#### NSC Technical Subcommittee Call Minutes – June 18, 2024

#### Participation [by region]:

- 1: Sara Johnson NH
- 2: Timothy Kirchgraber NY; Ed Bakos & Maxwell Graham NJ
- 3: Luke Hershey, Jeremy Hancher & Lee Ann Briggs PA
- 4: Ryan Ariail **SC**; Tony Pendola **NC**; Crystal Warren & Donovan Grimwood **TN** and La Trina Williams **MS**
- 5: Deb Jacobson IL; Kaitlyn Devries MI; Emilio Machado, Jennifer Feyerherm & Lisa Ashenbrenner-Hunt WI; Emily Ohde & Jennifer Theordore MN and Leigh Ann Harvey, Hani Sharaya, Chrystal Wagner & Mark Stoddard IN
- 6: Natalie Cota OK
- 7: Anni Poetzl **NE**; Jennifer Wittenburg & Christine Paulson **IA**; Rajavel Krishnamoorthy, Cris Brazil & Nancy Larson **KS**
- 8: Michael Gustafson MT
- 9: Griffin Hadlock, Kat Olson & Zach Rice NV

10: Jim Plosay - AK

Speakers: W. Caffey Norman, Squire Pattons Boggs & Clint Woods, Hexion

Unknown: Wally E and Kara

Tech-Subcommittee: <a href="https://nationalsbeap.org/committees/technical">https://nationalsbeap.org/committees/technical</a>

\*\* This presentation was recorded and will be posted on the National SBEAP YouTube channel at https://www.youtube.com/channel/UC5PupYpZ1W6IG8CtzCINK8Q \*\*

#### **EPA/TSCA** and Bans on Chlorinated Solvent and Formaldehyde

W. Caffey Norman, Squire Pattons Boggs & Clint Woods, Hexion

Messrs. Norman and Woods will share their knowledge and experience to help the SBEAP community better understand EPA rulemaking which includes bans or significant restrictions on the use of certain chemicals impacting certain small business industry sectors such as drycleaners.

How we can the SBEAPs participate in the regulatory review process in future rulemakings where a proposal to ban or significantly curtail certain chemicals which are also used by small businesses?

How we can encourage the EPA to include exemptions, exclusions and/or usage thresholds for very small businesses with negligible emissions (self-contained or virtually self contained equipment) where the loss of the use of that chemical would harm their livelihood?

How we can best serve the affected small businesses, especially with outreach and education?

#### **Bios**



W. Caffey Norman Squire Patton Boggs Partner, Washington DC USA (202) 457-5270 Caffey.Norman@squirepb.com

#### Excerpted from a three page bio

"...For many years he has developed and successfully implemented strategies to defend products targeted for phase out or use reduction. He has participated in EPA rulemakings to regulate hazardous substances under all the environmental statutes and has initiated legislative and judicial review of a

number of EPA regulations..."

"...He also has developed substantial expertise in dealing with scientific review boards and nonregulatory organizations such as the International Agency for Research on Cancer, the National Academy of Sciences, and the National Toxicology Program..."



Clint Woods, Global Director
Product Stewardship & Regulatory Affairs
Hexion Inc.
Clint.Woods@hexion.com

Hexion Inc. is a producer of formaldehyde, adhesives, and performance materials headquartered in Columbus, Ohio.

Prior to joining Hexion in December 2021, he served in several positions in government, including Deputy Assistant Administrator for the U.S.

Environmental Protection Agency's (EPA) Office of Air and Radiation, Professional Staff Member with the U.S. House Committee on Science, Space, and Technology, and Executive Director at the Association of Air Pollution Control Agencies.

Clint holds an MA in international commerce and policy from George Mason University and a BA from the University of Mary Washington. Originally from the Pacific Northwest, he now resides in Delaware County, Ohio with his family.

#### **Future topics:**

- July 16: Demonstration of the DOE RAPID (Regulatory and Permitting Information Desktop)
   Toolkit | Michael Gustafson | SBO ~ Montana DEQ
- August 20: Data Center Optimization Impacts and Unique Air Compliance Considerations, Jarrett Vigil & Kaitlin Urso, CDPHE CO SBAP
- September 17: Food Waste Reduction Jesse Walters & Kaitlin Urso, CDPHE CO SBAP.
- October 15: The New PM2.5 National Ambient Air Quality Standard, Michael Liebert, ALL4
- November 19: Demonstrating the MiEnvrio Portal & Oregon's Your DEQ Online platforms, Kaitlyn DeVries, EGLE and Hillarie Sales, OR DEQ
- December 17: Open forum discussion possibly relating to 2025 Annual Training
- January 21, 2025: Waste Tire Management in the US, John Sheerin, Director End of Life
  Tire Programs, US Tire Manufacturers Association; Susie Steinbach, Liberty Tire Recycling,
  and Kirsten Clemens, EGLE's (Michigan) Scrap Tire Specialist
- **February 18:** Printing topic, Gary Jones, Vice President, Environmental, Health & Safety Affairs, PRINTING United Alliance
- Other 1: AERR (Air Emissions Reporting Requirements) & MM2A (Major MACT to Area) Status and Final Steps
- Other 2: EPA Air Toxic Screen

**Next Call: July 16** 

1 pm CDT (2 pm EDT) (3<sup>rd</sup> Tuesday of month)



#### EPA Risk Evaluations and Risk Management Rules for Chlorinated Solvents under the Toxic Substances Control Act (TSCA)

North Carolina Department of Environmental Quality

Small Business Environmental Assistance Programs

June 18, 2024

W Caffey Norman Squire Patton Boggs 202-457-5270

#### Proposed/Final Risk Management Rules



- Final methylene chloride (dichloromethane or DCM)
   rule: 89 Fed. Reg. 39254 (May 8, 2024)
- Proposed perchloroethylene (perc) rule: 88 Fed. Reg. 39652 (June 16, 2023)
- Proposed carbon tetrachloride (CTC) rule: 88 Fed. Reg. 49180 (July 28, 2023)
- Proposed trichloroethylene (TCE) rule: 88 Fed. Reg. 74712 (October 31, 2023)
- All based on Risk Evaluations completed by EPA in 2020 and Revised Risk Determinations issued in 2022.

#### Highlights of Proposed/Final Rules



- EPA proposed to ban most industrial, commercial, and consumer conditions of use, accounting for from about one-third to almost all of the total annual production volume, depending on the solvent.
  - CTC a special case, as non-feedstock use already banned.
- For a number of conditions of use, EPA proposed implementation of Workplace Chemical Protection Plans (WCPPs) as an alternative to a ban. Some of these uses include, where applicable:
  - Manufacturing/import for uses other than those that would be banned
  - Feedstock for manufacture of HFCs/HFOs
  - Use as processing aid for EV battery manufacturing
  - Industrial and commercial use as a laboratory chemical
  - Paint and coating removal from safety-critical components of aircraft owned/operated by air carriers or commercial operators
  - Several safety-critical uses identified by NASA, DoD, FAA, Homeland Security
  - Disposal

#### Highlights of Proposed/Final Rules, cont.



- Some of the allowed uses are time-limited, in effect phasedowns.
- WCPPs must have an existing chemical exposure limit (ECEL) (8-hour time-weighted average (TWA)):
  - 2 ppm for DCM
  - 140 ppb for perc
  - 30 ppb for CTC
  - 1 or 4 ppt for TCE
- EPA also adopted, for DCM, a short-term exposure limit (STEL) (15-minute TWA) of 16 ppm.
- WCPPs must also include requirements on exposure limits, regulated areas, exposure monitoring, methods of compliance, respiratory and dermal protection, and training.

