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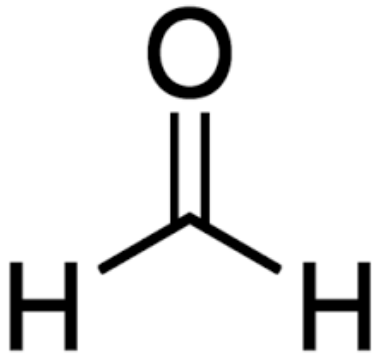
Environmental Protection Agency

December 2024
Office of Chemical Safety and
Pollution Prevention

Response to Science Advisory Committee on Chemicals (SACC) Peer Review and Public Comment on the Human Health Risk Evaluation for Formaldehyde

CASRN 50-00-0



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Acronyms and Abbreviations

AAPFCO	Association of American Plant Food Control Officials
AAVLD	American Association of Veterinary Laboratory Diagnosticians
ACC	American Chemistry Council
ADAF	age-dependent adjustment factors
AERMOD	AMS/EPA Regulator Model
AHHS	American Healthy Homes Survey
AIA	Aerospace Industries Association
AMTIC	Ambient Monitoring Technology Information Center
APA	Administrative Procedure Act
BBDR	biologically-based dose-response
BMC	benchmark concentration
BMCL	benchmark concentration lower bound
BMD	benchmark dose
BMDL	benchmark dose level
BMR	benchmark response
CARB	California Air Resources Board
CDC	Centers for Disease Control and Prevention
CDR	Chemical Database Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CPSC	Consumer Product Safety Commission
DER	Data Evaluation Report
DEVL	Dermal Exposure to Volatile Liquids
DNA	deoxyribonucleic acid
ECHA	European Chemicals Agency
ECRMD	Existing Chemicals Risk Management Division
EPA	U.S. Environmental Protection Agency
ETS	environmental tobacco smoke
EU	European Union
FACA	Federal Advisory Committee Act
FBR	fluidized bed reactor
FDA	Food and Drug Administration
FIAM	Formaldehyde Indoor Air Model
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	United States Government Accountability Office
GIS	geographic information system
HAP	Hazardous Air Pollutant
HEM	Human Exposure Model
HSRB	Human Studies Review Board
IDLH	Immediately Dangerous to Life and Health
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IIOAC	Integrated Indoor-Outdoor Air Calculator
IRIS	Integrated Risk Information System
IUR	inhalation unit risk
LHM	lymphohematopoietic malignancy

LLNA	local lymph node assay
LOAEL	lowest-observed-adverse-effect level
MDI	methylene diphenyl diisocyanate
MOA	mode of action
MOE	margin of exposure
NAS	National Academy of Sciences
NASEM	National Academies of Sciences, Engineering, and Medicine
NAICS	North American Industry Classification System
NCI	National Cancer Institute
NEI	National Emissions Inventory
NESHAP	National Emissions Standards for Hazardous Air Pollutants
NESIL	no expected sensitization induction level
NIOSH	The National Institute for Occupational Safety and Health
NMAM	NIOSH Manual of Analytical Methods
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEL	occupational exposure limit
OES	occupational exposure scenario
OEV	occupational exposure value
OMB	Office of Management and Budget
ONU	occupational non-user
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
OSHA	The Occupational Safety and Health Administration
PECO	Population, Exposure, Comparator, and Outcome
PEFR	peak expiratory flow rate
PESS	potentially exposed or susceptible subpopulation(s)
POD	point of departure
PPE	personal protective equipment
RV	recreational vehicle
SACC	Science Advisory Committee on Chemicals
SDS	Safety Data Sheet
TRI	Toxics Release Inventory
TRP	transient receptor potential cation channels
TSCA	Toxic Substances Control Act
TWA	time-weighted average
UF	uncertainty factor
US	United States
USDA	United States Department of Agriculture
VOC	volatile organic compound
WHO	World Health Organization
WOE	Weight of Evidence
WOSE	Weight of Scientific Evidence

Introduction

On March 15, 2024, the U.S. Environmental Protection Agency (EPA) published the *2024 Draft Risk Evaluation for Formaldehyde* and accepted public comment until May 14, 2024. Materials on the draft risk evaluation are available at www.regulations.gov in docket EPA-HQ-OPPT-2023-0613. A preparatory virtual public meeting was held on May 7, 2024, for reviewers and the public to comment on and ask questions regarding the scope and clarity of the draft charge questions, and the virtual peer review public meetings were held May 20-23, 2024.

This document summarizes the public and external peer review comments from the peer review that the EPA's Office of Pollution Prevention and Toxics (OPPT) received for the risk evaluation of formaldehyde. It also provides EPA/OPPT's response to the comments received from the public and the peer review. EPA/OPPT appreciates the valuable input provided by the public and peer review. The input resulted in numerous revisions to the risk evaluation document. The peer review and public comments are categorized by the nine themes listed below and where relevant and appropriate, organized by charge question.

Additionally, within each theme comments that cover similar issues are presented together.

1. Overarching Comments
2. Chemistry, fate, and transport of formaldehyde
3. Releases and concentrations of formaldehyde in the environment
4. Environmental Risk Assessment
5. Human Health Risk Assessment
6. Unreasonable Risk Determination
7. Systematic Review
8. Formatting and editing
9. Other comments

Table 1: Index of Public Comment Submissions Sorted by Submission Number

Submission Number	Commenter Name
EPA-HQ-OPPT-2023-0613-0004	Steve Gibb
EPA-HQ-OPPT-2023-0613-0005	Central Garden & Pet
EPA-HQ-OPPT-2023-0613-0006	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0007	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0008	Composite Panel Association (CPA)
EPA-HQ-OPPT-2023-0613-0064	American Forest & Paper Association (AF&PA) and American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0065	Environmental Protection Network (EPN)
EPA-HQ-OPPT-2023-0613-0066	American Veterinary Medical Association (AVMA)
EPA-HQ-OPPT-2023-0613-0067	National Aquaculture Association
EPA-HQ-OPPT-2023-0613-0068	The Engineered Wood Association (APA)
EPA-HQ-OPPT-2023-0613-0069	Anitox Corp
EPA-HQ-OPPT-2023-0613-0070	The Fertilizer Institute (TFI)
EPA-HQ-OPPT-2023-0613-0071	North American Insulation Manufacturers Association (NAIMA)
EPA-HQ-OPPT-2023-0613-0072	Independent Lubricant Manufacturers Association (ILMA)
EPA-HQ-OPPT-2023-0613-0073	Center for Truth in Science
EPA-HQ-OPPT-2023-0613-0074	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0075	Center for Environmental Health et al.
EPA-HQ-OPPT-2023-0613-0076	American Forest & Paper Association (AF&PA) and American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0077	University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE)
EPA-HQ-OPPT-2023-0613-0078	Kimberly Hazard
EPA-HQ-OPPT-2023-0613-0079	U.S. Senator Mike Braun et al.
EPA-HQ-OPPT-2023-0613-0080	American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0081	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0082	Composite Panel Association (CPA)
EPA-HQ-OPPT-2023-0613-0083	Decorative Hardwoods Association (DHA)
EPA-HQ-OPPT-2023-0613-0085	American Home Furnishings Alliance (AHFA)
EPA-HQ-OPPT-2023-0613-0087	Paul Selberg
EPA-HQ-OPPT-2023-0613-0088	Larry Jackson
EPA-HQ-OPPT-2023-0613-0089	Greg Esposito
EPA-HQ-OPPT-2023-0613-0090	Tom Morley
EPA-HQ-OPPT-2023-0613-0091	United States Small Business Administration (SBA)
EPA-HQ-OPPT-2023-0613-0092	Dustin Theis
EPA-HQ-OPPT-2023-0613-0093	Max Carter
EPA-HQ-OPPT-2023-0613-0094	Darryl Moss
EPA-HQ-OPPT-2023-0613-0095	The Fertilizer Institute (TFI)
EPA-HQ-OPPT-2023-0613-0096	Lela Graham
EPA-HQ-OPPT-2023-0613-0097	Methanol Institute (MI)
EPA-HQ-OPPT-2023-0613-0098	National Aquaculture Association

EPA-HQ-OPPT-2023-0613-0099	Erik Somerfeld
EPA-HQ-OPPT-2023-0613-0100	Gary Kanan
EPA-HQ-OPPT-2023-0613-0101	Fay Beydoun
EPA-HQ-OPPT-2023-0613-0102	Theresa Stechschulte
EPA-HQ-OPPT-2023-0613-0103	Sandra Jauregui
EPA-HQ-OPPT-2023-0613-0104	PotlatchDeltic Corporation
EPA-HQ-OPPT-2023-0613-0105	Jacob Welch
EPA-HQ-OPPT-2023-0613-0106	American Chemistry Council (ACC) Formaldehyde Panel (Part 1 of 2)
EPA-HQ-OPPT-2023-0613-0107	American Chemistry Council (ACC) Formaldehyde Panel (Part 2 of 2)
EPA-HQ-OPPT-2023-0613-0108	U.S. Senator Emanuel Jones
EPA-HQ-OPPT-2023-0613-0109	Braden Gourley
EPA-HQ-OPPT-2023-0613-0110	Jared Nace
EPA-HQ-OPPT-2023-0613-0113	American Chemistry Council (ACC) Formaldehyde Panel (Part 1 of 5)
EPA-HQ-OPPT-2023-0613-0114	American Chemistry Council (ACC) Formaldehyde Panel (Part 2 of 5)
EPA-HQ-OPPT-2023-0613-0115	American Chemistry Council (ACC) Formaldehyde Panel (Part 3 of 5)
EPA-HQ-OPPT-2023-0613-0116	American Chemistry Council (ACC) Formaldehyde Panel (Part 4 of 5)
EPA-HQ-OPPT-2023-0613-0117	American Chemistry Council (ACC) Formaldehyde Panel (Part 5 of 5)
EPA-HQ-OPPT-2023-0613-0118	Caleb Wright
EPA-HQ-OPPT-2023-0613-0119	Steven Rzeppa
EPA-HQ-OPPT-2023-0613-0120	Kattya Valdex Douglas
EPA-HQ-OPPT-2023-0613-0121	Dave Lewis
EPA-HQ-OPPT-2023-0613-0122	Nicholas Tellez
EPA-HQ-OPPT-2023-0613-0123	Alec LaPlante
EPA-HQ-OPPT-2023-0613-0124	Jeff Winston
EPA-HQ-OPPT-2023-0613-0125	Michael Andazola
EPA-HQ-OPPT-2023-0613-0126	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0127	American Chemistry Council (ACC)
EPA-HQ-OPPT-2023-0613-0128	U.S. Senator Mike Braun, et al.
EPA-HQ-OPPT-2023-0613-0129	American Chemistry Council (ACC) Formaldehyde Panel (Attachment 8 from Part 5 of 5)
EPA-HQ-OPPT-2023-0613-0130	Reuban D'Silva
EPA-HQ-OPPT-2023-0613-0131	Billy Mitchell
EPA-HQ-OPPT-2023-0613-0132	Sam Deley
EPA-HQ-OPPT-2023-0613-0133	Valerie Adams
EPA-HQ-OPPT-2023-0613-0134	Michael Wray
EPA-HQ-OPPT-2023-0613-0135	Joe Rozell
EPA-HQ-OPPT-2023-0613-0136	Marco Rauda
EPA-HQ-OPPT-2023-0613-0137	Louisiana-Pacific Corporation (LP)

EPA-HQ-OPPT-2023-0613-0138	Chad Thompson
EPA-HQ-OPPT-2023-0613-0139	Michelle Gorelow
EPA-HQ-OPPT-2023-0613-0140	Harvey Checkoway
EPA-HQ-OPPT-2023-0613-0141	The Fertilizer Institute (TFI)
EPA-HQ-OPPT-2023-0613-0142	American Home Furnishings Alliance (AHFA), International Wood Products Association (IWPA) and National Retail Federation (NRF)
EPA-HQ-OPPT-2023-0613-0143	Bakelite Synthetics
EPA-HQ-OPPT-2023-0613-0144	National Association of Landscape Professionals (NALP)
EPA-HQ-OPPT-2023-0613-0145	Raptor Pharm & Tox, Ltd
EPA-HQ-OPPT-2023-0613-0146	Shelly Russel
EPA-HQ-OPPT-2023-0613-0147	Composite Panel Association (CPA)
EPA-HQ-OPPT-2023-0613-0148	American Chemistry Council Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0149	Jonathan Pattilo
EPA-HQ-OPPT-2023-0613-0150	U.S. Representative Donald G. Davis et al.
EPA-HQ-OPPT-2023-0613-0151	American Veterinary Medical Association (AVMA)
EPA-HQ-OPPT-2023-0613-0152	American Wood Council (AWC) and American Forest & Paper Association (AF&PA)
EPA-HQ-OPPT-2023-0613-0153	Dennis Paustenbach
EPA-HQ-OPPT-2023-0613-0154	Lester Jackson
EPA-HQ-OPPT-2023-0613-0155	American Chemistry Council (ACC)
EPA-HQ-OPPT-2023-0613-0156	American Feed Industry Association (AFIA)
EPA-HQ-OPPT-2023-0613-0157	California Air Resources Board
EPA-HQ-OPPT-2023-0613-0158	American Association of Veterinary Laboratory Diagnosticians (AAVLD)
EPA-HQ-OPPT-2023-0613-0159	Anonymous
EPA-HQ-OPPT-2023-0613-0160	Jimmy Avery
EPA-HQ-OPPT-2023-0613-0161	Hexion Inc.
EPA-HQ-OPPT-2023-0613-0162	American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0163	ToxStrategies LLC
EPA-HQ-OPPT-2023-0613-0164	Celanese Corporation
EPA-HQ-OPPT-2023-0613-0166	American Wood Council and American Forest & Paper Association
EPA-HQ-OPPT-2023-0613-0167	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0168	Raptor Pharm & Tox, Ltd
EPA-HQ-OPPT-2023-0613-0169	Methanol Institute (MI)
EPA-HQ-OPPT-2023-0613-0170	Craig Gilchrist
EPA-HQ-OPPT-2023-0613-0171	U.S. Senator Donzella James
EPA-HQ-OPPT-2023-0613-0172	Louisiana Pacific Corporation (LP)
EPA-HQ-OPPT-2023-0613-0173	Squire Patton Boggs LLP
EPA-HQ-OPPT-2023-0613-0174	EGGER Wood Products, LLC
EPA-HQ-OPPT-2023-0613-0175	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0176	Independent Lubricant Manufacturers Association (ILMA)
EPA-HQ-OPPT-2023-0613-0177	Tunga Salthammer

EPA-HQ-OPPT-2023-0613-0178	American Veterinary Medical Association (AVMA)
EPA-HQ-OPPT-2023-0613-0179	Christoph Thriel
EPA-HQ-OPPT-2023-0613-0180	Exponent
EPA-HQ-OPPT-2023-0613-0181	Patty Stinson
EPA-HQ-OPPT-2023-0613-0182	ALL4 LLC
EPA-HQ-OPPT-2023-0613-0183	New Hampshire Timberland Owners Association (NHTOA)
EPA-HQ-OPPT-2023-0613-0184	Maine Forest Products Council
EPA-HQ-OPPT-2023-0613-0185	Kennis Wilkins
EPA-HQ-OPPT-2023-0613-0186	Southeastern Lumber Manufacturers Association (SLMA)
EPA-HQ-OPPT-2023-0613-0187	Mark Cardenas
EPA-HQ-OPPT-2023-0613-0188	Michigan Forest Products Council
EPA-HQ-OPPT-2023-0613-0189	Roseburg Forest Products Co.
EPA-HQ-OPPT-2023-0613-0190	American Forest & Paper Association (AF&PA) and American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0191	Rory Conolly
EPA-HQ-OPPT-2023-0613-0192	Arizona State Representative Myron Tsosie
EPA-HQ-OPPT-2023-0613-0193	Washington Forest Protection Association (WFPA)
EPA-HQ-OPPT-2023-0613-0194	American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0195	Georgia-Pacific Gypsum LLC
EPA-HQ-OPPT-2023-0613-0196	The Westervelt Company
EPA-HQ-OPPT-2023-0613-0197	LeeAnn McLaughlin
EPA-HQ-OPPT-2023-0613-0198	West Virginia Forestry Association (WVFA)
EPA-HQ-OPPT-2023-0613-0199	Aerospace Industries Association (AIA)
EPA-HQ-OPPT-2023-0613-0200	Melissa Vincent
EPA-HQ-OPPT-2023-0613-0201	Arizona State Representative
EPA-HQ-OPPT-2023-0613-0202	Composite Panel Association (CPA)
EPA-HQ-OPPT-2023-0613-0203	RV Industry Association (RVIA)
EPA-HQ-OPPT-2023-0613-0204	Harvey Clewell
EPA-HQ-OPPT-2023-0613-0205	American Wood Council (AWC)
EPA-HQ-OPPT-2023-0613-0206	Pennsylvania Farm Bureau (PFB)
EPA-HQ-OPPT-2023-0613-0207	Methanol Institute (MI)
EPA-HQ-OPPT-2023-0613-0208	California Department of Food and Agriculture's (CDFA) Antimicrobial Use and Stewardship (AUS)
EPA-HQ-OPPT-2023-0613-0209	State of Iowa Department of Justice, Office of the Attorney General
EPA-HQ-OPPT-2023-0613-0210	Anitox Corporation
EPA-HQ-OPPT-2023-0613-0211	American Chemistry Council (ACC)
EPA-HQ-OPPT-2023-0613-0212	William Thompson
EPA-HQ-OPPT-2023-0613-0213	Robinan Gentry and Chad Thompson
EPA-HQ-OPPT-2023-0613-0214	Alliance for Chemical Distribution (ACD)
EPA-HQ-OPPT-2023-0613-0215	National Association of Landscape Professionals
EPA-HQ-OPPT-2023-0613-0216	National Corn Growers Association (NCGA)
EPA-HQ-OPPT-2023-0613-0217	Louisiana-Pacific Corporation (LP)
EPA-HQ-OPPT-2023-0613-0218	The Toy Association

EPA-HQ-OPPT-2023-0613-0219	Center for Environmental Accountability (CEA)
EPA-HQ-OPPT-2023-0613-0220	American Chemistry Council (ACC)
EPA-HQ-OPPT-2023-0613-0221	Exponent
EPA-HQ-OPPT-2023-0613-0222	Dennis Paustenbach
EPA-HQ-OPPT-2023-0613-0223	National Funeral Directors Association (NFDA)
EPA-HQ-OPPT-2023-0613-0224	Alliance for Automotive Innovation
EPA-HQ-OPPT-2023-0613-0225	National Council for Air and Stream Improvement, Inc. (NCASI)
EPA-HQ-OPPT-2023-0613-0226	James Sherman
EPA-HQ-OPPT-2023-0613-0227	Decorative Hardwoods Association, (DHA) Hardwood Federation, and National Wood Flooring Association (NWFA)
EPA-HQ-OPPT-2023-0613-0228	PotlatchDeltic Corporation
EPA-HQ-OPPT-2023-0613-0229	Exponent
EPA-HQ-OPPT-2023-0613-0230	North American Insulation Manufacturers Association (NAIMA)
EPA-HQ-OPPT-2023-0613-0231	Pamela Dalton
EPA-HQ-OPPT-2023-0613-0232	Ohio Chemistry Technology Council (OCTC)
EPA-HQ-OPPT-2023-0613-0233	International Wood Products Association (IWPA)
EPA-HQ-OPPT-2023-0613-0234	American Foundry Society (AFS)
EPA-HQ-OPPT-2023-0613-0235	American Chemistry Council (ACC) Formaldehyde Panel
EPA-HQ-OPPT-2023-0613-0236	Linda D. Dell
EPA-HQ-OPPT-2023-0613-0237	Polyurethane Foam Association (PFA)
EPA-HQ-OPPT-2023-0613-0238	BASF Corporation
EPA-HQ-OPPT-2023-0613-0239	Robinan Gentry
EPA-HQ-OPPT-2023-0613-0240	IPC International, Inc
EPA-HQ-OPPT-2023-0613-0241	Asphalt Roofing Manufacturers Association (ARMA)
EPA-HQ-OPPT-2023-0613-0242	National Aquaculture Association
EPA-HQ-OPPT-2023-0613-0243	North American Home Furnishings Association (HFA)
EPA-HQ-OPPT-2023-0613-0244	Environmental Defense Fund (EDF)
EPA-HQ-OPPT-2023-0613-0245	The Fertilizer Institute (TFI)
EPA-HQ-OPPT-2023-0613-0246	Household & Commercial Products Association (HCPA)
EPA-HQ-OPPT-2023-0613-0247	Responsible Industry for a Sound Environment (RISE)
EPA-HQ-OPPT-2023-0613-0248	Integral Consulting Inc.
EPA-HQ-OPPT-2023-0613-0249	The Adhesive and Sealant Council
EPA-HQ-OPPT-2023-0613-0250	The Scotts Company LLC
EPA-HQ-OPPT-2023-0613-0251	The Fertilizer Institute et al.
EPA-HQ-OPPT-2023-0613-0252	Environmental Defense Fund (EDF)
EPA-HQ-OPPT-2023-0613-0253	American Feed Industry Association et al.
EPA-HQ-OPPT-2023-0613-0254	Gradient
EPA-HQ-OPPT-2023-0613-0255	Chad Thompson
EPA-HQ-OPPT-2023-0613-0256	American Soybean Association (ASA)
EPA-HQ-OPPT-2023-0613-0257	The National Association of Manufacturers (NAM)
EPA-HQ-OPPT-2023-0613-0258	SciPinion
EPA-HQ-OPPT-2023-0613-0259	Integral Consulting Inc.
EPA-HQ-OPPT-2023-0613-0260	Hexion Inc.

EPA-HQ-OPPT-2023-0613-0261	Environmental Protection Network (EPN)
EPA-HQ-OPPT-2023-0613-0262	American Coatings Association (ACA)
EPA-HQ-OPPT-2023-0613-0263	University of California, San Francisco et al.
EPA-HQ-OPPT-2023-0613-0264	American Chemistry Council (ACC)
EPA-HQ-OPPT-2023-0613-0265	Pennsylvania Grange
EPA-HQ-OPPT-2023-0613-0266	U.S. Tire Manufacturers Association (USTMA)
EPA-HQ-OPPT-2023-0613-0267	American Chemistry Council Diisocyanates Panel
EPA-HQ-OPPT-2023-0613-0268	Northwest Indian Fisheries Commissioner
EPA-HQ-OPPT-2023-0613-0269	Dow Chemical
EPA-HQ-OPPT-2023-0613-0270	American Home Furnishings Alliance (AHFA), International Wood Products Association (IWPA), and National Retail Federation (NRF)
EPA-HQ-OPPT-2023-0613-0277	Covestro LLC
EPA-HQ-OPPT-2023-0613-0278	Melissa Vincent
EPA-HQ-OPPT-2023-0613-0279	Grace Thomas
EPA-HQ-OPPT-2023-0613-0280	Ray Brown
EPA-HQ-OPPT-2023-0613-0281	Paul Putz
EPA-HQ-OPPT-2023-0613-0282	Doug Neil
EPA-HQ-OPPT-2023-0613-0283	Earthjustice et al.
EPA-HQ-OPPT-2023-0613-0286	Celanese Corporation
EPA-HQ-OPPT-2023-0613-0287	Earthjustice (Part 1 of 3)
EPA-HQ-OPPT-2023-0613-0288	Earthjustice (Part 2 of 3)
EPA-HQ-OPPT-2023-0613-0289	Earthjustice (Part 3 of 3)

Section 1 – Overarching comments

Comments associated with this issue are summarized in the subsections below.

Section 1.1 – Scope of the draft risk evaluation

General comments

Summary: A public commenter (0260) stated that EPA is required to use transparent criteria in instances where a statute gives EPA discretion in weighing scientific information, but the draft risk evaluation fails to do so in its selection of which risks to evaluate, how it evaluated unreasonable risk against background levels, and in its approach to excluding critical studies.

EPA Response: Under TSCA section 6(b)(4)(A), EPA is required to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by EPA, under the conditions of use. The revised assessment includes descriptions of various conditions of use of formaldehyde for which risks were evaluated for formaldehyde and explanation of the criteria used to evaluate studies and the conduct of the risk evaluation. The risk evaluation includes several technical support documents that detail EPA's approach to assessing human and environmental hazard and occupational, consumer, indoor air, ambient air, and environmental exposures to formaldehyde. The risk determination provides an explanation of those conditions of use that either significantly contribute to or do not significantly contribute to unreasonable risk. As described in the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 89 FR 37028, 37031 (May 3, 2024), "the Agency is fully committed to meeting the requirements in the law, and to being transparent in each risk evaluation with respect to how scientific information, technical procedures, measures, methods, protocols, methodologies, or models are being employed in a manner consistent with the best available science and how decisions are based on the weight of the scientific evidence, as required by 15 U.S.C. 2625(h) and (i)." The Rule further states, "The phrase WoSE or weight of evidence (WoE) is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to the quality of the studies evaluated, and how findings are assessed and integrated. EPA broadly uses the WoSE approach in many existing programs and has described the application of WoSE in Agency guidance used to classify carcinogens. EPA believes WoSE inherently involves application of professional judgment, in which the significant issues, strengths, limitations of the data, uncertainties, and interpretations are presented and highlighted." 89 FR at 37044 (references omitted).

Wood articles

Summary: Several public commenters (0172, 0174, 0183, 0184, 0188, 0193, 0194, 0196, 0198, 0217, 0227, 0228) stated that EPA correctly concluded that biogenic emissions are outside the scope of the draft risk evaluation. The commenters said that EPA should clarify that the term "biogenic emissions" applies broadly to any formaldehyde that was produced by an organism. Therefore, raw wood should be excluded from the scope of the draft risk evaluation, and any wood products that contribute to an unreasonable risk under any condition of use must rest that conclusion on the formaldehyde emissions that is attributable to formaldehyde-added components, according to the commenters.

A public commenter (0202) stated that EPA should formally remove products covered by the Formaldehyde Standards for Composite Wood Products Act of 2010 from the scope of the draft risk evaluation, commenting that EPA has no authority to alter or ignore the specific emissions limits in the

statute. The commenter said that the wood in composite wood products is a biogenic source of formaldehyde that is outside the scope of the draft risk evaluation. Another public commenter (0147) stated that, as a result of the Formaldehyde Standards for Composite Wood Products Act of 2010, the formaldehyde emissions from these products are very highly regulated. Similarly, two public commenters (0224, 0233) expressed concern that EPA has determined that it will include all composite wood products in the risk assessment, despite these products already being regulated under Toxic Substances Control Act (TSCA) Title VI and after initially determining that composite wood products and laminated products currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule were outside the scope. One of the commenters (0224) added that it is unclear why EPA is including a use already regulated by TSCA, saying that EPA is in effect overriding its existing TSCA regulations and possibly leading to unintended consequences, such as the potential to circumvent the requirements of the Administrative Procedure Act (APA). The other commenter (0233) said that EPA is failing to follow correct procedures under TSCA by unilaterally adding these products back to the scope without providing a revised scoping document and opening a comment period. A public commenter (0218) stated that formaldehyde emissions from particleboard, hardwood plywood, medium-density fiberboard and thin medium-density fiberboard are specifically and explicitly addressed by a separate congressional mandate. The commenter requested that EPA confirm the following statement: "since the formaldehyde considerations related to composite wood products are statutorily addressed independent of this action, the materials and conditions covered by TSCA Title VI will be excluded from further consideration and do not need to be covered further under the draft risk evaluation review or following risk assessment review."

Conversely, a public commenter (0244) remarked that EPA cannot dismiss the entire condition of use containing these wood products because it also contains paper, metal, stone, and other articles that are not included in the TSCA Title VI regulations.

EPA Response: EPA does not consider biogenic formation of formaldehyde, such as emissions from trees, plants, and soil microbes, to be conditions of use under TSCA section 3(4). The biogenic formation can contribute to total formaldehyde concentration in ambient air. EPA does not consider wood articles and composite wood products under TSCA Title VI to only emit biogenic sources of formaldehyde from the raw wood product. Very rarely are raw wood sources integrated into finished goods without additional fabrication which entails lamination and application of formaldehyde-based resins.

As first announced on June 30, 2021, and codified by regulation at 40 CFR 702.39(d)(9) in 2024, EPA is no longer excluding exposure pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations. As explained in the preamble to the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act* (89 FR 37028, May 3, 2024) EPA does not interpret TSCA section 6(b)(4)(D) to provide authority to exclude conditions of use or exposure pathways from the scope of TSCA risk evaluations and will no longer exclude from the scope of TSCA risk evaluations exposure pathways that are addressed or could in the future be addressed by other EPA-administered statutes and regulatory programs or under another Federal law administered by another agency. Accordingly, EPA is no longer excluding from the scope of the Risk Evaluation for Formaldehyde the exposure pathways as it pertains to composite wood products under TSCA Title VI.

EPA has determined that excluding TSCA Title VI regulated composite wood products from the formaldehyde risk evaluation would reduce the comprehensiveness of the risk evaluation and introduce

complexities and uncertainties due to the regulated vs. non-regulated materials that may be present in a finished good in indoor environments.

Replacement parts

Summary: A public commenter (0224) said that the draft risk evaluation makes no mention of TSCA section 6(c)(2)(D) and its exemption for replacement parts and suggested that EPA should clearly state in the final risk evaluation that replacement parts were not assessed and therefore remain exempt per TSCA section 6(c)(2)(D).
EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use (COUs). Consideration of TSCA section 6(c)(2)(D) is appropriate after a determination of unreasonable risk for the chemical substance and during any necessary risk management under TSCA Section 6(a). EPA found unreasonable risk for certain COUs that involve articles and based on the risk estimates and exposure scenarios for each COU, EPA will make a determination during risk management on whether or not to exempt replacement parts under TSCA section 6(c)(2)(D). Several COUs that significantly contribute to unreasonable risk involve articles and EPA suspects that certain articles would be considered replacement parts under those COUs. A detailed analysis on how replacement parts under certain COUs would be addressed would be considered during the risk management phase.

Section 1.2 – Conditions of use

General comments on conditions of use

Summary: A public commenter (0246) recommended that EPA focus on the manufacturing, processing, and intentional uses of formaldehyde that present the greatest likelihood of exposure if not properly managed, commenting that formaldehyde is a building-block chemical.
EPA Response: TSCA § 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA evaluated these COUs of formaldehyde identified and described in the *Conditions of Use of the Risk Evaluation for Formaldehyde*. These COUs include the manufacturing, processing, distribution in commerce, industrial, commercial, and consumer uses, and disposal of formaldehyde as required under TSCA. As explained in the final rule amending the Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA) (89 FR 37028, May 3, 2024), EPA lacks authority to exclude conditions of use from the scope of a risk evaluation. EPA must apply fact and professional judgment in determining whether a particular circumstance is known, intended or reasonably foreseen—and lacks authority to select among those circumstances for inclusion or exclusion. However, consistent with 40 CFR 702.37(a)(4), EPA has taken a fit-for-purpose approach in the risk evaluation, varying the types and levels of analysis for certain COUs and exposure pathways as necessary to determine whether formaldehyde presents an unreasonable risk of injury to health or the environment.

Formaldehyde-based resins

Summary: A public commenter (0230) described formaldehyde-based resin use in the fiberglass insulation industry. The commenter said that formaldehyde-based resins continue to be used in the fiberglass industry in certain products where a suitable substitute does not exist, the current uses are already well regulated by EPA and the Occupational Safety and Health Administration (OSHA), and the air emissions pose an acceptable risk under the Clean Air Act. The commenter recommended EPA affirm that this condition of use for formaldehyde poses no unreasonable risk and should not be subject to further regulation under TSCA. Finally, the commenter drew a distinction between insulation manufacturers who are resin users and resin manufacturers, commenting that resin uses should not be identified as conditions of use that require risk reduction measures because the formaldehyde has already been reacted into the resin during the resin manufacturing process.

A public commenter (0241) said that the draft risk evaluation misclassifies the conditions of use pertaining to asphalt roofing and fiberglass manufacturing, saying that "incorporation into a formulation, mixture or reaction product" and "processing as a reactant" have no relevance to formaldehyde use in this case. Inclusion of asphalt roofing manufacturing under this COU is misplaced, as none of these processes involve the mixing or blending of formaldehyde with other materials to obtain a product or mixture, only the use of finished fiberglass mat previously made with a urea-formaldehyde-based binder.

Another public commenter (0262) said that evaluating paints and adhesives separately from processing formaldehyde into resins would provide a more accurate assessment of the risks of this use. The commenter said that the current condition of use, processing as a reactant (all industries), includes both upstream activity of resin manufacture and downstream processing of resins into formulated products. According to the commenter, failing to distinguish these activities drives the assessment of paint, coatings, and adhesive formulation towards higher worker exposure than realistically experienced during these downstream activities. The commenter recommended EPA disaggregate the data for upstream and downstream uses to more accurately reflect the lower exposures experienced during downstream manufacture of formulated products.

A public commenter (0234) stated that EPA's draft risk evaluation omits the industrial/non-incorporative condition of use of formaldehyde in foundries, where resins produced from formaldehyde provide an essential material for production of castings. The commenter said that this omission could lead to unnecessary restrictions on the use of formaldehyde in this industry, potentially triggering detrimental impacts. The commenter said that the process description for foundries in the Draft Occupational Exposure Assessment for Formaldehyde does not provide a complete and representative overview of how formaldehyde is used in foundries. The commenter described the use of formaldehyde in foundries, including in the form of chemical binder systems, or resin systems, which are used to produce molds or cores for various processes.

Several public commenters (0183, 0184, 0188, 0194, 0196, 0198, 0228, 0270) said that the use of formaldehyde-based resins in wood products is already highly regulated under TSCA Title VI, California Air Resources Board (CARB) emission standards, and Canada's regulations. The commenters said that the risk assessment must consider the additional regulations on hardwood plywood, medium density fiberboard, and particle board.

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed

or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use (COUs). TSCA section 3(4) defines "conditions of use" as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA evaluated these COUs that were identified and described in the *Conditions of Use of the Risk Evaluation for Formaldehyde*. EPA must evaluate all COUs to determine if the chemical presents unreasonable risk, including those that are regulated under other federal statutes, and where EPA makes a determination of unreasonable risk, EPA will identify the COUs that significantly contribute to such determination. (See 40 CFR 702.37(a)(4), 702.39(d)(9), 702.39(f)).

Formaldehyde-based resins used in the manufacturing of fiberglass and mineral wool insulation products were determined to be a COU as a part of the category and subcategory: *Processing – Incorporation into an Article – Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing.* EPA received public comments from this commentor (0230) regarding fiberglass insulation as well as information from other sources to evaluate this COU. Formaldehyde resins are used in fiberglass, stonewool, rockwool, and slag wool building insulation materials as a binder. Sources also indicate the use of phenol-formaldehyde based resins to produce foam insulation. EPA determined that this COU does significantly contribute to the unreasonable risk to for formaldehyde to workers through acute dermal exposures, acute inhalation exposures, and cancer inhalation exposures.

