest fires; embalming fluids and products used to preserve animal specimens; other pesticides as defined in FIFRA; drugs for fisheries and hatcheries; animal feed; pacifiers and baby bottles; plastic products used for food storage and distribution; other formaldehyde uses that meet the definition of "food, food additive, drug, cosmetic, or device" as defined in the FFDCA, tail-pipe emissions from cars, trucks, and other vehicles; and secondary formation.
- **Biogenic sources and secondary formation can produce substantial amounts of formaldehyde** resulting in exposures in the occupational, indoor, and outdoor environments.

General Population – Ambient Air

- **Gen population exposures from ambient air emissions do not significantly contribute to the unreasonable risk.**
- The highest risk is above the 1×10^{-6} cancer benchmark for some communities - particularly those near releasing facilities and especially some facilities with releases attributed to combustion.
- Based on modeling estimates, individuals of the general population living within half mile of a releasing facility may be exposed to formaldehyde at high concentrations.
- The **highest reported emitters of formaldehyde** are affiliated with the following NAICS : Oil and Gas Drilling, Extraction, and Support Activities; **Wood Product Manufacturing**; and Wholesale and Retail Trade – Airport Operations.
- The highest estimated concentration from TSCA sources not related to combustion is from the **wood product manufacturing industry**.

General Population – Indoor Air

- EPA **did not identify risk from the general population long-term inhalation exposure to indoor air from wood articles** that would contribute to the unreasonable risk of formaldehyde.
- This **includes wood articles and composite wood products that are regulated pursuant to TSCA Title VI.**
- The highest formaldehyde concentrations from TSCA sources in indoor environments are expected in **newly constructed homes and mobile homes**.
    - **Concentrations from new formaldehyde-containing articles substantially diminish** within the first few months and years of the article life. Peak exposures to formaldehyde from these articles are expected to occur within 1 year of manufacture or use.

Occupational Exposure Values

Occupational Exposure Value	Parts per billion (ppb)
EPA Acute OEV 15-minute STEL	167
EPA Chronic OEV 8-hour TWA	108
Comparison of EPA Chronic OEV to OSHA and EU	
OSHA PEL 8-hour TWA	750 **7 times lower**
EU OEL 8-hour TWA	300 **3 times lower**

Note: EPA indicates that the OEVs are solely risk-based values and **do not constitute proposed or final regulatory limits** and that non-risk factors will be considered in RM.