#### Highlights of Proposed/Final Rules, cont.



- The proposed/final ECELs are based on the following endpoints:
  - 2 ppm for DCM based on liver toxicity (vacuolation in rats but no liver toxicity found in medical surveillance of hundreds of workers)
  - 140 ppb for perc based on neurotoxicity/cancer
  - 30 ppb for CTC based on cancer
  - 1 ppt for TCE based on fetal cardiac anomalies in rodents (not reproducible) or 4 ppt based on immunotoxicity in rodents
- Commenters noted that EPA did not use the "best available science" or the "weight of the scientific evidence" as required by TSCA in assessing the risks.
- Compare these limits to the OSHA permissible exposure limits (PELs):
  - 25 ppm (8-hour TWA) and 125 ppm STEL for DCM
  - 100 ppm for perc
  - 10 ppm for CTC
  - 100 ppm for TCE

## Comparison of Proposed ECELs to OSHA and Foreign Workplace Limits



		Foreign Country			PEL/EPA ECEL		
Chemical Name	France PEL	ce PEL Germany PEL Canada (Ontario) PEL PEL		OSHA PEL*			EPA ECEL
Methylene Chloride	20	50	100	100	25	2	12.5
Perchloroethylene	20	10	25	25	100	0.14	714
Carbon Tetrachloride	1	0.5	5	5	10	0.030	333

Trichloroethylene	10	6	10	10	100	0.0011 or 0.004	90,909 or 25,000
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<sup>\*</sup>Units in parts per million (ppm)

France: https://www.inrs.fr/media.html?refINRS=outil65

Canada: https://www.ontario.ca/laws/regulation/900833

Mexico: <a href="http://dof.gob.mx/nota\_detalle.php?codigo=5342372&fecha=28/04/2014">http://dof.gob.mx/nota\_detalle.php?codigo=5342372&fecha=28/04/2014</a>

Germany: TRGS-900.pdf & TRGS-910 (1).pdf

#### How Did We Get Here?



- In 2016, the Lautenberg Chemical Safety for the 21st Century Act was signed into law. It made substantial changes to TSCA, most notably requiring EPA to consider potentially exposed or susceptible subpopulations, including workers, in evaluating chemical substances.
- By including the word "workers," the Lautenberg Act upended 50 years of workplace regulation of toxic substances, hitherto the province of the Occupational Safety & Health Administration (OSHA). Permissible exposure limits under the Occupational Safety & Health Act (OSH Act) must reduce "significant risk" and be economically and technically "feasible," in accordance with the Supreme Court's 1980 *Benzene* decision.
- Under TSCA, on the other hand, where EPA finds "unreasonable risk" it must regulate "to the extent necessary so that the chemical substance no longer presents such risk." EPA's position is that "EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented" (87 Fed. Reg. 21706, 21712 Apr. 12, 2022)).
- EPA's methodology for determining risk has remained largely unchanged for 45 years.
- Unclear why American Chemistry Council supported Lautenberg Act with this language.

#### **WCCPs**



- Obviously, many firms in compliance with the OSHA limits will be unable to meet the ECELs. Remarkably, however, EPA also assumed that a number of workplace conditions of use would not be able to achieve the ECELs, and proposed that workplaces in the banned categories could no longer use the solvents even if they could show ability to comply with the much lower limits.
- TSCA provides for EPA to restrict uses that "present[] an unreasonable risk
  of injury to health or the environment" and to regulate only "to the extent
  necessary so that the chemical . . . no longer presents such risk." If a use
  complies with the ECEL, EPA would seem to lack authority to ban it.
- Interpreting similar statutory language, the Supreme Court held in *Benzene*: "before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm."

#### **Alternatives Assessments**



- TSCA § 6(c) provides that if a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."
- Where, as in these proposals, most uses would be banned, the alternatives assessment is obviously critical. Yet EPA's economic analyses completely fail to consider the impact on American manufacturing competitiveness of banning such uses:
  - For DCM use in furniture refinishing, EPA found that "alternatives to products containing methylene chloride may not be economically viable and may cause damage to the substrate. . . . The impact of a prohibition of methylene chloride for furniture refinishing could result in the closure" of some 5,000 firms. Goodbye antiques!
  - Perc and TCE are used to formulate nonflammable brake cleaners. There are 258,000 independent (mom and pop) auto repair shops. These are small businesses where there are many sources of flame/spark. Yet viable nonflammable alternatives were not identified.

#### Alternatives Assessment, cont.



- Another important category where EPA identified no alternatives to the solvents is use as a processing aid, such as the manufacture of battery separators or for heat transfer. Alternatives may react to form impurities, have too high a boiling point, or be flammable. Only these solvents are known to yield suitable products (*i.e.*, ones that meet specifications, work in customers' applications, and lack problematic impurities; meet applicable permitting requirements; and comply with process safety management requirements). (In response to comments, the final DCM rule did broaden the processing aid applications allowed to continue with a WCPP.)
- This underscores the key shortcoming in EPA's approach: it has failed to consider the physical/chemical properties of these chemicals that make them uniquely suited to hundreds of uses.
- The Small Business Regulatory Enforcement Fairness Act (SBREFA) requires particular attention be paid to the ability of small firms to comply with regulations. Yet where other options were available to regulate "to the extent necessary so that the chemical . . . no longer presents such risk," EPA proposed to allow only "regulated entities [that] may have fewer challenges implementing requirements to meet an ECEL [or STEL] because work activities may occur in sophisticated facilities or take place in a closed system."

#### Proposed Perc Rule/Dry Cleaning



- As noted, the proposed ECEL is a 99.86% reduction from the PEL.
- EPA proposed a ten-year phaseout for perc use in dry cleaning. The phaseout would proceed in stages:
  - 1. Prohibition on the use of perc in any dry cleaning machine acquired 6 months or more after adoption of the final rule;
  - 2. Prohibition on the use of perc in 3rd generation machines 3 years after adoption of the final rule;
  - 3. Prohibition on the use of perc in all dry cleaning and spot cleaning, including in 4th and 5<sup>th</sup> generation machines, 10 years after adoption of the final rule; and
  - 4. Prohibition on the manufacturing, processing, and distribution in commerce of perc for use as a dry cleaning solvent 10 years after adoption of the final rule.
- EPA justified this draconian phaseout on the basis that few perc machines are sold in the United States and dry cleaning machines are retired 15 to 25 years after the manufacture date. EPA estimates that 6,000 dry cleaners still use perc (a majority of the industry) and that about 60 machines are expected still to be in use at the end of the 10-year phaseout period.