EPA disagrees with the commentor (0241) suggestion of not including the use of formaldehyde-based resin use in the fiberglass insulation. Formaldehyde is mainly used to produce industrial resins (urea-formaldehyde, phenol-formaldehyde, polyacetal, and melamine-formaldehyde), accounting for approximately 50 percent of total consumption. These resins are used in a wide variety of applications, including plastics, composite wood products, foam, thermosets and molding compounds, adhesives, surface coatings, paper and textile treatment, and foundry binders. Formaldehyde also has several functional uses in the manufacture of plastic material and resins, including:

- As an intermediate for processing (as a reactant; incorporation into formulation, mixture, or reaction product);
- As an adhesive and sealant chemical for processing (as a reactant; incorporation into formulation, mixture, or reaction product);
- As a paint additive and coating additive not described by other categories for processing
- (incorporation into formulation, mixture, or reaction product);
- As a surface active agent for processing (incorporation into formulation, mixture, or reaction product);
- As a plasticizer for processing (as a reactant; incorporation into formulation, mixture, or reaction product);
- As an abrasive for processing (as a reactant);
- As an ion exchange agent for processing (as a reactant);
- As an agricultural chemical (non-pesticidal) for processing (as a reactant);
- As a processing aid, not otherwise listed for processing; and
- As a plastics hardener.

During the development of the Final Scope for the Risk Evaluation for Formaldehyde 50-00-0, EPA received information via public comment which indicate that urea-formaldehyde resin may be used in glass fiber roofing mats to bind the fiberglass fibers. EPA also received comment that formaldehyde has been found in emissions from heated storage tanks supplying the hot asphalt to fiberglass mat coating operations. Based on this information, EPA developed the following COU: *Processing—Incorporation into a formulation, mixture, or reaction product - Asphalt, paving, roofing, and coating*

materials manufacturing. The type of operation for the processing – incorporation into a formulation, mixture, or reaction product category includes the use of a chemical substance that is added to a product (or mixture) prior to further distribution of the product. In this case, urea-formaldehyde resin is added to a product or mixture as a binder to bind the fiberglass fibers in order manufacture the glass fiber roofing mats which are then used as a substrate for other roofing products.

EPA acknowledges comments (0262) regarding the COU *adhesives and sealants* and *paint and coatings.* These types of products are included under a number of different COUs, including processing, industrial use, commercial, and consumer uses. This allowed EPA to fully evaluate any potential significant contribution to the unreasonable risk for the full life cycle of formaldehyde in these products, including upstream and downstream COUs. EPA identified exposure scenarios related to the COUs of formaldehyde. An exposure scenario is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within a particular COU. Several of the COU categories and subcategories were grouped and assessed together in a single exposure scenario due to similarities in the processes or lack of data to differentiate between them. In the case of this COU, *Processing – Reactant – All Subcategories*, the 2020 CDR indicates that formaldehyde is processed as a reactant in the following industrial sectors: plastics product manufacturing; wood product manufacturing; paper manufacturing; plastics material and resin manufacturing; all other basic organic chemical manufacturing; agriculture, forestry, hunting, and fishing; paint and coating manufacturing; construction; adhesive manufacturing; petrochemical manufacturing; and synthetic rubber manufacturing. EPA evaluated with one single exposure scenario all the processing as a reactant COUs as a feedstock in the production of another chemical product via a chemical reaction in which formaldehyde is consumed. The *adhesives and sealants* and *paint and coatings* are further evaluated under commercial and consumer COUs to determine if downstream COUs significantly contribute to the unreasonable risk. Under these COUs, formaldehyde is used in a variety of paints and coatings, including lacquers, stains, varnishes, primers, topcoats, and specialty coatings.

In response to commenter (0234), the COUs for formaldehyde were developed beginning with the prioritization and scoping phase which ended with the publication of the Final Scope for the Risk Evaluation for Formaldehyde 50-00-0and were updated during the risk evaluation phase as described in the *Conditions of Use of the Risk Evaluation for Formaldehyde*. EPA identified that formaldehyde is used in the manufacture of basic metals and fabricated metal products. Several sources identified formaldehyde as a chemical intermediate in the production of foundry binders and that phenol-formaldehyde resins are used in foundry mold binders. The use of formaldehyde in foundries was not reported in the 2016 or 2020 Chemical Data Reporting. The use of foundries was included under the *Industrial Use - Paints and coatings; adhesives and sealants; lubricants* COU and evaluated with the Occupational Exposure Scenario (OES), *foundries.* Under this OES, EPA stated that workers are potentially exposed to formaldehyde during foundry processes during loading/unloading of transport containers, container and equipment cleaning, during decanting of resin into mixers, and during core making. Other literature sources stated common engineering controls are exhaust ventilation systems. EPA did not identify the extent to which workers used PPE at foundry facilities. Occupational non-users include employees (e.g., supervisors, managers) at foundry sites who do not directly handle formaldehyde. Therefore, the ONUs are expected to have lower inhalation exposures, lower vapor through-skin uptake, and no expected dermal exposure.

In response to the following commenters ((0183, 0184, 0188, 0194, 0196, 0198, 0228, 0270), as first announced on June 30, 2021, and codified by regulation at 40 CFR 702.39(d)(9) in 2024, EPA is no longer excluding exposure pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations. As explained in the preamble to the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act* (89 FR

37028, May 3. 2024) EPA does not interpret TSCA section 6(b)(4)(D) to provide authority to exclude conditions of use or exposure pathways from the scope of TSCA risk evaluations and will no longer exclude from the scope of TSCA risk evaluations exposure pathways that are addressed or could in the future be addressed by other EPA-administered statutes and regulatory programs or under another Federal law administered by another agency. Accordingly, consistent with the draft risk evaluation, EPA is no longer excluding from the scope of the Risk Evaluation for Formaldehyde the exposure pathways as it pertains to composite wood products under TSCA Title VI.
EPA has determined that excluding TSCA Title VI regulated composite wood products from the formaldehyde risk evaluation would reduce the comprehensiveness of the risk evaluation and introduce complexities and uncertainties due to the regulated vs. non-regulated materials that may be present in a finished good in indoor environment. In the final risk evaluation, EPA's indoor air exposure assessment for COUs involving composite wood products takes into consideration the emission standards established under TSCA Title VI and implementing regulations at 40 CFR part 770, as well as reasonably available information on emission factors for composite wood products following implementation of those standards.

Summary: A public commenter (0238) stated that formaldehyde is used to process and synthesize other substances such as 1,4 butanediol (BOO; CASRN 110-63-4) and its derivatives, neopentylglycol (NPG; CASRN 126-30-7), 4,4' Methylenedi (phenyl isocyanate) (MDI; CASRN 101-68-8) and its derivatives, chelating agents, and other substances. The commenter said that limiting or banning the use of formaldehyde for these processes would impact many end users. Finally, the commenter said that there are no reasonable alternatives for formaldehyde as a building block for producing these products, and the formaldehyde is managed in closed operational equipment and completely consumed during the manufacturing process.

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the TSCA conditions of use (COUs). As explained in the unreasonable risk determination, since EPA has determined that formaldehyde presents an unreasonable risk under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA will consider the comments received as it develops risk management options for formaldehyde. TSCA section 6(c)(2) requires that EPA considers several factors when selecting among possible TSCA section 6(a) requirements. TSCA section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that: the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety (15 U.S.C. 2605(g)(1)).

In selecting among prohibitions and other restrictions during risk management rulemaking, TSCA section 6(c)(2)(B) requires EPA to factor in, to the extent practicable, the following considerations: (i) The effects of formaldehyde on health and the magnitude of exposure of human beings to formaldehyde, (ii) the effects of formaldehyde on the environment and the magnitude of exposure of the environment to formaldehyde, (iii) the benefits of formaldehyde for various uses, and (iv) the

reasonably ascertainable economic consequences of the rule. In addition, TSCA section 6(c)(2)(C) requires that, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect.

Summary: A public commenter (0269) stated that the condition of use "processing as a reactant, manufacturing of base chemicals" covers 14 diverse industries under the same exposure assessment, for which EPA used worst case assumptions for all of the industries and tasks combined. The commenter said that these assumptions were then used for one overall dermal and inhalation exposure assessment that indicated unreasonable risk. The commenter wrote that this use of worst-case assumptions grossly overestimates risk and said it is EPA's responsibility to apply generally accepted risk assessment principles to refine these exposure estimates and break out the individual tasks and industries. The commenter said that it has two product lines, production of chelating agents and production of polymeric methylene diphenyl diisocyanate (MDI), that currently use formaldehyde for which there are no alternatives, meaning that the commenter would be unable to produce these products in the United States.

EPA Response: As described by the commenter, the *processing as a reactant* COU category contains six subcategories. All six subcategories were grouped and assessed together in a single occupational exposure scenario (OES) due to similarities in the processes or lack of data to differentiate between them. EPA then made an unreasonable risk determination based on a number of factors including, the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. For each OES, EPA provides risk estimates at central tendency and high-end exposures that are representative of the OES, indicating that not all activities and all sectors represented by the OES have the same level of exposure or risk. EPA's occupational exposure assessment is supported by a large body of workplace monitoring data specific to the exposure scenarios assessed., Some of the monitoring data identified (e.g., OSHA CEHD) were limited in contextual information such as site identification, worker activities and process conditions, such that EPA used the North American Industrial Classification System (NAICS) codes to assign data to the respective exposure scenario. In the final risk evaluation, EPA has explained how each COU significantly contributes to the unreasonable risk of formaldehyde, including the p*rocessing as a reactant* COUs. TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the TSCA COUs.

As mentioned in the Unreasonable Risk Determination, since EPA has determined that formaldehyde presents an unreasonable risk under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA will likely focus regulatory actions on the COUs that significantly contribute to the unreasonable risk of formaldehyde. TSCA section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that: the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;

compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety (15 U.S.C. 2605(g)(1)).

EPA will take into consideration the comments received as it develops risk management options for formaldehyde. TSCA section 6(c)(2)(A) requires that EPA considers several factors when proposing and promulgating a TSCA section 6(a) rule. In selecting among prohibitions and other restrictions, TSCA section 6(c)(2)(B) requires EPA to factor in, to the extent practicable, the following considerations: (i) the effects of formaldehyde on health and the magnitude of exposure of human beings to formaldehyde, (ii) the effects of formaldehyde on the environment and the magnitude of exposure of the environment to formaldehyde, (iii) the benefits of formaldehyde for various uses, and (iv) the reasonably ascertainable economic consequences of the rule. In addition, TSCA section 6(c)(2)(C) requires that, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect.

Polyurethane foam

Summary: A public commenter (0237) discussed how their member companies use formaldehyde, and how that use should be reflected in the draft risk evaluation. The commenter wrote that formaldehyde is not intentionally added to polyurethane foam, but is formed due to polyol oxidation and degradation. The commenter said that an independent certification body for polyurethane foam used in mattresses and furniture established a limit of 0.1 mg/m^3 for certified foams in 2015, and since that time have detected no failures of that limit. The commenter stated that EPA should ensure that this risk assessment reflects the "small and well-controlled role" of formaldehyde in the production and use of flexible polyurethane foam in upholstered furniture and mattresses.

EPA Response: EPA appreciates the added details and clarification when it comes polyurethane foam, in particular the certification system in place to ensure products emit low levels of formaldehyde.

Polyurethane foam falls under these two COU subcategories:

- *Commercial use - 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.*
- *Consumer use - 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.*

The commercial use of foam was evaluated using monitoring data under the Occupational Exposure Scenario (OES), *Installation and demolition of formaldehyde-based furnishings and building/ construction materials in residential, public and commercial buildings, and other structures.*

The consumer modeling considered the lowest and highest weight fractions identified in product and article safety data sheets. It should be noted that consumer modeling was conducted for all exposure scenarios where exposures were expected to be likely through a condition of use and associated scenarios, based on the best available information and data. Exposures were not assessed for scenarios which EPA expected to be unlikely based on the best available information and data.

Construction products

Summary: A public commenter (0195) stated that there is an inconsistency regarding listing the condition of use for "construction (including roofing materials)" which pertains to activities including fiberglass mats manufacturing and processing. The commenter recommended that EPA clarify why the condition of use "construction (including roofing materials)" is omitted from Table 2-1 and asked if this was an unintentional oversight. The commenter also recommended that EPA update the "Process Description (4.7.2.1)" and "Worker Activities (4.7.2.2)" sections with the "Other Composite Material Manufacturing" category in the Draft Occupational Exposure Assessment Document to clarify the relevance of the "construction (including roofing materials)" condition of use, to include the incorporation of fiberglass mats into gypsum wallboard manufacturing as an article. The commenter stated that there is uncertainty about the risk determination for this specific condition of use and it is unclear whether the activities related to fiberglass mats manufacturing within the "construction" condition of use present an unreasonable risk or not.

EPA Response: This was an accidental omission and the full COU should read: *Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing.* This COU has been corrected in the Unreasonable Risk Determination. Additionally, EPA would like to point out that this inconsistency was only represented in the Draft Unreasonable Risk Determination and the full COU was evaluated as a part of the entire risk evaluation and correctly listed in the Conditions of Use of the Risk Evaluation of Formaldehyde.

EPA is aware that there are very specific uses of formaldehyde such as the incorporation of fiberglass mats into gypsum wallboard manufacturing discussed by the commentor, that are assessed as part of large categories in the risk evaluation. EPA considers gypsum wallboard manufacturing to fall under the *Processing 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* COU. EPA has incorporated the process description and worker activities into the Occupational Exposure Assessment, Section 3.7.2 Other Composite Material Manufacturing occupational exposure scenario, which is assessed for the above referenced COU. EPA determined that this COU significantly contributes to the unreasonable risk of injury to health presented by formaldehyde. EPA intends to consider reasonably available information regarding specific uses of formaldehyde during the risk management rulemaking proceeding. As required with any Agency rulemaking subject to the notice-and-comment requirements of the Administrative Procedure Act (APA), EPA will provide opportunity for public comment on any proposed rule.

Aerospace applications

Summary: A public commenter (0199) stated that members of the Aerospace Industries Association (AIA) have reported additional uses of formaldehyde-containing materials that they would like to share with EPA: coatings (such as anti-friction coatings and varnish), cleaners, sheet molding compounds, a brazing alloy protective coating, phenolic fillers, landing gear shock strut fluid, chemical processing agents (including a bath stabilizer, reducing agent, photo resist, calibration/indicator standards), and potting compounds for electronic assemblies. The commenter added that formaldehyde is a constituent in pre-impregnated materials to make composites that are essential to the aerospace industry and have been used for decades. The commenter added that there are ongoing industry efforts to develop a bio-epoxy resin system alternative that may eliminate the need for formaldehyde formulation, however, it may take as long as 10 years to complete the necessary qualifications/certifications before becoming a viable alternative. The commenter also wrote asking that the Agency consider that the concentration of formaldehyde in these formulations may be present in trace amounts (<0.1%) or potentially excluded from the safety data sheets (SDSs) because of the proprietary nature of these formulations. The commenter stated that allowing an exemption for formulations or mixtures containing a de minimis concentration of no less than 0.1% of formaldehyde would allow for continued new materials research to proceed and stated that 0.1% is the commonly used cutoff value concentration under the Globally Harmonized System. Finally, the commenter stated that AIA members request that EPA provide advance notification if the Agency plans to regulate the presence of formaldehyde releasers as it pertains to by-products of thermal decomposition, however, it is AIA's current understanding that future TSCA regulatory actions will not impact these products.
EPA Response: As part of any proposed risk management, EPA will consider establishing a de minimus amount. In addition, as required by TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA will consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect. As required for any federal rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide notice and adequate time for public comment on any proposed risk management rulemaking.

Home furnishings

Summary: A few public commenters (0203, 0233, 0243, 0270) stated that EPA should consider exposure to formaldehyde from home furnishing and other interior wood finishes in a separate condition of use from cleaning products such as toilet and drain cleaners. One of the commenters (0270) said that EPA should create a separate condition of use for furniture, furnishings, and other interior wood finishes used in residences and find that exposure to formaldehyde from such condition of use does not contribute to an unreasonable risk to human health.
EPA Response: Based on these public comments and further information reviewed, EPA removed the toilet and drain cleaner Consumer Exposure Scenario from the 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.* EPA does not agree however that a separate COU is warranted just for wood and wood related products because the Agency has found that this COU includes several uses of formaldehyde-based resins in each of the listed products and articles. Formaldehyde-based resins are found in wood-based articles such as

composite wood articles. Wood panel articles may be used for shelving, furniture, doors, cabinets, and flooring. Formaldehyde based resins are also present in other wood products such as bamboo and cork flooring. Formaldehyde resins may also be present in fiberglass insulation and urea-formaldehyde foam insulation products which are found at local home improvement stores and department stores.

Fertilizer

Summary: A public commenter (0245) stated that EPA mischaracterizes conditions of use relevant to fertilizer in the occupational exposure assessment section and that it is apparent that EPA does not have a complete understanding of how formaldehyde is used to manufacture fertilizer products. The commenter said that EPA appears to be assuming there is free formaldehyde present in end-use fertilizer products and, as such, may not be fully aware of the chemistry of the relevant fertilizer products. Additionally, the commenter said that fertilizer manufacturing should only be included under the "processing as a reactant" condition of use, and not as "processing incorporation into a formulation, mixture or reaction product" condition of use. The commenter stated that the reasoning underlying the decision to categorize fertilizer manufacturing under two "processing" conditions of use is unclear and it appears that the categorization decisions for fertilizer manufacturing were based solely on Chemical Database Reporting (CDR) data and not an accurate understanding of the process chemistry or manufacturing practices. The commenter went on to share the differences between EPA's understanding of the term "urea formaldehyde" and the Association of American Plant Food Control Officials' (AAPFCO) definition of urea formaldehyde. The commenter stated that AAPFCO's definitions do not attempt to define products based on the quantity of fluidized bed reactor (FBR) incorporated in the synthesis of these materials, nor do they imply that any un-reacted or free-formaldehyde is present in these products. In the context of TSCA, however, urea formaldehyde would likely be interpreted to be UF-85 – a formaldehyde-based resin that does imply free formaldehyde. The commenter suggested that EPA revise the process description to represent the manufacturing of slow-release solid urea and triazone using the description of process chemistry and manufacturing practices provided in the submission.

EPA Response: The *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0* identified and described the categories and subcategories of COUs that EPA planned to consider in the formaldehyde risk evaluation. TSCA § 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA identified these conditions of use from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders both for uses currently in production and uses whose production may have ceased. During the entire risk evaluation process, EPA has continually refined the COUs as described in the *Conditions of Use of the Risk Evaluation for Formaldehyde*.

EPA disagrees with the commenter that fertilizer manufacturing should only be included in the *processing as a reactant* COU and not the *processing – incorporation into a formulation, mixture, or reaction product* COU. EPA utilized CDR data to construct the formaldehyde conditions of use table, along with other sources. Numerous companies included multiple submissions in CDR in which fertilizer products were submitted under the *processing – incorporation into a formulation, mixture, or reaction product.* As far as EPA is aware, the Agency has not received any information from such companies that the reports submitted in CDR are in any way inaccurate or do not reflect real world manufacturing processes of formaldehyde. Information that EPA received indicates that formaldehyde's functional use in the manufacture of pesticides and fertilizers is as an intermediate for

processing (as a reactant) and as an agricultural chemical for processing (incorporation into formulation, mixture, or reaction product.

Summary: A public commenter (0141) stated that three distinct nitrogen fertilizer products are produced using formaldehyde-based additives (urea, slow-release solid urea, and urea triazone liquid slow-release fertilizers), and that almost all producers of solid urea globally incorporate a formaldehyde-based additive in small amounts into the process reaction, most commonly urea-formaldehyde, to improve product handling and storage quality. The urea manufacturing conditions chemically ensure that the formaldehyde additives irreversibly react so there is no unreacted formaldehyde in the finished product. The commenter added that the three conditions of use that received preliminary unreasonable risk determinations and involve fertilizer manufacturing or its commercial use are: (1) Processing - as a reactant in (a)n intermediate in pesticide, fertilizer, and other agricultural chemical manufacturing; (2) Processing - incorporation into a formulation, mixture, or reaction product, in agricultural chemicals (non-pesticidal) in agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing; and (3) Commercial use in lawn and garden products. The commenter said that EPA's preliminary determinations do not, however, fully reflect the chemical process through which formaldehyde is used; the actual risk levels in the fertilizer manufacturing process; or a comprehensive evaluation of peer-reviewed studies and international assessments that is required pursuant to TSCA.

EPA Response: EPA presented the draft risk evaluation to the SACC for an independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA, fulfilling the requirements of TSCA. In addition, the draft risk evaluation was also available for public comment. EPA has taken in consideration the SACC review and all the public comments received in the final risk evaluation. In the Occupational Exposure Assessment for Formaldehyde, EPA has updated the process descriptions related to the manufacturing of fertilizer using formaldehyde in Section 3.3.1 Processing as a Reactant, but EPA did not determine that revisions in the estimation approaches to the scenario were needed based on the submitted information. In Section 3.24.1, EPA has revised the approach to the "Use of Fertilizers Containing Formaldehyde in Outdoors Including Lawns" with new approaches to estimating the production volume and has also incorporated information submitted on weight concentration, exposure durations, and exposure frequencies to address comments received during the public comment period.

Other comments

Summary: A public commenter (0226) stated that EPA must give priority to assessing known conditions of use rather than limiting the draft risk evaluation to evaluating hypothetical conditions of use (i.e., conditions of use where workers are not trained and/or do not adhere to laws and regulations) that often do not reflect reality to make the Draft Unreasonable Risk Determination. The commenter stated that it is unfounded and unacceptable for EPA to omit any quantitative evaluation of known conditions of use from the draft risk evaluation, for which the exposure scenarios have been characterized and/or where laws and regulations are enforced, workers are trained, and best practices are followed.

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use (COUs). TSCA section 3(4) defines "conditions of use" as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA evaluated the COUs identified and described in the *Conditions of Use of the Risk Evaluation for Formaldehyde*. EPA must evaluate all COUs to determine if the chemical presents unreasonable risk, and, where EPA makes a determination of unreasonable risk, EPA will identify the COUs that significantly contribute to such determination.

Pursuant to 40 CFR 702.39(f)(2), in determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios takes into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA does not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination. As explained in the final rule, *Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)*, 89 FR 37028, 37037-38 (May 3, 2024), EPA believes that the assumed use of PPE in a risk determination could lead to an underestimation of the risk to workers. For example, workers may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, their employers are out of compliance with OSHA standards, the PPE is not sufficient to address the risk from the chemical, or their PPE does not fit or function properly. EPA recognizes that many companies likely have well-established occupational control measures in place. Where information on known occupational control measures was made available, the Agency took that information into account in the exposure assessment. Information from the risk evaluation's exposure assessment will also be considered during the risk management proceeding and can be useful in facilitating consistency with broader industry best practices where possible.

Summary: A public commenter (0261) asked for EPA to provide the total number of occupational conditions of use and the total number of consumer conditions of use.

EPA Response: As shown in the Unreasonable Risk Determination for Formaldehyde, EPA evaluated 63 conditions of use (COU) in total. Fifty-one COUs were evaluated under the Occupational Risk Assessment and twelve COUs were evaluated under the Consumer Risk Assessment.

Summary: A public commenter (0283) stated that, while EPA identified more than 60 conditions of use for formaldehyde, it is often impossible to determine whether a given facility falls within one or more of them, making it very difficult for workers or fenceline community residents to determine the extent of their respective risks.

EPA Response: As a part of the Human Health Risk Assessment, EPA utilized a combination of bottom-up analyses of EPA reporting programs and top-down analyses of U.S. economic data and industry-specific data in order to estimate the number of facilities within each occupational exposure scenario (OES) which then informed the risk characterization and risk determination. This process is further detailed in the Occupational Exposure Assessment, Section 2.2. EPA did not evaluate risk on a facility-by-facility basis. In the Environmental Release Assessment, EPA categorizes releases per industry sector, using the primary NAICS code reported by the facility. However, a facility may report additional NAICS codes or the primary NAICS code may not align with their use of formaldehyde. Therefore, EPA uses this categorization as a characterization of the releases for the conditions of use and not an assignment of the site to a COU. In addition, a facility may have multiple uses of

formaldehyde which fall under multiple conditions of use depending on their use of formaldehyde. None-the-less, the categorization and modeling of facilities based on industry sector categories is cross-walked to one or more TSCA COUs, but do not cross-walk to a specific facility that cross-walks to a specific COU.

Section 1.3 – Activities determined not to be conditions of use under TSCA

Summary: A public commenter (0178) said that most, if not all, animal biologics meet the definition of "drug" or "device" and are lawfully marketed in the United States when in compliance with the Virus-Serum-Toxin Act. The commenter asked if EPA's regulatory authority terminates when formaldehyde is labeled and an ingredient for animal biologics.

EPA Response: TSCA section 3(2)(B)(vi) excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." A chemical substance would cease to be subject to TSCA as soon as it meets one of the relevant FFDCA definitions and is manufactured, processed, or distributed in commerce for use as such. See, e.g., 42 Fed. Reg. 64,572, 64,585-86 (Dec. 23, 1977) (Response to Comments 37 & 40). Particular jurisdictional decisions under the FFDCA are fact-specific. EPA recommends that the commenter contact the U.S. Food & Drug Administration (FDA) if questions remain regarding whether specific products are appropriately considered a drug or device under FFDCA section 201.

Summary: A public commenter (0253) expressed appreciation for EPA's clarification that a range of formaldehyde-based products used in the animal agriculture industry are non-TSCA uses. However, the commenter asked EPA to confirm that these non-TSCA uses, particularly for clean out activities in poultry houses and barns, will not be subject to future risk management under the TSCA framework.

EPA Response: TSCA section 3(2)(B)(vi) excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." The use of formaldehyde in animal feed or as an animal drug meets the definition of a "food, food additive, [or] drug," respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (Formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004. A chemical substance would cease to be subject to TSCA as soon as it meets one of the relevant FFDCA definitions and is manufactured, processed, or distributed in commerce for use as such. See, e.g., 42 Fed. Reg. 64,572, 64,585-86 (Dec. 23, 1977) (Response to Comments 37 & 40). TSCA section 3(2)(B)(ii) also excludes from the definition of "chemical substance" "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." Formaldehyde that is a component of a pesticide product would not be subject to regulation under TSCA insofar as it is actually manufactured, processed, or distributed in commerce for use as a pesticide (for example, use as a registered pesticide to fumigate facilities such as poultry and swine confinement houses). As to the use of formaldehyde for other purposes in agricultural applications that do not fall under an exclusion from the "chemical substance" definition under TSCA section 3(2)(B), particularly to the extent that such activities fall under the conditions of use for

formaldehyde that significantly contribute to the unreasonable risk presented by formaldehyde, such uses may be subject to any proposed risk management action under TSCA.

Summary: A public commenter (0208) stated that the California Department of Food and Agriculture's Antimicrobial Use and Stewardship program appreciated EPA's removal of "agriculture, forestry, fishing, and hunting" from some aspects of this review and correctly identified that the use of formaldehyde as a pesticide is outside the TSCA's scope. The commenter also appreciated EPA's acknowledgment that the Food and Drug Administration (FDA) currently regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR 573.460 and as an animal drug (formalin) to control external parasites on hatchery fish and their eggs under 21 CFR 529.1004. The acknowledgment that the use of formaldehyde for these purposes meets the definition of a "food, food additive, [or] drug," respectively, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), and is therefore excluded from the TSCA 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use, enshrines FDA's authority over formalin as an animal drug approved for use in aquaculture. The commenter added that the formaldehyde risk analysis findings may result in unintended consequences that inadvertently, negatively affect aquaculture and animal feed producers' legitimate access to formaldehyde for FDA-approved uses.

EPA Response: EPA understands and is aware of the ubiquitous nature of formaldehyde and the potential lack of viable alternatives in certain industry-specific uses. The use of formaldehyde in animal feed or as an animal drug meets the definition of a "food, food additive, [or] drug," respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, as noted by the commenter, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004. EPA intends to consider the potential for incidental downstream impacts on such specialized uses during any TSCA risk management proceeding. Following issuance of the final risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to address the unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA considers many factors when developing any proposed risk management activities for COUs that are determined to significantly contribute to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the Administrative Procedure Act (APA), EPA will provide opportunity for public comment on any proposed rule.

Summary: A public commenter (0178) added that the use of formaldehyde for slide fixation was within the scope of the draft risk evaluation and fumigation appears to be within the scope of FIFRA, so there are concerns about the direct impacts on the availability and affordability of formaldehyde for these uses.

EPA Response: TSCA section 3(2)(B)(ii) excludes from the definition of "chemical substance" "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." As stated in the Conditions of Use document, EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning;

and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977 (May 4, 1988)). These products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses. Other uses of formaldehyde as a laboratory chemical remain within the scope of the TSCA risk evaluation, such as fixative use for slide preparation. Formaldehyde can be used in commercial laboratories for microscope slide preparation and is used to bind proteins to make cells or tissues more structurally solid in the short term. For example, an animal cell may be mobile on a glass slide so a fixative that contains formaldehyde could be applied to that slide, so the cell is no longer mobile. EPA has determined that these fixative purposes are in scope because this use is considered non-pesticidal. Use for slide preparation could potentially have a short-term fixative (non-preservation) purpose if there is no intent to preserve the tissue for later analysis.

EPA understands and is aware of the ubiquitous nature of formaldehyde and the potential lack of viable alternatives in certain industry-specific uses. EPA intends to consider potential impacts on such specialized uses during any risk management proceeding. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment on any proposed rule.

Summary: A public commenter (0223) agreed with EPA's decision to exclude several products as pesticides subject to evaluation and potential regulation under FIFRA, including embalming fluids, products used to preserve animal specimens, and products used to preserve the integrity of bodily fluids for laboratory analysis.

EPA Response: In the final TSCA risk evaluation, as in the draft, EPA confirms that such products (described in 40 CFR 152.25(c)) meet the FIFRA definition of "pesticide" and are therefore excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) when manufactured, processed, or distributed in commerce for use as a pesticide.

Summary: Two public commenters (0151, 0178) stated that, although EPA has excluded feed additives, new animal drugs, and some laboratory uses of formaldehyde from the scope of the preliminary determination of unreasonable risk, the American Veterinary Medical Association is still seeking clarification regarding the potential impacts on upstream conditions of use that may impact veterinarians and their clients, such as indirect impacts on the availability and affordability of formaldehyde for use in animal biologics, new animal drugs, feed additives, and tissue preservation. Specifically, the commenters asked if they are correct in "interpreting that the term 'directly' and phrase 'when manufactured, processed, or distributed in commerce for that use' mean any regulatory authority EPA has terminates at the point a bulk drug label is affixed to a container of active or inactive ingredient for use as a new animal drug or feed additive."

EPA Response: Foods, food additives, drugs, cosmetics, and devices are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA). TSCA section 3(2)(B)(vi) excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." 15 U.S.C. § 2602(2)(B)(vi). The substance ceases to be subject to TSCA as soon as it meets one of the relevant FFDCA definitions and is manufactured, processed, or distributed in commerce for use as such. See, e.g., 42 Fed. Reg. 64,572, 64,586 (Dec. 23, 1977) (Response to Comment 40). EPA has previously stated that as soon as the FDA regulates a product, its manufacture, processing, or distribution in

commerce solely for an FDA regulated use will be excluded from the jurisdiction of TSCA. See 42 Fed. Reg. at 64,586 (Response to Comment 40).

If a substance is manufactured, processed, or distributed for undifferentiated uses, then the substance will be presumed to be subject to TSCA for the purposes of any relevant EPA regulation. See 42 Fed. Reg. at 64,585 (Response to Comment 37). If a substance has multiple uses, only some of which are regulated under FFDCA, then the manufacture, processing, distribution, and use of the substance for the remaining uses is within the jurisdiction of TSCA. See 42 Fed. Reg. at 64,585 (Response to Comment 37).

Under the relevant FFDCA definitions, substances that are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms. For example, EPA has previously stated that intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA. See 42 Fed. Reg. 64,586 (Response to Comment 41). The FDA considers intermediates and catalysts to be components of such products and subject to regulation under the FFDCA. Accordingly, any such substance would be excluded from regulation under TSCA, provided that it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic or device, consistent with TSCA section 3(2)(B)(vi).

Section 1.4 – Organization of the draft risk evaluation

Summary: A public commenter (0214) said that the draft risk evaluation comprises a "staggering" amount of content to review, and that it is difficult to follow document to document. The commenter stated that the conditions of use are difficult to follow from the executive summary document to the condition of use document to the unreasonable risk determination document, and also said that there is a lack of naming consistency for conditions of use between and among the various documents. The commenter additionally stated that EPA needs to do a better job mapping conditions of use with consumer use scenarios and generally mapping conditions of use more clearly through the various documents to meet its APA requirements. Finally, the commenter questioned whether EPA has met its APA requirements due to the lack of clarity and organization disarray.

EPA Response: The EPA acknowledges that the risk evaluations for formaldehyde is a large and complex document collection. This is in part due to the magnitude of available scientific information on formaldehyde coupled with the complex toxicology and exposure profiles for formaldehyde. In addition, EPA acknowledges that the evaluation of formaldehyde hazard and exposure is challenging. The formaldehyde risk evaluation comprises a series of modular assessments to help organize information in a more digestible and coherent format. Each module contains sub-assessments that inform adjacent, "downstream" modules. A basic diagram showing the layout and relationships of these assessments is provided within each module. The executive summary is designed to be accessible to the general public, while the remainder of the risk evaluation and the associated supplemental documents provide a high level of detail targeted at technical experts to provide transparency and support for the underlying science.

Regarding the conditions of use, EPA has made every effort to include detailed description of the COUs under evaluation in the *Conditions of Use of the Risk Evaluation for Formaldehyde* module to help make clear distinctions and naming similarities. As the commentor has correctly pointed out, there have been instances of naming inconsistencies across the various documents and the Agency has made

every effort to make these clear in the Conditions of Use, Unreasonable Risk Determination, and other assessment modules.

EPA has updated its COU-to-consumer exposure scenario tables and figures in the Consumer Exposure Assessment technical support document for improved clarity. This includes a reorganization of consumer products per COU. EPA has done its best to be clear and consistent across all documents.

Summary: A public commenter (0246) recommended that EPA provide a document map, similar to the risk assessment document maps, focusing on the documents. The commenter suggested that the document map be incorporated into or referred to within the executive summary to help readers navigate the information available.

A public commenter (0261) said that the human health risk assessment document is often difficult to read and suggested that more detailed explanations and justifications would have been helpful. The commenter also said that it would have been helpful to have more references to primary source documents to guide the reader where to find more information.

EPA Response: EPA appreciates these suggestions and has tried to improve clarity and transparency of the document where possible.

Section 1.5 – Public comment and peer review process

Comments requesting an extension to the comment period and for EPA to re-issue the draft risk evaluation

Summary: Several public commenters (0081, 0095, 0097, 0098, 0104, 0128, 0148, 0150, 0169) requested that the comment period be extended by at least 30 days to allow more time for the peer review panel and other stakeholders to review the materials and prepare comments for EPA. Additionally, a public commenter, in multiple submissions to the docket (0081, 0148), stated that granting the extension request is consistent with other statutory and regulatory timelines for TSCA. As an example, the public commenter cited the Risk Evaluation Framework Rule, which provided 60 days for public comment.