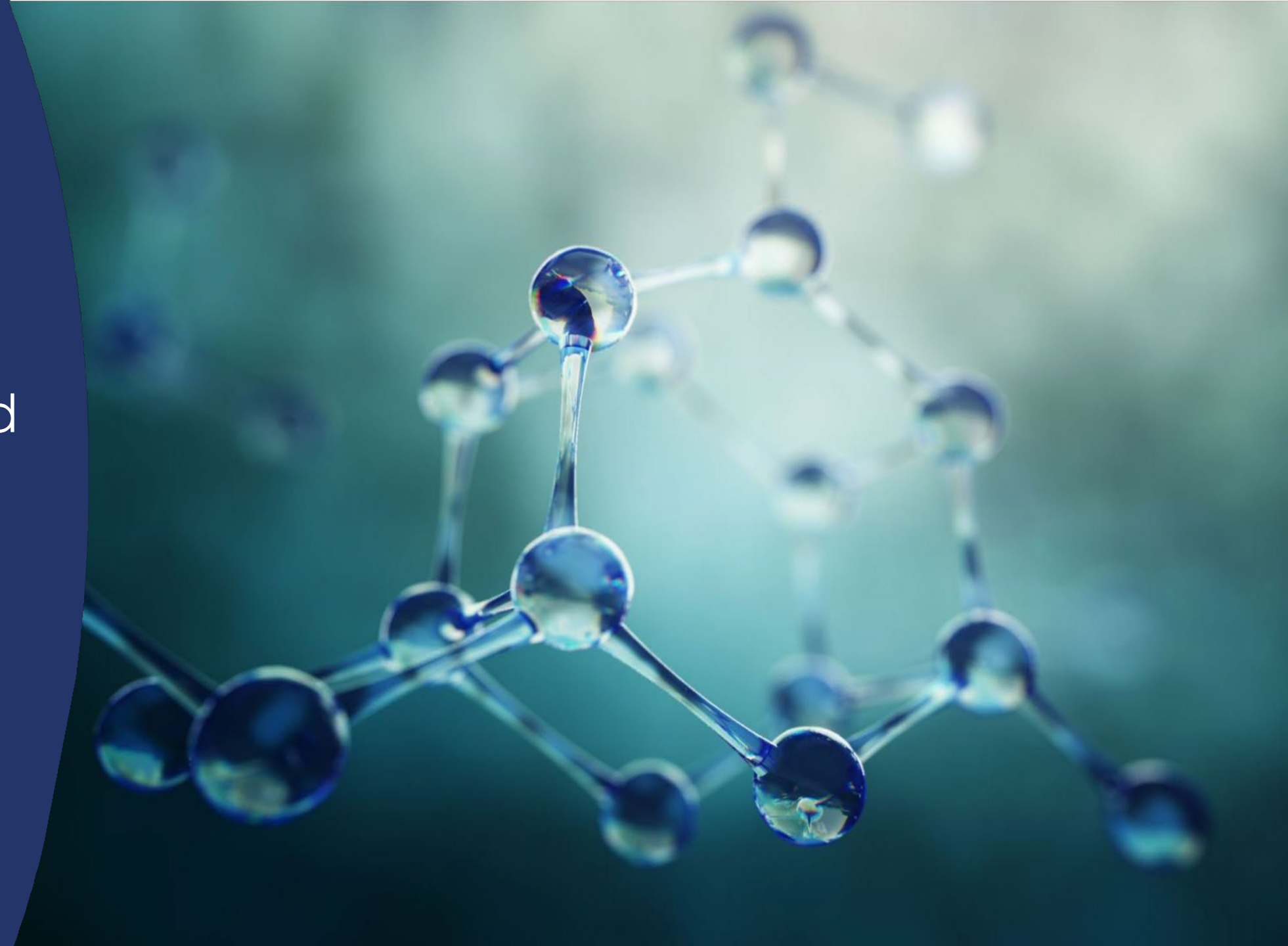
Occupational Exposure Values Comparison

Country	ppb (TWA)
United Kingdom	2000
Australia	1000
South Africa Mining	1000
USA – OSHA	750
Austria	300
Denmark	
European Union	
Finland	
France	
Germany (AGS)	
Germany (DFG)	
Ireland	
Italy	
Latvia	
New Zealand	
Norway	
Romania	
South Korea	
Spain	
Sweden	
Switzerland	
USA EPA OEV	108 ppb

Best Available Science vs. TSCA RE

Best Available Science for Formaldehyde	**What EPA Did in Final TSCA Risk Evaluation**
Sensory irritation is the most sensitive endpoint that is protective of all other effects.	✅EPA relied on sensory irritation for acute effects. ❌EPA relied on IRIS for chronic effects: respiratory effects for non-cancer and NPC for cancer.
Controlled chamber studies are the gold standard as opposed to observational epidemiology studies.	EPA relied on controlled chamber studies for acute effects. EPA relied on observational epi studies for chronic effects.
A causal association between inhaled formaldehyde and myeloid leukemia is not biologically plausible.	Did not quantify leukemia risk; used only NPC IUR. Noted that this may result in a 4-fold underestimate of risk.
EPA should adopt a threshold dose-response MOA for cancer risk.	✅ Some SACC panelists supported a threshold assumption. ❌ EPA applied a non-threshold, linear cancer risk model based on IRIS.
Formaldehyde does not follow Haber's Law meaning concentration is the driver not duration.	✅ No duration adjustment applied for acute OEV. ❌Uncertainty factor (reduced to 3) applied for acute OEV. ❌ Uncertainty factor and duration adjustment applied for chronic OEV based on IRIS. ❌EPA treats acute and chronic effects separately.

Next Steps and Stakeholder Engagement



Key Dates for 2025 and Beyond

Dec 2024: EPA determined that formaldehyde presents an unreasonable risk to human health.

~ Sept 2025

EPA Small Business Advocacy Review Panel

Aug 22nd Nomination Deadline

≈ Early 2026

Projected Risk Mgmnt Rule Proposal

~ Dec 2027

Projected Final Risk Mgmt Rule

2027 – 2032*

Mandatory Compliance Dates for Identified Restrictions

*within 5 years

EPA Revisions to Procedures for Chemical Risk Evaluations Under TSCA expected for public comment soon.

Risk Management Options

There are several actions EPA can take to address unreasonable risks. Some examples of these actions, alone or in combination, may include:

- Bans, restrictions or limitations on the manufacture, processing or distribution in commerce
- Bans, restrictions or limitations for particular uses above a certain concentration
- Requirement for labels, warnings, instructions
- Requirements for recordkeeping, monitoring or testing
- Prohibitions or restrictions on commercial use or disposal
- Requirement for manufacturers/processors to communicate the unreasonable risk determination to downstream users and the public.