#### TCE Alternatives Assessment



- TCE is a special case. EPA apparently recognized the infeasibility of achieving the ECEL of 1.1 or 4 ppt, as it proposed not that owners or operators comply with the ECEL but that they ensure to the extent possible that no person is exposed to an airborne concentration of TCE in excess of the ECEL.
- In addition to being infeasible, neither proposed TCE ECEL can be reliably measured in the workplace. Both values are below the practical limit of detection (recognized by EPA to be 36 ppb). Indeed, 1 ppt is close to typical background TCE concentrations in urban air.
- Given EPA's conclusion that most users will never be able to achieve the ECEL, clearly great effort would be required to meet the TSCA 6(c) mandate: If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."
- Yet remarkably, EPA's Alternatives Analysis acknowledged that: "EPA did not find it
  practicable to consider alternative processes that may be reasonably available as a
  substitute for processes involving TCE when the proposed prohibitions or restrictions
  would take effect"

#### Coordination with OSHA



- TSCA § 9 requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."
- EPA says it coordinated with OSHA on the proposed rules, and states that gaps exist between OSHA authority to set workplace standards under the OSH Act and EPA's obligations under TSCA § 6.
- But worker health and safety falls under the jurisdiction of OSHA. Its comprehensive regulatory framework provides protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the proposed rules. Taking steps that may lead to the removal of products from the marketplace where workplaces comply with these existing requirements may not be consistent with TSCA either as initially enacted or as revised by the Lautenberg Act.
- Legislative history supports the position that TSCA was intended to fill gaps in regulation, not to supplant existing regulatory frameworks.

#### **Small Business Concerns**



- The proposals clearly discriminate against small businesses. Where other long-term options are available, including WCPPs which EPA would allow for long-term phaseout and exemption periods, it is inconsistent with TSCA for EPA to conclude it "does not believe that long-term implementation of the WCPP would be a feasible means of addressing unreasonable risk indefinitely; thus prohibition of the use [] for affected COUs is ultimately necessary to address the risk so that it is no longer unreasonable."
- EPA's uncertainty as to whether most users can comply with its ECELs is not a sufficient reason to eliminate any compliance option for such users, most of which are small businesses. The only justification for such a ban is that it would present an "unreasonable risk" that EPA "does not believe" is feasibly addressed through WCPPs, though these same WCPPs would be in place for long-term phaseout and exemption periods.
- Also, the proposed definition of "retailer" would make it impossible for most small businesses to obtain product, as sales would be restricted solely to commercial suppliers.

#### **Likely Litigation Issues**



- Interpretation of "unreasonable risk"
- Failure to use 'best available science"
- Failure to rely on "weight of the scientific evidence"
- Unreasonable risk determinations lack substantial evidence
- Inadequate consideration of alternatives
- Having determined that ECELs eliminate unreasonable risk, (i) any
  workplace in compliance with ECEL should not be subject to use ban and
  (ii) uses meeting ECEL should be allowed to continue without time limit
- Deviation from TSCA, 2017 Procedures for Chemical Risk Evaluation, and 2020 Risk Evaluations in and following 2022 issuance of Revised Risk Determinations:
  - EPA determined there was unreasonable risk for each solvent as a "whole chemical" instead of making determinations for each condition of use.
  - EPA used high-end exposure estimates assuming non-compliance with OSHA limits even though such compliance is part of "circumstances" of use.
- Non-compliance with SBREFA

## Comparison of US and Foreign Workplace Limits to Expected EPA ECELs



		Foreign Countr	y PELs*		Expected EPA						
Chemical Name	France PEL	Germany PEL	Canada (Ontario) PEL	Mexico PEL	OSHA PEL*	ECEL Based on IRIS Potency Factor*	PEL/EPA ECEL				
From First 10 Priority List											
Perchloroethylene	20	10	25	25	100	0.14**	714				
Methylene Chloride	20	50	100	100	25	2**	12.5				
Trichloroethylene	10	6	10	10	100	0.0011 or 0.004**	90,909 or 25,000				
Carbon Tetrachloride	1	0.5	5	5	10	0.030**	333				
	From Second 20 Priority List										
Formaldehyde	0.3	0.3	1.5	0.3	0.75	0.011**	68				
Ethylene Dichloride	2	Tolerable 1 Acceptable 0.2	1	PEL not listed	50	0.008	6,250				
		From Recen	t List of 15 Pr	iority Chemic	cals						
Benzene	1	Tolerable 0.6 Acceptable 0.06	0.5	0.5	1	0.03	33				
Vinyl Chloride	1	1	1	1	1	0.068	15				
Other Chemicals											
Butadiene, 1,3 -	1	Tolerable 2 Acceptable 0.2	2	2	1	0.012	83				
Chloroprene	PEL not listed	Tolerable 1.4 Acceptable 0.14	10	10	25	0.0008	31,250				

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\*units in parts per million (ppm)

\*\* These ECELs have already been announced by EPA based on completed Risk Evaluations (draft in the case of formaldehyde). For the rest a value corresponding to a 1 X 10<sup>-4</sup> potential risk has been derived based on the EPA Integrated Risk Information System (IRIS) potency factor.

France: <a href="https://www.inrs.fr/media.html?refINRS=outil65">https://www.inrs.fr/media.html?refINRS=outil65</a>

Canada: <a href="https://www.ontario.ca/laws/regulation/900833">https://www.ontario.ca/laws/regulation/900833</a>

Mexico: http://dof.gob.mx/nota\_detalle.php?codigo=5342372&fecha=28/04/2014

Germany: TRGS-900.pdf & TRGS-910 (1).pdf

#### Conclusion



- If adopted as proposed, these rules will cripple US manufacturing competitiveness by offshoring production of hundreds of important products to Europe, Mexico, China, etc. – NO OTHER COUNTRY IN THE WORLD HAS IN PLACE OR UNDER CONSIDERATION WORKPLACE LIMITS APPROACHING THE PROPOSED ECELs, WHICH ARE UNACHIEVABLE FOR MANY MANUFACTURING USES.
- Thank you.