Alternatively, some public commenters (0080, 0082, 0083, 0085, 0091, 0137, 0151) requested that EPA extend the public comment period for at least 60 additional days to allow for sufficient review of the technical information. Another public commenter (0209) offered support for extending the public comment period without a recommendation for a specific extension timeline.

Some public commenters (0081, 0095, 0097, 0098, 0104, 0128, 0148) suggested that EPA hold hybrid or in-person peer review meetings, instead of virtual meetings, to ensure equitable participation, and recommended that EPA also host a public webinar and provide a 60-day comment period after the webinar to elicit public feedback. Two public commenters (0150, 0209) stated that EPA should hold at least one in-person public meeting on the draft risk evaluation to enhance public participation.

Some public commenters (0128, 0150, 0219) recommended that EPA seek additional input from other federal agencies, including the United States Department of Agriculture (USDA), FDA, and Department of Defense following the August 2023 recommendations from EPA's Human Studies

Review Board (HSRB) that a more coordinated approach is needed to evaluate formaldehyde regulation.

Another two public commenters (0214, 0224) stated that EPA's rush to judgement has effectively denied the important advice and review of the SACC and recommended that EPA re-issue the draft risk evaluation and seek public comment after the SACC review.

A public commenter (0260) recommended that EPA reset the risk evaluation processes for formaldehyde and recommit to meaningful public comment and rigorous peer review process that embraces scientific quality over rushed deadlines.

EPA Response: EPA recognizes the importance of having an inclusive and participatory process in risk evaluation and appreciates receiving valuable input from all stakeholders involved during the comment period. EPA did not extend the comment period for the draft formaldehyde risk evaluation that closed on May 14, 2024. EPA provided a 60-day period for public comment on the draft risk evaluation, consistent with 40 CFR 702.43(c) and with the Agency's statutory obligations under TSCA section 6(b)(4)(G)-(H), which require completion of a risk evaluation as soon as practicable but not later that 3-3.5 years after initiation, and no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation. Despite the multiple extension requests, as shown throughout this document, extensive public commentary was provided.

Various aspects of the formaldehyde risk evaluation have been the subject of multiple peer review and comment periods as well as the subject of internal EPA review and also shared with other agencies.

Comments stating that EPA's plan for peer review for the formaldehyde risk evaluation violates TSCA and the Risk Evaluation Framework Rule requirements

Summary: Several public commenters (0007, 0260, 0264, 0210, 0218, 0219, 0245, 0257), stated that EPA's plan for peer review for the draft risk evaluation violates TSCA and the Risk Evaluation Framework Rule requirements. Two of the commenters (0007, 0245) added that EPA is "leveraging" and "deferring" to prior limited peer reviews from the National Academies of Sciences, Engineering, and Medicine (NASEM), HSRB, and SACC, meaning that the SACC peer review will only focus on a few specific issues, thus, no peer review of the draft risk evaluation will be made. Similarly, other commenters (0214, 0235, 0260) said that EPA cannot rely on the 2023 NASEM report that provides recommendations for improving the draft Integrated Risk Information System (IRIS) Assessment for formaldehyde for meeting its peer review obligation as that was not the aim of the NASEM report. One of the commenters (0235) also said that EPA's charge to NASEM was "unduly narrowed" in a manner as to prevent them from conducting a robust review of the scientific analyses in the assessment. Another commenter (0007) said that a peer review process that excludes key elements of the draft risk evaluation is inconsistent with section 26(h) of TSCA, violates key provisions of the Federal Advisory Committee Act (FACA), the Clean Air Act, as well as the Agency's current rule, Procedures for Chemical Risk Evaluation Under the Amended TSCA.

A public commenter (0260) stated that EPA's Scientific Integrity Policy directs EPA to "ensure that decisions are based on or informed by science that has completed independent peer review and has been finalized"; "ensure that draft documents released as part of transparency efforts are not relied upon for decision making"; and "ensure that all novel methods or models are appropriately peer reviewed prior to use."

A public commenter, in two submissions to the docket (0007, 0260), stated that EPA must respond to past peer reviewer and public comments, and that the SACC review should incorporate these comments.

A public commenter (0075) requested that EPA and the SACC review the IRIS Assessment and NASEM peer review rather than duplicate efforts. Another commenter (0226) stated that EPA should not have disregarded previous public comments from previous reviews so that EPA could instead substitute the IRIS Assessment conclusions and requested that EPA revise the draft risk evaluation to reflect the best available science and incorporate input from public comment.

A public commenter (0244) stated that ACC seeks to undermine the scientific process for evaluating the unreasonable risks associated with formaldehyde by using the SACC to reopen the IRIS Assessment. The commenter remarked that the IRIS Assessment did not include over 70 studies, many of which were funded by ACC and conducted by industry consultants. The commenter said that ACC claims these studies were conducted to fill critical knowledge gaps, but in essence they were intended to influence the outcome of the draft risk evaluation. The commenter added that the exclusion of the studies is at the heart of ACC's legal challenge to delay and overturn the IRIS Assessment.

EPA Response: EPA sought peer review by the Science Advisory Committee on Chemicals (SACC) on a wide range of charge questions covering human health hazard, water and land pathways, occupational assessment, consumer assessment, indoor air assessment, ambient outdoor air assessment, and aggregate exposure. The peer review conducted on the draft formaldehyde risk evaluation is consistent with the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 89 FR 37028, 37041-42 (May 3, 2024) (codified at 40 CFR 702.41), and in accordance with TSCA section 26(h), (i) and (o).

Since the public comment period and SACC peer review, EPA has finalized the IRIS assessment. Drafts of the IRIS formaldehyde assessment underwent multiple rounds of internal EPA review, as well as external review by other federal agencies. The assessment was also made available for public comment and submitted for external peer review by (NASEM). NASEM provided an opportunity for the public to nominate committee members, an opportunity for public comment on the proposed committee, and provided three opportunities for the public to comment directly to the study committee throughout the duration of the review. Additionally, NASEM accepted written public comments throughout the duration of the external peer review. In August 2023, the NASEM released its Review of EPA's 2022 Draft Formaldehyde Assessment (NASEM, 2023). Subsequently, IRIS released the final Toxicological Review of Formaldehyde – Inhalation in August of 2024 {U.S. EPA, 2024, 11854950} (also referred to as the IRIS assessment or final IRIS assessment throughout this document). IRIS provided responses to NASEM and public comments on the draft in Appendix F of the Supplemental Information document. In that appendix, IRIS responded to public comments identifying a list of studies that were identified as not being considered in the IRIS assessment. The IRIS response states "Of these 76 studies, 7 met the assessment PECO criteria. The 69 remaining studies contained no primary data, or were out of scope (e.g., no health-related information). Of the seven studies that meet the assessment PECO criteria, all seven were/are cited."

EPA notes that the litigation that one commenter (0007) refers to as "ongoing" has been resolved. On March 15, 2024, the U.S. District Court for the District of Columbia dismissed claims that NASEM and EPA violated FACA in peer reviewing EPA's draft IRIS risk assessment for formaldehyde.

Multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB)—

have provided review of various aspects of the formaldehyde assessment. EPA recognizes that the HSRB, SACC and NASEM provided feedback on several overlapping issues; some peer review feedback was consistent across panels whereas some feedback was inconsistent, providing divergent views. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

The final TSCA formaldehyde risk evaluation is consistent with TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence (TSCA section 26(i)) standards.

Comments stating that EPA's plan for peer review for the formaldehyde risk evaluation violates other federal requirements

Summary: A public commenter, in two submissions to the docket (0007, 0260), stated that EPA's peer review is inconsistent with EPA and the Office of Management and Budget (OMB) Information Quality and Peer Review Agenda requirements. The commenter (0007) remarked that EPA has not issued a similar required peer review plan for the draft risk evaluation and that EPA should rectify this oversight by issuing a peer review plan for public comment and identifying the forthcoming draft risk evaluation as a "Highly Influential Scientific Assessment" or "Influential Scientific Information." The commenter (0260) also stated that EPA has failed to follow Agency and White House requirements for information quality and peer review for "influential" science. The commenter stated that EPA is obligated to meaningfully consider and incorporate public and peer review comments relevant to the draft risk evaluation of formaldehyde, comments and recommendations from NASEM reviews, and comments and recommendations from the HSRB. According to one of the commenters, the December 2023 notice of forthcoming peer review suggests that EPA has not adopted these recommendations.

EPA Response: The Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin) requires the Agencies to subject influential scientific information to peer review prior to dissemination but gives the Agency "broad discretion" in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. Further, the Bulletin instructs the Agency to consider tradeoffs between depth of peer review and timeliness. This includes the consideration of costs of peer review – both direct costs and costs of potential delay in government and private actions that result from peer review.

Given the guidance documents, EPA's peer review can focus on the novel information, applications, and analysis that will benefit from independent, expert peer review. Both the OMB Bulletin and the EPA Peer Review Handbook 4th Edition (EPA Handbook) outline circumstances where peer review may not be necessary. Specifically listed is work that has been previously peer reviewed in a manner consistent with the OMB Bulletin and the EPA Handbook; if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach; or when a scientific or technical methodology or information being used are commonly accepted.

Charge questions

Summary: A public commenter, in two submissions to the docket (0007, 0260), stated that EPA should seek Federal Agency comments on draft charge questions prior to release, as well as substantive interagency review of the draft risk evaluation. The commenter reasoned that, in order to be consistent with section 9 of TSCA and Executive Order 12866, EPA should consult and coordinate with other federal agencies and other parts of EPA by seeking their comments on EPA's draft charge questions (as

well as the draft risk evaluation) prior to public comment on the draft charge questions or on the pool of ad hoc peer reviewers. The commenter added that federal agencies have provided significant recommendations regarding fundamental scientific issues that need resolution for EPA assessments of formaldehyde as well as specific charge questions appropriate for peer review. The commenter (0007) listed the following examples of previously submitted comments/reviews that EPA should consider: the Small Business Administration, OMB, the White House Council on Environmental Quality, the Department of Defense, the National Aeronautics and Space Administration, and the Consumer Product Safety Commission (CPSC). The commenter (0260) further stated that there is no evidence that EPA has sought comments from other federal agencies or engaged in any meaningful formal or interagency review. Another public commenter (0128) expressed concerns that the interagency coordination efforts required by section 7 of the Endangered Species Act, section 9 of TSCA, and EPA's IRIS process. The commenter said that when EPA announced that it "intends to defer to the draft 2022" IRIS Assessment for forthcoming regulatory activities under TSCA and FIFRA, the assessment fails to live up to the interagency review process that is required.

The public commenter, along with another (0079) suggested that EPA should consider a full interagency review process for any draft or final risk evaluation that could impact the utilization of formaldehyde. The commenters added that this process should be overseen by OMB, include a process consistent with Executive Order 12866, last at least 60 days, and seek input from all relevant agencies and sub-agencies.

EPA Response: TSCA does not require, nor does EPA believe it is appropriate to hold, formal interagency review on the Agency's scientific products. EPA consults and coordinates with Federal partners, holding regular meetings to brief other Agencies on TSCA actions. Specifically, after the publication of draft risk evaluations, EPA engages with interested Agencies and often takes comment on particular uses. EPA consulted with other relevant Federal agencies in that manner during the formaldehyde risk evaluation process consistent with 40 CFR 702.47, and will continue to engage with other Agencies during the development of risk management rulemaking. Most TSCA section 9 provisions are typically relevant only after EPA has determined that a chemical substance presents unreasonable risk and is considering risk management options (see, e.g., TSCA section 9(a) ("If the Administrator determines that [one or more chemical activities] presents an unreasonable risk…."; 9(c) (describing coordination "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")). The E.O. 12866 process is for centralized interagency review of regulatory (rulemaking) actions and not for the review of technical or scientific documents (e.g., risk evaluations or charge questions).

Summary: Two public commenters, one in two submissions to the docket (0007, 0148, 0260), stated that the scope of review and of the charge questions should not be unduly narrow, and the constrained nature of the charge questions is at odds with related Agency policies. The commenter (0007) cited instructions from the EPA Peer Review Handbook that highlight the attributes of acceptable charge questions. The commenter went on to provide additional recommendations to EPA for the charge questions: EPA should utilize key recommendations from other peer review bodies, including NASEM and the HSRB, and independently validate, through the SACC, whether these recommendations have been fully addressed in the draft risk evaluation; EPA should adopt statutorily derived charge questions; EPA should spend a day educating the new SACC panel on TSCA requirements, including the important science standards and the Risk Evaluation Framework Rule which incorporates these

requirements; and EPA should seek feedback on the charge from other federal agencies and incorporate past recommendations regarding key scientific issues to be resolved.

Several public commenters (0007, 0155, 0167) suggested many additional charge questions for EPA to incorporate. One public commenter (0007) separated the suggested charge questions into the following topics: best available science, weight of scientific evidence, inclusion of available information and identification of key studies, EPA's approach to chronic cancer risks, independent evaluation of past peer review recommendations, mode of action (MOA), TSCA implementation, FIFRA scientific standards, and resolving prior EPA determinations on formaldehyde and best available science.

Another public commenter (0153) said that EPA should request that the SACC consider alternative methodology in deriving point of departure (POD) values in the listed charge questions. Another public commenter (0252) disagreed, stating that peer reviewing PODs after the review by NASEM is inefficient and contrary to EPA's recent stance on conserving resources on peer reviews. The commenter expressed further concern that the SACC would call into question the PODs and many other aspects of the IRIS Assessment and questioned EPA's approach to incorporating feedback from NASEM and the HSRB.

Some public commenters (0148, 0207, 0190) stated that the existing charge questions should be modified to align with the mandatory scientific standards for conducting TSCA risk evaluations. The commenters stated that the scope of the draft charge questions for the peer review are insufficient because they exclude: (1) key scientific questions and (2) key elements of the draft risk evaluation. Furthermore, they said that it is not sufficient for EPA to simply ask the SACC to comment on "strengths," "uncertainties," and "appropriateness" of the approaches taken by EPA without reviewing whether the underlying data is consistent with TSCA's requirements for decisions based on the best available science and weight of the scientific evidence. The commenters reasoned that to help promote the rigor of the review and to ensure its consistent with TSCA scientific standards, it is important to incorporate the TSCA standards into the charge questions.

Additionally, one of the commenters (0148) provided multiple recommendations for ways in which to incorporate best available science, weight of scientific evidence, and reasonably available information for the SACC to discuss and consider incorporating into the charge questions. The commenter stated that, as required under section 26(h) of TSCA, for each element of the draft risk evaluation, peer reviewers should evaluate the degree to which "scientific information, technical procedures, measures, methods, protocols, methodologies, or models" are "employed in a manner consistent with the best available science." The commenter also added that section 26(k) of TSCA requires that, when carrying out obligations under TSCA, including conducting risk evaluations, EPA "shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." As such, the commenter stated that for each important data set, including data to inform hazard and exposure, peer reviewers should comment on whether EPA has considered all reasonably available information. Another public commenter (0161) stated that EPA's draft charge questions do not reference the need to "integrate" key studies that are available to the Agency and that EPA's timeline for this review and forthcoming risk evaluation actions could undermine the rigor of this peer review.

EPA Response: The Agency focused the SACC charge on its data analysis and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed, as further described below. As previously mentioned, multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals

(SACC), and the Human Studies Review Board (HSRB)—have provided review of various aspects of the formaldehyde assessment. It is not appropriate to ask multiple peer review panels the same questions – it is not a good use of agency resources and it also leads to the perception that is not response to or considerate of prior peer review.

EPA recognizes that the HSRB, SACC and NASEM provided feedback on several overlapping issues; some peer review feedback was consistent across panels whereas some feedback was inconsistent, providing divergent views. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

Summary: Several public commenters (0148, 0161, 0260) stated that EPA's draft charge questions do not mention "unreasonable risk" or seek advice on whether the Agency's approach is based on the best available science or if it has integrated all reasonably available information. The commenter (0148) expressed that the SACC should provide comments on the underlying scientific framework that EPA is proposing for reaching a determination of whether formaldehyde poses an unreasonable risk under its conditions of use. The commenter said these comments should include consideration of how EPA has integrated available information on biogenic, endogenous, and background exposures of formaldehyde to inform unreasonable risk. The commenter also stated that the SACC should comment on whether or not EPA has clearly articulated which conditions of use present an unreasonable risk, as opposed to which conditions of use contribute to an unreasonable risk.

EPA Response: As stated in the preamble to the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act*, 89 FR 37028, 37042 (May 3, 2024), "Consistent with the 2017 final rule, EPA will not seek peer review of any determination as to whether the risk is 'unreasonable,' which is an Agency policy determination. Consistent with OMB and EPA guidance, the purpose of peer review is the independent review of the science underlying the TSCA risk evaluation, not a review of EPA's policy determinations. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is 'unreasonable.' (15 U.S.C. 2605(i)). This is consistent with the statutory purpose of the SACC, "to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title' (15 U.S.C. 2625(o)(2))."

Summary: Several public commenters (0148, 0161, 0249, 0142) stated that the SACC should comment on the occupational exposure value (OEV), specifically, the underlying scientific basis for deriving the OEV calculations and whether the OEV value is supported by the best available science and weight of scientific evidence.

Another public commenter (0161) said that draft charge questions fail to even mention the draft OEVs, nor seek the SACC's comment on whether they are derived based on the best available science and other TSCA scientific standards.

Another public commenter (0162) stated that the charge questions do not allow for the SACC to consider alternative studies or methodologies to inform an OEV calculation because it was derived from the IRIS Assessment. The commenter questioned if the IRIS Assessment could be relied upon because it is not subject to the same legal standards as TSCA. The commenter requested that EPA add a charge question that would allow for a robust review of the 11ppb OEV, including an examination of

the European Union (EU)'s standard and a critical review of studies being used in support of the proposed 11ppb limit.

A public commenter (0232) discussed the first time in which the TSCA risk evaluation has included a workplace standard, and stated that EPA should seek comment on the proposed limits and their scientific basis in the charge questions.

EPA Response: The occupational exposure values for formaldehyde presented in Appendix E of the Human Health Risk Assessment document are calculated values "derived based on standard occupational scenario assumptions of 8 hours/day, 5 days/week exposures for a total of 250 days exposure per year, and a 40-year working life" using the PODs that were subject to peer review. By including this calculation in Appendix E of the draft human health risk assessment, EPA provided an opportunity for comment on the calculations. EPA has considered SACC and public comments on hazard values, uncertainty factors and exposure assumptions and made appropriate revisions to Appendix E. For example, EPA revised the uncertainty factor applied to the acute inhalation value from 10 to 3 based in part on SACC feedback and this change has been incorporated into the revised occupational exposure values. The OEVs presented in Appendix E are not workplace standards. As further clarified in Appendix E, "TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus these occupational exposure values represent risk-only numbers. In risk management rulemaking for formaldehyde following the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the occupational exposure values presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c)".

Summary: A public commenter (0260) stated that EPA's charge questions also do not solicit input from the SACC on the carcinogenic MOA for formaldehyde. The Agency has adopted the draft IRIS Assessment's linear, low-dose approach without seeking comment on whether non-linear, threshold approaches utilized by the World Health Organization (WHO) and the European Chemicals Agency (ECHA) are more consistent with TSCA scientific standards.

A public commenter (0148) stated that, due to the importance of the inhalation unit risk (IUR) value and the fact that EPA is relying on a draft IRIS value that has not gone through a robust peer review, it would be helpful to have the SACC comment on the derivation of the IUR value. The public commenter recommended a charge question on the IUR value.

EPA Response: SACC reviewers provided feedback to EPA on the carcinogenic MOA and the IUR for formaldehyde. For example, the SACC report states that "The majority of the information presented in session did not favor a IUR approach, and rather supported a threshold approach." However, the SACC report also states that "Several Committee members disagreed with this approach and supported the IUR approach as the most appropriate." Overall, "The Committee recommended that the EPA consider the best available science to determine if a threshold or non-threshold approach is best for evaluating cancer, and if needed revise the Draft Human Health Hazard Assessment." The SACC report also stated, "Many Committee members commented there is no evidence of multiple modes of action leading to the same adverse outcome in the same individual and the same tissue," and "Many Committee members… recommended using a mode of action approach where there is a threshold concentration below which no cancer is anticipated." Conversely, the SACC report also states that "A minority of members agreed with the EPA's conclusion that "there is sufficient evidence that a

mutagenic mode of action contributes to risk of nasopharyngeal cancer (NPC)from inhaled formaldehyde."

Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment for formaldehyde. Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Based on the mode of action analysis presented in the IRIS assessment, IRIS concluded there is sufficient evidence that a mutagenic mode of action contributes to risk of nasopharyngeal cancer from inhaled formaldehyde. Similarly, the NASEM review concluded that "While there is uncertainty in the degree to which nonmutagenic processes may also contribute to the carcinogenic activity of formaldehyde inhalation at the point-of-entry tissues, there is sufficient evidence to support the assumption that a mutagenic MOA is involved in the carcinogenesis of formaldehyde in the upper aerodigestive tract in humans" (NASEM, 2023). EPA IRIS's mode of action analysis is provided within Section 3.2.5 of the final IRIS assessment and responses to comments on mode of action analysis and consideration of comments suggesting a threshold approach for cancer are addressed in Section F.4 in Appendix F of the IRIS Supplemental Information document. Further discussion on how IRIS derived the cancer IUR is provided in Section 5.2 of the IRIS assessment.

Summary: A public commenter (0260) stated that EPA's charge questions omit any reference to TSCA section 6(c)(2) and section 6(g), as well as tools to exempt "de minimis" exposures identified in EPA's Risk Evaluation Framework Rule and recent risk management rules. The commenter expressed that this represents a missed opportunity for the Agency to seek comments on these key uses early in the regulatory process and receive expert advice from the SACC on these issues.

EPA Response: EPA will consider whether a threshold or de minimus amount, or a potential exemption under TSCA section 6(g), is appropriate as part of any risk management rulemaking actions following conclusion of the risk evaluation process. EPA examines a number of considerations in accordance with TSCA section 6(c) when developing risk management rulemaking to address the identified unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Other comments on the peer review process

Summary: A public commenter (0148) stated that individual peer reviewers should be asked to record their key findings and recommendations in writing before and after the May 20-23, 2024 meeting. The individuals' key findings should be made available to the public and part of the administrative record. The commenter reasoned that this would be consistent with EPA's Scientific Integrity Policy, which extends to special government employees.

A public commenter (0260) stated that the operation of the SACC's May 7, 2024 meeting raised concerns regarding the opportunity for independent advice as well as a potential "chilling effect" on public participation. The commenter said that the May 7, 2024 meeting included public comments at the very end of the meeting and that they were interrupted while raising legitimate concerns regarding the scope of the peer review. The commenter recommended EPA and the SACC review the EPA Peer Review Handbook as well as Initiatives to Enhance Public Involvement in Advisory Activities.

A public commenter (0260) stated that EPA's sequencing and combination of public comment and peer review is inappropriate, citing the "highly unusual and inappropriate" comingling of public comments and peer review activities. The commenter remarked that EPA's decision to maintain a single docket for both functions make it unclear whether comments should be directed to EPA or the SACC.

EPA Response: EPA maintains that the peer review requirements under TSCA were satisfied by the SACC peer review and are consistent with EPA's 2015 Peer Review Handbook (4th Edition). Specifically, the SACC followed EPA's guidance for peer review and represented the most judicious use of Agency resources for meeting the peer review needs.

Section 1.6 – Other overarching comments on program implementation and policy

IRIS Assessment

Summary: Several public commenters (0142, 0194, 0214, 0232, 0235, 0260, 0219, 0245) stated that the draft risk evaluation is legally flawed for relying on the draft IRIS Assessment for most human health conclusions. The commenters said that EPA's reliance on the draft IRIS Assessment (as opposed to a final IRIS Assessment) violates TSCA's best available science requirement because it has neither completed an external peer review nor responded to public comments and is thus not consistent with the TSCA best available science standard. Two public commenters (0214, 0235) wrote that reliance on the draft IRIS Assessment violates EPA's updated draft Scientific Integrity Policy, which states that it is EPA's policy not to rely on draft documents for decision making and undermines the legitimacy of the notice and comment process in violation of the APA. Some commenters (0210, 0218, 0219, 0235, 0245, 0257) expressed concern that the IRIS Assessment has been relied upon in the risk evaluation, given the concerns and criticisms raised about the assessment's adequacy and accuracy, the adherence of the IRIS Assessment to TSCA section 26(h) standards, and that EPA has yet to revise the IRIS Assessment based on review and feedback from NASEM. One of the commenters (0218) noted that the IRIS Assessment has not been authorized by Congress and thus should not serve as the basis for TSCA regulatory actions. Another commenter (0128) said that the IRIS Assessment has not been subject to a robust interagency review and coordination process and reliance on the previous 2022 assessment would cause harm to several industries.

A public commenter (0235) stated that the draft formaldehyde IRIS Assessment is not consistent with the seven-step process outlined in the IRIS Handbook, including by failing to release an IRIS Assessment plan, failing to have the study evaluation conducted independently by at least two reviewers, and failing to consistently apply inclusion and exclusion criteria during the systematic review step, resulting in the exclusion of over 100 relevant publications. In addition, the commenter said that the draft IRIS Assessment is not based on the weight of scientific evidence as required by TSCA.

EPA Response: Multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB)—have provided review of various aspects of the formaldehyde assessment. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

As described in more detail in Section 5.2 of this response to comment document, SACC and public commenters provided feedback on the IRIS RfC, IUR and MOA conclusions. Since the public comment period and SACC peer review, EPA has finalized the IRIS assessment. Drafts of the IRIS

formaldehyde assessment underwent multiple rounds of internal EPA review, as well as external review by other federal agencies. The assessment was also made available for public comment and submitted for external peer review by (NASEM). NASEM provided an opportunity for the public to nominate committee members, an opportunity for public comment on the proposed committee, and provided three opportunities for the public to comment directly to the study committee throughout the duration of the review. Additionally, NASEM accepted written public comments throughout the duration of the external peer review. In August 2023, the NASEM released its Review of EPA's 2022 Draft Formaldehyde Assessment (NASEM, 2023). Subsequently, IRIS released the final Toxicological Review of Formaldehyde – Inhalation in August of 2024 {U.S. EPA, 2024, 11854950} (also referred to as the IRIS assessment or final IRIS assessment throughout this document). IRIS provided responses to NASEM and public comments on the draft in Appendix F of the Supplemental Information document.

Summary: Two public commenters (0267, 0235) noted that RfC values are developed as part of IRIS Assessments, and RfCs are commonly known as values below which there is "no appreciable risk." The public commenters stated that, by relying on information developed for an IRIS Assessment RfC, EPA is using values that are developed to protect against essentially all risks, which is well beyond the statute's requirements. One commenter (0235) said that, by using this approach, EPA is setting the stage for risk management rules that will be seeking to reduce risks beyond the extent necessary.

A public commenter (0145) remarked that EPA is using the wrong standard for protection. The commenter said that TSCA requires EPA to regulate "to the extent necessary so that the chemical substance or mixture no longer presents or will present an unreasonable risk" while the IRIS program uses a "without/no appreciable risk" standards. The commenter concluded that EPA is relying on IRIS values that set a no appreciable risk standard that is below ambient and indoor air levels for formaldehyde, rather than the TSCA standard, and asked that EPA sever the IRIS formaldehyde assessment from the risk evaluation entirely.

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified by EPA as relevant to the risk evaluation, under the conditions of use (COUs). Whether a given risk is "unreasonable" is an Agency policy determination. EPA disagrees that consideration and use of IRIS hazard values is inconsistent with the TSCA "unreasonable risk" standard. As described in more detail in Section 5.2 of this response to comment document, SACC and public commenters provided feedback on the IRIS hazard values. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

The unreasonable risk determination for formaldehyde is based on the information in each of the assessments, appendices and technical support documents that comprise this risk evaluation, in accordance with TSCA section 6(b). It is also based on TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702 including, to the extent practicable, the amendments to the procedures for chemical risk evaluation under TSCA finalized in May 2024 (89 FR 37028; May 3, 2024). While EPA considers calculated risk estimates relative to benchmarks when characterizing and determining risk, whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA also depends upon risk-related factors beyond exceedance of benchmarks, such as the

endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, frequency of exposure, population exposed), and the confidence in the information used to inform the hazard and exposure values. Responses to related comments on the IRIS assessment are provided in Section F.1.3 of the IRIS Supplemental Information document.

Draft risk evaluation

Summary: Multiple public commenters (0148, 0141, 0142, 0145, 0147, 0168, 0172, 0174, 0183, 0184, 0188, 0190, 0194, 0196, 0209) said that the Lautenberg Amendments require EPA to use the "best available science" when making science-based decisions, consider "reasonably available information," and make decisions based on the "weight of the scientific evidence." Several of the commenters (0141, 0142, 0145, 0190, 0194) said that the SACC review should not be limited by EPA's draft charge questions that exclude these key scientific standards and should be required to make their decisions based on the weight of the scientific evidence and the best available science.

A public commenter (0241) agreed with the comments of the American Chemistry Council's Formaldehyde Panel, specifically that the draft risk evaluation does not meet TSCA's requirements to rely on the best available science and failed to comply with the procedural peer review requirements of the FACA, that the draft risk evaluation failed to develop a science-based evaluation framework that accounts for significant background levels of formaldehyde, and that EPA does not provide a sufficient legal basis to find that formaldehyde presents an unreasonable risk of injury to human health and the environment.

Two public commenters (0169, 0210) said that the draft risk evaluation fails to consider the weight of the scientific evidence by excluding more than 100 key studies and reviews and failing to integrate conclusions and methods from other authoritative bodies like the EU, the WHO, or other EPA offices. Some public commenters (0202, 0226) provided a list of key studies and peer review and public comments that they say were excluded from the risk evaluation.

EPA Response: The Risk Evaluation Framework Rule states that "the phrase WoSE or weight of evidence (WoE) is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to the quality of the studies evaluated, and how findings are assessed and integrated. EPA broadly uses the WoSE approach in many existing programs and has described the application of WoSE in Agency guidance used to classify carcinogens (Ref. 29). EPA believes WoSE inherently involves application of professional judgment, in which the significant issues, strengths, limitations of the data, uncertainties, and interpretations are presented and highlighted". As described in more detail in Section 5.2 of this response to comment document, SACC and public commenters provided feedback on weight of evidence.

Multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB)—have provided review of various aspects of the formaldehyde assessment. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

IRIS provided responses to public comments on the draft IRIS assessment in Appendix F of the Supplemental Information document. In that appendix, IRIS responded to public comments identifying a list of studies that were identified as not being considered in the IRIS assessment. The IRIS response

states "Of these 76 studies, 7 met the assessment PECO criteria. The 69 remaining studies contained no primary data, or were out of scope (e.g., no health-related information). Of the seven studies that meet the assessment PECO criteria, all seven were/are cited." IRIS responded to comments related to the conclusions and methods used by other health agencies in section F.5 and a summary of the assessments conducted by other national and international health agencies is provided in Appendix G of the IRIS Supplemental Information document.

Summary: A public commenter (0260) said that the draft risk evaluation's rushed process appears to be driven more by deadlines in a proposed consent decree than a commitment to regulation based on the best available science. In addition, the commenter said that EPA's "ban all uses" approach contradicts TSCA's requirements. The public commenter also stated that EPA failed to consider, assess, and integrate available information on the significant health, environmental, public safety, economic, security, and infrastructure benefits of formaldehyde usage. According to the commenter, these omissions are part of an inconsistent, arbitrary, and capricious approach, with unclear criteria, for how EPA decides which uses and risks it evaluates and how it determines unreasonable risk for these uses.

EPA Response: EPA is committed to meeting both the statutory deadlines for risk evaluation under TSCA section 6(b)(4)(G) and the statutory scientific standards under TSCA section 26(h) and (i). Pursuant to the statutory requirements of TSCA section 6(b)(4)(A) and (F), the Risk Determination does not consider costs or other non-risk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use; the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimates. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimates and the risk characterization. EPA acknowledges the commenters' risk management concerns. Because the Agency has determined that formaldehyde presents an unreasonable risk, the law requires EPA to address those risks. EPA expects to consider as part of risk management rulemaking a variety of approaches for addressing the unreasonable risk presented by formaldehyde, but expects to focus rulemaking on those conditions of use the Agency has determined significantly contribute to the unreasonable risk of formaldehyde. Pursuant to TSCA section 6(c), in proposing and promulgating a rule, EPA considers many factors, including reasonably available information with respect to the benefits of the chemical substance for various uses (TSCA section 6(c)(2)(A)(iii)) and the reasonably ascertainable economic consequences of the rule (TSCA section 6(c)(2)(A)(iv)).

Summary: A public commenter (0260) stated that Congress did not provide authority for the Agency to: propose draft OEVs as part of existing chemical risk evaluations under section 6 of TSCA; fundamentally change and alter its position regarding key elements of its process for risk evaluations following 2017 rulemaking required in TSCA section 6(b)(4); or unilaterally trump TSCA requirements to evaluate conditions of use, hazard, and exposure through policy decisions to render single risk determinations for a "whole chemical" or to exclude any consideration of personal protective equipment (PPE) and other industrial hygiene practices.

EPA Response: The issues discussed by the commenter were considered and resolved by the Agency in the 2024 final rule, *Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)*, 89 FR 37028 (May 3, 2024). The Agency's discussion and response to public comments on these issues appears in Units IV.E. and F. of the final rule preamble and in the Response to Comment document available in the rulemaking docket (EPA-HQ-OPPT-2023-0496). The codification of process in this final rule better align with the statutory text and structure, Congressional intent, and applicable court decisions. In addition, as explained in Unit I.B of that final rule preamble, EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *See FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). As part of the proposed Procedural rule, EPA solicited comment on how EPA could improve the transparency of any risk-based occupational exposure values derived from the risk evaluation process. Commenters generally expressed a strong desire for more opportunity for public review and scientific input on how risk-based occupational exposure values are derived, and a more formalized approach for the development of any corresponding regulatory limits. In response to the public comments, the final rule now includes the requirement that the Agency EPA committed to make publicly available any risk-based occupational exposure values calculated as part of the risk evaluation. The occupational exposure values (OEVs) for formaldehyde are described in Appendix E of the Human Health Risk Assessment. EPA notes that these are solely risk-based values derived from peer-reviewed hazard endpoints, and do not constitute proposed or final regulatory limits, though they can be used to inform risk management rulemaking. When proposing any regulatory occupational exposure limit or other risk management approach during risk management rulemaking, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, the continued need for critical or essential uses, the potential for different occupational requirements for these uses, and existing occupational exposure control approaches and technologies. Additional responses to public comments regarding OEVs may be found in Section 5.3 of this document.