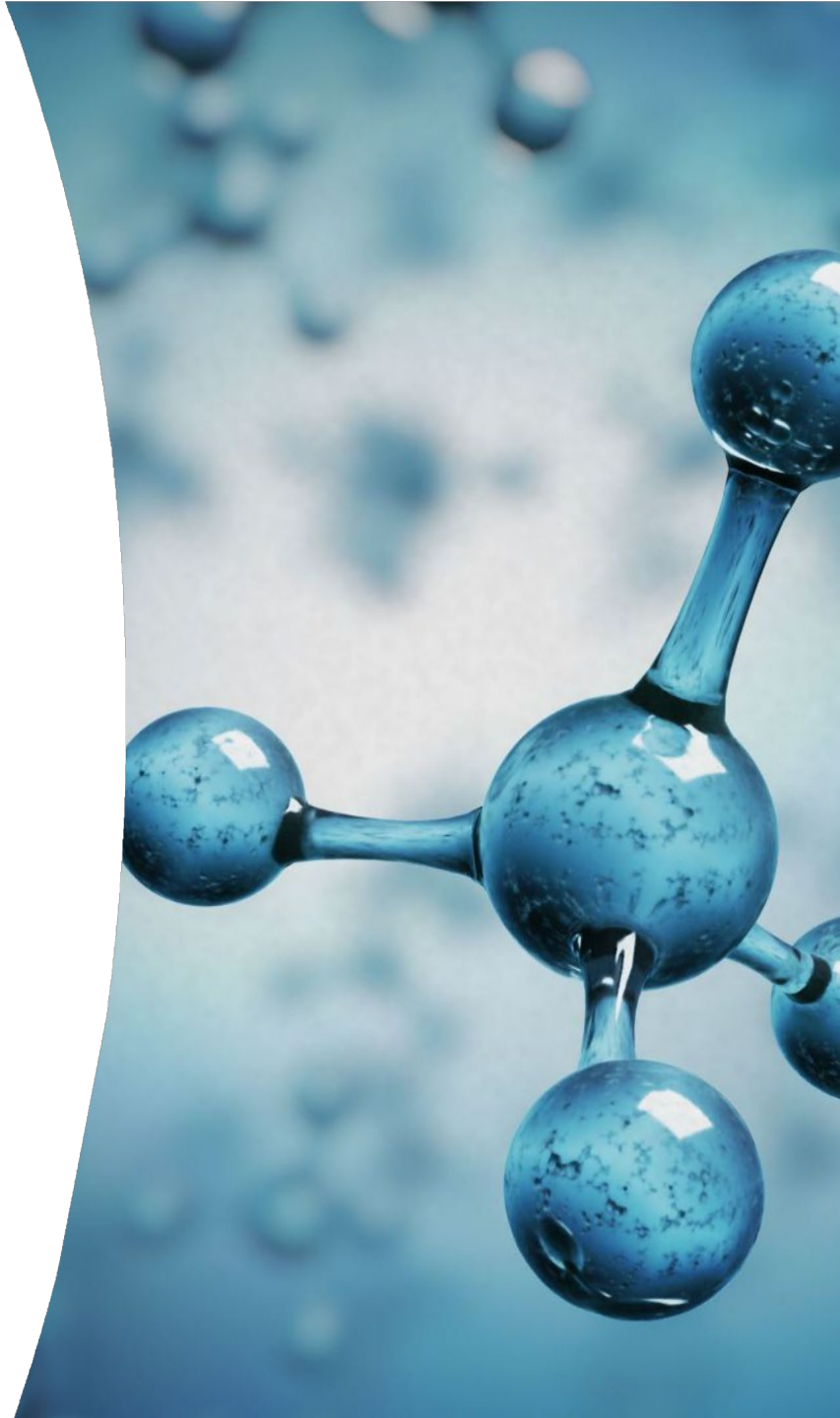
Potential Impacts and Current Status

Potential Impacts

- Supply chain disruptions if manufacturing is severely restricted
- Limited or no alternatives for most applications
- Critical use exemptions are time-limited
- Unachievable workplace limits and standards

Current Status

- **Ask for EPA**: Fix the scientific deficiencies and finalize a Risk Management Rulemaking that is consistent with the best available science and Congressional intent within the statutory timelines
- **Next Step**: EPA to convene a Small Business Advocacy (SBAR) Panel to solicit input from small businesses on the risk management options being considered by EPA, **Aug 22nd nominations deadline**.



What Steps Can You Take

- **Monitor** key policy developments: executive orders, policy decisions and legal rulings
- **Participate** in the regulatory process:
  - Actively participate in public comments
  - Submit relevant exposure data and IH practices to EPA
  - Promote science-based regulation
- **Communicate and collaborate** regularly
  - Activate and engage your customers and suppliers
- **Engage** your congressional contacts to support legislative efforts
- **ACC Formaldehyde Panel is a resource** for additional information; membership opportunities across the value chain