W Caffey Norman Squire Patton Boggs 202-457-5270



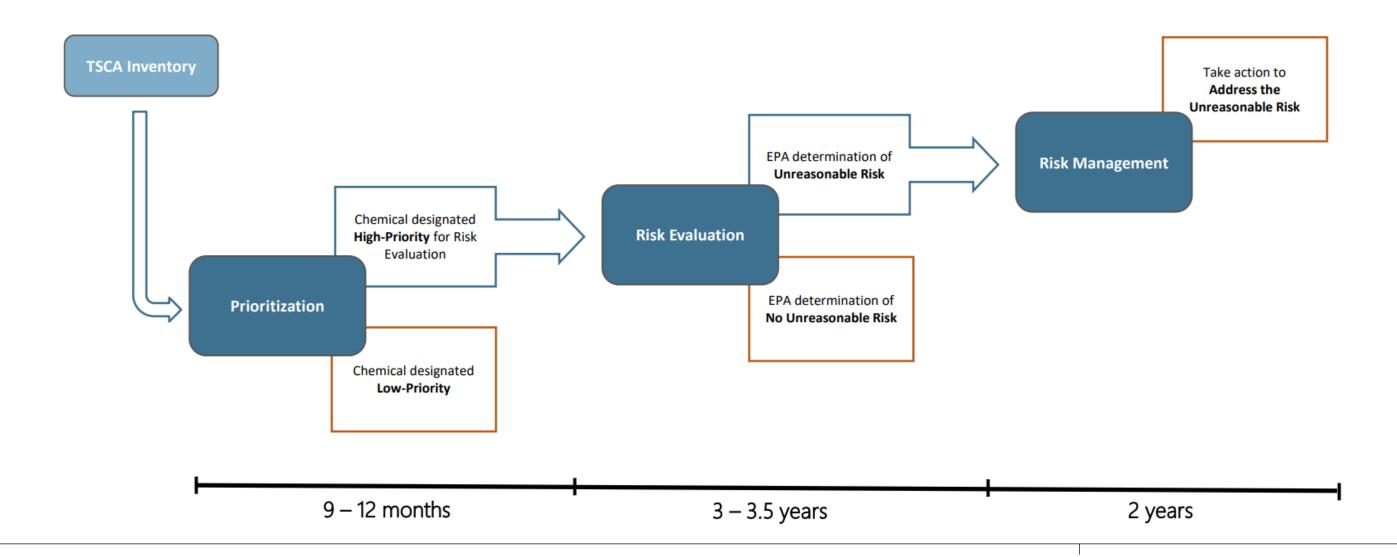
## **Outline**

- TSCA Existing Chemical Review Process
- Upcoming TSCA Risk Evaluation and Risk Management Activities
- Intersection of EPA's Clean Air Act, TSCA, and IRIS Programs
- Background on Formaldehyde and EPA's TSCA Risk Evaluation of Formaldehyde
- Key takeaways and comments on EPA's Draft Evaluation of Formaldehyde
- Potential Action Items for SBOs
- Appendix contains additional background on key provisions of TSCA



## Toxic Substances Control Act (TSCA) – Existing Chemical Process

- TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016 and requires, among other things, that EPA conducts:
  - a prioritization process to determine if chemical substances are a high- or low-priority for risk evaluation, and
  - risk evaluation for every designated High-Priority Substance, to determine whether there is an unreasonable risk to health or the environment, without consideration of costs or non-risk factors, based on the weight-of-scientific-evidence, using the best available science.
- The entire lifecycle of a chemical is considered for chemical releases associated with uses that are covered under TSCA and is broader in scope than media-specific





## **Examples of TSCA Risk Management**

- 5 Chemicals are in their final or soon-to-final final risk management rules after EPA determinations regarding "unreasonable" risk based on certain conditions of use
  - Chrysotile Asbestos
  - Trichloroethylene
  - Perchloroethylene
  - Methylene chloride
  - Carbon Tetrachloride
- Examples of conditions of use with widespread indirect effects:
  - Sheet gaskets used in chemical production containing chrysotile asbestos
  - Industrial and commercial use as laboratory chemical
  - Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing
  - Industrial/commercial use as an industrial processing aid in the manufacture of petrochemicals-derived products and agricultural products
  - Processing into formulation, mixture or reaction product for other chemical products and preparations
- Remainder of first 10 priority chemicals (risk management likely in 2024-2026):
  - Proposed risk management (comment deadline 7/29/24): NMP (n-Methylpyrrolidone);
  - Awaiting risk management: 1,4-Dioxane; 1-Bromopropane; Asbestos (remaining/legacy); HBCD (Cyclic Aliphatic Bromide Cluster), PV29 (CI Pigment Violet 29)



## Next 20 High Priority Chemicals (risk evaluations in 2024-2026)

- p-Dichlorobenzene
- 1,2-Dichloroethane
- trans-1,2- Dichloroethylene
- o-Dichlorobenzene
- 1,1,2-Trichloroethane
- 1,2-Dichloropropane
- 1,1-Dichloroethane
- Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2- dibutyl ester)
- Butyl benzyl phthalate (BBP) 1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester
- Di-ethylhexyl phthalate (DEHP) (1,2-Benzene- dicarboxylic acid, 1,2- bis(2ethylhexyl) ester)

- Di-isobutyl phthalate (DIBP) (1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester)
- Dicyclohexyl phthalate
- 4,4'-(1-Methylethylidene)bis[2, 6dibromophenol] (TBBPA)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phosphoric acid, triphenyl ester (TPP)
- Ethylene dibromide
- 1,3-Butadiene
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8hexamethylcyclopenta [g]-2benzopyran (HHCB)
- Formaldehyde
- Phthalic anhydride



## **New TSCA Priority Existing Chemicals**

Chemical Name	Existing Assessments	CDR	TRI	HAP	MCL	Hazardous Substance	Hazardous Waste	Carcinogen	Persistent and Bioaccumulative	Environmental Hazard Data	Environmental Exposure Data
4,4'-Methylene bis(2- chloroaniline)	PPRTV	✓	1	✓				✓	✓		<b>*</b>
Acetaldehyde	IRIS	1	1	✓		1	1	1		✓	✓
Acrylonitrile	IRIS, <u>ATSDR</u>	✓	1	✓		<b>✓</b>	<b>✓</b>	✓		~	<b>V</b>
Benzenamine	IRIS, PPRTV	<b>✓</b>	~	~		✓	<b>✓</b>	✓		✓	✓
Vinyl chloride	IRIS, <u>ATSDR</u>	<b>✓</b>	1	✓	✓	✓	<b>✓</b>	✓	<b>✓</b>	✓	✓

#### **Potential Uses**

4,4'-Methylene bis(2-chloroaniline): CASRN 101-14-4

· Manufacturing and processing of chemicals (e.g., rubber, plastics, resins)

Manufacturing and processing of chemicals (e.g., adhesives, petrochemicals)

· Intermediates for products (e.g., packaging and construction materials)

Manufacturing and processing of chemicals (e.g., plastics, paint, petrochemicals)

Manufacturing and processing of chemicals (e.g., dyes, pigments, plastics, petrochemicals)

· Manufacturing and processing of chemicals (e.g., plastics)

$$CH_2$$
  $CN$   $NH_2$   $C=C$ 

 Other substances considered: Benzene; Bisphenol A; Ethylbenzene; Napthalene; Styrene; Tribromomethane; 4-tert-Octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol); Hydrogen fluoride; N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)



# There are three regulatory programs that pose risk to Hexion and its customers. These programs and their potential risks are interrelated

## **TSCA**

Timing: "Unreasonable risk" determination by end of 2024 (lawsuit on deadline); Risk management rules effective 2027 - 2032

Focus: Worker / customer exposures across more than 60 conditions of use

Major threats: National bans on some conditions of use, very low OELs (10-50 parts per billion) Use of IRIS drives bans, unachievable workplace standards

(OEL)

## **IRIS**

Timing: 2024 and beyond (episodic)

Focus: Outdoor air for customer facilities in certain communities

#### Major threats:

Localized, episodic use of precautionary IRIS level for local community concern, litigation, permitting, enforcement

## Clean Air Act

Timing: Deadline-driven

Use of toxics standards by source categories (not imminent).