Summary: A public commenter (0235) stated that EPA's single unreasonable risk determination approach is not fit for the purpose of the formaldehyde evaluation and is inconsistent with the statute because it reads out of the statute "under" the conditions of use and replaces it with "based" on the conditions of use. The commenter also stated that the single determination approach is inconsistent with Congressional intent. Another public commenter (0219) said that EPA is required by the regulation at 40 CFR 702.47 to include separate risk determinations for each condition of use and seems to be relying instead on the Agency's recently amended regulations that are effective July 22, 2024 which will remove that requirement. The commenter said that this reliance on the recent regulatory change is contrary to the purpose and intent of TSCA and unlawfully disregards the mandates imposed by the regulations at the time of the drafting of the risk evaluation.

EPA Response: In the May 3, 2024 amendments to the framework rule for TSCA risk evaluations, EPA amended regulatory text to "codify a requirement that EPA make a single risk determination on the chemical substance at the conclusion of the TSCA risk evaluation process, as opposed to individual risk determinations on each individual use of the chemical" (89 FR 37028). EPA explained in that final rule how the single risk determination approach "align[s] EPA's process with the statutory text and structure" and "ensures that the Agency is best positioned to incorporate reasonably available information, make determinations consistent with the best available science and based on the weight of scientific evidence, including, where appropriate, risk determinations that consider aggregate exposure resulting from multiple conditions of use." EPA also explained in that rule that, "[f]or risk evaluations in process as of the date of the final rule, EPA would expect to apply the proposed changes to those risk

evaluations only to the extent practicable, taking into consideration the statutory requirements and deadlines.… EPA believes it will be practicable, however, to make a single determination of unreasonable risk on the chemical substance as contemplated in the law and codified in this rule." Consistent with both the statutory text and final procedural rule, EPA made a single determination of unreasonable risk for the chemical as part of this risk evaluation of formaldehyde.

Other legal issues

Summary: A public commenter (0260) said that EPA has not established a TSCA assistance office for manufacturers and processors as required under section 26(d) of TSCA, nor has it fulfilled its annual reporting requirement to Congress, as required by section 30 of TSCA, since 2016. The commenter also said that EPA has not fulfilled its obligations to consult with Tribes. Additionally, the commenter stated that section 26 of TSCA requires the administrator to publish an annual plan that identifies the chemical substances for which risk evaluations are expected to be initiated or complete that year. The commenter stated that it appears the Agency acknowledged this requirement but has not published a plan since 2021. The commenter said that publication of such a plan would significantly improve transparency and meaningful public comment.

EPA Response: EPA considers these comments outside the scope of the formaldehyde risk evaluation and not germane.

Section 2 – Chemistry and fate and transport of formaldehyde

Comments associated with this issue are summarized in the subsections below

Section 2.1 – Physical and chemical properties

No comments are associated with this issue

Section 2.2 – Environmental fate and transport assessment

Summary: In response to Charge Question 2.1, a public commenter (0180) agreed with EPA's assessment that formaldehyde is not persistent in water and soil and thus there is expected to be negligible exposure from TSCA conditions of use via water and land pathways. The commenter further stated that EPA's data analysis and "conservative approach" to addressing uncertainties support these conclusions. The commenter discussed formaldehyde's degradation in the open environment, the predicted low bioaccumulation factor, and the process for treatment in biological wastewater that in their view, support the conclusion that formaldehyde would not represent an ecological risk from the TSCA conditions of use through the water and land pathways.

EPA Response: EPA agrees with the comment and has not made any substantial changes to the environmental fate and transport assessment.

Summary: A public commenter (0180) supported EPA's assertion that indoor air would not represent an ecological risk nor alter pathways for outdoor exposures via land or water, stating that indoor mechanical ventilation systems and natural degradation of formaldehyde through photolysis would negate the possibility.

EPA Response: EPA agrees with the comment and has not made any substantial changes for how ecological risk could be impacted by indoor air.

Summary: In response to Charge Question 4.2, the SACC noted that the Chemical Fate Document Figure 3.1 does not include hydrocarbon or other atmospheric organic compounds that are photochemically converted to formaldehyde or other precursor compounds.

EPA Response: While EPA agrees that many atmospheric compounds are photochemically converted to formaldehyde, Figure 3-1 is intended as a simplified depiction of how formaldehyde released from TSCA Industry Sector might be transported and transformed in the environment. The figure does not account for all possible transformations of the chemical as there could be many and they could not be characterized with any certainty. It is also not intended as a graphic for all sources of formaldehyde in the environment as mentioned elsewhere in the risk evaluation. The chemistry, fate, and transport assessment is conservative and may not cover all possible transport and transformation of formaldehyde.

Section 2.3 – Other comments

No comments are associated with this issue

Section 3 – Environmental release assessment: formaldehyde air releases

Comments associated with this issue are summarized in the subsections below

Section 3.1 – Approach and methodology

Summary: The SACC recommended specific line by line changes to the Chemical Releases Document, in response to Charge Question 4.2, including providing support for using North American Industry Classification System (NAICS) categories to assign a condition of use, disagreeing with the dismissal of the highest fugitive release in Table 2-1, suggesting adding new National Emissions Inventory (NEI) data to Table 3 in Appendix D, and recommending that Toxics Release Inventory (TRI) and NEI reported values be checked against other large networks of air monitoring data such as the Air Monitoring Technology Information Center (AMTIC). The committee suggested more clarity in Appendix G with a site not fitting the COU, statements on non-TSCA use, and CBI claims on production volume.

The SACC also provided similar line edits to Appendix G and provided an overall recommendation that EPA require users and producers to provide data needed for a thorough assessment of emissions.

EPA Response: EPA appreciates feedback on use of NAICS code for the formaldehyde risk evaluation.

For comment related to Table 2-1 in the Environmental Release Assessment, EPA did not list the highest value in TRI for fugitive emissions because EPA determined that the source of formaldehyde is outside the purview of TSCA. The source as documented in the TRI form is due to naturally occurring formaldehyde present in beets, which is released during the processing of the beets. For Table 3 in Appendix D, EPA did add the total air emissions as reported in 2020 NEI. In appendix G, EPA includes that commercial COUs are not directly correlated with industrial sectors so that appendix section includes a review of the release potential based on expected release sources, potentially applicable industrial sectors, and other alternative approaches considered for each COU. Some sites within an industrial sector may not fit with a commercial use. For the specific comment on non-TSCA uses, these products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)) and are

therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses.

Regarding checking reported release values against AMTIC data, while it is possible to do so, the more direct comparison would be to compare estimated concentrations from modeled results to monitoring data which EPA has expanded upon in the relevant documents following SACC review.

Section 3.2 – Air release estimates of formaldehyde

No comments are associated with this issue

Section 3.3 – Weight of scientific evidence conclusions for environmental releases from industrial and commercial sources

No comments are associated with this issue

Section 3.4 – Other comments

No comments are associated with this issue

Section 4 – Environmental Risk Assessment

Comments associated with this issue are summarized in the subsections below

Section 4.1 – Environmental risk assessment

Summary: A public commenter (0235) stated that overall, the evaluation of environmental risks is reasonable. Additionally, the commenter said that in regard to the overall fate and transport of the transformation products methylene glycol and ploy(oxy)methylene glycol, to ensure that uncertainties are addressed and considered, the Agency is overly conservative with regard to formaldehyde in the environment and likely overestimates the presence of formaldehyde from TSCA conditions of use. The commenter remarked that they agree with EPA's analyses and conclusions and support the finding that there is also no risk to environmental or human receptors through exposure to these pathways.

EPA Response: EPA agrees that the Environmental Risk Assessment is reasonable and conservative. As a result, only minor changes were made to the assessment. EPA disagrees that the risk evaluation overestimates the presence of formaldehyde from TSCA conditions of use. The risk evaluation for formaldehyde has sought to characterize the many sources of formaldehyde in the environment using multiple lines of evidence. This characterization work has bolstered confidence in the presence of formaldehyde in air, water, and land.

Summary: Two public commenters (0180, 0261) agreed with EPA's analysis and conclusions that formaldehyde does not present a risk to aquatic systems or organisms. One public commenter (0261) concurred with EPA's expression of "high confidence" in the draft risk evaluation because the approach followed the draft systematic review protocol, including the use of chemical-specific methodologies, and used several lines of evidence to support the environmental risk evaluation.

Alternatively, the SACC disagreed with several conclusions of the Draft Environmental Risk Assessment, including that formaldehyde presents no risk to aquatic or terrestrial organisms through

soil and water exposure. The SACC also disagreed with the assumption that formaldehyde is not expected to persist or be detected in aquatic systems. The group recommended that EPA assess the release of formaldehyde to water and include a high centile exposure estimate in the assessment.

The SACC also recommended that the draft assessment include the range of formaldehyde concentrations in water that are below the detection limits, and if there is low confidence in analytical data, then additional monitoring data is needed. The SACC stated that there was insufficient evidence provided to draw a conclusion that negligible concentrations of formaldehyde can be found in water, especially if wastewater treatment plants remove 58% of formaldehyde and there is no evidence to conclude that natural systems would dissolute compounds any better.

EPA Response: EPA believes the environmental risk assessment to be reasonable and conservative. As such, EPA has not made any significant changes to its assessment. The wastewater removal rate of 58% has been noted to be based on an older study not representative of modern wastewater treatment operations.

Summary: The SACC commented that the approach regarding estimating the effectiveness of wastewater treatment plants is contrary to the standard TSCA approach. The SACC went on to say that if measured values are not available for the exposure assessment, the Exposure and Fate Assessment Screening Tool should be used to conservatively model potential releases. Alternatively, the SACC recommended that actual data through traditional or New Approach Methodology are needed before a conclusion is reached. The SACC was divided across suggested approaches, with several members in favor of probabilistic approaches being required throughout the risk evaluation while others stated that Weight of Evidence (WOE) approaches should be viewed with caution because they are not quantitative, and uncertainties are difficult to evaluate. Other committee members strongly supported the WOE approach.

In response to Charge Question 2.1, the SACC noted that EPA did not use a probabilistic assessment, which the SACC described as the current "state of science" for risk assessment. The SACC requested that a more conservative LC value (LC05 or LC20) be used, as suggested by previous SACCs, and that EPA report confidence intervals for the regression analysis.

EPA Response: EPA disagrees with the comment. Searching and identifying the wastewater removal endpoint was conducted in a manner consistent with the Draft Systematic Review Protocol. As a result, it is based in the standard approach. The recommendation that EPA use the Exposure and Fate Assessment Screening Tool (or EFAST) does not account for the limitations of the model. EFAST is not able to account for the formaldehyde's rapid transformation and would overestimate formaldehyde concentrations in water. As a result, the tool was not used.

Every TSCA risk evaluation is conducted in a fit-for-purpose manner. The formaldehyde risk evaluation used the best available tools and data for the assessment. EPA believes the environmental risk assessment to be reasonable and conservative. As such, EPA has not made any significant changes to its assessment.

Summary: The SACC noted that in the human health assessment, atmospheric modeling illustrated that formaldehyde could spread from facilities and generate exposures, which the SACC recommended be modeled for the environmental exposure assessment. They noted that this pathway may lead to exposure by important agricultural resources such as cattle and crops.
EPA Response: As shown in the environmental risk assessment, hazard values for ecological receptors are generally well below monitored and modeled formaldehyde concentrations in air. The recommendation was provided in the draft and the revised risk evaluation.

Section 4.2 – Environmental hazard assessment

No comments are associated with this issue

Section 4.3 – Environmental exposures assessment

Summary: In responding to Charge Question 4.2, the SACC commented that the models represented in the environmental exposures document should consider all formaldehyde sources and then consider which of the identified sources should be reduced or eliminated. The SACC went on to note that releases of formaldehyde and precursor compounds should be considered as mobile sources, and combustion sources and industrial releases should be addressed in any comprehensive risk determination.
EPA Response: EPA has updated its analysis to reflect the SACCs recommendation.

Section 4.4 – Other comments

No comments are associated with this issue

Section 5 – Human Health Risk Assessment

Comments associated with this issue are summarized in the subsections below

Section 5.1 – Human health risk assessment

General comments

Summary: A public commenter (0263) expressed that EPA inappropriately applied non-risk considerations to downgrade risks and disregarded considerations that would increase concerns for risks from formaldehyde exposure. The commenter said that all the additional factors (e.g., background concentrations) considered by EPA are applied in a manner to reduce the level of concern regarding formaldehyde risks and to downplay high cancer and non-cancer risks across multiple exposure settings and scenarios. The commenter added that EPA makes no mention of additional factors that increase the level of concern for formaldehyde exposure, and this does not represent the best available science. The commenter remarked that EPA does not mention the following additional factors, which increase the level of concern: aggregate exposure, risk of leukemia, use of central tendency exposure and risk estimates, and the application of an insufficient human variability factor.
EPA Response: EPA has revised the draft risk determination in consideration of public comments, revisions to the risk assessment, and further consideration of reasonably available exposure and hazard information. EPA is confident that the revised Human Health Risk Assessment is health protective and

based on the best available information with regards to hazard assessment. Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses on aggregate exposures. For COUs evaluated quantitatively, to determine if a COU significantly contributed to unreasonable risk, EPA compared the risk estimates of the scenario used to evaluate the COUs and considered whether the risk from the COU was best represented by the central tendency or high-end risk estimates. This risk evaluation discusses important assumptions and key sources of uncertainty in the risk characterization, and these are described in more detail in the weight of the scientific evidence and overall confidence in exposure assessment (Section 2.5), as well as the weight of scientific evidence and overall confidence in hazard assessment (Section 3.2) in the Human Health Risk Assessment.

EPA considers sources of human variability and susceptibility in derivation of PODs and uncertainty factors. Potential aggregate exposures and risks are further discussed in Section 4.3 of the Human Health Risk Assessment. Uncertainty around leukemia risk is further discussed in the Human Health Hazard Assessment and in Section 3 of the Human Health Risk Assessment. Consistent with recommendations from NASEM, EPA has not quantified risk to myeloid leukemia.

Summary: A public commenter (0219) expressed that male reproductive effects should not be included in the draft risk evaluation. The commenter stated that EPA used the draft IRIS Assessment to support its inclusion of male reproductive effects, but EPA did not include the uncertainties associated with male reproductive effects. The commenter said that EPA discusses the uncertainty attached to study results that evaluated reproductive toxicity in males in the draft IRIS Assessment. The commenter stated that EPA cannot comply with TSCA's scientific standards by relying on EPA's draft IRIS Assessment to support is conclusions that male reproductive effects can be attributed to formaldehyde exposure.

EPA Response: The risk evaluation includes limited reference to the evidence for male reproductive effects identified in the IRIS assessment in the context of summarizing the range of endpoints considered in the IRIS dose-response analysis and in the context of considering lifestage and sex-specific considerations. These are accompanied by references to the IRIS assessment which provides a more in depth discussion of the underlying data and the weight of evidence in support of each endpoint. In Table Apx C2, EPA has added more specific characterization of the confidence in that endpoint, noting that the "IRIS assessment concludes "evidence indicates" formaldehyde "likely causes" male reproductive effects based on robust evidence in animals and slight evidence in people." The quantitative analysis included in the risk evaluation relies on PODs based on other endpoints and does not rely on any male reproductive effects.

Summary: A public commenter (0178) asked if EPA should examine absolute risk or increased risk associated with regulated activities.

EPA Response: For each COU considered in this risk evaluation, EPA has characterized the increased risk associated with that particular source of formaldehyde exposure. In Section 4.3 of the Human Health Risk Assessment, EPA has also qualitatively characterized aggregate exposures and risks that may occur for people exposed through multiple exposure pathways, such as workers or consumers who are also exposed to typical levels of formaldehyde in indoor air at home. Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-

related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

Summary: The SACC recommended that EPA "provide a competent, state-of-the-art, versatile, exposure and risk model with at least the following capabilities: 1) Probabilistic capability for overall algorithm calculations as well as for most (if not all) factors within the algorithms; 2) Visibility and access for changing values and or distribution shapes of data for algorithmic values (utilizing at least 7 basic approaches to data probability distribution); 3) Aggregation across multiple exposure opportunities introduced in time-dependent continuums across people's lifetime, and for different population groups, as chosen by the assessor; 4) Ability to set model factors such that the assessor can consider different environmental scenarios setting up exposure opportunities; 5) Based on person-oriented modeling framework with options for data utility, periods of analysis, output reports on data utilization, chosen assessment metrics, etc." The SACC recommended that such software be programmed and reviewed by professional model developers with maintenance plans to support the model, improve it (with estimated updating plans), and/or archive key modules as needed. The SACC provided recommendations for freely available software that EPA may utilize, such as the exposure and risk assessment models utilized by the Office of Pesticide Programs, EPA's own "General Principles for Performing Aggregate Exposure and Risk Assessments," and a software developed by LifeLine to facilitate an aggregative quantitative analysis. One SACC member also suggested using quantitative assessments from other global assessments conducted by authoritative organizations that used comparable data, but reached significantly different conclusions using different statistical approaches and much more scientifically competent models. The SACC member recommended that these assessments be recognized formally with discussions as to why EPA was more confident in their own assessments than in those from other countries.

EPA Response: EPA is continuously looking for high quality fit-for-purpose tools that assist with conducting chemical exposure and risk assessments. Specifically, all models considered must be applicable to relevant TSCA conditions of use, appropriate for the chemical of interest among other considerations. EPA will continue to consider these comments for future assessments and will continue applying the best available tools for its risk assessments as appropriate. As part of this effort, EPA considers other authoritative assessments.

Risk values

Summary: A public commenter (0235) stated that EPA notes in the draft Human Health Risk Assessment that it is unable to rely on the risk values developed. The commenter expressed that this is appropriate, and the flaws in EPA's development of the risk values do not allow them to be used. The public commenter noted that EPA is not setting unreasonable risk at the 95th percentile indoor air level, as described in the American Healthy Homes Survey (AHHS) II. The commenter expressed concern, however, that the draft risk evaluation does not provide any other exposure level that could inform the determination of unreasonable risk. The commenter stated that no framework is provided, and stakeholders are left to guess at the considerations that EPA used to reach its conclusions for each condition of use. The public commenter expressed that EPA should provide stakeholders with a clear, consistent, transparent, and science-based framework. Finally, the public commenter said that it would

be much easier for EPA to have a transparent framework for unreasonable risk determinations if EPA had followed the best available science and considered the unique properties of formaldehyde.

EPA Response: TSCA COUs were reassessed for the revised formaldehyde risk assessment. This included a reassessment of wood articles. Specifically, wood articles were re-assessed according to the Formaldehyde Emissions Standards for Composite Wood Products final rule, using the IECCU model. This approach is expected to better represent exposures from wood articles currently being sold on the market. The IECCU modeling does not consider the entire supply chain where formaldehyde peak emissions occur after it has been manufactured (with a given weight fraction) but materials sit on a shelf before purchase, and are mostly often installed in a home weeks to months later. To best represent realistic peak exposures after the article has been installed into a home, EPA used emission rates based on the most recent and reasonably available studies, instead of the concentration of the formaldehyde in-article formulation reported by the manufacturer. Together, the CEM modeling and IECCU modeling represent potential exposures to formaldehyde in indoor air.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

The unreasonable risk determination is based on the information in previous sections, the appendices and technical support documents of the modules that comprise this risk evaluation in accordance with TSCA section 6(b). It is also based on TSCA's best available science (TSCA section 26(h)), weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702 including, to the extent practicable, the amendments to the procedures for chemical risk evaluation under TSCA finalized in May 2024 (89 FR 37028; May 3, 2024). Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses on aggregate exposures and cumulative risk. Where EPA had a medium or robust confidence in the risk estimate, a determination of unreasonable risk was made.

Regarding the Indoor Air Analysis, EPA considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air, but the monitoring data do not provide information about the relative contributions of each source. EPA also used models to estimate formaldehyde concentrations from TSCA conditions of use that cannot otherwise be distinguished from other sources of formaldehyde reflected in measured indoor concentration data. EPA used the Consumer Exposure Model (CEM) to estimate long-term indoor air exposures and refined the results with IECCU modeling to estimate acute and long-term risks for exposure to formaldehyde in residential indoor air associated with specific TSCA COUs. EPA found that for the four consumer COUs evaluated under an aggregate approach to exposure to the indoor air, there is no unreasonable risk to the general population in indoor environments.

Summary: A public commenter (0249) recommended that EPA not only provide risk estimates for worst-case exposures that contain the highest weight fractions of formaldehyde. The public commenter recommended EPA also present estimates that reflect the low levels of formaldehyde present in the majority of products that their members use and produce. The public commenter stated that EPA

should refine their assessment for conditions of use where EPA found risks, in order to evaluate risks based on known exposure parameters, not just upper-bound levels.

EPA Response: For the occupational exposure assessment, EPA generally uses monitoring data to estimate inhalation exposures, but in cases where scenarios were modeled a range of weight concentrations were used with probabilistic approaches to estimate the high-end and central tendency. Providing the central tendency (50^{th} percentile) in addition to the high-end (95^{th} percentile) of the dataset shows a more complete picture of magnitude of the workers exposures within the exposure scenario that may result in risk within U.S. workplaces. For dermal exposures, EPA does use the maximum concentration to be protective, but EPA notes if lower concentrations were identified. EPA may explore alternative approaches to dermal assessments for future chemicals, but EPA often does not have the chemical-specific data on the distribution of workers across the entire exposure scenario who may use specific products and their weight concentrations. The use of the maximum concentration provides risk estimates for the group of workers using it at the highest concentration for the exposure scenario and protective of use of other lower concentration products. For the consumer exposure assessment high-end exposure estimates are presented as a conservative estimate of potential consumer exposure from TSCA COUs using CEM. This was based on the highest weight fractions EPA could identify from actual product safety data sheets. Though these are not the only key drivers of exposure concentrations when using CEM which include duration, frequency and amounts used. For the indoor air exposure assessment, low, medium and high-end estimates are presented to capture a range of estimated exposures using IECCU. Though for the indoor air exposure assessment initial article weight fractions alone are deemed inappropriate for the assessment of exposures after the article has been added to a home therefore emission rates are the key drivers for such estimates.

Summary: A public commenter (0219) stated that EPA's risk value is inconsistent with risk values derived by other international scientific bodies. The commenter expressed that EPA's risk value is set lower than the WHO guideline, and this is especially jarring because the WHO guideline ensures public health protection from even the most sensitive effect, not just "unreasonable risk." The commenter wrote that EPA's value effectively transforms TSCA's unreasonable risk standard into an impermissible zero risk standard.

EPA Response: This comment appears to refer to the OEV for acute sensory irritation effects, which was 0.062 mg/m^3 in the draft. In the revised Human Health Risk Assessment, EPA modified this value to 0.167 mg/m^3 (0.2 ppm) to reflect the change in uncertainty factor from 10 to 3. The WHO indoor air guideline established "for the protection of public health" from formaldehyde in indoor air is 0.1 mg/m^3 (0.08 ppm). The OEV is a calculated value based on dose-response information in controlled human exposure studies and should not be interpreted as a regulatory limit. As further clarified in Appendix E, "TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus these occupational exposure values represent risk-only numbers. In risk management rulemaking for formaldehyde following the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the occupational exposure values presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c)."

Summary: A public commenter (0226) said that the draft risk evaluation does not follow EPA's guidelines for calculating average and upper-bound risks. The commenter specifically stated that no direct calculations of upper bound exposures were conducted, which is in direct conflict with EPA

guidelines. The commenter added that only central tendencies were presented in the draft risk evaluation, even though prior TSCA risk evaluations have presented risks calculated for high-end exposures. The commenter wrote that including the upper-bound exposures in relation to central tendency exposures would better characterize the entire distribution and provide more clarity regarding the overly conservative exposure criteria in the draft risk evaluation.

EPA Response: EPA disagrees with this comment. In the Human Health Risk Assessment, EPA consistently evaluated exposure and risks for both upper-bound (typically 95th percentile) and central tendency exposures for all exposure scenarios where sufficient data were available, consistent with EPA guidance.

Risk estimates based on high-end exposure levels (e.g., 95th percentile) are generally intended to cover individuals with sentinel exposure levels, whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure.

For occupational COUs, EPA provided a high-end and a central tendency risk estimate for the final risk evaluation – a change from the draft evaluation based on further Agency review. The high-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. The distributions may show large variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. Providing the central tendency (50th percentile) in addition to the high-end (95th percentile) of the dataset shows a more complete picture of the worker exposure scenarios that may result in unreasonable risk. For acute effects, the use of the high-end risk estimate was used to make a risk determination as the hazard effect can occur after experiencing the exposure only once and no additional assumptions on frequency are needed. For long-term cancer risks, the risk determination was also based on the high-end risk estimates, unless otherwise noted, since EPA generally used monitoring data (i.e., workplace measured concentrations) that represents a range of exposure scenarios across workers and, in most cases, cannot be tied to specific worker exposure groups.

For consumer COUs, EPA only provided a high-end risk estimate to account for PESS populations using consumer-based products.

Summary: A public commenter (0263) recommended EPA utilize epidemiological dose-response data to generate quantitative estimates of non-cancer risks. The commenter stated that EPA relied on the calculation of a margin of exposure (MOE), which is a simplistic approach that only examines the ratio of the POD to the exposure level and determines whether this ratio indicates risk. The commenter said that the MOE does not estimate the proportion of the exposed population projected to experience a specified health endpoint or the number of individuals affected, and it perpetuates the flawed notion that a safe level of chemical exposure can be identified for a diverse population. The commenter added that the draft IRIS Assessment identified epidemiological studies with suitable data for POD estimation for multiple endpoints, and the commenter recommended EPA use the dose-response data from these studies to estimate dose-response functions that can be used to quantify the risks of non-cancer effects at relevant exposure levels. The commenter provided an illustration of the recommended approach, using the pooled odds ratio from the Navigation Guide systematic review of formaldehyde and asthma by Lam et al. to calculate the estimated formaldehyde exposure levels associated with various levels of risk.

EPA Response: EPA relied on existing accepted guidance to evaluate noncancer dose-response information on formaldehyde using an MOE approach. Epidemiology dose-response data provide the quantitative basis for the EPA IRIS RfC used to assess risks from chronic exposures for the general population. As discussed in Section 5.2 of this document, some SACC and public commenters raised concerns about the quality of the epidemiology studies. EPA will continue to iteratively refine our dose-response approaches as appropriate in future assessments.

Background exposure to formaldehyde

Summary: Two public commenters (0262, 0226) stated that the limitations of background levels and naturally occurring formaldehyde have not been clearly identified in the exposure assessments. One public commenter (0262) expressed that it is critical that EPA emphasize natural sources and background levels of formaldehyde, which are often at higher levels than TSCA conditions of use. The public commenter recommended EPA incorporate a quantitative adjustment to exposure values based on background levels and naturally occurring sources, if possible. Another public commenter (0235) similarly stated that EPA's consideration of biogenic sources of formaldehyde as "background" obscures the large contribution of these sources to the overall risk. The commenter said that EPA sought to use the standard approach it used to evaluate other TSCA chemicals that do not have biogenic exposures, without thinking about a more appropriate paradigm to evaluate health risks due to formaldehyde exposures. A public commenter (0226) recommended EPA make appropriate revisions to account for naturally occurring formaldehyde and homeostasis in the draft IRIS Assessment and the draft risk evaluation.

A public commenter, in both a joint submission and an individual submission to the docket (0190, 0194), said that the SACC should understand that formaldehyde is an endogenous compound in the human body and should charge EPA with more fully evaluating the impact of the endogenous presence of the substance into the risk assessment. The commenter wrote that formaldehyde is naturally produced as a metabolic byproduct by all living organisms, and the inability of inhaled formaldehyde to alter normal endogenous blood concentrations suggests that this metabolic feature most likely protects internal organs from effects of low levels of formaldehyde.

EPA Response: The risk evaluation focuses on exposure to TSCA conditions of use but provides risks associated with other sources of formaldehyde. One method used to do so is through integrating AirToxScreen modeling results from 2019 and 2020. In addition, the risk evaluation acknowledges that exposure can occur from multiple other sources. Risk from formaldehyde exposure through these other sources can be understood to occur in addition to the risks estimated for specific COUs and exposure pathways evaluated in this assessment.

The potential impact of endogenous formaldehyde is discussed in the IRIS responses to NASEM and public comment provided in Appendix F of the Supplemental Information document accompanying the IRIS assessment.

Summary: Two public commenters (0263, 0283) expressed that EPA understated formaldehyde's risks by ignoring the extent to which background exposures exacerbate the risks that people experience from formaldehyde's conditions of use under TSCA. One public commenter (0283) specifically defined "background" as all formaldehyde exposures that EPA has not included in its analysis of formaldehyde's conditions of use, including biogenic formation, uses of formaldehyde that fall outside of TSCA's definition of chemical substance, secondary formation or combustion-related exposures that

are not attributable to TSCA conditions of use, and other unattributed sources of formaldehyde in indoor and outdoor air. The commenters (0263, 0283) stated that risk is a function of someone's total exposure to formaldehyde, so people with higher background exposures will experience greater risks from formaldehyde's conditions of use than people with lower background exposures. The public commenters said that EPA's failure to properly account for background exposures violates TSCA for two reasons: (1) ignoring background exposures is contrary to the best available science; and (2) ignoring background exposures violates TSCA's mandate to evaluate and address risks to potentially exposed or susceptible subpopulations (PESS). One commenter (0283) specifically noted that many of the formaldehyde-containing products that are not directly regulated under TSCA, such as hair smoothing and straightening products, are marketed to Black women, and Black people are also disproportionately harmed by the releases of formaldehyde from TSCA's conditions of use. The commenter remarked that, by ignoring background exposures, EPA understates formaldehyde's risks to Black women and other vulnerable populations.

A public commenter (0283) stated that EPA does not need to calculate the precise contributions of background exposures to account for their existence. The commenter suggested several ways that EPA could estimate background exposures without any additional information. First, the commenter suggested EPA could estimate background exposures by subtracting the exposures associated with a given condition of use from the exposures detected in ambient or indoor air. Second, the commenter suggested EPA could assign a default background contribution, as it has done under the Safe Drinking Water Act, Clean Water Act, and Resource Conservation and Recovery Act. Finally, the commenter stated that EPA has data that can be used to quantify at least some background formaldehyde exposures; for example, NEI provides national, state, and county-level data on biogenic and mobile source releases of formaldehyde. The commenter wrote that EPA cannot continue to understate formaldehyde's risks by failing to consider background exposures.

EPA Response: EPA acknowledges that all individuals are exposed to formaldehyde from multiple sources. The formaldehyde risk evaluation uses both monitoring data and models to characterize people's exposure at work, at home, in vehicles, and when they are outside. The associated risk with these exposures is context specific and complex. As noted in the Executive Summary for the risk evaluation as well as in the risk determination, EPA has noted where there is risk and whether it is unreasonable.

PESS

Summary: A public commenter (0261) expressed support for the attention EPA paid to the fenceline communities. The commenter stated that Table 4-2 shows the disproportionate cancer burden on African Americans and Native Americans, when compared to Whites, Other, and Multiracial and Latino/Hispanic subpopulations. The commenter added that Table 4-3 reinforces this reality, as it presents the demographic details of the population with estimated cancer risk higher than or equal to 1 in 1 million.

EPA Response: EPA has retained these analyses.

Summary: A public commenter (0263) stated that EPA has not appropriately identified PESS. The commenter said that EPA excluded multiple potential PESS and did not apply a transparent methodology for quantifying the risk of harm to each identified PESS using the best available science.

The commenter recommended EPA prepare a comprehensive methodology to identify PESS and quantify their risks consistently across the TSCA risk evaluations. The commenter noted that the listing of potential PESS in Table 4-4 is a useful initial step. The commenter said, however, that EPA's identification of PESS fails to adequately consider life-stages, pre-existing disease or underlying health conditions, individual activities (such as recreational exercise or smoking), geographic factors, socio-demographic factors, nutrition, genetics, and other chemical and non-chemical stressors.

Another public commenter (0283) stated that EPA understated risks to PESS in multiple situations. The commenter provided several examples of this, such as the fact that EPA did not identify specific data on other sources of increased exposures associated with socioeconomic status and the fact that EPA did not consider increased inhalation rates and volumes during pregnancy. In addition, the commenter remarked that EPA did not consider higher respiration rates for children. The commenter stated that EPA will understate risks and thus violate TSCA without an adequate analysis of the risks faced by PESS.

EPA Response: As described in Section 4.2.6 of the Human Health Risk Assessment, "EPA considered PESS throughout the exposure and hazard assessments supporting this analysis. Table 4-5 summarizes how PESS were incorporated into the risk evaluation through consideration of increased exposures and/or increased biological susceptibility". Specifically, EPA considered groups or lifestages with greater exposure to formaldehyde, including people exposed to formaldehyde at work, those who frequently use consumer products containing high concentrations of formaldehyde, people living or working near facilities that emit formaldehyde, and people living in mobile homes and other indoor environments with high formaldehyde concentrations are expected to have greater exposures. EPA evaluated risks anticipated for a range of scenarios under TSCA COUs where exposures are expected to be greatest.

EPA also considered groups or lifestages that may be more susceptible to the health effects of formaldehyde exposures. For example, children have developing respiratory systems and narrower airways that may make them more susceptible to the respiratory effects of formaldehyde. The chronic inhalation hazard value is derived in part based on dose-response information in children with asthma and is supported by dose-response information on lifestage-specific reproductive and developmental effects in humans and animals. The chronic inhalation hazard value incorporates information on several sensitive groups; therefore, EPA used a value of 3 for the UF_H to account for human variability. In addition, EPA applied ADAFs to lifetime cancer risk estimates to account for increased susceptibility to nasopharyngeal cancer following inhalation exposure during early life.

EPA intends to continue iteratively refining the approach to PESS in future risk evaluations, taking into consideration feedback from the public and peer reviewers, lessons learned through previous assessments and chemical-specific concerns.

Summary: A public commenter (0263) said that the uncertainty factors (UFs) identified by EPA are insufficient for protecting PESS. The commenter stated that EPA rejected the application of UFs to account for the elevated risk to PESS, and EPA only quantitatively adjusted for differences in human susceptibility with the application of the standard human variability UF. The commenter wrote that, instead of increasing the use of UFs to account for the range of vulnerability in the human population, EPA proposed to decrease UFs, which is not scientifically supported and will result in underestimation of risk for PESS. Moreover, the commenter stated that EPA concluded no further adjustment is necessary for identified PESS due to lack of chemical-specific data for PESS. The commenter said that

TSCA does not require chemical-specific data, and the best available science demonstrates that both intrinsic and extrinsic factors can increase susceptibility to harm from chemical exposures. The commenter stated that, when chemical-specific data are absent, generic adjustment factors should be applied to ensure that risks to PESS are not underestimated.

Two public commenters (0244, 0283) expressed concern that EPA relied on the intra-species UF to address risks to PESS. The commenters remarked that EPA assumed, without support, that application of the intra-species UF would address risks to virtually all PESS. The commenters stated that the intra-species UF is only intended to account for variations in susceptibility within the general population of healthy adults. The commenters said that this approach violates TSCA's mandate to address risks to PESS and recommended that EPA assess risks to distinct groups of PESS separately. One commenter (0283) added that EPA has applied a ten-fold UF even in circumstances where it did not identify any PESS, and the commenter stated that the same adjustment cannot account for those who are known to experience increased susceptibility. The commenter recommended that EPA should adopt additional UFs to ensure that it is adequately considering PESS, if EPA lacks sufficient information to evaluate susceptibility to formaldehyde specifically across all relevant subgroups.