American Chemistry Council | Formaldehyde Panel

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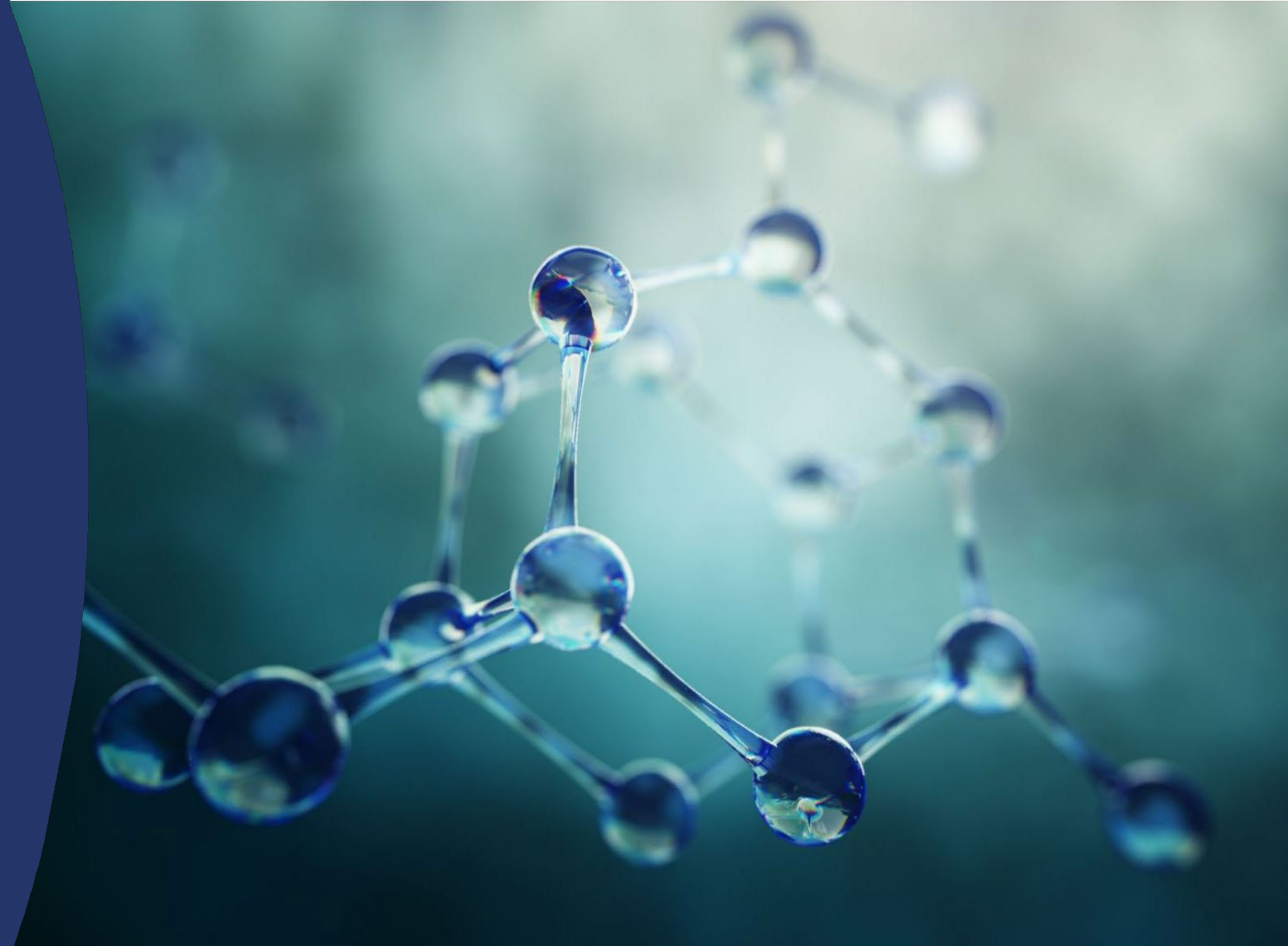
Backup Slides