Best estimate is late 2020s; air

Focus: Outdoor air for chemical and wood products facilities

Major threats: Costly customer controls

National product/process bans or unworkable occupational limits could threaten substantial portion of U.S. business

Community-, customer-, or sector-specific regulations, litigation, or other actions threaten a smaller, less predictable portion of U.S. business

pollution

controls



# EPA FORMALDEHYDETSCA RISK EVALUATION - KEY DATES AND MILESTONES



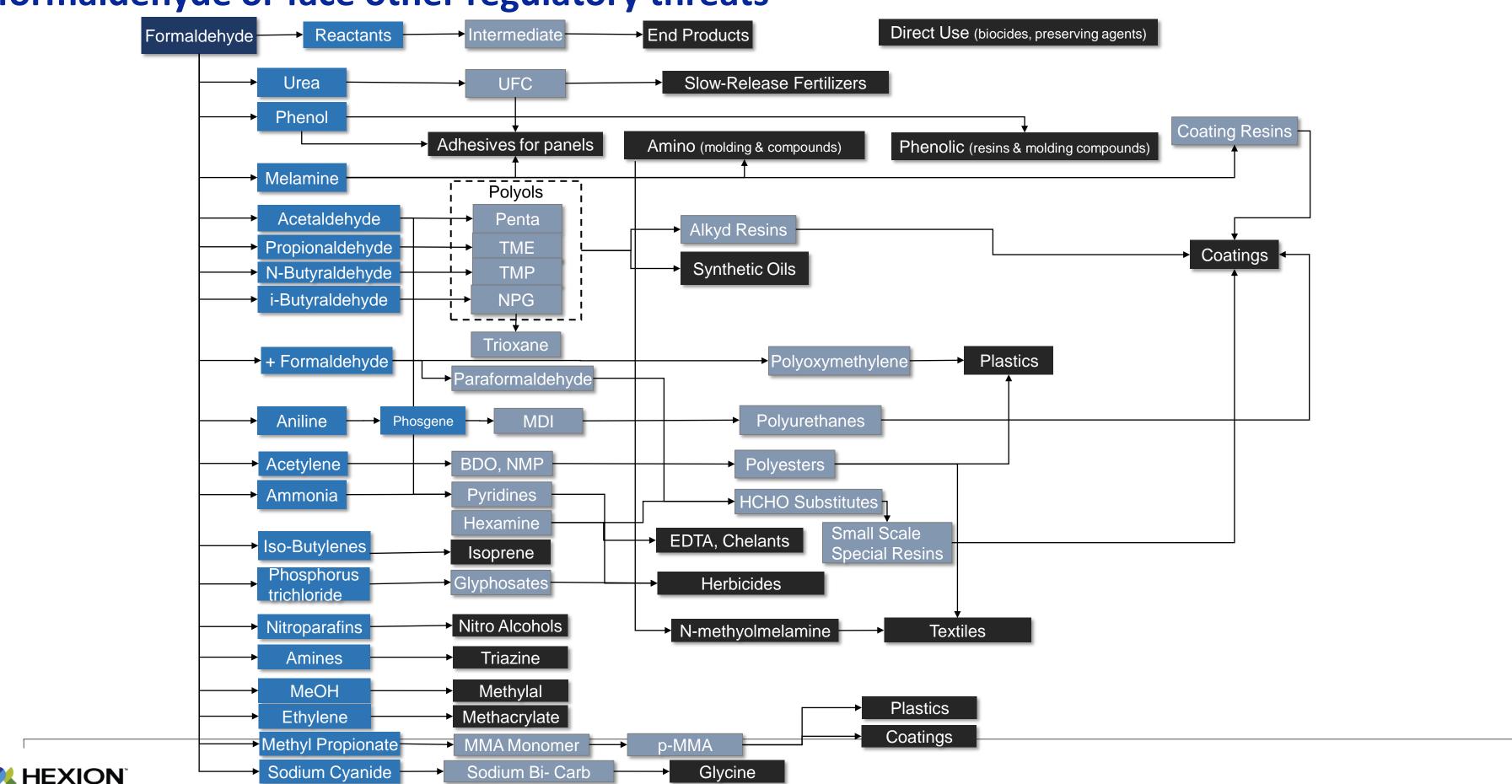
#### IRIS Finalized - FY 2024

- Step 5: Revise Assessment
- Step 6: Interagency
- Step 7: Final Assessment

- Jan 25, 2024 Deadline for Nominations for Peer Reviewers
- March 2024 Public Comment on Candidate List of Ad Hoc Peer Reviewers
- Before SACC Peer Review Public Comments on Charge Questions
- May 2024 Written and oral comments to EPA and Peer Reviewers

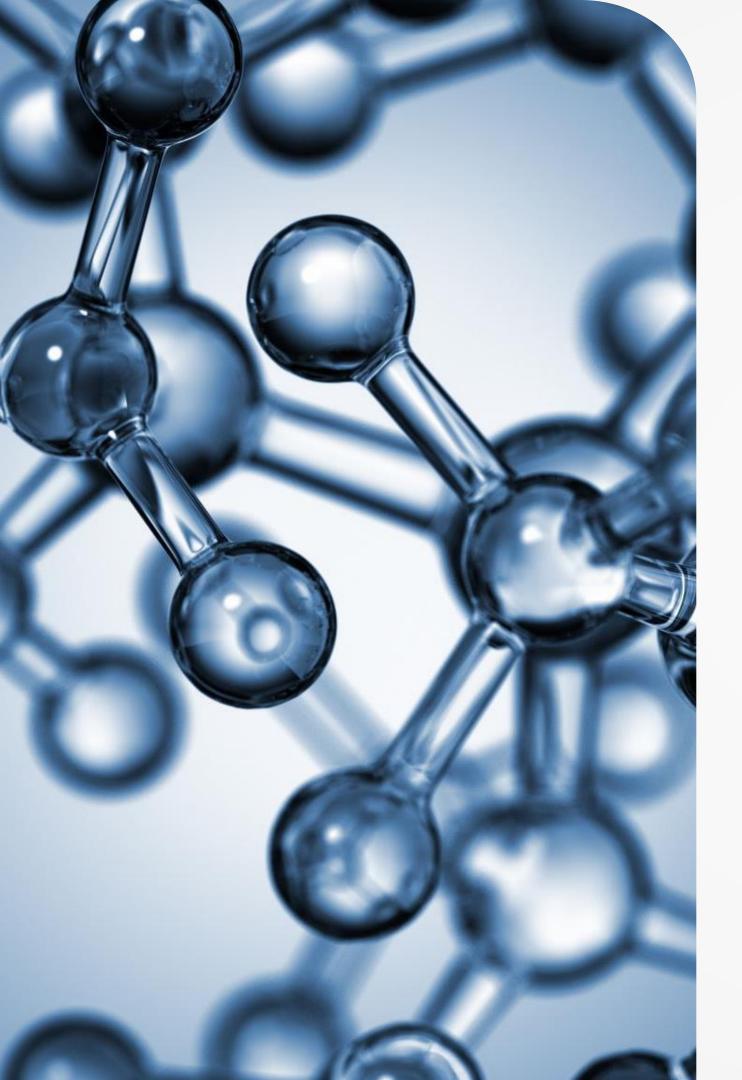
# Formaldehyde is a building block chemistry with limited substitutes, and many rely on formaldehyde or face other regulatory threats