EPA Response: EPA considers multiple PESS groups in characterization of hazard and risk (including all lifestages, individuals with pre-existing health conditions, and genetic predispositions). EPA does not necessarily provide distinct risk estimates for each subpopulation, because some are already represented by the risk estimates presented while others are not quantifiable based on available information (e.g., genetic predisposition, other health conditions). In the absence of quantitative information on the impact of genetic variability, pre-existing health conditions, lifestage, or other factors on susceptibility across the population, EPA applied an uncertainty factor of 3 to account for interindividual variability for acute and chronic inhalation exposures and a factor of 10 for dermal exposure. The uncertainty factor for the chronic inhalation was reviewed by the NASEM. The uncertainty factors for acute inhalation and dermal exposure were reviewed by the SACC and the acute inhalation uncertainty factor was revised from 10 to 3 based in part on SACC feedback. EPA acknowledges that there is uncertainty around the magnitude of variation in toxicokinetic and toxicodynamic factors across individuals and whether these uncertainty factors is sufficient to protect potentially susceptible subpopulations.

Summary: A public commenter (0283) stated that EPA failed to identify all PESS, because EPA largely ignored PESS who fall into this category due to aggregate or cumulative exposures due to known or foreseeable combinations of exposures from various conditions of use and across multiple exposure pathways. The commenter recommended EPA remedy this in the final Risk Evaluation by considering all relevant aggregate and cumulative exposures, identifying the PESS that face such exposures, and evaluating the risks faced by those groups. The commenter said that many commenting organizations have previously explained to EPA how it can gather relevant information and quantify the risks from cumulative chemical exposures, and EPA should use those methods. The commenter stated that EPA cannot simply ignore that source of increased susceptibility or rely on purely qualitative assessments that have no bearing on EPA's ultimate risk determinations.

EPA Response: In Section 4.3 of the Human Health Risk Assessment, EPA has qualitatively described the potential for aggregate exposure across known or foreseeable combinations of multiple exposure scenarios to increase risk for some individuals. In Section 4.2.6 and Appendix C of the Human Health Risk Assessment, EPA provides some qualitative discussion on the potential for co-exposures to other chemical and non-chemical stressors may contribute to susceptibility for some individuals. EPA has recently consulted with the Science Advisory Board on a draft approach for considering co-exposure.

The SAB report was recently published. EPA is reviewing this report and may, if appropriate consider additional analysis for future risk evaluations but these calculations have not been developed for formaldehyde. See https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2657&clear=18&session=4647294490129

Aggregate and cumulative exposure

Summary: The SACC stated that they generally disagreed with EPA's conclusion that there is too much uncertainty to support quantitative aggregation across multiple exposure sources and said that the lack of an attempt to quantify appeared to result from a lack of technical tools, an approach using exposure scenario categories that are far too broad, and dismissal of valuable information. The SACC said that the lack of any sort of quantitative analysis was likely leading to an underestimate of risk for those who are potentially the most exposed (i.e., those who are experiencing exposure across multiple exposure routes) and that an aggregate exposure assessment would more accurately capture exposures in homes and the workplace. Several SACC members said that there was a substantial amount and diversity of available data to support a probabilistic approach to explore aggregate exposure across scenarios. The SACC said that, if a quantitative probabilistic approach is not possible, some members noted that another alternative approach for the current risk assessment would be to conduct screening-level sensitivity analysis, which could develop exposure and risk estimates for worker and consumer conditions of use with medium or high confidence that would be reasonably expected to co-occur and include ambient exposures using AirToxScreen and AMTIC.

The SACC strongly recommended that EPA add vehicle air as a microenvironment relevant for all populations. One SACC member strongly recommended adding challenged urban communities as a unique community exposure scenario for ambient air representation, as this would apply to mixed use urban conditions of comingling of residential, public, and commercial space nearby constant emissions from businesses utilizing formaldehyde-based products and necessary venting of those indoor business spaces into close proximity of the broad population groups.

Some public commenters (0261, 0283) disagreed with EPA that there is too much uncertainty to do more than a qualitative aggregate exposure assessment and recommended that EPA develop and implement more robust aggregate analyses. For example, a public commenter (0283) stated that EPA failed to aggregate exposures across all relevant exposure routes, exposure pathways, and conditions of use. The commenter wrote that potential uncertainties do not provide a valid excuse to ignore reasonably foreseeable circumstances by which individuals are exposed to formaldehyde, given that EPA is required to consider those who are exposed from multiple conditions of use and through multiple pathways.

A public commenter (0283) stated that EPA failed to account for aggregate exposures from multiple facilities releasing formaldehyde in fenceline communities, failed to consider aggregate exposures associated with the conditions of use that were qualitatively assessed and failed to aggregate the exposures from industries associated with multiple conditions of use of formaldehyde. Moreover, the commenter noted that EPA failed to aggregate exposure and risk across different exposure routes on the basis that risks are not additive across routes, and the commenter stated that this approach is at odds with the evidence that there are systemic effects from oral and inhalation exposure routes.

A public commenter (0261) expressed that EPA used both monitoring and modeled data in their analyses, with a stated preference for monitoring data. The commenter said, however, that existing data was insufficient or completely lacking in some cases. The commenter stated that this is an unfortunate situation and leaves the overall exposure assessment in a weakened state. The commenter remarked that formaldehyde possesses a robust hazard database, and ample opportunity has been available to EPA to use its data-gathering authorities to fill some of the exposure data gaps by requiring the generation of monitoring data for scenarios within the reach of TSCA.

Other public commenters expressed that EPA's qualitative approach to aggregate exposures is reasonable due to significant uncertainty in combining indoor and outdoor exposures (0235) and that there is not enough data to assess aggregate exposures (0182).

EPA Response: EPA acknowledges the importance of characterizing aggregate exposures and risks that are expected to occur for individuals exposed through multiple exposure scenarios (e.g. workers can be expected to also have some exposure to formaldehyde through indoor air at home). EPA has qualitatively discussed the potential for aggregate exposure and risks across these scenarios. As stated in Section 4.3 of the Human Health Risk Assessment, "In cases where risks from two exposure scenarios are similar (*e.g.*, occupational risks for some COU may be in the same range as risks from indoor air exposures at home based on AHHS II monitoring data), aggregate risks could be as much as double the risk from each pathway in isolation. These types of aggregate risks were not quantified for specific combinations of scenarios. Risks for individual exposure scenarios should be interpreted with an appreciation for potential aggregate exposures and risks."

EPA used the HEM model to consider aggregate exposure from multiple facilities releasing formaldehyde. The HEM model results reported in Tables 4-2 and 4-3 represent ambient air exposures for communities based on aggregation of all nearby sources reporting releases to TRI. As described in Section 4.2.4.4, "these cancer risk estimates are based solely on formaldehyde emissions from facilities reporting to TRI, and represent the aggregation of exposures from multiple nearby facilities." In the revised risk assessment, EPA further characterized potential aggregate exposures by mapping locations with multiple facilities reporting formaldehyde releases that are in close proximity. This information can be found in the ambient air technical support document.

For occupational COUs, EPA's analysis is expected to reflect the total occupational exposure experienced by an individual. Exposure estimates are generally reflective of aggregate exposure that occur for a worker in the course of their job because they are largely based on personal monitoring data that is expected to reflect the range of specific tasks, including other co-occuring COUs. Therefore, no further aggregation is needed within a COU to fully capture worker exposures.

EPA did not aggregate risks across exposure routes (i.e. inhalation and dermal) because there is no common quantitative basis for doing so. As stated in Section 4.3 of the Human Health Risk Assessment, "for formaldehyde, cancer risk is only quantified for inhalation exposures and therefore cannot be quantitatively aggregated across multiple routes." Similarly, because noncancer risks are qualitatively different for different routes of exposure (inhalation PODs are based on sensory irritation and respiratory effects while dermal PODs are based on skin sensitization), EPA did not assume these to be additive.

Summary: Several public commenters (0263, 0244, 0283) noted that EPA did not conduct a cumulative risk assessment, which underestimates risk. The commenters wrote that EPA failed to consider the potential increased risk to the general population, workers, and PESS when co-exposures

to other carcinogens occur. The commenters recommended EPA evaluate formaldehyde and other carcinogens currently undergoing risk evaluation as a class of chemicals and conduct a cumulative risk assessment. The commenters said that co-exposures to formaldehyde and multiple other carcinogens are prevalent in certain communities in the United States. The commenters specifically recommended that EPA consider 1,3-butadiene in the draft risk evaluation, given the shared health outcomes and high likelihood of co-exposures to 1,3-butadiene and formaldehyde. One public commenter (0244) said that failing to account for chemical co-exposures underestimates risks to people living near facilities co-releasing formaldehyde and 1,3-butadiene and violates TSCA. The commenter specifically stated that people co-exposed to 1,3-butadiene and formaldehyde face greater risks of leukemia and other cancer and non-cancer effects than would be expected based on consideration of exposures to formaldehyde alone. One commenter (0283) stated that TSCA requires the consideration of those who experience susceptibility because of the cumulative chemical exposures, such as fenceline communities who are exposed to multiple chemicals with similar health effects. One public commenter (0263) added that EPA must also consider non-chemical stressors that increase an individual's susceptibility to harm from chemical exposures when conducting a cumulative risk assessment.

EPA Response: EPA acknowledges the potential for risks from co-exposures to chemical and non-chemical stressors. In Section 4.2.6 and Appendix C of the Human Health Risk Assessment, EPA qualitatively considers the potential for such co-exposures to increase susceptibility to formaldehyde. Quantitative consideration of cumulative risks is beyond the scope of the current risk evaluation. EPA has recently consulted with the Science Advisory Board on a draft approach for considering co-exposure. The SAB report was recently published. EPA is reviewing this report and may, if appropriate consider additional analysis for future risk evaluations but these calculations have not been developed for formaldehyde. See https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2657&clear=18&session=4647294490129

Summary: A public commenter (0182) said that using multiple data sources do not, in many cases, work in conjunction with each other without making assumptions on time scales and distances. The commenter also said that because each source of data has layers of uncertainty, these compound upon one another such that the accuracy of the overall results and conclusions is unclear. The commenter stated that the uncertainties included:

- The aggregation of multiple sampling periods and collection methods of AMTIC, together to generate a national annual ambient background value that cannot be apportioned by source, does not consider regional variations, and is not based on any annual sampling data.
- The assertion that the monitoring data can be used to aggregate exposures and risks from all sources (including indoor settings) is unsupportable. Indoor concentrations are typically higher than outdoor, and exposure indoors comes in the form of both inhalation and skin contact.
- AirToxScreen modeling was used to attempt to assess national annual concentrations of formaldehyde by source type. The data itself is broad-brushed and the emission information drawn from the NEI is based on annual facility-wide emissions. Because the AMTIC data is not able to identify the contributing sources of formaldehyde, comparison to the AirToxScreen results, which only contain model-predicted impacts from industrial sources, is problematic.
- The Human Exposure Model (HEM), while potentially appropriate to assess risk, is reliant on questionable assumptions in determining generic source types and thus is flawed. Additionally, the HEM and AMTIC ambient concentrations cannot be comparatively assessed.

- The Integrated Indoor-Outdoor Air Calculator (IIOAC) modeling is old and dependent on AMS/EPA Regulator Model (AERMOD) modeled concentrations, which used parameterizations that cannot be altered to fit the scenario being reviewed. AERMOD is not designed to calculate indoor concentrations or concentrations so close to a potential emission source. Additional analysis is not possible because EPA does not elaborate on the parameters chosen as input for the IIOAC model.

The commenter concluded by stating that the various data reviewed and generated does not provide any basis for accurate calculation of exposure indoors. For the assessment of aggregate exposures outdoors, the data sources have the potential to offer some insight but would require refinement and better inputs to improve their accuracy and address the levels of conservatism that are built into each of the data sources contributing to the analysis.

EPA Response: The AMTIC, AirToxScreen, HEM, and IIOAC results/datasets were not used to assess indoor air exposures to formaldehyde. While EPA recognizes and acknowledges the limited comparability of the various data sets used for the outdoor (ambient) air assessment within the risk assessment package, AMTIC, AirToxScreen, and HEM data were all used for specific purposes to contextualize overall exposures via ambient air. This contextualization was then used to help characterize exposures and associated risks which were based and derived from the TSCA COU specific IIOAC modeled concentrations. Although input parameters used for IIOAC are described in the ambient air exposure assessment module and included in supplemental files, EPA will consider additional discussion/description around IIOAC inputs within the ambient air exposure assessment module.

EPA identified articles that are expected to be significant contributors to indoor air according to the literature and supported by the SACC. The revised formaldehyde indoor air exposure assessment provides updated indoor air modeling using IECCU through which EPA incorporated expected exponential decay and through which EPA incorporated article emission rates from the 2016 Composite Wood Products Rule, assuming compliance. Both models are based on article weight fractions and/or emission rates and factors from finished goods as reported in safety datasheets and literature. Together, the CEM and IECCU modeling provides EPA the ability to determine the relative contributions of TSCA COUs to indoor air. In addition, the indoor air exposure assessment was also led significantly by various sources of indoor air monitoring including the AHHS II.

Comments on specific passages/figures

Summary: A public commenter (0246) stated that the passage beginning at line 247 of the Consumer Exposure Assessment is unclear as to whether it applies to negligible exposure or limitations of available models and data. The public commenter wrote that the corresponding section in the consumer exposure scenarios indicates negligible exposures are attributable to these conditions of use, and the public commenter recommended that EPA clarify.

EPA Response: EPA has revised the consumer exposure assessment to improve clarity of expected negligible exposures and limitations associated with the Consumer Exposure Assessment.

Summary: A public commenter (0246) wrote that a passage at line 275 of the Human Health Risk Assessment refers to “pesticides and other formaldehyde uses regulated by the Food and Drug

Administration," but pesticides are regulated under FIFRA. The public commenter recommended that EPA clarify.

EPA Response: EPA has corrected this passage in the executive summary of the Human Health Risk Assessment.

Summary: The SACC asked how representative the parameters used for IIOAC and AERMOD/HEM are, given that in Table 2-1 of the Ambient Air Exposure Assessment, the NEI has stack parameters for some sources.

EPA Response: The [stack] parameters used for IIOAC [presented in Table 2-1 of the revised Ambient Air Exposure Assessment Module] are national averages based on analyses and reviews conducted during the development of the IIOAC model. These same default parameters were used as inputs for HEM to allow comparability of modeled concentrations between HEM and IIOAC. Given the formaldehyde ambient air exposure assessment was not a site-specific assessment but rather a broader national level assessment using an industry sector approach, and release statistics across each industry sector, EPA feels it is appropriate and representative to use the national average default parameters from IIOAC. Even though EPA used the default parameters within IIOAC to model ambient concentrations used to characterize exposures and derive associated risk estimates, EPA conducted and included in the ambient air exposure assessment a sensitivity analysis using HEM for two different stack heights (10 meters and 25 meters) to see the impact of a higher stack height on modeled results and included those findings in the ambient air exposure assessment. As expected, while the 10 meter stack height showed slightly higher concentrations and the highest impact of stack releases typically around 100 meters, the 25 meter stack height results showed slightly lower concentrations and the highest impact of stack releases typically around 1,000 meters but did not significantly change the overall findings relied upon to characterize exposures and derive associated risk estimates in the risk evaluation. Therefore EPA believes the parameters used in the formaldehyde risk evaluation are appropriate and representative for a national level assessment of formaldehyde under TSCA.

Summary: The SACC requested that EPA clarify how the data presented in Figure 2-8 of the draft Human Health Risk Assessment were derived and provide a better legend and caption for the figure. The SACC requested that EPA clarify if the figure represents a specific year or is it an annual average over the 6-years of data, and also identify and discuss the extent that multiple facilities contribute to elevated concentrations in any location. The SACC requested that EPA clarify what the dots represent in the figure. The SACC said that it appears as if concentrations are assigned to specific points, but this does not match the description of the figure.

The SACC said the following regarding Figure 2-8: the figure "demonstrated the modeled annual formaldehyde concentrations for each census block with the census block shaded in different colors to indicate its range and its relationship to the 95th percentile of the biogenic threshold. However, it was unclear what the benefit of showing whether a census block has an estimated ambient formaldehyde exposure annual concentration that is larger than a US-wide biogenic threshold. Both the ambient formaldehyde concentration and the concentration of formaldehyde related to biogenic sources/phenomena vary spatially, hence it appeared to evaluate that it would make more sense to understand whether in a specific block the amount of formaldehyde concentration due to TRI releases is greater than the 95th percentile of formaldehyde concentration due to biogenic sources at that

location. This would be more protective to the population as it sets a threshold that is location specific."

EPA Response: A description of the methodology by which the data in Figure 2-8 of the revised Human Health Risk Assessment was described in the Draft Ambient Air Exposure Assessment for Formaldehyde. EPA has further clarified this in the Ambient Air Exposure Assessment for Formaldehyde following peer review.

Summary: A public commenter (0246) expressed concern about how the data are presented in Figure 2-9 of the Human Health Risk Assessment. The public commenter stated that, although the distance values are equidistant, they vary by four orders of magnitude. The public commenter recommended EPA present the data in another manner.

The SACC requested that EPA clarify how the data presented in Figure 2-9 were derived and provide a better legend/explanation for the figure. The SACC said that it is unclear how the total concentration, which is assumed to be the sum of fugitive and stack release, has a median that is smaller than the median for one of the two terms that defines it. The SACC said that the spatial distribution of the concentrations is obscured because the concentrations for all the receptors are lumped together at each distance.

The SACC said that Figure 2-9 attempted to compare the distribution of the ambient exposure concentration at the receptor points and evaluate the contribution of fugitive release versus stack release at different distances from a TRI sites. However, the SACC said it is unclear how the total, which is assumed to be the sum of fugitive and stack release has a median that is smaller than the median for one of the two terms that defines it. Secondly, these results do not consider the spatial distribution as the concentrations for all the receptors are lumped together, so for example there could be a receptor at 10m from a TRI site for which the concentration due to stack release is larger than the concentration due to fugitive release and that might be true for all the receptors in a particular region of the United States because of meteorological conditions and of dispersal. Yet one would not be able to identify this type of pattern as here the results are collated over space, according to the SACC.

EPA Response: EPA clarified language around Figure 2-9 in the revised Human Health Risk Assessment. In general, the total median concentration is the central modeled value within a data set (rather than a mean/average across the modeled results at a given distance). As a result, the median value may be the same as the "mean" or "average." For example, if there are significantly more low modeled stack releases (and associated concentrations) from facilities that report no fugitive releases, then the "central" value across the entire total dataset may be lower than the central value for only the fugitive releases as can be seen in Figure 2-9 at 10 meters.

Summary: A public commenter (0178) referenced pages 59 to 60 of the draft Human Health Risk Assessment and stated that EPA provided method detection limits along with sample concentrations on a submission-by-submission basis, ranging from 0.000011 to 1.2 g/m^3. The commenter said that concentrations of formaldehyde ranged from below the method detection limit to 60.1 g/m^3, and entries with reported concentrations below the method detection limit were substituted with a value of 0 g/m^3. The commenter asked what the scientific rationale is for lowering the values below the method detection limit to zero.

EPA Response: Many substitution methods are used in risk evaluations. EPA used zero substitution as it was the most appropriate for the dataset in this assessment.

Summary: A public commenter (0240) stated that Table 3-1 of the draft Human Health Risk Assessment lists the hazard value for "Inhalation Chronic non-cancer (Long-term, >6 months)" as "BMCL10 = 0.017 ppm (0.021 mg/m^3)," but this value was listed as 0.017 ppm and 0.21 mg/m^3 under the "Hazard Values" tab in EPA's formaldehyde draft Risk Evaluation Occupational Risk Calculator.

EPA Response: EPA has corrected this typo in the revised occupational risk calculator. While the mg/m^3 value reported in the draft for reference was incorrect, all of the calculations were performed in terms of ppm and there was therefore no impact on risk estimates.

Summary: The SACC suggested that EPA, in Table 4-2 of the draft Human Health Risk Assessment, should consider rounding to a level with more confidence based on the uncertainty in exposure data and population data (Census data is also uncertain) and provide a presentation of uncertainty limits (e.g., confidence intervals).

EPA Response: The population numbers in Table 4-2 of the revised Human Health Risk Assessment are provided directly by the HEM output files based on the 2020 census data, therefore there is no external analysis conducted by EPA where confidence intervals may be developed around the population numbers.

Summary: A public commenter (0261) discussed Section 4.2.1.1 of the draft Human Health Risk Assessment. The commenter wrote that this section includes a statement summarizing how many TSCA conditions of use have risk estimates below the benchmark or have cancer risk estimates above the acceptable threshold. The commenter stated that this summary should also include a reiteration of whether the risk estimate was based upon a median or high-end exposure and the rationale/justification for that choice.

EPA Response: EPA used the high-end (95^{th} percentile) modeled concentrations from the IIOAC model to derive risk estimates. The rationale/justification of the release and exposure scenarios, modeled concentrations, operating scenarios, etc. are provided in Section 2.1 of the revised Ambient Air Exposure Assessment for Formaldehyde. A summary of the release and exposure values used to derive the risk estimates are reiterated in Section 2.4.2.1 of the Human Health Risk Assessment of Formaldehyde which in turn refers the reader to Section 4.2.4.2. The Risk Determination document provides the rationale for overall unreasonable risk conclusions.

Section 5.2 – Human health hazard assessment

Acute inhalation hazard value

Selection of sensory irritation as the basis for the acute POD

Summary: Some SACC members stated that sensory irritation is the most relevant and scientifically justifiable endpoint, but there was a lack of agreement among SACC members that sensory irritation is an adverse health effect. Some SACC members expressed that sensory irritation is not conventionally defined as an adverse effect, and some SACC members said that mild sensory irritation is a reversible effect. Moreover, some SACC members noted that sensory irritation is a subjective endpoint that can be influenced by odor. Other SACC members said that sensory irritation could interfere with normal

functioning of people engaged in certain tasks and POD values based on sensory effects could be useful to avoid worker decrements in function.

SACC members discussed the evidence for sensory irritation as the basis of the POD. SACC members suggested that the appropriate data set for benchmark dose modeling is "moderate" eye irritation. SACC members said that moderate irritation is more arguably an adverse effect, while mild irritation is not. However, some SACC members expressed that moderate effects are not debilitating, so there is still no adverse effect. The SACC suggested that an alternative health endpoint to sensory irritation might be histopathologically detectable irritation, noting that as exposure concentrations increase to or beyond 2 ppm, tissue damage and associated irritation/inflammation begins to occur, leading to cell damage.

A public commenter (0261) said that sensory irritation is an appropriate endpoint upon which to base acute inhalation hazard values and that the weight of evidence narrative is scientifically sound and well-supported by the available data. Other public commenters (0231, 0219) discussed the fact that sensory irritation is not an adverse effect and reflects a normal physiological response to stimuli. Another public commenter (0179) stated that it is important to understand the mechanisms underlying sensory irritation when evaluating NOAECs. Another public commenter (0235) stated that sensory irritation does not occur at typical indoor and outdoor exposure levels associated with TSCA uses of formaldehyde. The commenter remarked that it is well-accepted that if there is protection against sensory irritation, then there is protection against all other potential adverse effects.

EPA Response: EPA concluded that sensory irritation is an appropriate basis for the acute inhalation POD. This is consistent with other authoritative sources who have set acute PODs for formaldehyde (listed in Appendix A of the Human Health Hazard Assessment for Formaldehyde) and supported by members of both the HSRB and the SACC. As noted by some SACC members in the SACC report, "eye or other mucous membrane irritation can have adverse impacts if the worker or individual in the general population is hampered in the safe performance of their occupation or transportation, as examples'. While it is noted in the SACC report that "In general, "mild sensory irritation" is not seen as being adverse for AEGLs and is considered on a case-by-case basis", the AEGL-1 for formaldehyde is based on a NOAEL for eye irritation in a controlled human exposure study. The mode of action for sensory irritation is discussed in Section 4.1.1 of the hazard assessment and was discussed in more detail in the IRIS assessment.

Studies used as the basis for dose-response

Summary: The SACC reviewed the studies identified by the HSRB review for the selection of the POD and concluded that data from these studies could be useful in supporting the selection of the POD. Some SACC members encouraged EPA to more heavily weigh the Kulle (1993) and Kulle et al. (1987) studies as the basis for the candidate POD. The SACC said that the supporting studies cited in the Draft Human Health Hazard Assessment (Liu et al., 1991 and Hanrahan et al., 1984) are of limited quality, but the final four studies used by EPA to develop the acute inhalation POD (Kulle, 1993; Kulle et al., 1987; Lang et al., 2008; Mueller et al., 2013) are of high quality. The SACC noted that there are only three acute studies listed in Table 4-2 in the Draft Human Health Hazard Assessment, but Charge Question 1.1 indicates that four studies were used to establish the POD.

A public commenter (0244) said that EPA should consider two additional studies: Pazdrak et al. (1993) and Krakowiak et al. (1998), noting that both found evidence of adverse effects following formaldehyde exposures at lower concentrations than the acute POD selected in the draft risk

evaluation. Consistent with previous comments from the HSRB, several public commenters (0166, 0186, 0190, 0194, 0231, 0235, 0258) expressed concern about EPA's reliance on observational studies and stated that controlled human studies are considered the gold standard. One commenter (0179) noted that NOAECs derived from high-quality human volunteer studies will be lower than NOAECs derived from a chronic inhalation study in rodents. Another commenter (0190, 0194), stated that early studies investigating the irritant properties of formaldehyde generally did not properly account for its acrid or pungent odor and suggested that EPA instead rely on state-of-the-art studies that were published in this century, such as Mueller et al. and Lang et al.

EPA Response: EPA has revised Section 4.1.2 to clarify which studies were used quantitatively to support dose-response and to provide a more detailed rationale for the extent to which each was used to inform POD selection. EPA considered four controlled human exposure studies on sensory irritation in Section 4.1.2 of the hazard assessment. Based on feedback from the HSRB, EPA relied on three of these studies quantitatively in dose-response analysis (see Table 4-2 of the hazard assessment). As discussed in Section 4.1.2 of the hazard assessment, Kulle et al (1987 and 1993) is the primary basis for the acute inhalation POD and Lang et al. (2008) and Mueller et al. (2013) are used as supporting studies that identify effect levels very similar to those reported in Kulle et al. EPA agrees with commenters that Lang and Mueller are uniquely informative because they include 15-minute peak in exposure that capture effects that may result from short-term increases in concentration. However, the complex study design complicates interpretation of dose-response information in those studies because it is not clear if the lower continuous exposure concentrations would have been sufficient to produce a response in those individuals in the absence of the peaks.

EPA reviewed the Pazdrak et al. (1993) and Krakowiak et al. (1998) as part of the IRIS assessment and described both studies as having poor exposure characterization/uncertainties related to exposure methodologies that reduce confidence in the results for application in quantitative dose-response analysis (discussed in more detail in the IRIS supplemental information appendices).

EPA agrees with commenters that the observational epidemiology studies included in the dose-response analysis of the draft IRIS assessment (Liu et al., 1991; Hanrahan et al., 1984) are not appropriate for dose-response analysis for the acute inhalation POD. As stated in Section 4.1.2, "While these observational epidemiology studies provide additional information on sensory irritation effects, they measure effects over a much longer duration than the controlled exposure studies and are less directly informative for derivation of an acute peak exposure level. These studies are therefore not considered for dose-response analysis for acute POD derivation."

Summary: A public commenter (0235) said that EPA and the SACC should be aware of forthcoming human exposure studies being conducted by the Monell Chemical Senses Center and the Leibniz Research Centre, which are currently evaluating the effects of formaldehyde to inform setting standards for formaldehyde.

EPA Response: The risk evaluation was completed based on the best available science available at the time of the assessment.

Consideration of duration adjustments for the acute inhalation POD

Summary: The SACC recommended EPA further clarify the development of "peak threshold concentration levels," and the SACC suggested EPA use the lowest continuous concentration at which

an effect was reported versus the peak concentration. The SACC noted that it is appropriate not to factor in duration of exposure for the acute endpoint, as Haber's Law does not apply in the case of formaldehyde. The SACC also commented on EPA's use of the term "threshold" to describe the POD. The SACC said that a NOAEL cannot be interpreted as a level of exposure at which there is no effect. The SACC also noted that the statement that the POD based on Kulle (1993) and Kulle et al. (1987) emphasizes peak concentration mischaracterized the POD, because the POD was not selected based on a study that incorporated peaks of exposure. Similarly, a public commenter (0263) stated that, even if the EPA-selected POD was characterized by study authors as a NOAEC, the BMD modeling shows that a 10 percent elevation in symptoms may occur at lower doses.

A public commenter (0258) convened an independent panel and reported that panelists agreed that the 2024 draft risk evaluation should not make duration adjustments to the acute POD. In contrast, another public commenter (0244) recommended EPA apply a duration adjustment for the acute inhalation POD, stating that that duration of exposure has a clear and substantial role for the development of adverse effects and that the available evidence suggests that the irritation effects of formaldehyde may be better represented by a power-law function.

EPA Response: EPA does not apply any duration adjustment to the acute inhalation POD in the revised Human Health Risk Assessment. EPA has revised the hazard assessment to delete reference to "peak threshold concentrations" and provided more specific explanation on the basis for the POD and its intended relevance for different exposure durations. While two of the studies used in dose-response analysis include 15-minute exposures to higher concentrations that may be considered "peaks", the primary quantitative basis for the POD is based on effects reported following a 3-hour exposure period. The resulting POD is intended to apply to all acute exposure durations. As discussed in Section 4.1.2, "Because sensory irritation is an immediate response and is not expected to be proportional to the duration of exposure, no duration adjustment is applied. This is consistent with the recommendations from the HSRB and supported by the SACC. The resulting POD for acute sensory irritation is considered comparable to all acute exposure durations (including 15-minute, 8- or 24-hour exposures)." EPA has not performed alternate duration adjustments such as the power-law function because there are not sufficient data to determine how duration may influence effect levels. EPA acknowledges that this is a source of uncertainty in the acute inhalation POD. As stated in the discussion of sources of confidence and uncertainties, "There is some uncertainty around the degree to which duration influences effect levels for sensory irritation because there are no studies available that provide direct evidence that effect levels following 8- or 24-hour exposures are the same as effects following 2 to 5 hours of exposure".

POD derivation

Summary: The SACC recommended that EPA review the approaches taken by other governmental authorities, which set exposure limits consistent with the best available science based on the weight of the scientific evidence. The SACC recommended EPA carefully reevaluate the available data to determine if 0.5 ppm or a concentration that is lower or higher should be used as a lowest-observed-adverse-effect level (LOAEL) POD. Some SACC members agreed with the Agency's selection of a POD of 0.5 ppm based on Kulle (1993) and Kulle et al. (1987). Some SACC members recommended that benchmark dose modeling should be used whenever possible to determine a POD. In addition, the SACC recommended EPA improve documentation of the benchmark dose modeling, including reporting the benchmark dose response and actual dose-response data that were used as the input for the benchmark dose modeling.

A public commenter (0244) said that evidence from additional controlled exposure studies of formaldehyde suggests that the proposed acute inhalation POD is not sufficiently health protective and two commenters (0244, 0263) recommended that EPA use BMC modeling rather than a NOAEL to derive an acute inhalation POD from Kulle et al. (1987).

EPA Response: EPA selected an acute inhalation POD based primarily on BMD modeling of effects in the study reported in Kulle (1993) and Kulle et al. (1987). The selected POD is supported by LOAEL and NOAEL information from Lang et al (2008 and Mueller et al (2013) which were not amenable to BMD modeling due to the complexity of the study design. Specifically, the variable exposure levels throughout the exposure periods in each of those studies prevents estimation of the particular level that resulted in observed effects. EPA has revised the hazard assessment to clarify that the POD of 0.5 ppm based on the BMDL calculated based on Kulle et al. happens to be equal to the NOAEL in the study (see summary in Table 4-2 and BMD documentation in Appendix B of the hazard assessment). EPA believes use of BMD modeling and consideration of data from multiple high quality controlled human exposure studies to be consistent with the best available science.

Confidence and uncertainty factors for acute inhalation

Summary: The SACC recommended EPA clearly justify the selection of a UF applied to the POD. Members of the SACC who do not support the selection of sensory irritation as the basis for the POD said that there was no need for the application of an UF, and SACC members who supported the application of an UF to the POD supported a lower UF due to the lack of pharmacokinetic differences for a direct-acting portal of contact toxicant. Of the members supporting an UF, some supported the use of 10, while others supported the use of 3. The SACC noted that application of an UF for interindividual variability is consistent with irritation reported by Mueller et al. (2013) in hypersensitive individuals and with high variability across individuals reported in all controlled exposure studies. The SACC recommended EPA consider the application of an UF of 1 or 3, since the study population in Mueller et al. (2013) consisted of individuals sensitive to formaldehyde. The SACC recommended EPA clearly define "intraindividual variability." The SACC expressed that one source of confidence in the POD is that the POD was developed using human rather than animal data.

Some commenters (0190, 0194, 0235) indicated that a UF of 10 is unnecessarily conservative for a non-adverse reversible effects such as sensory irritation. One public commenter (0222) stated that the UF was unnecessarily low because the population studied is considered a susceptible cohort. One commenter (0153) stated that agencies outside of EPA have opted to use low or no UFs in their calculations. Another commenter (0266) said evidence indicates that a UF of no more than 2 is sufficient to account for differences in age, lifestyle, and health. In contrast, a public commenter (0261) said that EPA appropriately applied a UF of 10 to account for what should be identified as inter-individual variability.

EPA Response: EPA has revised the hazard assessment to reduce the total UF for the acute inhalation POD to 3 and to provide a clearer rationale for the selected UF. As stated in Section 4.1.2.1 of the hazard assessment "After considering recommendations from SACC and HSRB peer reviews to consider a lower uncertainty factor, EPA applied a total UF_H of 3 to account for human variability in toxicodynamics but not toxicokinetics. Sensory irritation is a point-of-contact effect and toxicokinetic differences across people are unlikely to contribute to human variability in the sensory irritation response. As described in Section 2.5 of the National Resource Council (NRC) Standing Operating Procedures for Developing Acute Exposure Guideline Levels for Hazardous Chemicals {NRC, 2001, 192042}, direct irritation and/or corrosivity occurs at the point of contact such that absorption,

distribution, metabolism, excretion (ADME) characteristics are not factors that would significantly influence the irritant response. Therefore the toxicokinetic component of the UFH was reduced to 1 and the resulting overall UFH is 3."
The revised assessment further states that "The UF_H of 3 is applied to account for human variability in toxicodynamics that may not be captured in the controlled human exposure studies used as the basis for dose-response. These studies rely on relatively small samples of healthy adult volunteers. While Mueller et al. (2013) includes a subset of study participants who are identified as "sensitive", the study population does not specifically seek to include a susceptible subpopulation and is not expected to capture the full range of human variability. The UF of 3 is also consistent with high variability across individuals reported in all controlled exposure studies. It is further supported by observational epidemiology evidence in Liu et al. (1991) suggesting that some individuals (*e.g.*, those with chronic respiratory conditions) may be more susceptible to sensory irritation."