Risk Evaluation Document Summary Map

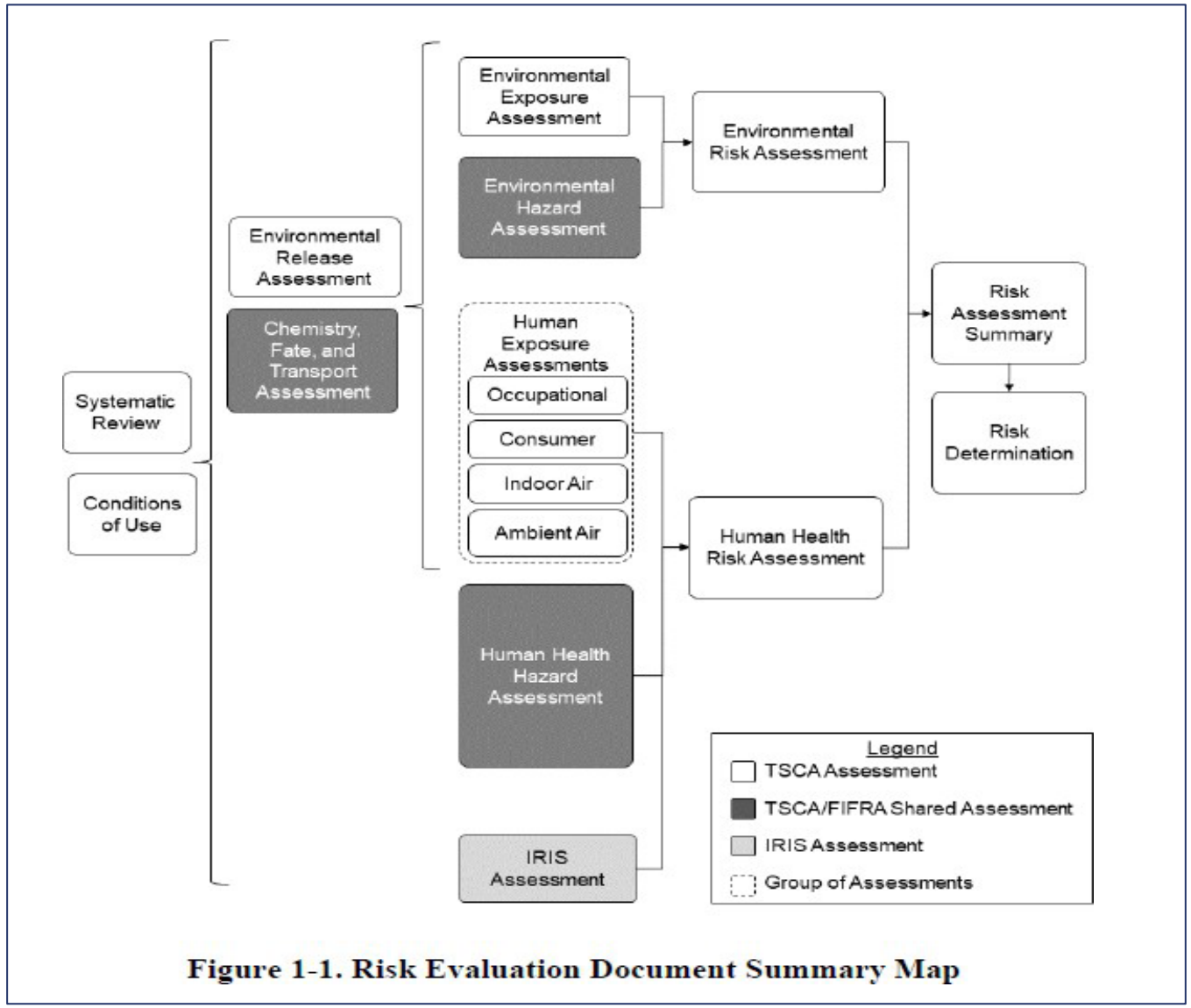


Figure 1-1. Risk Evaluation Document Summary Map

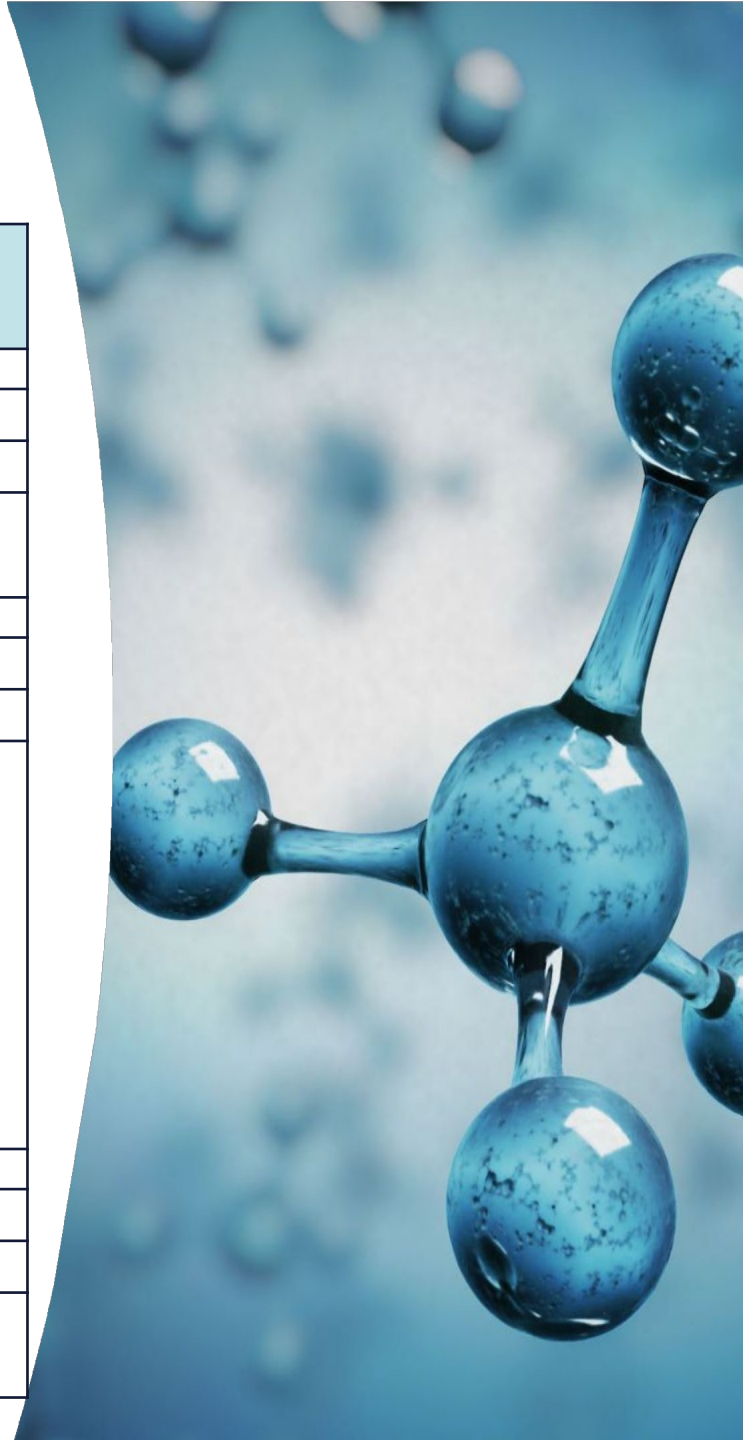
Formaldehyde Risk Evaluation and Supporting Documents

View the supporting documents in Docket EPA-HQ-OPPT-2023-0613.