Responsible Chemistry



# Essential Chemical Building Block

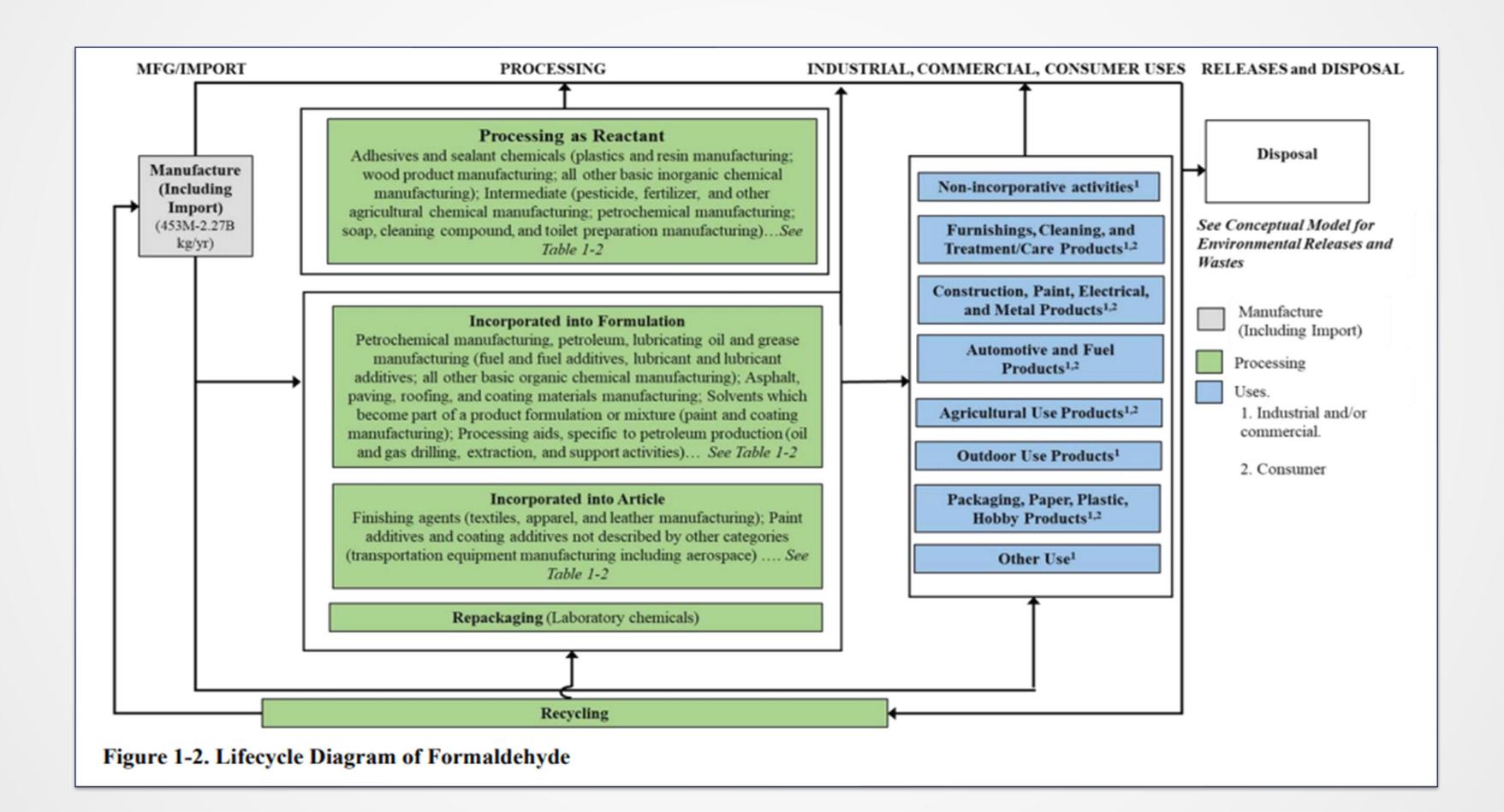




# TSCA Risk Evaluation Draft Unreasonable Risk Determination

- TSCA requires EPA to conduct a risk evaluation to determine whether a **chemical substance** presents an unreasonable risk of injury to health or the environment, **without consideration of costs or other non-risk factors**.
- "In this draft risk evaluation, **EPA preliminarily finds** that formaldehyde presents an unreasonable risk of injury to human health."
- A final unreasonable risk determination triggers EPA to issue a proposed (1 year later) and final risk management rule (2 years later). The only risk management tools EPA has deployed in last 2 years are bans and workplace exposure limits.

## **EPA Lifecycle Diagram of Formaldehyde**



## March 2024 Draft U.S. EPA TSCA Risk Evaluation

- "In this draft risk evaluation, EPA preliminarily finds that formaldehyde presents an unreasonable risk of injury to human health. However, these risks result from specific activities using, and products containing, formaldehyde and therefore may not apply to everyone, everywhere."
- "EPA confirmed formaldehyde is released to land, water, and air.... Due to its reactivity, formaldehyde is not expected to persist in land or water."
- No risk to aquatic organisms, terrestrial organisms, or plants.
- "Not all sources are considered in the Draft TSCA Risk Evaluation, either because they occur naturally or because they are regulated under other statutes."
- EPA is looking at an intermediate and chronic non-cancer Occupational Exposure Value (similar to 8-hour TWA PEL) of 11 parts per billion, a draft acute/shot-term non-cancer Occupational Exposure (similar to 15-minute STEL) of 50 parts per billion, and a draft lifetime cancer Occupational Exposure Value of 108 parts per billion.