Use of the IRIS assessment

Summary: SACC members and public commenters offered a range of opinions and concerns related to OPPT's use of chronic hazard values from an IRIS assessment that was still in draft. Most SACC members recommended EPA finalize the IRIS Assessment, incorporating the recommendations of NASEM, before completing the formaldehyde risk evaluation.

Several public commenters (0186, 0194, 0219, 0230) expressed concern about EPA's reliance on the draft IRIS Assessment. For example, commenters expressed that it was unfortunate that the Office of Chemical Safety and Pollution Prevention (OCSPP) did not have a final IRIS Assessment document available (0261) and noted that the draft IRIS Assessment is not procedurally or substantively appropriate for use in a TSCA risk evaluation, fails to incorporate numerous peer-review recommendations, and was not peer-reviewed in a manner consistent with TSCA's scientific standards (0194). One commenter suggested that reliance on the IRIS review leaves opportunity for EPA to miss key studies, which might have been identified in an independently conducted hazard assessment (0230). Another commenter (0235) stated that a standard IRIS value approach is inappropriate for the draft risk evaluation. Another public commenter (0283) stated that the best available science on formaldehyde inhalation hazards is reflected in the draft IRIS Assessment, and EPA should rely on the hazard analyses and associated PODs from the IRIS Assessment.

EPA Response: Since the public comment period and SACC peer review, EPA has finalized the IRIS assessment. Drafts of the IRIS formaldehyde assessment underwent multiple rounds of internal EPA review, as well as external review by other federal agencies. The assessment was also made available for public comment and submitted for external peer review by (NASEM). NASEM provided an opportunity for the public to nominate committee members, an opportunity for public comment on the proposed committee, and provided three opportunities for the public to comment directly to the study committee throughout the duration of the review. Additionally, NASEM accepted written public comments throughout the duration of the external peer review. In August 2023, the NASEM released its Review of EPA's 2022 Draft Formaldehyde Assessment (NASEM, 2023). Subsequently, IRIS released the final Toxicological Review of Formaldehyde – Inhalation in August of 2024 {U.S. EPA, 2024, 11854950} (also referred to as the IRIS assessment or final IRIS assessment throughout this document). IRIS provided responses to NASEM and public comments on the draft in Appendix F of the Supplemental Information document.

Multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB)—

have provided review of various aspects of the formaldehyde assessment. EPA recognizes that the HSRB, SACC and NASEM provided feedback on several overlapping issues; some peer review feedback was consistent across panels whereas some feedback was inconsistent, providing divergent views. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

Chronic inhalation hazard value

Summary: Some SACC members raised concerns with the chronic RfC and recommended an alternate approach using sensory irritation as the most sensitive endpoint. For non-cancer chronic effects, some SACC members raised concerns about the quality of the epidemiology studies used to derive the chronic RfC in the draft IRIS assessment and the weight of evidence (WOE) for a causal link between formaldehyde exposure and outcomes other than sensory irritation. For example, the SACC report states "Several Committee members disagreed with using the toxicity values in the current Draft Risk Evaluation (DRE) for formaldehyde, and the majority of committee members recommended incorporating NASEM and HSRB recommendations to revise the formaldehyde toxicity values reached by IRIS."

Many SACC members expressed reservations and difficulty with reviewing the values due to the draft status of the IRIS assessment at the time of their review. For example, SACC stated "Many members expressed reservations about the specifics surrounding the value of using the unedited 2022 Draft IRIS document since it is not final and the comments from NASEM review have not yet been incorporated." Further the SACC noted that "One needs to access the IRIS document to understand the basis of the 0.007 mg/m^3 RfC. Since the IRIS document has not yet been finalized, it is difficult to understand the review and selection process." The SACC also commented on the relevance of the chronic inhalation POD for adult populations, stating that "The POD is based on pulmonary function response in children. The POD representing this PESS will be protective of adults and workers. However, several Committee members hold the view that applying the POD (based on responses in children) to adult workers is not appropriate."

Some public commenters (0190, 0194, 0153, 0166, 0235) suggested that a POD based on sensory irritation in controlled human studies is relevant for both acute and chronic exposure to formaldehyde and may be protective of cancer and non-cancer effects described following chronic exposures. Some of these commenters cite the fact that Haber's law does not apply to formaldehyde-induced sensory irritation.

Some public commenters (0219, 0222, 0225, 0230, 0235, 0236) also raised concerns about specific studies used as in dose-response and POD derivation in the draft IRIS assessment and/or the dose-response methods used to interpret the data. For example, a commenter (0222) stated that EPA's chronic reference concentration derivation and the reliance on the data from Krzyzanowski are not supported by exposure-response information on formaldehyde, citing the fact that the study didn't adequately control for background formaldehyde concentrations. In contrast, another public commenter (0261) expressed that the Human Health Hazard Assessment appropriately uses the chronic, non-cancer inhalation hazard endpoints and PODs derived in the draft IRIS Assessment. The commenter said the dataset available for the qualitative and quantitative analysis underlying the derivation of a chronic, non-cancer hazard value is more robust than is often seen and that the studies considered most useful were based upon observations in humans. In addition, public commenters (0166, 0211, 0230, 0235, 0259)) noted that the use of studies in children may not be appropriate for the identification of a

POD for adults. Another public commenter (0153) expressed that some of the data EPA relied upon was less robust than what EPA normally expects of stakeholders. Another public commenter (0159) provided a list of comments from the authors of key studies regarding EPA's 2022 draft formaldehyde IRIS Assessment.

EPA Response: Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment for formaldehyde. Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Discussion regarding study selection is provided in Section 2.1.1 of the IRIS assessment. Discussion regarding the weight of evidence for noncancer respiratory effects is provided in sections 3.2, 4.2, and 5.1.5 the IRIS assessment. Comments on study selection, weight of evidence for noncancer effects, and sensory irritation are addressed in Sections F.1 and F.3 in Appendix F of the IRIS assessment supplemental materials.

Cancer MOA

Summary: The SACC raised scientific questions about the conclusions related to formaldehyde exhibiting a mutagenic mode of action. For example, the SACC report stated, "Many Committee members commented there is no evidence of multiple modes of action leading to the same adverse outcome in the same individual and the same tissue," and "Many Committee members… recommended using a mode of action approach where there is a threshold concentration below which no cancer is anticipated." Conversely, the SACC report also states that "A minority of members agreed with the EPA's conclusion that "there is sufficient evidence that a mutagenic mode of action contributes to risk of nasopharyngeal cancer (NPC) from inhaled formaldehyde."

In addition, several public commenters (0163, 0213, 0239, 0226, 0138, 0235) expressed that the best available science supports a non-genotoxic MOA for formaldehyde. Many public commenters (0204, 0213, 0222, 0239, 0226, 0219, 0235) discussed EPA's use of a linear low-dose extrapolation approach to estimate cancer risk and suggested that this linear approach is inconsistent with the overwhelming scientific evidence supporting the existence of a threshold for the carcinogenicity of formaldehyde. Several public commenters (0204, 0191, 0239) discussed BBDR modeling and remarked that analysis published by Conolly et al. supports the lack of linear dose-response.

EPA Response: Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment for formaldehyde. Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Based on the mode of action analysis presented in the IRIS assessment, IRIS concluded there is sufficient evidence that a mutagenic mode of action contributes to risk of nasopharyngeal cancer from inhaled formaldehyde. Similarly, the NASEM review concluded that "While there is uncertainty in the degree to which nonmutagenic processes may also contribute to the carcinogenic activity of formaldehyde inhalation at the point-of-entry tissues, there is sufficient evidence to support the assumption that a mutagenic MOA is involved in the carcinogenesis of formaldehyde in the upper aerodigestive tract in humans" (NASEM, 2023). EPA IRIS's mode of action analysis is provided within Section 3.2.5 of the final IRIS assessment and responses to comments on mode of action analysis and consideration of comments suggesting a threshold approach for cancer are addressed in Section F.4 in Appendix F of the IRIS Supplemental Information document.

IUR value

Summary: The SACC report states that "The majority of the information presented in session did not favor a IUR approach, and rather supported a threshold approach." However, the SACC report also states that "Several Committee members disagreed with this approach and supported the IUR approach as the most appropriate." Overall, "The Committee recommended that the EPA consider the best available science to determine if a threshold or non-threshold approach is best for evaluating cancer, and if needed revise the Draft Human Health Hazard Assessment."

Public commenters (0138, 0163) note that agency does not provide an explanation for characterizing confidence in the IUR as medium and encourage the SACC to weigh in on whether confidence could be improved by considering the best available science. Some commenters (0138, 0213, 0163, 0213) noted review articles that were not included in the IRIS assessment, suggesting that consideration of these analysis would represent the best available science and/or may influence the weight of evidence in support of the IUR. One commenter (0138) states that the IUR predicts increased cancer risks at concentrations lower than typical human exposures.

Other public commenters raised concerns about the study used as the quantitative basis for IUR derivation and the modeling methods applied. For example a public commenter (0230) stated that EPA derived their recommended IUR based on modeling of nasopharyngeal cancers reported by Beane Freeman et al. (2013) and failed to incorporate the findings of many additional analyses on the same cohort. Another public commenter (0226) expressed concern that the results of Beane-Freeman et al. (2013) were used to derive the IUR, because the study only accounted for formaldehyde exposures during the employment period and did not account for variable exposure to air concentrations during times outside of the assessment window. This commenter also stated that stated that the draft IRIS Assessment deviated from EPA Cancer Risk Assessment Guidelines to develop an IUR that is 200 times more stringent than supported by the guidelines and estimated that, in total, modeling adjustments used to interpret the data from the study increased the IUR potency by over 1000-fold. .

EPA Response:
EPA is using the cancer conclusions and cancer value for formaldehyde inhalation presented in the final IRIS assessment and peer reviewed by NASEM for those scenarios under TSCA and FIFRA where chronic exposure is expected. Based on available human and animal data, the final IRIS assessment evaluated the weight of evidence and performed dose-response analysis for several respiratory and non-respiratory cancer types to derive an inhalation unit risk (IUR).

Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Further discussion on how IRIS derived the cancer IUR is provided in Section 5.2 of the IRIS assessment. Comments on the consideration of a threshold approach for cancer, the dose-response analysis derived from the Beane Freeman et al (2013) paper, and confidence in the IRIS unit risk estimate are addressed in Section F.4 in Appendix F of the IRIS Supplemental Information document {U.S. EPA 2024}.

Myeloid leukemia

Summary: Some members of the SACC questioned the association between formaldehyde exposure and myeloid leukemia, noting that "there is no biologically plausible mode of action whereby formaldehyde can arrive at the bone marrow to result in direct toxicity" (p. 88 of the SACC Report). Other SACC reviewers agreed that there is "evidence that formaldehyde can cause acute and chronic myelogenous leukemia" (p. 103 of the SACC Report).

Several public commenters (0200, 0138, 0140 0163, 0278, 0235, 0212) argued that the associations between formaldehyde and myeloid leukemia are not supported by the weight of the scientific evidence or are not biologically plausible. Commenters note that the draft IRIS Assessment lacks a clear causality framework for determinations regarding lymphohematopoietic cancers and that EPA did not consider Gentry et al. (2020). Some commenters (0138, 0163, 0200, 0278, 0235) argue that EPA's statement that risk estimates "may underestimate total cancer risk by as much as 4-fold" based on conclusions in the IRIS Assessment that formaldehyde likely causes myeloid leukemia by a genotoxic MOA is not supported. Other public commenters argued that there is strong evidence that formaldehyde exposure causes myeloid leukemia in humans (0261) and that that EPA underestimates formaldehyde's cancer risks by failing to account for the connection between formaldehyde and leukemia (0283).

EPA Response: EPA has not quantified the risk to myeloid leukemia. Discussion of the available evidence for myeloid leukemia can be found in Section 3.3.3 of the IRIS assessment. The IRIS conclusions for cancer hazard are summarized in Section 4.3. Comments on the IRIS hazard conclusion regarding formaldehyde and myeloid leukemia are addressed in Section F.4.1 in Appendix F of the IRIS assessment supplemental materials. Ultimately, EPA only included quantitative cancer risk for the nasopharyngeal cancer outcome as part of the final IUR.

Dermal hazard value

POD Study Selection Considerations

Summary: Several public commenters (0190, 0194, 0226, 0259, 0235) specifically discussed the studies that EPA relied on to derive the dermal POD. Comments included that relying on the Flyvholm et al. (1997) study is problematic, because effects were only seen in occluded patch tests where the patch was left on the skin for two days; that the draft risk evaluation did not conduct a systematic review for dermal hazards; the use of the Flyvholm et al. (1997) study is limited by the small number of individuals, and HSRB indicated that the study could only be used as part of the derivation of a POD if the limitations are taken into account; that the Fischer et al. (1995) study is not reliable, as EPA made assumptions to derive a dose-response curve for the study; and that results from LLNAs do not provide dose-response data useful for quantitative risk evaluation.

Conversely a different commenter (0261) stated that the dermal hazard values presented in the draft risk evaluation will be useful both for OPPT in its TSCA risk evaluation for formaldehyde and for OPP's registration renewal risk assessment and agreed with EPA's determination that skin sensitization is the most sensitive non-cancer effect following dermal exposure.

The SACC noted that additional intentional dosing human studies were identified through systematic review, which EPA did not rely on to establish a POD. The SACC expressed that these studies could

provide information in the weight of scientific evidence and should be discussed in more detail, to make clear the rationale to use only two studies.

The SACC stated that the Draft Human Health Hazard Assessment used human data, animal data, and computational data to develop a number of dermal sensitization PODs, and the SACC expressed that human data should be preferred. The SACC additionally expressed disagreement with HSRB's statement that any of the results of the human studies reviewed were based on one individual.

EPA Response: As discussed in the Human Health Hazard Assessment (Section 4.2), OCSPP based the dermal POD for skin sensitization on human, animal, and in vitro data. The selection of the Flyvholm and Fischer human patch test studies to support the POD was based on a review of many human studies. Details of the methodology for screening studies is included in the TSCA Systematic Review Protocol for formaldehyde (included as a supplemental file to the risk evaluation). Based on comments from the SACC, a list of the human studies screened as part of the analysis has been added to this chapter. The Agency consulted with the HSRB on the scientific validity and ethics of two human dermal patch test studies that were determinative in establishing the POD (Flyvholm et al., 1997 and Fischer et al., 1995). The HSRB reviewed the studies in detail and discussion of the interpretation of the study results was a focus of the HSRB meeting. The HSRB agreed with the EPA's assessment that these studies were scientifically sound and ethically conducted for use in establishing a POD for formaldehyde skin sensitization when considered with other available data. OCSPP incorporated HSRB comments regarding specific study details directly into the data evaluation records (DERs) and other comments related to the use of the studies for POD determination directly into the assessment. This included incorporating benchmark dose (BMD) analyses into the assessment and using results from Fischer et al. (1995) only as supporting evidence, which was recommended by the HSRB. However, as discussed below, the results from the Fischer BMD analysis were used as a consideration in the selection of the model output from the Flyvholm BMD analysis. Some commentors referenced a publication by Stewart et al., 2023, which contained a risk assessment that referred to one of the human studies (Marzulli and Maibach, 1974) that was reviewed as part of the studies screened for the draft Human Health Risk Assessment. This study was not used for endpoint selection for induction based on ethical concerns with the conduct of the study, which induced allergic reactions to formaldehyde in the test subjects; additionally, when relevant PODs and UFs are considered, this study would not change the regulatory endpoint used for dermal sensitization.

Regarding the use of occluded patch tests (vs. non-occluded) for the derivation of an endpoint, an occluded scenario is within the potential exposures of both FIFRA and TSCA formaldehyde uses. Considering the volatile nature of formaldehyde, it is reasonably assumed that the endpoint based on a occluded patch test would be protective of a non-occluded test. Additionally, the available repeat open application test (ROAT) test results from the Flyvholm study had uncertainty associated with the amount of product applied, as noted by the HSRB in their review, and therefore made the negative results in the study difficult to interpret and not suitable for quantitative use.

Benchmark Dose (BMD) Analysis

Summary: Some public commentors raised concern over the study used and which model output was selected from the BMD analysis (0190, 0194, 0235) and stated EPA did not follow their typical BMD modeling criteria and instead chose the lowest BMD lower limit value, which resulted in a BMD lower limit value that is below what should have been used. Another public commenter (0283) stated that

EPA's acute dermal POD is not based on the most health-protective data because BMD modeling of a controlled human exposure study by Fischer et al., results in a lower POD.

The SACC agreed with the BMD analyses because they use data from the entire dose response curve rather than a single endpoint such as the NOAEL or LOAEL, which are based entirely on the doses selected for testing and commended EPA on the use of BMDL to obviate the possibility of 1/20 response being considered a LOAEL. The SACC recommended EPA provide the input data as well as the output data for the BMD models in Appendix B2. The SACC wrote that EPA did not justify using Flyvholm et al. (1997) data over Fischer et al. (1995) data, and the SACC noted that the Fischer study had the lowest Benchmark Dose Lower Confidence Limit value at 10 percent. The SACC recommended EPA provide the rationale for using Flyvholm et al. (1997) as the primary study for development of the elicitation POD.

EPA Response: As discussed in the Human Health Hazard Assessment (Section 4.2), although BMD modeling was conducted using the Flyvholm study alone, the Fischer study alone and both studies combined, the BMDL generated based on the Flyvholm study alone was the value used in the final POD derivation. This BMD analysis was chosen based largely on the feedback from the HSRB that the Fischer study only be used as supporting evidence for POD selection. The BMDL results from the combined dataset was only used to explore the impact of combining the data from both studies and the BMDL from the single study was used in POD selection. The selection of the log-probit BMDL from the analysis was based on Benchmark Dose Technical Guidance along with consultation with OPP's Health Effects Division. The guidance allows for professional judgement in the curve selection, including considering the AIC, the relative values of the predicted BMDL as well as the curve fit of the data. Additionally, the selection of the lowest BMDL from the Flyvholm modeling was based on consideration of the output from the Fischer study alone, which predicted a lower value for the BMDL. Inputs for the BMD models were added to Appendix B2 of the hazard assessment based on the SACC comment (output date was already included in the appendices).

POD based on elicitation vs induction

Summary: A public commenter (0259) wrote that the appropriate endpoint to use for a sensitization benchmark is a measure of induction potency while another public commenter (0226) expressed that dermal sensitization is driven by concentration. A public commenter (0254) recommended that EPA consider the appropriateness of establishing thresholds for sensitization elicitation. The commenter stated that EPA derived PODs for sensitization induction and elicitation, but risk assessment methodology was developed for preventing sensitization induction, not elicitation.

The SACC said that EPA justifies using a POD based on two human studies of elicitation rather than induction of skin sensitization to protect sensitive sub-subpopulations. The SACC said that no justification was provided for deriving an induction POD or the rationale for selecting an animal study to derive the induction POD. The SACC stated that the Draft Human Health Hazard Assessment should provide the rationale for focusing on the local lymph node assay (LLNA) study from Basketter et al. (2003) when there are additional LLNA studies available in literature. The SACC recommended EPA consider Griem et al. (2023), which compares induction and elicitation doses in humans.

EPA Response: OPP established OCSPP's use of elicitation data from dermal sensitization studies in 2004, when hexavalent chromium was presented to the agency's FIFRA Scientific Advisory Panel as a case study for quantitating dermal sensitization in risk assessment and as a dose exposure in units of

ug/cm^2. Since that time, the agency has continued to use elicitation data for quantitating dermal sensitization hazard and risk, when scientifically sound data are available (U.S. EPA. (2020). In addition, LLNA data have been used to assess sensitization potency in quantitative risk assessment for years. As discussed above, EPA used the systematic review process outlined Section 4.6.1.1 in the *Systematic Review Protocol for the Risk Evaluation for Formaldehyde* (U.S. EPA, 2023) to screen studies to arrive at the LLNA study used in the assessment; however, additional language has been added to Section 4.2 of the hazard chapter to describe additional LLNA studies available in the open literature and the range of results across LLNA studies, such as provided in Hoffman et al, 2018. In the formaldehyde risk assessment, multiple lines of evidence based on human and animal *in vivo* data, as well as *in vitro* data, were used to establish the POD; consistent effect levels were observed across studies and reflected the expected relationship between elicitation and induction thresholds. The use of skin sensitization as the basis of the dermal endpoint for risk assessment, including the elicitation endpoint, was evaluated and supported by both the HSRB and the SACC, with the SACC specifically supporting the use of human studies. In the final hazard chapter updates and based on recommendations from the SACC, OCSPP has revised the discussion to focus on the elicitation threshold from the human patch test study as the POD for use in the risk assessment; however, considering the PODs and UFs applied for any of the data (human, animal or in vitro) for either elicitation or induction, risk conclusions would be the same regardless of the endpoint selected. Discussion of Griem et al. (2023) has been added to Section 4.2 of the Human Health Hazard TSD.

Uncertainty Factor Selection

Summary: A public commenter (0190, 0194) also said that sensitization benchmarks, often referred to as no expected sensitization induction levels (NESILs) typically do not apply UFs and that applying UFs for human extrapolation and human variability to a sensitization benchmark is unnecessary. Another public commenter (0259) specifically referenced Basketter et al. (2008) and said that EPA's application of UFs yield an overly conservative estimate of the likely threshold of induction based on this study. The public commenter said that other NESILs have been reported in the peer-reviewed literature and should be considered. The commenter stated, for instance, that a NESIL of 37 g/cm2 was recommended for formaldehyde by ECHA and a NESIL of 10 g/cm2 was recommended by Stewart et al. (2023). The public commenter (0226) additionally wrote that large UFs to account for intra- and inter-species uncertainties are not needed for point-of-contact tissue irritants, because there are not intra- or inter-species differences in pharmacokinetics.

Several public commenters (0205, 0259, 0235) recommended that EPA should consider reducing the toxicokinetic UFs for both the interspecies and human variability to 1 while another public commenter (0226) similarly stated that it is inappropriate to apply UFs to a POD from an animal study that does not provide results that can be quantitatively extrapolated to humans. The commenter also wrote that, for human studies, adding an additional UF for intra-species differences is not supported when the sensitive subpopulation is the population being tested. An additional public commenter (0254) specifically discussed the appropriateness of an inter-species UF when several independent investigations show strong correlation between LLNA EC3 values and human no observed effect levels for sensitization induction.

The SACC expressed disagreement with the selection of a UF of 10. The SACC expressed that the POD for elicitation does not require an intraspecies UF of 10, because it was based on reactions of human adult subjects that were sensitive to formaldehyde. In addition, the SACC stated that it is well

accepted that UFs for interspecies extrapolation are unnecessary when using LLNA data. The SACC recommended EPA reconsider and justify the use of a UF of 10.

The SACC stated that Section 4.2.1, page 20, of the Draft Human Health Hazard Assessment indicates that methanol is not a sensitizer and cites the ECHA. The SACC said that the ECHA's determination was based on animal studies, and the SACC asked if EPA has searched for human skin sensitization data for methanol.

The SACC stated that in the Draft Human Health Hazard Assessment, lines 708-714, pages 20-21, the doses applied should be converted to micrograms per square centimeter, so that they can be readily compared to one another and with the doses applied for skin sensitization assessments. In addition, the SACC wrote that line 710, page 20 should note that 37 percent formaldehyde was applied, and the Industrial Bio-Test Laboratory study results should be qualified with uncertainty due to the scientific integrity controversy at the Industrial Bio-Test labs during the 1970s.

The SACC wrote that Section 4.2.2 of the Draft Human Health Hazard Assessment says that skin sensitization is the most sensitive non-cancer endpoint with which to derive a dermal POD. The SACC expressed that this statement would be more convincing if all the doses for studies reviewed in the weight of scientific evidence were converted to the same units so that the reader could compare effect doses.

The SACC stated that the "Sources of Confidence and Uncertainties" section on page 26 of the Draft Human Health Hazard Assessment characterizes the dermal PODs as derived from an extensive dataset, but the dataset is not provided. In addition, the SACC stated that another source of uncertainty that should be discussed for the induction POD is that the LLNA does not measure the apical endpoint of skin sensitization.

EPA Response: OCSPP retained the UF of 10 for intraspecies variability in the final assessment to account for human variability in the toxicokinetics and toxicodynamics of the elicitation response. It is recognized that public commentors, SACC and HSRB recommended the consideration of a UF_H value lower than 10 and several factors were considered in the decision to retain a UF of 10. The physical integrity of the skin, genetics, chronic skin conditions, and other factors can influence the permeability of the stratum corneum {Friedmann and Pickard, 2010, 5370947}. In addition, there is variability across sensitized individuals in the magnitude of the response. Sensitization is understood to be proportional to the conditions of an individual's induction. Induction resulting from larger initial exposures or from repeated lower dose exposures may result in more potent responses {Friedmann and Pickard, 2010, 5370947}. While the study populations included in Flyvholm et al, (1997) and Fischer et al., (1995) are limited to individuals who are already sensitized, the small sample sizes included in the studies are not sufficient to capture the full range of variability within that group. Based on the currently available information, EPA did not identify sufficient toxicokinetic and/or toxicodynamic data to support reduction of the UF_H at this time.

Other SACC dermal comments

Summary: The SACC stated that Section 4.2.1, page 20, of the Draft Human Health Hazard Assessment indicates that methanol is not a sensitizer and cites the ECHA. The SACC said that the

ECHA's determination was based on animal studies, and the SACC asked if EPA has searched for human skin sensitization data for methanol.

The SACC stated the doses for dermal irritation studies should be converted to micrograms per square centimeter, so that they can be readily compared to one another and with the doses applied for skin sensitization assessments. In addition, the SACC noted that the Industrial Bio-Test Laboratory study results should be qualified with uncertainty due to the scientific integrity controversy at the Industrial Bio-Test labs during the 1970s.

The SACC stated that the "Sources of Confidence and Uncertainties" section on page 26 of the Draft Human Health Hazard Assessment characterizes the dermal PODs as derived from an extensive dataset, but the dataset is not provided. In addition, the SACC stated that another source of uncertainty that should be discussed for the induction POD is that the LLNA does not measure the apical endpoint of skin sensitization.

EPA Response: Human skin sensitization data for methanol was not screened as part of the hazard data review. The skin irritation studies cited in the hazard chapter generally did not provide adequate study information to convert the testing units to ug/cm2. Language regarding the IBT Lab study uncertainty and additional language in the uncertainties section has been added to the chapter. The editorial comments made by the SACC were also integrated into the final hazard chapter.

Oral hazard value

Study quality and weight of evidence narrative

Summary: The SACC said that the three studies selected were the most appropriate for developing candidate PODs, and the final POD selected was supported by the discussion. The SACC expressed that gastrointestinal effects are plausibly the most sensitive effects. The SACC said, however, that rating the two animal oral studies as uninformative due to the lack of a water-restricted control group "may be too severe", given there is no evidence that reduced water intake can induce stomach pathology. SACC members agreed that the Til et al. (1989) and Civo Institute TNO, (1987) studies are useful.

A public commenter (0226) stated that for the oral exposure hazard characterization, EPA should have identified human studies that provide direct quantitative information about the effects of oral exposure to formaldehyde and used them to perform a reality check on their derivation of the draft sub chronic and chronic RfDs for formaldehyde.

EPA Response: EPA continues to rely on the three key studies identified by the SACC as the most appropriate for developing candidate PODs. Consistent with SACC comments and the narrative in Section 4.3 of the Human Health Hazard Assessment, EPA has modified the data quality rating narrative in the systematic review appendix for the key studies with reduced water intake in high dose groups to clarify that EPA still considers these studies useful for dose-response.

EPA would welcome additional human evidence on the hazards associated with oral exposure to The commenter did not provide or cite specific human epidemiology studies that evaluate and quantify the effects of oral exposures to formaldehyde. None were identified through EPA's systematic review process. In the absence of human data, EPA regularly relies on evidence from animal studies.

Need for an oral POD

Summary: Some SACC members recommended EPA reconsider the use of oral hazard data in the risk evaluation, and the SACC members said that potential exposure routes such as plastic products, pesticide residues in food, and formaldehyde in drinking water are currently considered outside the scope of the draft report.

A public commenter (0261) asked if there are exposure scenarios that would warrant the selection of an acute oral POD. The commenter stated that, in 1993, the Office of Water issued Health Advisories for formaldehyde in drinking water, and they issued an acute Health Advisory and a short-term, subacute Health Advisory.

EPA Response: While EPA derived oral hazard values, EPA's consideration of oral exposure to formaldehyde in the TSCA risk evaluation is limited to a qualitative assessment of oral exposure from products/articles (see the Consumer Exposure Assessment). EPA did not identify quantifiable sources of oral exposure resulting from TSCA COUs and therefore did not perform quantitative risk assessment for the oral exposure pathway.

POD derivation and UF selection

Summary: The SACC commended EPA for deriving a POD for chronic, non-cancer effects via oral exposures. The SACC stated that the POD, draft weight-of-scientific evidence, UF calculations, and overall confidence are reasonable.

A public commenter (0226) stated that the derived oral POD and proposed UFs do not adhere to EPA guidance. The commenter said that deriving an oral human equivalent dose for portal-of-entry effects when the chemical is in water, as it was in the Til et al. (1988) study, is not supported by EPA guidance and that gastrointestinal irritation from formaldehyde in drinking water is concentration and not dose-dependent. The commenter further asserted that a POD based on concentrations in drinking water that can cause gastrointestinal tissue irritation does not require an UF for either pharmacokinetic or pharmacodynamic intra-species or inter-species differences.

EPA Response: EPA appreciates input on the derivation of PODs and UFs for subchronic and chronic effects of oral exposure and has retained the same values presented in the draft.
EPA guidance supports derivation of an oral human equivalent dose for portal of entry effects. The 2011 EPA guidance on body weight ¾ scaling provides the following conclusions regarding application of the Dosimetric Adjustment Factor and portal of entry effects: "Pending, or in lieu of, the development of specific information to employ an interspecies dosimetric adjustment based on dose to the specific site of toxicity within the gastrointestinal tract, the BW3/4-based DAF is recommended as the default to derive a HED involving oral portal-of-entry toxicity… This science-based policy decision provides consistency with methods used for scaling oral exposures for cancer assessment (USEPA, 2005)" https://www.epa.gov/sites/default/files/2013-09/documents/recommended-use-of-bw34.pdf. Consistent with this agency guidance, toxicokinetic differences were addressed through application of a DAF. EPA applied a Ufa of 3 to account for toxicodynamic differences across species. Agency guidance states that "With the calculation of an HED using the DAF approach, a default value of 3 is recommended for the UFA in the absence of additional, relevant information."

Summary: The SACC stated that the text presenting the POD selection uses the term "threshold," but symptoms/effects may occur at lower doses. The SACC expressed that a NOAEL is a function of study design and cannot be interpreted as a level of exposure at which there is no risk.

EPA Response: While this comment was made in response to the charge question on oral hazard values, it appears to be a comment on another part of the hazard assessment as the term "threshold" is not used in this section.

Consideration of alternate endpoints

Summary: SACC members agreed that the point of entry action of formaldehyde is well-documented, but systemic distribution beyond the point of entry is less well-documented. Some SACC members expressed that the focus on point of entry effects may minimize additional physiological effects. The SACC stated that EPA mentioned several non-cancer outcomes, but said that the data are insufficient. The SACC recommended EPA provide more detail about this insufficiency. In addition, the SACC recommended EPA provide the doses tested for all major effects considered in Section 4.3.1 on page 27 of the Draft Human Health Hazard Assessment. The SACC recommended EPA strengthen the justification for effects beyond local, point of entry effects and that EPA should justify how formaldehyde would get to the target site and produce the associated reproductive and developmental or neurological responses.

In addition, the SACC recommended EPA include a citation for the statement that "methanol may contribute to developmental effects."

EPA Response: EPA considered evidence for a range of potential effects resulting from oral exposure to formaldehyde. While some studies evaluate immune reproductive or developmental endpoints, all of these studies were confounded by the presence of methanol and none were assessed quantitatively. EPA has revised the discussion in Section 4.3.1 of the Human Health Hazard Assessment to clarify the limitations of the available studies. EPA has provided effect levels reported in these studies where possible, but noted that the doses achieved were not reported for some studies. As recommend by the SACC, EPA has added a citations for statements related to the potential developmental effects of methanol. Given the lack of quantitative information on these alternate endpoints, EPA did not include further discussion of the biological plausibility or mode of action of the effects.

Characterization of confidence and uncertainties

Summary: SACC members expressed that the "Source of Confidence and Uncertainties" section was generally well-presented. SACC members stated that one important limitation that was missing is that no human studies were available to derive a POD.

The SACC recommended EPA strengthen the justification for effects beyond local, point of entry effects. In addition, the SACC recommended EPA consider life stage susceptibility, unless data support evidence of no differences in early life.

EPA Response: EPA appreciates feedback on the discussion of sources of confidence and uncertainties. EPA agrees that human data would improve confidence and has included acknowledgement that this analysis relies on "a limited database of animal studies."

While EPA considered available evidence for alternate endpoints that may be of particular concerns for early lifestages, there are no available studies that evaluate those endpoints that are not confounded by the presence of methanol. As stated in Section 4.3.2 of the Human Health Hazard Assessment, "The lack of data on these endpoints and sensitive groups and lifestages following oral exposure could be perceived as uncertainty; however, the likelihood of a lower POD being identified based on these outcomes is low given the effect used as the basis of the current PODs (gastrointestinal effects) are close to the portal of entry, first pass metabolism via the oral route, and the reactivity of formaldehyde." Gastrointestinal effects are the most sensitive endpoint evaluated among the available studies that are not confounded by the presence of methanol. Furthermore, while EPA derived oral hazard values, EPA did not identify quantifiable sources of oral exposure resulting from TSCA COUs and therefore did not perform quantitative risk assessment for the oral exposure.

Other oral hazard topics

Summary: The SACC recommended a series of other specific revisions and line edits to the Draft Human Health Hazard Assessment to improve the clarity and accuracy of the assessment.

EPA Response: EPA has considered line-specific comments and made modifications throughout Section 4.3 of the hazard assessment to improve accuracy and clarity.

Other hazard comments

Summary: A public commenter (0151) stated that they were not able to access some of the data and references cited in the Human Health Hazard Assessment. The commenter said that some of the articles linked lead to a pay wall, which reduces the ability for scientific review of the manuscript. In addition, the commenter stated that they were unable to review Ambient Monitoring Hazardous Air Pollutants (HAPs) Data By Year, because Microsoft Access blocked macros from running.

EPA Response: EPA aims to provide citations and facilitate public access where possible, but is not able to circumvent pay walls for the public. EPA will continue to make an effort to maximize transparency and accessibility of documents where possible.