- Risk Evaluation for Formaldehyde: Environmental Risk Assessment (pdf) (721.95 KB)
- Risk Evaluation for Formaldehyde: Chemistry, Fate, and Transport Assessment (pdf) (797.26 KB)
- Risk Evaluation for Formaldehyde: Environmental Release Assessment (pdf) (1.77 MB)
- Risk Evaluation for Formaldehyde: Environmental Exposure Assessment (pdf) (570.47 KB)
- Risk Evaluation for Formaldehyde: Environmental Hazard Assessment (pdf) (907.38 KB)
- Risk Evaluation for Formaldehyde: Executive Summary (pdf) (235.2 KB)
- Risk Evaluation for Formaldehyde: Human Health Hazard Assessment (pdf) (1.12 MB)
- Risk Evaluation for Formaldehyde: Conditions of Use (pdf) (1.15 MB)
- Risk Evaluation for Formaldehyde: Human Health Risk Assessment (pdf) (5.21 MB)
- Risk Evaluation for Formaldehyde: Occupational Exposure Assessment (pdf) (4.98 MB)
- Risk Evaluation for Formaldehyde: Consumer Exposure Assessment (pdf) (979.37 KB)
- Risk Evaluation for Formaldehyde: Indoor Air Exposure Assessment (pdf) (2.12 MB)
- Risk Evaluation for Formaldehyde: Ambient Air Exposure Assessment (pdf) (3.62 MB)
- Risk Evaluation for Formaldehyde: Unreasonable Risk Determination (pdf) (501.54 KB)
- Risk Evaluation for Formaldehyde: Nontechnical Summary (pdf) (156.13 KB)
- Risk Evaluation for Formaldehyde: Response to Comments (pdf) (1.55 MB)

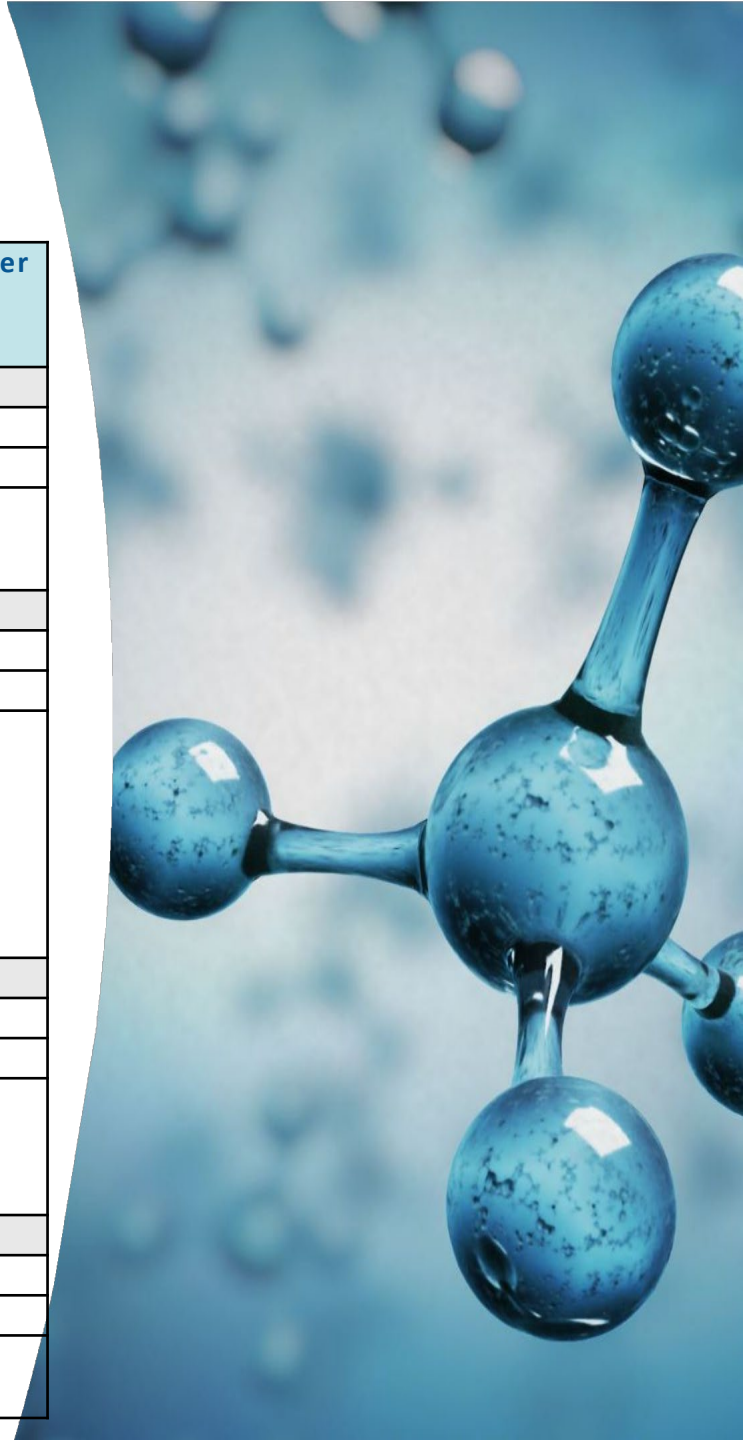
Basis for Unreasonable Risk Determination for Human Health (Occupational COU)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-Cancer	Cancer
Processing	Processing - Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; Basic organic chemical manufacturing	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	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	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Processing-Reactant	Bleaching agent in wood product manufacturing	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		