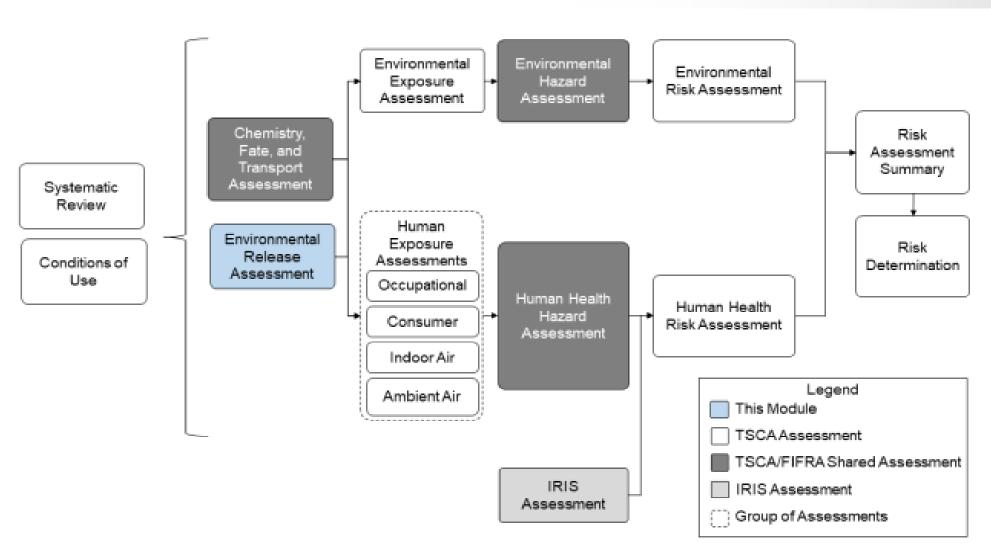


Figure 1-1. Risk Evaluation Document Summary Map

# Existing Chemical Exposure Limits (ECELs)

Chemical	OSHA PEL (ppb)	EU OEL (ppb)	EPA ECEL (ppb)	PEL/EPA ECEL
Methylene Chloride	25,000	100,000	2000	12.5 times lower
Perchloroethylene	100,000	20,000	140	714 times lower
Carbon Tetrachloride	10,000	10,000	30	333 times lower
Trichloroethylene	100,000	10,000	4	25,000 times lower
Formaldehyde	750	300	11 ppb*	~ 70 times lower

<sup>\*</sup>Formaldehyde number is referenced as an "Occupational Exposure Value"

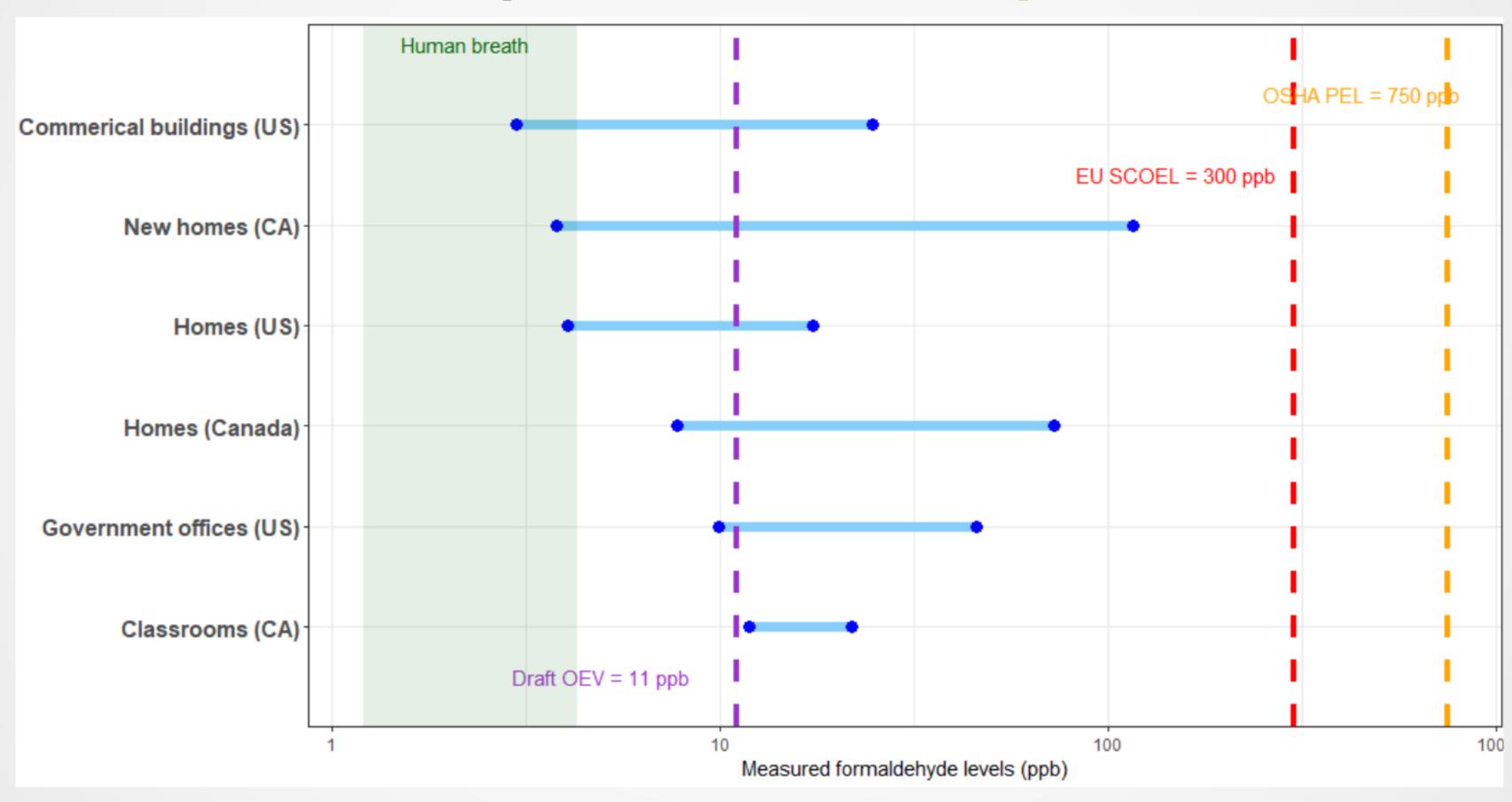
## **Workplace Limits Reality Check**

EPA's occupational exposure values for formaldehyde constitute unachievable workplace limits and are an unreasonable starting point for risk evaluation or risk management.