Summary: A public commenter (0226) said that the draft risk evaluation seems to have proposed a new UF for intra-individual variability. The commenter stated that, since EPA does not have any guidance on applying UFs for intra-individual variability, any reference to or use of this UF should be removed.

EPA Response: This was a typo and has been corrected.

Summary: The SACC said that the IRIS assessment concluded that "inhalation of formaldehyde likely causes increased risk of developmental, and female and male reproductive toxicity given the appropriate exposure circumstances," however, since it is unlikely for oral or inhaled formaldehyde to get past the site of exposure, what exposure scenario would result in formaldehyde arriving into the reproductive tract or fetus? The SACC said that the Til et al. (1988) and Tobe et al. (1989) studies resulted in no histologic alterations in the reproductive or endocrine tissues, and the studies that do identify some testicular effects could have been caused by frank toxicity to the whole animal and not site-specific toxicity to the organ.

The SACC said that the IRIS assessment concluded that "the evidence suggests but is not sufficient to infer that formaldehyde inhalation might cause multiple manifestations of nervous system health effects in humans given relevant exposure circumstances," however, what would these exposure circumstances be and how would formaldehyde enter the central nervous system via inhalation, dermal, or oral exposure?

EPA Response: As stated in Section 4.3.2 of the Human Health Hazard Assessment, "The lack of data on these endpoints and sensitive groups and lifestages following oral exposure could be perceived as uncertainty; however, the likelihood of a lower POD being identified based on these outcomes is low given the effect used as the basis of the current PODs (gastrointestinal effects) are close to the portal of entry, first pass metabolism via the oral route, and the reactivity of formaldehyde." Gastrointestinal effects are the most sensitive endpoint evaluated among the available studies that are not confounded by the presence of methanol.

Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment for formaldehyde. Discussion regarding the plausible modes of action for reproductive and developmental effects in the absence of systemic circulation is provided in Section 3.3.2 of the IRIS assessment and discussion regarding the weight of evidence for these effects in provided in Section 4.2.

Summary: The SACC said that acute and chronic exposures from industrial releases of formaldehyde which can be attributed to the Toxic Substance Control Act's conditions of use based on IIOAC modeling, are less than the formaldehyde concentration in a typical home.

EPA Response: EPA is unclear which exposures the SACC is referring to "based on IIOAC modeling". If the exposure estimate is referring to the indoor concentrations provided by IIOAC, that estimate is based on a ratio of approximately 0.64 to 1 (indoor vs. outdoor) and should be lower than the outdoor modeled concentration. That concentration, however, is based on infiltration of outdoor air to the indoor environment and therefore represents one piece of the overall formaldehyde exposure in the indoor environment. Other sources in the indoor air will also contribute to overall formaldehyde exposure in the indoor environment. Due to the tightening up of homes, etc. for energy efficiency, constant releases/off-gassing in close quarters in the indoor environment, and other factors it is expected that indoor concentrations of formaldehyde would be higher than ambient outdoor concentrations (whether monitored or modeled). Additionally, monitored indoor concentrations are often an aggregate concentration and therefore again is expected to be higher than outdoor air. Also, the data presented in the draft document discussed this difference and found the general relationship that occupational exposure > indoor air exposure > outdoor air exposure.

Section 5.3 – Occupational exposure assessment

General comments

Summary: A public commenter (0235) stated that EPA's occupational exposure assessment is inappropriately conservative, not reflective of the best available science, and does not apply a consistent and transparent framework for judging the quality of exposure information. For example, the public commenter noted that, for some of the conditions of use evaluated, EPA has high confidence in modeled risks, but lower confidence when monitoring data were used. The commenter said that this appears counterintuitive, as EPA should have less confidence in the data when modeled data are used.

EPA Response: EPA considers monitoring data to generally be higher on the hierarchy of preferences during evidence integration. However, monitoring data do not inherently imply higher confidence. The confidence in monitoring data should be based on its data quality rating, alignment with the exposure scenario, and its expected representativeness of the entire industry being assessed. As part of weight of scientific evidence, EPA considered whether the data reasonably capture the variability in occupational exposures expected across the exposure scenario. Similarly, model result confidence was weighed based on the data quality of the input parameters and distributions and how well the models address variability within the exposure scenario.

Summary: A public commenter (0235) expressed that EPA's dermal and inhalation modeling approach is conservative. The commenter stated that EPA appears to use the highest level of percent weight of formaldehyde for the exposure scenarios, regardless of whether or not this value is representative. The commenter remarked that it appears EPA has relied on a single SDS for some categories, rather than considering all the available data. The public commenter stated that EPA must account for variability in products, because one product might contribute to an unreasonable risk, while another product has a different percent formaldehyde and does not. The public commenter stated that EPA's conservative approach might be appropriate for a Tier 1 screening level assessment, but EPA makes no effort to refine its inputs and results in cases where EPA uses overly conservative assumptions and finds potential risks. The commenter expressed that this is inconsistent with EPA guidance and best practices.

A public commenter (0226) stated that a better recognition of the reliability and utility of product concentration limits for dermal sensitization should enable better conclusions to be reached in the draft risk evaluation and those conclusions are highly likely to result in a reversal of the Unreasonable Risk Determination conclusions. The commenter said that basing the exposure assessment on product-specific information and/or measured data rather than overly conservative assumptions and estimates, then ground truthing those estimates before including them in the draft risk evaluation is necessary. The commenter added that most of the occupational conditions of use that contribute to the unreasonable risk presented by formaldehyde are due to acute dermal exposures in the workplace.

EPA Response: EPA considered all reasonably available data in the draft risk evaluation. In some cases, only a few sources on weight fraction were identified. As EPA may lack resolution on the distribution of weight fractions for a given occupational exposure scenarios, EPA's objective is to provide the central tendency and high-end exposure estimate for the worker handling the maximum concentration expected. EPA may consider the effect of lower concentrations of formaldehyde in products during risk management.

Summary: A public commenter (0270) suggested that EPA consider three sets of monitoring data collected at their member facilities in 2011, 2017, and 2024, which confirm very low occupational exposures.

EPA Response: EPA reviewed the summary statistics provided in the public comment and has discussed this information along with other non-discrete monitoring data in Section 3.12 Industrial Use- Non-incorporated Activities – used in: Construction. In general, the data identified for lamination supported the central tendency estimates for the respective condition of use.

Summary: The committee recommended

- EPA document if Monte Carlo or Latin Hypercube sampling methods were used to estimate inhalation exposures.
- Age and duration of exposure along with exposure frequency are critical variables (Section 2.1.2). Please explain if significant changes in the exposure model are associated with these variables?

EPA Response: EPA uses Monte Carlo modeling approach to estimate exposures for four exposure scenarios: use of fertilizer, use of formaldehyde in oilfield well production, use of lubricants, and use of automotive car products. The simulation runs included distributions for the exposure duration and frequencies. EPA uses a default exposure frequency of 250 days for this risk evaluation, but EPA used modeled estimates for the fertilizer scenario. This information is included in the Supplemental Formaldehyde Occupational Exposure Modeling Results.

Transparency

Summary: A public commenter (0261) stated that the information provided in the supplemental file: Occupational Risk Calculator was not readily accessible, and the file was therefore useless. The commenter suggested that EPA provide these estimates in the appendix to the risk assessment.

A public commenter (0262) recommended that EPA provide a list of studies used for each condition of use with a date and information about how to obtain the study.

Two public commenters (0211, 0221) stated that the information provided in the individual conditions of use tabs in the supplemental file do not contain the sample time period for OSHA CEHD. The public commenters recommended that the data should be included in the individual OES subfiles for transparency of basis for sample selection.

EPA Response: EPA provides several supplemental files that provide additional information such as sources of occupational data, sample details, modeling details and individual risks estimates for each exposure scenario. These supplemental files associated with the occupational risk assessment are:

(1) Supplemental Formaldehyde Occupational Monitoring Data, which contains spreadsheets for each occupational exposure scenario with the monitoring data mapped to the respective occupational exposure scenario. Each sheet generally includes the hero ID of the source, year of study, sample date, and other details of the sampling as provided in the source.

(2) Supplemental Formaldehyde Occupational Exposure Modeling Summary or Results, is a collection of files that include the raw output of the Monte-Carlo simulations for the modeling approaches that used a probabilistic approach. It also includes summary excel files for each model which details the different parameters, selected value or distribution of values and rationale for selection.

(3) Supplemental Occupational Risk Calculator, is an excel file that provides the risk estimates for all occupational exposure scenarios.

These files are available on the formaldehyde TSCA docket [EPA-HQ-OPPT-2018-0438].

Draft OEV

Summary: Many public commenters (0164, 0214, 0230, 0238, 0246, 0260, 0267, 0269, 0235, 0079, 0089, 0096, 0128, 0190, 0194) stated that the draft OEV of 11 ppb is not reasonable. The public commenters (0164, 0214, 0230, 0238, 0246, 0260, 0267, 0269, 0235, 0089, 0128, 0147, 0162, 0166,

0187) stated that background concentrations are typically at or above the proposed value, and it is not realistic to expect an OEV of 11 ppb to be achievable in any workplace when set below background levels. A public commenter (0235) expressed that EPA's reliance on the POD and UFs suggested by the draft IRIS Assessment is at the heart of the flawed OEV. One public commenter (0164) specifically noted that 95 percent of homes measured around 32 ppb, and the commenter stated that a charge question should be included to review the draft OEV. Another public commenter (0260) similarly wrote that it is inappropriate to exclude the draft OEVs from the peer review process. A public commenter (0270) stated that numerous studies evaluating formaldehyde have shown that the threshold for odor detection is significantly lower than the ocular or nasal irritation threshold, and to date, no chemical has been identified as having an irritation threshold lower than its odor threshold and formaldehyde is no exception.

Two public commenters (0172, 0235) stated that EPA does not need to apply a 10x UF in the calculation of the OEV. One of the commenters (0235) noted that HSRB recognized that the key chamber studies included hypersensitive individuals and younger individuals, who are more sensitive to sensory irritation.

In addition, many public commenters (0214, 0267, 0269, 0087, 0090, 0092, 0101, 0109, 0110, 0128, 0134, 0135, 0136, 0146, 0185) stated that EPA's OEV is misaligned with other recognized authoritative scientific bodies globally. For example, many public commenters (0214, 0079, 0089, 0090, 0092, 0093, 0099, 0101, 0102, 0105, 0109, 0118, 0119, 0122, 0123) specifically noted that the EU's OEL was updated in 2023 to 300 ppm, and that the proposed standard is 30 times below that. Another public commenter (0269) wrote that authoritative EU scientific bodies agree that there is a threshold below which adverse effects do not occur, and these authorities agree that this level is well above typical indoor and outdoor exposure levels. Two public commenters (0267, 0110) stated that the draft OEV is set below the detection limit for all National Institute for Occupational Safety and Health (NIOSH) and OSHA-approved formaldehyde analytical methods, which, according to one commenter (0267) could require workers to wear continuous supplemental air support to protect against exposure from merely standing too closely in the same room. The commenter expressed that this would add an undue economic burden to manufacturers, with little benefit. A public commenter (0189) stated that the proposed OEV does not take into account the physical restrictions imposed by the US EPA's plywood and composite wood products NESHAP which requires wood products manufacturers to construct enclosures to capture and control emissions of formaldehyde, methanol, and other organic emissions from wood product pressing.

A public commenter (0235) stated that an OEV of 300 ppb is supported by high-quality scientific studies and MOA and mechanistic information, which informs sensitive subpopulations and would be protective for workers and the general population. In addition, the public commenter expressed that an OEV of 300 ppb would allow EPA to consider information about the lack of sensory irritation and pulmonary effects at typical indoor levels. Other public commenters (0153, 0222) stated that in 1997 they, along with colleagues, determined that 300 ppb was an acceptable OEL for formaldehyde.

A public commenter (0260) stated that Congress did not provide authority to EPA to propose draft OEVs as part of existing chemical risk evaluations, and the inclusion of draft OEVs violates TSCA section 9(c). The commenter recommended EPA reject these values and their derivation as inconsistent with TSCA and its scientific requirements.

A public commenter (0202) stated that the publication of an OEV that is "likely to change" according to EPA, is a disservice to the industry and to citizens at large. The commenter said that the OEV

suggested that every American household and workplace today presents an unreasonable risk. Additionally, the suggestion by EPA that an unreasonable OEV will be addressed in the management stage of the proceeding through controls to meet higher limits suggests that the Agency will regulate to a different, less stringent level, according to the commenter. The commenter said that this would leave EPA open to litigation threat from environmental interests. Similarly, another public commenter (0244) said that EPA's decision to consider certain section 6(c) non-risk factors to set a less protective OEL is another instance of discounting risks to workers.

A public commenter (0235) stated that EPA should derive the OEV using an approach consistent with the approach taken by the EU. The commenter expressed that EPA should use data from the high-quality controlled chamber studies that support a value of 300 ppb or higher. The commenter added that formaldehyde-induced observed symptoms of sensory irritation are dependent on concentration (not length of time), so no adjustment factor is necessary to account for different durations of exposure. Similarly, other commenters (0172, 0174, 0184, 0188, 0194, 0196, 0198, 0228, 0259) said that EPA arbitrarily chose to use observational studies instead of chamber studies in calculating the draft intermediate and chronic non-cancer OEV of 0.011ppm. One of the commenters (0194) stated that EPA's HSRB recently found that it is inappropriate to rely on observational studies for formaldehyde exposures when chamber studies are available.

Further, the public commenters (0172, 0174, 0184, 0188, 0194, 0196, 0198, 0202, 0217, 0228) stated that the draft risk evaluation found that a 0.5 ppm (500 ppb) is the NOAEC for inhalation exposures. Because no UF is warranted for formaldehyde, and because the OEV should be based on acute exposures, according to the commenters, it follows that the OEV should be 500 ppb.

A public commenter (0153) expressed that EPA's methods for developing this guideline for formaldehyde (in apparent reference to the occupational exposure value) strayed from traditional risk assessment approaches. The commenter suggested that EPA use Lang et al. (2008) and Mueller et al. (2013) to derive the OEV, which have also been used by the EU Scientific Committee on Occupational Exposure Limits and the WHO.

Regarding allergy, the SACC said that Annesi-Maesano et al. (2012) and Venn et al. (2003) are studies of school children and area samples (school and home) that were used rather than personal samples to characterize exposure. Thus, these studies do not align to a PECO statement appropriate to an OES and risk characterizations conducted with a toxicity reference value for adult workers based on these studies will be unnecessarily conservative. One SACC member noted that an OEL derived study finding in children PESS would be protective of adult workers. One SACC member stated that an OEL that is lower than background concentrations in a normal home is not a suitable OEL and suggested that the POD needs to be revisited. This member suggested that the EPA should review the derivations of other country's OELs and recalculate an appropriate OEL. The SACC suggested that EPA review comments provided by a board of German experts in charge of the derivation of OELs that discussed major challenges of this particular end point for regulatory toxicology.

Additionally, the SACC stated that Although the Mueller et al. (2014) study is an acute duration study, formaldehyde does not accumulate in the body and Habers' Law does not apply for formaldehyde. Thus, use of this study may be appropriate for setting a POD for chronic exposures, according to the SACC.

EPA Response: EPA has revised Appendix E Occupational Exposure Value Derivation. EPA calculated occupational exposure values of 167 ppb (209 µg/m^3) based on the acute non-cancer hazard

value for sensory irritation and 108 ppb (133µg/m^3) based on the adult-based IUR (as opposed to the ADAF-adjusted IUR) used to assess extra lifetime cancer risk for nasopharyngeal cancer.

The occupational exposure values for formaldehyde presented in Appendix E of the Human Health Risk Assessment document are calculated values "derived based on standard occupational scenario assumptions of 8 hours/day, 5 days/week exposures for a total of 250 days exposure per year, and a 40-year working life" using the PODs that were subject to peer review. EPA has considered SACC and public comments on hazard values, uncertainty factors and exposure assumptions and made appropriate revisions to Appendix E. For example, EPA revised the uncertainty factor applied to the acute inhalation value from 10 to 3 based in part on SACC feedback and this change has been incorporated into the revised occupational exposure values. The OEVs presented in Appendix E are not workplace standards. As further clarified in Appendix E, "TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus these occupational exposure values represent risk-only numbers. In risk management rulemaking for formaldehyde following the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the occupational exposure values presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c)".

In response to the commenter (0260) who asserted that the inclusion of draft OEVs violates TSCA section 9(c), the commenter misreads the meaning of that statutory provision. TSCA section 9(c) provides that the exercise of authority by EPA under TSCA will not displace Occupational Safety and Health Administration (OSHA) jurisdiction or preempt OSHA regulation by operation of section 4(b)(1) of the Occupational Safety and Health (OSH) Act, 29 U.S.C. 653(b)(1). It does not serve as a limitation on EPA's authority under TSCA, but rather ensures that when EPA does act under TSCA, such action will not limit OSHA's authority under the OSH Act (see, e.g., S. Rpt. 94-698, at 23 (1976)).

Summary: A public commenter (0230) said that, while EPA has not developed an existing chemical exposure limit for worker exposures to formaldehyde over an 8-hour or 12-hour TWA, the provided inhalation, chronic, non-cancer hazard value can be temporally adjusted to predict an approximate worker exposure benchmark over an 8-hour TWA, and this benchmark would be approximately 25 ppb. The commenter added that NIOSH Manual of Analytical Methods (NMAM) provides methods for workplace exposure monitoring, but using existing validated sampling and analytical methods for formaldehyde to measure concentrations below the approximate worker exposure benchmark poses a challenge, as this value is towards the lower end of the working range for both NMAM 2016 and NMAM 3500.

EPA Response: EPA provides a list of monitoring methods used by governmental agencies, which have typically been validated and are considered to be acceptable methods for measuring formaldehyde for regulatory purposes. During risk management, EPA may consider additional actions, if needed, as part of any proposed risk management activities, such as consideration of other monitoring methods, additional implementation timelines to validate other methods, alternative interim exposure limits.

Occupational Exposure Scenarios (OESs)

Summary: A public commenter (0220) expressed that risk was characterized and determined by condition of use as opposed to exposure scenario, even though many conditions of use had multiple

exposure scenarios and some exposure scenarios represented more than one condition of use. The commenter stated that, for at least one condition of use, more than one OES was identified, and it was not noted which of the OESs was chosen to represent the condition of use. Another public commenter (0235) similarly stated that it was difficult to identify EPA's decision-making as to which OES exposure assessment results were used in the risk characterization and risk determination for certain mapped conditions of use.
EPA Response: EPA calculates risk estimates for all exposure scenarios, which is provided in the Supplemental Occupational Risk Calculator included in the public docket. For risk determination, EPA's objective is to understand the risk on a condition of use basis, and therefore EPA highlighted the exposure scenarios driving risk for the individual conditions of use.

Summary: A public commenter (0220) stated that EPA assumed a full occupational year of exposure for some OESs that are predominantly intermittent. The commenter said that it is critical that EPA seek time and use data for use in these exposure assessments.
EPA Response: EPA determines the exposure frequency based on the reasonably available information for the given occupational exposure scenario. For most occupational exposure scenarios, EPA did not have chemical-specific information on the use frequency of formaldehyde for a given occupational exposure scenarios, therefore, EPA assumed 250 days of exposure per year.

Derivation of exposure values

Summary: Two public commenters (0211, 0221) stated that the assumption of zero exposure for un-sampled time periods is a reasonable and appropriate assumption. The public commenter noted that OSHA generally recommends collecting full-shift samples for at least 7 hours. The public commenters stated that using samples collected for less than 480 minutes to calculate an 8-hr TWA, with the assumption that the un-sampled time period is zero, is a standard industrial hygiene practice when exposure is not expected to occur outside the sampling period.
EPA Response: EPA agrees that this is a practice followed by OSHA, EPA has kept the approach of assuming un-sampled time is zero with respect to data from OSHA.

Summary: A few public commenters (0211, 0221, 0235) stated that a breathing rate adjustment factor is not justified in the calculation of a chronic non-cancer exposure estimate and in the derivation of an 8-hour OEV. In addition, the public commenters wrote that there is no justification of a breathing rate adjustment factor in the derivation of the Average Daily Concentration. The commenters added that breathing rate adjustments are not generally used to evaluate inhalation exposure and have not been used in risk evaluations for other chemicals.
EPA Response: Consistent with Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry, EPA applies a breathing rate adjustment for occupational risk calculations to account for elevated breathing rate experienced during light to medium activity, when the hazard values are derived from data from general population exposures expected to occur at rest. This is in line with SACC recommendations for the draft TCE risk evaluation to account for differences in breathing rate from a resting rate.

Summary: Two public commenters (0211, 0221) expressed that EPA's use of a 15 to 30-minute sample duration for the evaluation of short-term exposures is appropriate. The commenter stated that, although use of a collection period of 15 minutes is ideal, OSHA has recognized sample duration up to 35 minutes as representative of short-term exposure for comparison to the short-term exposure limit. The public commenter further added that they agree that, for comparison to acute health criteria, the short-term samples should not be further averaged or adjusted but should be used as discreet points of comparison. The public commenter added that short-term samples should not be used in any derivation of 8-hour TWA concentrations and should only be compared to acute hazard endpoints.

EPA Response: In the final risk evaluation, EPA has also considered a short-term estimate of exposures monitored from 15 minutes up to 60 minutes. These estimates are compared to the acute hazard endpoints.

Summary: A public commenter (0226) stated that peak inhalation estimates were between 85 – 237,902 ug/m^3 across all conditions of use. However, the NIOSH Immediately Dangerous to Life and Health (IDLH) is 24 – 24,980 ug/m^3. Therefore, the commenter stated that the high-end exposure estimates to not "pass a reality check" as it is highly problematic to conclude full shift exposures at IDLH concentrations occur or that peak exposures ten times greater than IDLH concentrations occur in the workplace. If employees were actually exposed at concentrations within an order of magnitude lower than the high-end concentrations cited in the draft risk evaluation, there would be high mortality.

EPA Response: The range of short-term exposure estimates used to determine peak exposures are mostly supported by workplace monitoring data at sites within the U.S. These ranges are the air concentrations measured within the breathing zone of the worker; however, these air concentrations are not adjusted for respirator protection that the worker may have worn during sampling. EPA integrates air concentration without these adjustments across different sites including sites which may use respirators and sites that do not, and therefore can review the impact of respiratory protection in the occupational risk calculator.

OSHA Chemical Exposure Health Data (CEHD)

Summary: The SACC stated that it is unclear whether EPA used monitoring data other than those data supplied by OSHA. If so, EPA should explain how such data were used, and if not, EPA should consider utilizing those data. The SACC stated that the OSHA data are likely to represent higher end exposures and may not represent the full range of exposures in different occupational settings. Some SACC members suggested that using the median from OSHA data as a measure of central tendency might still be a health-protective approach for all workers. But there is disagreement on this point, since workers who do not use formaldehyde or formaldehyde releasing products are considered separately, as ONUs.

In additional, several public commenters (0211, 0220, 0221, 0235, 0266) discussed the use of the OSHA Chemical Exposure Health Data (CEHD). A few public commenters (0211, 0220, 0221, 0266) stated that there is significant uncertainty in the OSHA CEHD, which was used as a primary or exclusive dataset for many OESs. Two commenters (0220, 0221) expressed that OSHA exposure monitoring data is intended to characterize exposure profiles for workers with the highest exposures and yields statistically biased high estimates. Furthermore, the public commenters stated that OSHA CEHD does not include specific information as to the processes samples or worker activities and introduces substantial uncertainty. Another public commenter (0235) noted that the OSHA CEHD

database is based on targeted OSHA inspections, which often seek to catch worst-case chemical exposures. The public commenter added that the large majority of samples are from CEHD for some scenarios, and EPA does not transparently present what the exposure values would be with and without the CEHD, even though EPA's systematic review protocol says the CEHD database has low to medium quality. Similarly, other public commenters (0211, 0221) recommended EPA provide a clear framework for evaluating the overall confidence of the occupational exposure assessment when considering the "data quality rating of air concentrations." The public commenter added that it appears that the CEHD were used disproportionally to the other sources for some conditions of use and the data were combined without consideration of weighing.

EPA Response: EPA used OSHA data from 1992-2021, which was rated a medium overall quality score. In addition, EPA used other sources from systematic review which were rated medium and high, which can be found in *Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure and Supplemental Occupational Inhalation Monitoring Data Summary*. During the SACC meeting for perchloroethylene, committee members specifically addressed this topic and added the following to the final SACC report: "Most OSHA data are from regular inspections and are not expected to be higher than usual. One SACC member added that in their state approximately 15% of OSHA inspections are for issues, with the remaining 85% as routine visits." The cause of OSHA inspection may include a worker complaint, referral, recent worker incident, or a random selection for a regional emphasis program, but the cause of the inspection does not necessarily have to be formaldehyde-related for compliance officers to monitor for formaldehyde. Therefore, EPA believes OSHA inspection data are reasonably representative of industry conditions and further believs that no negative weighing of OSHA data are needed.

Summary: A public commenter (0266) requested that EPA not include the 16 samples from OSHA's CEHD database because EPA has not made clear its rationale for grouping together facilities in NAICS codes 326211 (tire manufacturing (except retreading)), 326220 (rubber and plastics hoses and belting manufacturing), 326291 (rubber product manufacturing for mechanical use), and 326299 (all other rubber product manufacturing). Additionally, the commenter suggested that EPA remove four data points that measured the exposure concentrations for workers while they were manually weighing formaldehyde containing resins, which represent outdated work practice and exposure conditions. The commenter provided additional worker samples that measure acute inhalation exposure at their member companies' facilities.

EPA Response: EPA determines the occupational exposure scenarios based on the conditions of use, expected sources and worker activities, and the availability of data. NAICS 326291 (Rubber product manufacturing for mechanical use) and 326299 (All other rubber product manufacturing) are still included to be comprehensive of all potential uses of formaldehyde in rubber product manufacturing. Sites within these NAICS code include manufacturers of mud flaps, bed mats, floor mats, rubber gaskets, other rubber components (all other rubber product), and steering wheels (Rubber product for mechanical use). In addition, EPA welcomes the information on changes in processes during tire manufacturing. However, as only one company noted that they shifted to automated processes for weighing, EPA did not remove these data from the assessment as other companies may still be manually weighing.

Summary: The SACC noted that data that were excluded due to an inability to assign an OES could have been assigned to an "unknown" OES for comparison to "assigned" OES data. However, if the numbers of these samples are small relative to the typical numbers of samples, or skew to low

concentrations, the SACC said they are concerned that excluding high-exposure, unassigned data might lead to underestimates of risk. Additionally, the SACC noted that exposures in hair and nail salons are not included in the OESs. The SACC said that these jobs are often done by women from racial or ethnically minority populations, which are populations that have systematically been left out of OSHA protections. The SACC said that formaldehyde's use in a salon by a worker interacting with members of the public should be considered a TSCA use, even if its manufacturing and distribution is not considered a TSCA use. Specifically, the cosmetologist's use of keratin treatment and similar hair-straightening hair care products at elevated temperature has been reported to release high concentrations of formaldehyde.

EPA Response: TSCA section 3(2)(B)(vi) excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." In addition, TSCA section 3(2)(B)(ii) also excludes from the definition of "chemical substance" "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." This includes formaldehyde used in hair or nail care products or other biocidal uses of formaldehyde in beauty or nail salons.

EPA had approximately 1,500 samples of OSHA data that were not assigned to an occupational exposure scenario. Based on the NAICS code, EPA did not have confidence that the site would be applicable to a TSCA condition of use within the scope of this risk evaluation. This includes 455 samples at funeral homes and crematories, 333 samples at beauty salons, barber shops and nail salons, as well as 93 samples at sites categorized as food manufacturing which EPA expect include non-TSCA activities. In addition, the list of unassigned OSHA data includes other industry sectors that EPA is uncertain on the source of formaldehyde. Given the other sources (e.g., combustion) of formaldehyde, EPA did not equate that a site with measured formaldehyde in air had to be due to a TSCA COU and has left this data as unknown.

Summary: The SACC agreed with the hierarchy delineated by EPA where monitoring data are prioritized relative to modeling approaches and OELs. There was general agreement that the 50th percentile is a reasonable measure of central tendency, however, the central tendency is not an appropriate value to use as the exposure in a risk assessment. The SACC also suggested that EPA should restrict data to the last 10 years, or investigate if there are changes over time to decide the most appropriate time period.

- State whether there is information about variable times during the workday that are likely to have multiple sources of exposure to workers due to manufacturing processes.
- Provide information that describes factors that influence exposure at different job sites, such as the building, work conditions, air flow, and type of manufacturing. State whether these factors were included in the analysis.
- Use higher centile values such as 90th or 95th centile to represent exposures for a deterministic evaluation.

EPA Response: EPA documents the reasonably available information on process descriptions, exposure sources, worker activities, and other conditions of the workplace in the Occupational

Exposure Assessment for Formaldehyde. These documents may not cover information such as building type and air flow as these are not often provided with the identified data.

EPA calculates a 50th percentile and 95th percentile for every exposure scenario, and all of these risk estimates are provided in the Occupational Risk Calculator for Formaldehyde.

EPA did not restrict data to the last 10 years as for most scenarios it would significantly limit the available monitoring data which reduces the overall confidence that the monitoring data addresses the variability across sites for a given COU. In addition, EPA does not have information to support that significant shifts in processes occurred industry-wide that would justify reviewing only the last ten years for all COUs. However, EPA does consider the temporal representativeness of the data during data source evaluation and weight of scientific evidence conclusions.

Summary: The SACC provided other recommendations for EPA:

- Is there a background level against which the sample could be compared? If so, does this background constitute a control?
- Determine any residual exposure, dermal or other exposure routes that can be affecting individual exposure/sensitivity.
- Explain the criteria for using 'task-based monitoring data' in lieu of 15-minute peak exposure peak data' (Line 1049, page 45 Draft Health Hazard Risk Assessment).

EPA Response: Generally, EPA has determined that air concentrations experienced in workplaces are generally higher than as estimated in ambient air. EPA did not aggregate risks across exposure routes (ie inhalation and dermal) because there is no common quantitative basis for doing so. As stated in Section 4.3 of the Human Health Risk Assessment, "for formaldehyde, cancer risk is only quantified for inhalation exposures and therefore cannot be quantitatively aggregated across multiple routes." Similarly, because noncancer hazards are qualitatively different for different routes of exposure (inhalation PODs are based on sensory irritation and respiratory effects while dermal PODs are based on skin sensitization), EPA did not assume these to be additive. EPA has expanded its acute risk characterization and calculates 50th and 95th percentile of the monitored dataset using three breakdown: 15-minute, 15-minute to 60-minute, and 16 minute to 330 minute. EPA uses the higher estimated air concentrations to be protective.

Summary: The SACC stated that it appears that EPA only used samples that were equal in time to 15 minutes, and that they should consider including samples less than 15 minutes to see how those exposures differ. While SACC members concluded that EPA's 15-minute approach is appropriate, the key studies for the health effect (irritation) involved daily exposures of 3-5 hours. The SACC said that monitoring data from full-shift samples could be compared to the acute POD in some circumstances. For example, when workplace conditions of use reflect tasks not performed every day, the acute POD may be more relevant to worker health than the chronic concerns addressed by the chronic occupational exposure guidance value and should be considered as an alternative. Workers whose formaldehyde tasks are infrequent, or variable might be better served by risk characterizations where their 8 hour TWA exposures are compared to the acute POD.

The SACC recommended

- Determine if the 15-minute sample is reflective of high and low levels due to variation of materials used in manufacturing processes during the workday.

Despite these concerns, the SACC concluded that monitoring data based on 15-minute samples that have been extracted from larger data sets for full workdays should provide a realistic estimate of occupational exposure via inhalation.

EPA Response: EPA has expanded its acute occupational risk analysis to include 15-minutes as well as other longer sampled durations. EPA has incorporated two additional distributions to best identify the peak exposures of formaldehyde for the conditions of use.

Summary: A public commenter (0266) expressed support for the data used to calculate the chronic inhalation occupational exposure and develop chronic non-cancer risk estimates for workers under the rubber product manufacturing condition of use, and the conclusion that this condition of use does not contribute to unreasonable risk.

EPA Response: For the revised assessment, EPA has incorporated the additional information submitted for rubber product manufacturing.

Summary: A public commenter (0262) recommended that EPA update the confidence factor, based on data limitations. The commenter stated that EPA does not consider differentiation of upstream processing and downstream formulation of products when evaluating the overall confidence factor for the condition of use for processing as a reactant. The public commenter said that EPA concluded that the weight of scientific evidence is moderate to robust, and this is based on EPA's confidence in the quality of the underlying data. The commenter recommended EPA revise its confidence factor to "low" for certain worker activities, in order to identify that this condition of use does not include data related to downstream formulation of paint, coatings, and adhesives.

EPA Response: The occupational exposure scenario for 'Processing as a Reactant' was given a moderate to robust weight of scientific evidence conclusion. The scenario covers the processes and/or sites that use formaldehyde as a reactant. Based on the provided information, EPA considers the comment may be describing formulation processes which are covered by another occupational exposure scenario of Processing of Formaldehyde into Formulations, Mixtures, or Reaction Products.

Summary: Two public commenters (0211, 0221) noted that EPA discarded a large number of samples that did not meet the 5.5-hour sample duration cut-off, when calculating the 8-hour TWA concentrations from the OSHA CEHD. The commenters expressed that this may lead to an overestimation of the central tendency and high-end air concentrations for many conditions of use. In addition, the public commenters stated that there are clearly instances when processes that involve formaldehyde exposure only occur during a fraction of the 8-hour time period, and it would still be appropriate to adjust those values to an 8-hour TWA based on the task and process involved and the lack of employee exposure after the tasks are completed. The public commenters expressed that it is reasonable to assume that in those scenarios in which a significant proportion of the data fall in the 200 to 330-minute range, the OSHA inspector was likely capturing the relevant exposure period. A few public commenters (0211, 0221, 0235) recommended that EPA perform a sensitivity analysis to determine the impact if samples over 200 minutes were included as 8-hour TWA adjusted values, for those conditions of use in which a significant portion of the data falls between 200 and 330 minutes. Moreover, the public commenters recommended EPA consider whether it is appropriate to use the same sampling duration cut-off point value for all OESs, or whether the value should be OES-specific.

The SACC noted the approach of only including a sample if it was collected for longer than 5.5 hours, and assumption of 0 exposure for any unsampled time is in line with OSHA guidelines for including and interpreting partial-shift air samples. However, OSHA follows this approach for legal reasons and cannot issue a citation otherwise. When using occupational exposure data in a human health risk assessment, the SACC recommended that more health-protective approaches should be explored.

The SACC acknowledged that it is challenging to make assumptions about unsampled time and to decide a minimum length of sample time that could be used to infer a full 8-hr shift exposure. Overall, the committee felt that the strengths and limitations of using partial-period samples (samples collected for less than a full 8-hr shift) were clearly described. When using occupational exposure data in a human health risk assessment, the SACC recommended that more health-protective approaches should be explored. The SACC also noted that assuming no exposure during the unsampled period could underestimate the true full-shift exposure. Several committee members acknowledged 10% is an acceptable underestimation to justify the chosen approach, but also noted that shifts longer than 8 hours are common among industrial workers, which could lead to even greater underestimation. Unfortunately, the OSHA data supplied to the EPA contained no information on shift length, so there is no practical way to estimate the magnitude of this effect. In considering other potential sample durations, the SACC recommended EPA repeat the analysis in Appendix E using samples of other times (such as at least 4 hours). Additionally, the SACC suggested that if available, EPA could rely on OSHA inspector notes to consider how to interpret a sample that is not 8 hours in duration.