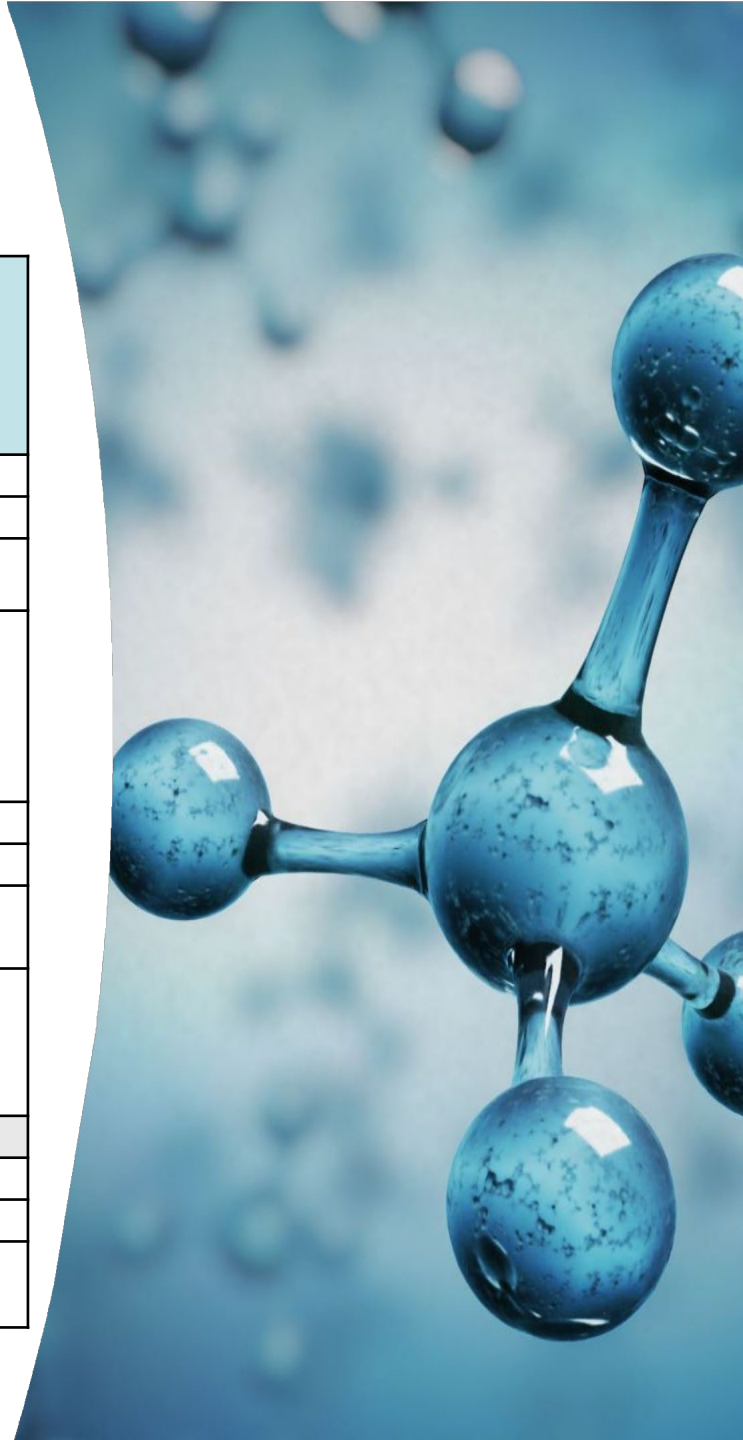
Basis for Unreasonable Risk Determination for Human Health (Occupational COU)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-Cancer	Cancer
Processing	Processing-Incorporation into an article	Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation	x	x
			General Population	Inhalation – Ambient Air		
Commercial Use	Furnishing treatment/care products TITLE VI COU➔	Floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/ surface treatment products.	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Furnishing treatment/care products TITLE VI COU➔	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	Worker	Dermal	x	
				Inhalation	x	x
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Packaging, paper, plastic, hobby products	Paper products; plastic and rubber products; toys, playground, and sporting equipment	Worker	Dermal		
				Inhalation		
			ONU	Inhalation		
			General Population	Inhalation-Ambient Air		