For example, 11 parts per billion of formaldehyde is:

- Almost 70 times below OSHA PEL (750 ppb)
- Almost 30 times below the recently updated European Union occupational limits (300 ppb)
- Just above the level of formaldehyde in exhaled human breath
- Below the detection limit for OSHA-approved formaldehyde analytical methods
- Below levels measured in ambient air and below levels seen in typical U.S. residences

## **Workplace Limits Reality Check**



## **Docket Postings**

### **220 Postings Out of 230 Total Public Submissions**

- Trade Associations (50+)
- Community and Union Leaders (~35)
- Elected Officials (30+)
- Scientific Experts, Former EPA Officials, Authors of Key Studies (26)
- Companies (12)
- NGOs (5)
- State or Tribal Organizations (3)

ACC Blogpost: Diverse Group of Stakeholders, Experts, and Peer Reviewers Identify Major Issues with EPA's Draft Formaldehyde Risk Evaluation Under TSCA - American Chemistry Council

# Beyond the potential mitigation actions, there are potentially favorable regulatory dynamics

### **EPA Implementation Issues**

Lack of cost-effective alternatives

Formaldehyde is far more ubiquitous than other chemicals

Inconsistency with federal (OSHA, VA, CDC) and int'l standards (EU, WHO)

Lack of EPA resources to implement

Formaldehyde use/exposure in industries key to EPA/Administration priorities (EVs, semiconductors, defense/aerospace, ag)

Difficult to regulate workplaces

High background HCHO levels vs. IRIS

# Mitigating Circumstances

Regulatory threats to HCHO alternatives

TSCA exemptions for wood products regulated by CARB/TSCA Title VI

TSCA exempt products below de minimis level (<0.1% formaldehyde)

Not new. HCHO considered a probable or known carcinogen for more than 40 years

Low Hexion facility profile in community

5-10 years for EPA or states to fully use new IRIS

Strong IH program and extensive exposure data

#### Intervening Events

Adverse peer reviews

Legislation

Litigation

Elections

Congressional oversight

Government shutdowns

State/other federal agency pushback





## **Potential Action Items**

- Engage small businesses in your state to raise TSCA awareness, including regarding indirect effects
- TSCA contains key provisions related to inter-/intra-agency consultation and coordination as well as development of complementary state programs to address unreasonable risks
  - No interagency consultation on risk evaluations (see <u>SBA Advocacy comments on "framework" rule</u>)
  - No EPA/OSHA MOU
  - No engagement with OSH ACT-delegated state programs or Departments of Labor
  - Little engagement with state environmental programs
- Advocate for small business seat at the table EPA has rejected requests for SBREFA Small Business
   Advocacy Review Panels prior to TSCA risk management
  - See October 2023 request from American Feed Industry Association, American Home Furnishings Alliance, Business and Institutional Furniture Manufacturers Association, Catfish Farmers of America, Composite Panel Association, Florida Aquaculture Association, Kitchen Cabinet Manufacturers Association, National Aquaculture Association, National Funeral Directors Association
- Engage OAQPS on Potential Inconsistencies with Clean Air Act
  - NATA/AirToxScreen
  - Air Emissions Reporting Requirements Rules and role of IRIS
  - "Best Available Science" and "Acceptable Risk" under Section 112
  - Modeling and Monitoring Methods



## Appendix – Additional Background



## Coordination with Other Agencies and Regulators – 1/2

- Significant interest in EPA's TSCA activities related to formaldehyde from other federal agencies, state regulators, international bodies, and other parts of EPA. HSRB can help EPA to carry out its TSCA-related coordination requirements by encouraging the Agency to engage other agencies with differing approaches as part of the risk evaluation process.
- Other federal and state regulatory programs, many with existing short-term exposure limits:
  - OSHA Formaldehyde standard (29 CFR 1910.1048)
  - EPA Clean Air Act and TSCA Title VI standards
  - Acute Exposure Guideline Levels (AEGLs) for Airborne Chemicals
  - Fish & Wildlife Service Formaldehyde Exposure Control Standards for federal Fisheries and other facilities
  - CDC/ATSDR Medical Management Guidelines
  - Department of Veterans Affairs Formaldehyde Program
  - HUD product standards
  - FDA approvals
  - State-delegated programs under the OSH Act and other environmental laws
- In limited opportunities for interagency review of EPA's formaldehyde assessments, including in 2022, other agencies offered relevant, detailed, and unaddressed scientific concerns



## Coordination with Other Agencies and Regulators – 2/2

- Relevant executive orders (EO):
  - EO 12866 Regulatory Planning and Review (interagency review of significant guidance)
  - EO 13609 Promoting International Regulatory Cooperation ("International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.")
  - EO 13132 Federalism ("[E]nsure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.")
- TSCA contains several provisions relevant to coordination with other agencies:
  - Section 9 (15 U.S. Code § 2608) requires coordination by EPA for risk evaluation activities with other parts of EPA, agencies which oversee other laws that could address unreasonable risks, and "the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency" to reduce duplication and burdensome requirements while maximizing enforcement. It also established that the EPA Administrator "shall not… be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."
  - Section 28 (15 U.S. Code § 2627) provides for complementary state programs to carry out TSCA requirements to prevent
    or eliminate unreasonable risks
  - Section 26(a) (15 U.S. Code § 2625(a)) authorizes all federal departments and agencies to make "make its services, personal, and facilities available… to assist" EPA in administering TSCA as well as allowing for them to furnish all relevant information to the Administrator.



## Key TSCA Science Requirements

#### **TSCA Scientific Standards**

- <u>Best Available Science</u>: EPA "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," including the "extent of independent verification or peer review" of the science; the "extent to which the variability and uncertainty" of the science is evaluated and characterized; and the extent to which this science is "reasonable for and consistent with the intended use of the information."
- Weight of Scientific Evidence: EPA "shall make decisions based on the weight of the scientific evidence" and directs that "In conducting a risk evaluation under this subsection, the Administrator shall... describe the weight of the scientific evidence for the identified hazard and exposure." EPA's definition incorporates requirement for systematic review method, preestablished protocol, and identification/evaluation of streams of evidence and studies.
- <u>Integration of Available Information</u>: "In conducting a risk evaluation... the Administrator shall... **integrate and assess available information** on hazards and exposures for the conditions of use of the chemical substance...."

## What Can TSCA Do For You?

## **Interagency Requirements**

- <u>Interagency Consultation</u>: TSCA Section 9(d) requires: "...the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes."
  - Long-standing executive orders also require interagency review of "significant" EPA actions.
  - Substantial Congressional interest in TSCA interagency coordination.
- <u>Inter/Intra-Agency Referrals</u>: TSCA Section 9(e): ): "if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law... the Administrator shall make such information available to the relevant Federal agency...."
- <u>Inter/Intra-Agency Evaluation</u>: Section 9(b): "the <u>Administrator shall consider</u>... all relevant aspects of the risk... and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."

## What Can TSCA Do For You?

**Exemptions, Prohibitions, and Non-Discretionary Duties** 

- <u>Consideration of Alternatives</u>: EPA must "consider... whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute..." (Section 6(c)(2) of TSCA)
- <u>Time-Limited Critical Use Exemptions for Risk Management</u>: TSCA Section 6(g) provides for limited exemptions for uses in which: Compliance would "significantly disrupt the national economy, national security, or critical infrastructure"; "critical or essential use for which no technically and economically feasible safer alternative is available"; The use "provides a substantial benefit to health, the environment, or public safety."
- Prohibition on Prescribing Occupational Standards: "the Administrator shall not... be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health."
- Annual Report and Other Non-Discretionary Duties: EPA is required to provide annual reports to the President and Congress on "major problems encountered" under TSCA, "actions taken to coordinate with such other Federal departments, agencies, or instrumentalities," and a list of all chemical risk evaluations to be initiated or completed each year.