Basis for Unreasonable Risk Determination for Human Health (Consumer COU)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Human Health Effects: Acute Non-cancer
Consumer Use	Furnishings treatment/care products TITLE VI COU➔	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	Consumer	Dermal	x
				Inhalation	x
			Bystander	Inhalation	x
			General Population	Inhalation – Indoor Air	
	Construction, paint, electrical, and metal products TITLE VI COU➔	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	Consumer	Dermal	x
				Inhalation	x
			Bystander	Inhalation	x
			General Population	Inhalation – Indoor Air	
	Packaging, paper, plastic, hobby products	Paper products; plastic and rubber products; toys, playground, and sporting equipment	Consumer	Dermal	
				Inhalation	x
			Bystander	Inhalation	x
			General Population	Inhalation – Indoor Air	



Human Health Risk

- EPA expects **inhalation** to be a **major route of exposure** for occupational, consumer, indoor air, and ambient air.
- EPA expects the **dermal route** to be **another significant route** of exposure to formaldehyde or occupational and consumer COUs where dermal contact to formaldehyde may occur.
- **Oral** is **not a likely pathway** of exposure.
- EPA **relying on** conclusions in the final **IRIS Assessment** for chronic exposures, and the HSRB for acute exposures.

Workers at Most Risk

- Workers who are in workplaces where formaldehyde is made or is used are at the most risk from formaldehyde exposure.
- EPA is basing its unreasonable risk determination for workers on:
  - (1) acute, non-cancer effects (sensory irritation) due to peak inhalation exposures;
  - (2) non-cancer effects (skin sensitization) due to dermal contact; and
  - (3) cancer risk due to long-term inhalation.
- Inhalation exposure for most OESs were estimated based on actual monitoring data; EPA used ACC IH monitoring data
- Dermal exposure data was not available for any of the COUs so EPA used modeling.

Consumers Next-Highest Risk

- People who frequently use certain consumer products that contain formaldehyde are the next-highest risk.
- EPA is considering sensory irritation and skin sensitization to evaluate risks to consumers.
- Focus is on use of products like automotive-care products like car waxes; crafting supplies such as some glues and sealants; and fabrics, textiles, and leather goods treated with formaldehyde.
    - Highest acute inhalation exposure estimates are for adhesives and sealants as well as for paint and coatings.
    - Highest concentrations of formaldehyde due to acute dermal exposures were estimated for exterior car waxes and polishes followed by photographic processing solutions.
- **Products regulated under Title VI do not significantly contribute to the unreasonable risk due to acute inhalation effects to consumers**.

Consumers Next-Highest Risk

- EPA focused its risk determination on consumer uses that pose **acute inhalation and dermal risks**.
- **EPA does not expect most consumer exposures to be chronic in nature** since these products generally tend to be infrequently used and have relatively short durations of use.
- In the Draft RE, EPA assumed consumer uses of products containing formaldehyde were chronic and continuous (i.e., 24 hours per day, 7 days per week), but for the **Final RE, the Agency assumes that uses are less frequent** for consumer products and focuses on peak exposures.
- EPA also presents the 1-year average estimated consumer formaldehyde concentrations.

Dermal - Consumers

- The highest exposures were for users of **car wax and polish products** while the lowest was for users of crafting paints likely for an art project such as finger painting.
- For Thin Film Exposure modeling, EPA assumed the consumers' hand(s), finger(s) or other skin layer may be covered with a viscous layer of the liquid product during use and may linger until washed away.
- EPA has medium confidence in the dermal exposure estimates because the estimates were derived using a standard peer-review model based on measured data on the retention of liquids on the skin surface. The Agency does not have higher confidence in the reported values because **EPA did not have monitored formaldehyde dermal exposure data to ground truth these exposure estimates.**

Dermal - Workers

- The highest dermal exposure estimates were for use of formulations containing formaldehyde for manual spray applications and use of formulations containing formaldehyde in automotive care products.
- All COUs expect one – additive in rubber product manufacturing - could lead to sensitization with repeated exposure from dermal exposure.
- Dermal exposure data were not reasonably available for any of the COUs considered. As a result, dermal exposures were modeled using Modified EPA/OPT 1- and 2-Hand Dermal Exposure Models.
- **Dermal exposure to solid articles are not quantified, as the chemical will be entrained in the article and concentrations of formaldehyde in articles are low such that exposure will be limited**.

Occupational Exposure Values

- **Acute OEV of 167 ppb (209 µg/m3)**
  - Based on sensory irritation in Kulle et al. 1987 chamber study
  - The UF for sensory irritation revised from 10 to 3. The UF of 3 used to account for human variability. No duration adjustment.
  - The acute OEV serves as the STEL to protect against 15-minute exposures.
- **Chronic OEV of 108 ppb (133µg/m3)**
  - Based on the IRIS developed IUR from the Beane-Freeman et al. 2013 epi study used to assess lifetime cancer risk for NPC.
  - The chronic OEV serves as an 8-hour TWA.

Note: EPA indicates these are solely risk-based values and **do not constitute proposed or final regulatory limits** and that non-risk factors will be considered in RM.