EPA Response: EPA acknowledges the recommendation from the SACC. For this risk evaluation, EPA has kept the current approach with consideration that the current approach potentially underestimates exposures and chronic risks, however, the current approach support chronic risks for most COUs without an assumption of exposure during the unsampled time. For clarification, EPA's current approach integrates samples measured longer than 8 hours for workers who may have shifts longer than 8 hours. As the length of their shift is unknown, EPA calculates the time weighted average based on the time sampled, and that average is used in exposure estimates as is. EPA is currently exploring more health protective approaches and may consider alternative approaches for future assessments for other chemicals.

Summary: A public commenter (0219) stated that EPA's determination that formaldehyde presents an unreasonable risk is driven by the Agency's assessment of occupational exposures. According to the commenter, EPA admits that the data underlying its inhalation exposure estimate for occupational conditions of use are limited due to "uncertainties in the representativeness of the data due to some scenarios having limited exposure monitoring data in literature". However, despite these "glaring uncertainties", according to the commenter, EPA determined that it has a "high level of certainty" that all but two occupational conditions of use contribute to unreasonable risk for workers due to inhalation exposures. The commenter stated that EPA assumes no PPE is worn despite evidence to the contrary, and dismisses any mitigating effects of PPE that may significantly drive down exposure estimates for workers. Other uncertainties in the data include assuming no engineering controls are in place for the occupational condition of use "Commercial use chemical substances in automotive and fuel products automotive care products; lubricants and greases; fuels and related products" and that worker activities involving spray applications were equivalent to immersive exposures to formaldehyde for the dermal exposure model. The commenter recommended that EPA re-examine the uncertainties related to its assessment of each occupational condition of use to determine which conditions of use may in fact not present an unreasonable risk. Similarly, a public commenter (0224) stated that EPA said it would "consider and incorporate applicable engineering controls and PPE into exposure scenarios" in its final

scoping document, and the commenter said that they should be considered when evaluating exposure and the reduced risk associated with the use of formaldehyde. Another public commenter (0226) said that it is understandable for EPA to evaluate risks for hypothetical conditions of use where workers are not trained and/or do not adhere to laws and regulations. However, the commenter said that it is unfounded and unacceptable for EPA to omit any quantitative evaluation of known conditions of use from the risk evaluation for which the exposure scenarios have been characterized and/or where laws and regulations are enforced, workers are trained, and best practices are followed. The commenter stated that stakeholders have worked diligently to provide COU-specific exposure and use data to EPA.

EPA Response: EPA considers the occupational risk assessment of formaldehyde to be a strong assessment based on a large dataset of workplace monitoring in U.S. workplaces since the last regulatory exposure limit update. The use of personal sampling monitoring data on U.S. workers inherently accounts for the engineering controls and administrative practices that may be present at different workplaces. EPA estimated risks without assuming that personal protective equipment is in place because EPA cannot guarantee, absent reasonably available information confirming that, in all cases, personal protective equipment is provided and worn, and effective at reducing exposures. EPA recognizes that there are subpopulations of workers who are not covered by Occupational Safety and Health Administration (OSHA) standards. However, EPA also is aware that many employers are subject to OSHA standards and do take measures and provide equipment to protect the safety of workers in their facilities that can reduce risk if fitted and worn properly.

To ensure the Agency is adequately accounting for potential effects to all potentially exposed or susceptible subpopulations, and based on the reasonably available information, EPA did not assume that such personal protective equipment is always used and effective at reducing worker exposures when making its unreasonable risk determination. However, where the reasonably available information indicates that, for some companies or facilities, personal protective equipment is in use for certain conditions of use and is adequate to address the unreasonable risk, EPA can consider that in risk management, as appropriate.

Summary: A public commenter (0220) listed several recommendations for EPA, including:

- EPA should refine its risk evaluation by soliciting, identifying, and reviewing monitoring data for each exposure scenario for which no data were used.
- EPA should use consistent and clear inclusion/exclusion criteria for formaldehyde exposure data.
- EPA should solicit information from the regulated industries or streams of commerce to provide validation, or to correct, assumptions inherent in default values for modeling.
- EPA should perform targeted analyses that identify and assess similar exposure groups within relevant occupational populations.
- Where monitoring data or surrogate monitoring data were used, EPA should consider revising its approach using a frequentist statistical approach that considers all data points rather than selecting subsets of data or maximum data points.

EPA Response: Throughout the prioritization and risk evaluation processes EPA solicits public comment multiple times – two 90-day public comment periods during prioritization, after the publication of the draft scope, and again after the publication of the draft risk evaluation. At each opportunity EPA encourages stakeholders to submit additional available exposure data or address incorrect assumptions. For most of the scenarios, EPA did not have the needed meta-data to be able to identify and assess similar exposure groups. In the few cases where such information was available,

EPA used the additional information to identify the worker groups most at risk in the risk characterization discussion, in lieu of performing additional analyses, in the Human Health Risk Assessment for Formaldehyde. EPA acknowledges the suggestion for alternative statistical approaches and may explore other approaches in future assessments of future chemicals.

Summary: A public commenter (0223) stated that they commissioned a formaldehyde exposure study in funeral homes across the country to assess current exposure risk to embalmers and employees of funeral homes using formaldehyde-containing embalming fluids. The results of the study, according to the commenter, show that full-shift exposures to formaldehyde (mean 0.152 ppm) were well below the current OSHA permissible exposure limit. The commenter stated that when comparing the results of the National Funeral Directors Association Study to the previously published literature, there were observable stark differences, and it is clear that the previously existing dataset does not accurately represent contemporary exposures to formaldehyde during embalming.

EPA Response: EPA's review of the submitted information indicated that this occupational scenario is outside the scope of this risk evaluation. EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning; and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977 (May 4, 1988)). These products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses.

Use of Monitored Data at Foreign Workplaces

Summary: A public commenter (0142) stated that the principal issue that EPA claims to have identified for OESs is "sensory irritation", but only associated with furniture based on several studies that are dated from 1995 and/or from locations outside of the United States, including Brazil, Nigeria, Malaysia, and Indonesia. The commenter said that EPA has made no effort to establish the relevance of these dated studies from outside the United States to current manufacturing practices in the United States. Additionally, the commenter stated that short-term exposure data relied upon by EPA to estimate the central tendency and maximum formaldehyde occupational exposures were obtained from studies completed in southeast Asia or Nigeria, and using sampling and analysis methods that appear to not be compliant with existing OSHA methods or OSHA-compliant equipment. Similarly, another public commenter (0233) stated that EPA should rely on reasonably available information that demonstrates that current furniture manufacturing under the U.S. regulatory framework does not contribute to an unreasonable risk of occupational exposure, instead of relying on outdate occupational studies from furniture product that predate more current occupational standards. Further, EPA did not perform an analysis demonstrating how exposure levels at facilities in Brazil southeast Asia, or Nigeria would be relevant to a U.S. facility.

A public commenter (0240) expressed concern for EPA's evaluation of the monitoring data, and discussed the data EPA summarized under the processing aid condition of use as an example. The commenter stated that the area monitoring data consisted of two samples referenced in Ho et al. (2013), and that EPA used the area monitoring data as short-term exposure estimates and listed the values as 0.019 ppm and 0.023 ppm. The commenter compared these values with the values listed in the Occupational Monitoring Data Summary, which stated that the number of data points was six or two

different sites and listed the "Discrete Value" of 0.016 ppm and 0.0229 ppm and the "FA Short-term TWA concentration(s)" of 0.016 ppm and 0.023 ppm. The commenter said that Ho et al. (2013) visited two electroplating factories in summer and winter and collected six samples during each visit. According to the commenter, under Table 3, the authors reported mean values of 0.0136 ppm for Factory A and 0.0187 ppm for Factory B. Under Table 4, the authors used the reported mean values for quantifying risks. The reported mean values under Table 4 were, however, 0.0167 ppm for Factory A and 0.0229 ppm for Factory B. The commenter stated that the discrepancy in these tables is unclear, and Ho et al. (2013) did not provide the individual sample values. However, according to the commenter, EPA determined that the overall data quality for Ho et al. (2013) was "Medium." EPA's data quality evaluation of Ho et al. (2013) included a comment under the reliability domain, which stated "Assessment uses high quality data that are not from frequently-used sources and there are no known quality issues." The commenter said that the discrepancies in Ho et al. (2013) and in EPA's documentation of this study are concerning, and suggest issues with the quality and reliability of EPA's review of the monitoring data in general.

EPA Response: In the draft risk evaluation, EPA primarily used the 15-minute and 8-hr time weighted averages for occupational risk characterization but provided short-term/task-based monitoring data from identified peer-reviewed sources that received data quality scores of medium or above in the Occupational Exposure Assessment such as Ho et al. (2013) which was not used in determining acute risk estimates. EPA has revised the assessment to consider sample durations longer than 15 minutes and include those samples from the OSHA CEHD database. For most exposure scenarios, EPA determined that sufficient monitoring data from U.S workplaces were available that foreign monitoring data were not incorporated into the exposure estimates. These sources and their monitoring results remain available in the Supplemental Formaldehyde Occupational Monitoring Data Summary.

Risks to Occupational Non-Users (ONUs)

Summary: The SACC determined that there was inadequate consideration of ONUs, and that EPA provided an inaccurate distinction between "workers" and "ONUs", and then only calculated risk to workers. The SACC said that ONUs are expected to have exposures that are equal to or less than workers. Additionally, the SACC said it is unclear whether janitors, maintenance employees, and lab workers should be classified as workers or ONUs.

Several SACC members agreed that the use of sensory irritation is an appropriate way to assess the acute, non-cancer occupational risks for formaldehyde. The SACC said that monitoring data are linked to potential risk to individuals with occupational exposure at likely high concentrations, and the risk should also reflect non-target individuals also considered for potential risk, like office workers.

EPA Response: EPA uses the term "workers" to refer to individuals who are expected to handle formaldehyde and have direct contact with the chemical at the workplace, while EPA uses the term "ONUs" to refer to individuals who work in the general vicinity of formaldehyde-related activities but do not handle formaldehyde and do not have direct contact with formaldehyde.

In this risk evaluation, EPA assessed chronic risks to ONUs for all COUs, which are provided in the Supplemental Occupational Risk Calculator. For acute risk for ONUs, EPA did not quantify risk estimates but has indicated that their risks for sensory irritation are expected to be similar or lower than workers. The underlying exposure basis for the acute risk characterization is based on short-term exposure monitoring taken while workers are completing high exposure tasks and therefore may not be appropriate to assign to an ONU. Where acute risks occurred at the central tendency estimates, EPA

determined that certain occupational COUs significantly contribute to the unreasonable risk due to the acute sensory irritation for ONUs.

Processing as a Reactant

Summary: A public commenter (0269) stated that EPA's assumptions in the draft risk evaluation for the commenter's two uses grossly overestimate exposure and do not represent current operational and industrial hygiene practices. The commenter said that their two uses are represented by the condition of use of "Processing as a reactant, Manufacturing of basic chemicals," which groups 14 diverse industries under the same exposure assessment. The public commenter wrote that their two uses occur outdoors and in a closed system, and EPA used inhalation monitoring data that are not representative. The public commenter expressed that two reports that they had submitted were used in the draft risk evaluation, but these reports were for a facility that the commenter divested in 2019. In addition, the public commenter stated that the sample data in the reports were for a non-routine task, and more routine exposures have lower exposures.
EPA Response: Based on the information provided by Dow Chemical for the Freeport TX site, EPA acknowledges that the exposures to formaldehyde at this site are at lower end of the distribution, below the central tendency values of the condition of use. However, EPA's objective is not to characterize risk for individual sites but to characterize occupational risks for a range of sites operating within a given condition of use. EPA has incorporated the submitted data within the processing of reactant exposure estimates. For use of monitoring data of non-routine tasks, EPA has incorporated this data as it is being used to support the acute risk characterization.

Asphalt Roofing and Fiberglass Mat Manufacturing

Summary: A public commenter (0241) specifically stated that asphalt roofing and fiberglass mat manufacturing operations exposures are well below existing regulatory limits. In addition, the public commenter wrote that they are in the process of reviewing a large number of recently submitted samples that could nearly double the current formaldehyde dataset, and the commenter said they plan to provide EPA updated metrics in a future submission.
EPA Response: EPA reviewed the submitted industrial hygiene study and compared the monitoring data with the exposure estimates determined by discrete monitoring data used by EPA in the Other Composite Material Manufacturing section in the Occupational Exposure Assessment for formaldehyde. EPA acknowledges that the roofing plant had overall lower exposures than exposures estimated for the exposure scenario while exposures at the fiberglass mat plants exposures are well represented by the estimates.

Peak Exposures in Oil and Gas Industry

Summary: The SACC stated that it is unfortunate that EPA could not calculate peak exposures for many activities in the oil and gas industry, which tends to occur in short bursts, during maintenance and repair, or when a chemical mixture is introduced to the system.
EPA Response: EPA has revised the assessment to model inhalation exposures for formaldehyde use in oilfield well production using formaldehyde-specific information reported in FracFocus 3.0. Risk

estimates for short-term (peak) exposures are accounted for in the Human Health Risk Assessment for Formaldehyde, this analysis is provided in the Occupational Exposure Assessment Section 3.14.

Paints, Coatings, Adhesives and Sealants

Summary: A public commenter (0262) stated that EPA identified solvent-based paint with 30 to 60 percent formaldehyde content, and the commenter expressed that this value may not be representative of solvent-based paints and is clearly not representative of water-borne paints. In addition, the commenter said that EPA identified formaldehyde concentrations in the range of 1 to 30 percent maximum concentration for adhesives, and the commenter recommended EPA provide some context regarding limited use of higher concentration products.

EPA Response: EPA identified a max concentration from 30 to 60 percent of formaldehyde through CDR reporting. EPA also judged that this concentration may be a concentrated product and considered 1 to 30 percent to be more plausible range for use of paints or adhesive but accounted that a product between 30 to 60 percent may be purchase as a concentrate and diluted to desired need at the user site.

Use of fertilizer

Summary: A public commenter (0245) stated that EPA incorrectly described the process for how formaldehyde is used in the manufacturing of urea under the Processing as a Reactant OES, and suggested that EPA resolve these errors in the final risk evaluation. Further, the commenter recommended that EPA revise the process description to represent the manufacturing of slow-release solid urea and triazone. In the process description section, EPA stated that it does not know the starting concentration of formaldehyde for each process under the OESs and that specific information about containers used for processing formaldehyde as a reactant. The commenter said that the most common formaldehyde based reactant (FBR) used to produce urea, slow-release solid urea, and triazone is urea-formaldehyde concentrate which is 60% formaldehyde, 25% urea, and 15% water. The commenter also stated that the two exposure scenarios used by EPA for the estimation of inhalation exposure (container unloading and container cleaning) are not accurate. The commenter added that EPA should revise the risk determination to "reasonable risk" for occupational use of fertilizers and revise the OES and condition of use category titles to "Use of Fertilizers Containing Reaction Products of Formaldehyde in Outdoors Including Lawns." The commenter also stated that there are several concerns with the model inputs used by EPA, such as the selection of lower/upper bounds of production volumes from CDR datasets and the selection of a triangular distribution for the mass fraction. In this case, a lognormal distribution would be a more appropriate representation of the actual distribution when conducting the Monte Carlo simulation.

For the OES for use of fertilizer containing formaldehyde in outdoors including lawns, the draft Occupational Exposure Assessment assumes that commercial containers for fertilizer may be similar to those of agricultural pesticides. The commenter stated that this assumption is not correct, and that the size of the application containers would vary greatly depending on what the fertilizer is being applied to. Additionally, the commenter, along with another public commenter (0248), said that the assumption that end users are exposed to formaldehyde is incorrect. Another public commenter (0250) stated that EPA must revise its draft risk evaluation to accurate reflect conditions of formaldehyde use in fertilizer production.

Two public commenters (0144, 0215) disagreed with EPA's assumption of 8-hour daily exposure over the course of 250 days for inhalation exposure estimates. The commenter stated that for maintenance of landscapes, which depends on the growing season, the estimate of eight hours per day exposure is unrealistic and it is closer to six-hour days over the course of 168 exposure days. Similarly, another public commenter (0216) stated that the assumptions made in the Draft Occupational Exposure Assessment are nowhere near reflective or real-world use patterns and potential for exposure. For example, the commenter said that in corn production, urea-based fertilizer is applied once and possibly twice a year; loading into dedicated equipment takes minutes not hours, and workers do not come close to "continuous formaldehyde exposure". Another public commenter (0256) said that exposure modeling inputs for occupational risk from the use of urea fertilizers dramatically overstate the exposure risk to applicators based on the number of days and hours that a urea would be applied. The commenter said that at maximum, occupational exposure risk to a farmer from urea application is at most 30 days per year, with a maximum of 30 minutes per day.

A public commenter (0247) expressed concern for the absence of relevant data in the TSCA risk assessment process, specifically for the "Commercial Use Chemical Substances in Agriculture Use Products Lawn and Garden Products" condition of use, and asked EPA to reevaluate this product use category based on technical data submitted to the docket by The Fertilizer Institute and the National Association of Landscape Professionals.

EPA Response: EPA has updated the process description of Processing as a Reactant in the revised Occupational Exposure Assessment based on the additional details in the public comment. EPA has updated modeling to develop a daily use rate based on expected fertilizer use between agricultural and landscaping applications. Based on the provided information that formaldehyde should be consumed during reaction and only present at impurity or contaminant levels, EPA used 0.1% as the concentration consistent with the SDSs and other measured data. EPA has revised the approach to use exposure durations and exposure frequencies from the Monte Carlo simulation considering 1 to 30 days for agricultural applications and 100 to 250 days for landscaping applications.

Summary: Two public commenters (0245, 0248) stated that for the "Use of Fertilizers Containing Formaldehyde in Outdoors Including Lawns" OES, EPA indicated it applied the EPA Mass Balance Inhalation Model to the exposure points using engineering judgement. In addition, the commenters stated that EPA stated that the ChemSTEER User Guide for the EPA/OPPT Mass Balance Inhalation Model and the Chemical Engineering Branch Manual for the Preparation of Engineering Assessments, Volume 1 were used for estimating a vapor generation rate and exposure duration. However, the commenters said that this leads to confusion as the EPA Mass Balance Inhalation Model is a part of the ChemSTEER modeling software program, yet no indication was given as to whether the software was used in the calculation of these parameters. The commenters stated that this should be clarified. Further, the commenters stated that the lack of documentation prevents full understanding of the methods used for estimating exposures to formaldehyde in fertilizers, and that EPA does not provide sufficient rationale regarding selection of equations and models, specifically those provided in Appendix C.6 and the Supplemental Information File: Draft Occupational Exposure Modeling.

EPA Response: The reference to the ChemSTEER User guide is to provide a reference which contains the model equations, default parameters, and additional information on the other available models. EPA did not utilize the ChemSTEER software to model exposures as the software uses a deterministic approach. EPA uses a probabilistic software, @Risk, to model exposures for Use of Fertilizers Containing Formaldehyde in Outdoors Including Lawns.

Dermal Exposure to Liquids

Summary: A few public commenters (0214, 0220, 0240) stated that EPA relied on modeling data when assessing the occupational exposure for formaldehyde through dermal routes, because formaldehyde dermal exposure data were not available. One public commenter (0220) expressed that EPA used one screening-level model for both occupational and consumer exposures, and, according to their own guidance, EPA should proceed with more sophisticated models if screening models do not achieve the assessment objective. The commenter specifically commented on the Dermal Exposure to Volatile Liquids (DEVL) model and expressed concern that the DEVL model does not assume any evaporation from the skin surface for the substance under evaluation. The public commenter stated that there are inherent scientific limitations to such an approach, and the lack of consideration of the evaporation rate of substance from the skin surface can lead to an estimate of exposure that is a beyond-upper-bound value or is infeasible based on physical-chemical properties. The commenter said that the model introduces a substantial amount of uncertainty into the exposure assessment process, compared to modeling approaches that take into account the flux of a chemical on the skin surface and other loss mechanisms. Finally, the public commenter said that there were ultimately three liquids used in the study of liquid retention on the skin (mineral oil, cooking oil, and bath oil), and none of these have physical-chemical properties that are similar to formaldehyde. Similarly, other public commenters (0240, 0259) questioned EPA's use of highly viscous liquids to inform the quality of a chemical substance remaining on the skin after an exposure event, or Qu, given that formaldehyde exists as a gas at room temperature and a low-viscosity liquid when in solution. The original public commenter (0220) stated that EPA did not provide a basis for its assumption that such scenarios would be similar to dermal contact with formaldehyde in the workplace. The commenter recommended EPA consider a flux-based approach to dermal exposure assessment. The public commenter stated that a more sophisticated modeling approach would account for the specific chemistries of formaldehyde solutions, would include a better-defined and better-modeled evaporation pathway for formaldehyde, would include loss mechanisms for bulk runoff and/or reaction of formaldehyde, and could include using probabilistic methods to define input ranges and distributions for dermal modeling parameters that better account for the realistic use of engineering controls, administrative controls, and PPE. One of the commenters (0259) also stated that EPA's Qu values do not account for variation in skin loading intensity from different tasks or operations which is important within broad conditions of use such as manufacturing/importing, where certain tasks could have higher potential exposure. The commenter also said that EPA calculated maximum dermal exposure scenarios that were so high, even gloves could not protect against unreasonable risk. The commenter recommended that EPA consider the IH SkinPerm model for estimating dermal loading.

EPA Response: For the formaldehyde risk evaluation, the hazard effect occurs at the point of contact and the time associated with elucidating that effect is not determined. EPA does not directly use the Dermal Exposure to Volatile Liquids model as the model calculates an absorbed dermal dose, which is not appropriate for this dermal hazard effect. EPA uses the default loading parameter with percent of formaldehyde in formulation to calculate the amount of formaldehyde which may contact the skin, without consideration of absorption or evaporation. IHSkinPerm is a model for estimating dermal absorption to ultimately derive an absorbed dermal dose, which is not the objective of this risk evaluation based on the hazard effect being assessed. EPA acknowledges the limitation of the dermal loading in Section 4.2 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the Dermal Exposure Assessment, including that the Qu value is based on dermal loading values of

viscous liquids which may overestimate dermal loading for less viscous formulations containing formaldehyde assessed in this risk evaluation.

Summary: A public commenter (0220) noted that EPA stated that it did not account for or consider the use of exposure controls in any dermal exposure scenarios. The commenter stated that it seems inconsistent with EPA's approach to exposure assessment to assume that no exposure controls exist and encouraged EPA to consider assessing exposure controls. Similarly, another commenter (0194) stated that the proposed OEV places emphasis on dermal exposures that is not commensurate with the industrial risk of dermal exposure and did not consider the use of PPE.

EPA Response: EPA has included the use of protection factors from ECETOC TRA v3 within the occupational risk calculator. For this risk evaluation, EPA did not estimate the impact of engineering control strategies on dermal risk, as a quantitative approach has not been established for OPPT to address the impact of engineering controls in a quantitative manner. However, EPA is continuously reviewing work available on alternative dermal exposure estimation approaches and may apply new approaches in future risk evaluation. During risk management, EPA may further consider the PPE and engineering controls already in use to mitigate dermal exposures.

Summary: A public commenter (0220) expressed that, for multiples OESs, EPA assumed that the maximum concentration for any dermal contact with formaldehyde was 60 percent, based on a range of 30 to 60 percent maximum concentration. The commenter stated that it is unclear what fraction of domestic manufacturing scenarios would have a concentration of 30 to 60 percent formaldehyde in their processes. Similarly, the public commenter noted that EPA assumed that the maximum concentration for any dermal contact with formaldehyde was 1 to 30 percent for multiples OESs. The commenter stated that it is again unclear what fraction of domestic manufacturing scenarios would have a concentration of 1 to 30 percent formaldehyde in their processes.

EPA Response: As discussed in Occupational Exposure Assessment for Formaldehyde, EPA estimated dermal exposures using available information, including CDR and literature sources. In the 2020 CDR, 30 out of 37 facilities that domestically manufactured formaldehyde reported a range of 30 to 60 percent formaldehyde concentration. EPA also had sources from literature and public comments that formaldehyde is generally sold commercially at a maximum of 56-60% formaldehyde. For other COUs, EPA may rely on CDR for the maximum expected concentration but in some cases, EPA made professional judgement decisions to rely on lower maximum concentrations identified in other sources as it was more supported by the information EPA identified for the use of the chemical for the exposure scenario.

Summary: A public commenter (0220) stated that the "assessor" needs to determine if EPA performed an uncertainty analysis for the occupational dermal exposure assessments, because there was no apparent uncertainty analysis in the draft risk evaluation documents. The commenter expressed that the need for an uncertainty assessment is particularly prominent because of the use of screening-level models. In addition, the public commenter wrote that EPA could further address the uncertainty by performing targeted analyses that identify and assess similar exposure groups within relevant occupational populations.

EPA Response: EPA revised the Occupational Exposure Assessment for Formaldehyde to include clear sections that discuss the limitations and uncertainties associated with the approaches used in this

assessment. This discussion is in Section 4.2 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty.

Summary: A public commenter (0269) stated that EPA used the default dermal loading of 2.1 mg/cm2, and this value was derived based on tasks in which wetted materials are directly handled by workers, which is nothing like the commenter's exposure scenario. Finally, the public commenter stated that they understand that EPA does not consider PPE as part of their risk evaluation process, but PPE is required to be used in this industrial setting because formaldehyde is corrosive at these concentrations. The commenter said that the actual dermal exposure would be zero.

EPA Response: EPA considers the default dermal loading of 2.1 mg/cm^2 applicable to dermal contact activities that include routine maintenance activities, manual cleaning of equipment, filling drums, connecting transfer lines, sampling, and bench-scale liquid transfer. These are activities that EPA expect will be completed by workers across the different sites during processing of formaldehyde as a reactant. An individual site may have automated some of these activities such that the opportunity of dermal contact by a worker is significantly reduced, however given that dermal risk is based on an acute effect, the risk estimates are also protective of non-routine events such as trouble-shooting that may result in dermal contact.

Generally, EPA may consider the plausibility of any dermal exposure if there is an immediate and severe acute reaction to the worker such as handling extremely hot materials. For the stated corrosive effect, EPA did review reasonably available hazard studies on dermal hazard. While available studies do indicate the formaldehyde is corrosive, EPA did not conclusively identify the concentration at which formaldehyde may have a corrosive effect.

Section 5.4 – Consumer exposure assessment

Consumer exposure assessment modeling and data

Summary: Several public commenters expressed concern with EPA's consumer exposure assessment. A public commenter (0246) expressed support for EPA's utilization of information collected as part of formaldehydes use report developed during the scoping part of the risk evaluation process, but is concerned that the information is outdated given the several years delay between the publication of the scoping documents and the draft risk evaluation. For example, the commenter said that EPA used GoodGuides for ingredient information, but the GoodGuides website is inoperative after an acquisition. The commenter recommended EPA use SmartLabel to extract information. Also, EPA used version 3.0 of the Consumer Exposure Model (CEM) for consumer exposure modeling when the most recent version available is version 3.2, and recommended that EPA review exposure estimates obtained from CEM to see if updates to version 3.2 of the model may affect those estimates, and remodel those scenarios accordingly. Additionally, the commenter, along with others (0142, 0219) expressed concern for EPA's reliance upon the outdated Westat survey, now nearly 40 years old, to inform typical consumer product and article use patterns, and recommended that EPA update consumer exposure models based on the Westat model to ensure accuracy and relevance. Additionally, the commenter (0246) recommended annotating the conception diagram or table (i.e., color-coding or shading) to indicate when CEM modeling results are implausible.

Some public commenters (0218, 0229, 0235, 0286) disagreed with EPA's use of high-end scenarios in its modeling assessments, such as the use of maximum weight fraction value of 30% formaldehyde in

some plastic and rubber articles, and (0235, 0286) that peak concentrations presented for the laundry and dishwashing products condition of use were based on estimated concentrations from use of dishwashing products instead of laundry detergents. One of the commenters (0286) said these models are based on data that are not directly relevant to the products in these categories and were not intended for use in a risk evaluation exposure assessment. The commenters (0235, 0246) said that EPA often derived these weight fractions from a single product or reference, and did not provide those references to the public. One of the commenters (0235) said that if there is variability in products or types of products within a condition of use, EPA must account for this. Other public commenters (0229, 0259, 0286) stated that all modeling inputs, results, and assumptions for each consumer exposure scenario should be available to the public.

One of the commenters (0286) stated that it does not appear EPA used the commenter's formaldehyde release data in the draft consumer exposure assessment for relevant conditions of use. The commenter said that data they provided to EPA on extractable formaldehyde concentrations from polyoxymethylene provide a more appropriate weight fraction value for these consumer exposure modeling scenarios compared to the 30% value used in the assessment. Similarly, another public commenter (0229) agreed that it does not appear EPA used data provided by Celanese.

Two public commenters (0229, 0286) said that it was difficult to follow the modeling input spreadsheets and to reproduce modeling results. It was unclear, for example, why dermal and ingestion input values were included in the model input spreadsheets for the plastic and rubber products and toys, playground, and sporting equipment product types when neither route was evaluated. Additionally, the commenters said that EPA did not provide the exposure results for all models assessed.

A public commenter (0259) stated that multiple exposure scenarios included youths and children, in addition to adults, but it is highly unlikely that individuals under 18 would be using these products. By including individuals under the age of 18, the scenarios were overestimating exposures by artificially increasing years of exposure. For example, the Lifetime Average Daily Dose increased by 64% by including youths and children as product users.

Finally, a public commenter (0235) said that EPA's modeling did not account for the effect that physical barriers in products have on reducing emissions of formaldehyde, impacting both dermal and inhalation exposures. For instance, wood panels are rarely used without some form of finish, laminate, painting or coating which impact formaldehyde releases.

EPA Response: EPA appreciates feedback on the best available consumer formulation data including those presented in the formaldehyde Use Report. EPA provided its consumer modeling inputs for replication of the exposure estimates. If a manufacturer presented a range up to 30%, 30% was assumed to be the maximum percent in formulation per the relevant SDS. There is a possibility that any one of the assessed products and articles could have been reformulated to incorporate less or more formaldehyde in formulation. If a product or article was determined to be discontinued associated exposures were not assessed for the revised assessment of formaldehyde. However, EPA depended on the best available data, including information and data from the Use Report and SDS' among others, to support its exposure assessment of formaldehyde in consumer products and articles. CEM 3.0 was the latest available version of the CEM model for which the outputs are expected similar compared to version 3.2 outputs.

EPA recognizes the age of the Westat database. However, it has been used and is currently being used for other chemical risk evaluations as it is the best available data regarding human behavior related to

the assessed conditions of use. In the future, if a newer dataset on consumer behaviors and activity patterns is available EPA will consider its use.

Aside from the text and Table 2-1 of the Consumer Exposure Assessment (technical support document), EPA described conditions of use for which exposures were quantified.

For the revised Consumer Exposure Assessment, EPA did not assess exposures to consumer laundry products or consumer dish washing products because no relevant consumer products were found on the consumer market.

Ambient or outdoor release data are not relevant to the consumer exposure assessment. Instead, ambient air exposure is relevant to the environmental, general population and fenceline exposure assessments.

EPA acknowledges receipt of the Celanese data regarding polyoxymethylene. For the final Indoor Air Exposure Assessment of consumer articles it has been incorporated into Appendix D.2 of the Indoor Air Exposure Assessment. As a matter of transparency, EPA presented all routes, products and articles initially considered for consumer exposure assessment. For a number of reasons, as noted in the Consumer Exposure Assessment (technical support document), the oral route, some products and articles were eventually deemed to be out of scope or qualitatively assessed.

EPA disagrees that people under 18 are unlikely to be exposed to formaldehyde according to the products assessed. For example, it is reasonable to assume that people under 18 may be formaldehyde via glue especially if they are art students involved in craft projects. To be protective of populations expected to use the products and articles identified, relevant age groups were assessed. It should be noted that the assessed age-groups were done according to CEM default associations with certain products and articles based on literature.

EPA does not assume that the consumer will be wearing a physical barrier or PPE during use of a product or article. Regarding certain finishes and coatings, EPA re-modeled wood products using the Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and presents this data in its Indoor Air Exposure Assessment. While EPA has improved confidence in its higher tier modeling, EPA recognizes the potential restrictive impact of such barriers as an uncertainty in the reduction of exposure.

Summary: A public commenter (0229) stated that in the *Draft Consumer Exposure Assessment for Formaldehyde*, EPA categorized consumer products containing formaldehyde in 12 conditions of use, and developed 30 exposure scenarios to assess consumer exposures under these 12 conditions of use. As a result, many of the conditions of use evaluated contained at least two consumer exposure scenarios. However, the commenter said that when presenting the results, EPA provided the exposure results for "representative" exposure scenarios within each condition of use and did not provide the exposure results from all other models/exposure scenarios. The commenter said that without access to all of the modeling results for every exposure scenario, it is difficult to assess whether it was appropriate for EPA to apply the calculated risk estimates of one "representative" scenario to all exposure scenarios.

The SACC concluded that EPA's Standard 30 scenarios are incomplete. The SACC recommended discussing the full range of "indoor enclosures" and "vehicle space" rather than "residence". Also, exposures of many populations are parsed by the scenarios when considered product-by-product or

scenario-by-scenario, when actual exposures result from combinations of many scenarios. This might be acceptable if those were "reassembled" in a competent, probabilistic exposure assessment model that yielded representative exposure profiles when direct monitoring was absent or inadequate. The SACC was concerned about such presentations of exposure, especially when probabilistic statistical approaches for data usage and modeling are not employed. Of particular concern to the SACC is the absence of exposure and risk assessments for "processing", "distribution in commerce" and "use" scenarios. The environments in which such exposures could manifest are also too limited. The SACC strongly recommended the EPA consider example scenarios that they provided for processing and distribution in commerce.

Additionally, the SACC suggested that the consumer exposure document be revisited to consider formaldehyde release from transportation to determine a fuller extent of formaldehyde exposure. The SACC was also concerned that the consumer exposure assessment did not adequately address children's exposures. The SACC concluded that the definitions of "condition of use" and the "standard scenarios" should not inhibit realistic exposure assessment, and do not need to be so limiting.

EPA Response: EPA presented all relevant quantified exposure results in the *Consumer Indoor Air Acute and Chronic Inhalation Risk Calculator*, including representative and non-representative exposure scenarios.

The commentors point to occupational exposure scenarios that are not applicable to consumers. For example, exposures from processing, distribution in commerce (i.e., transportation) are beyond the scope of the consumer exposure assessment which focuses on exposures from the use of products and articles. EPA cross-walked conditions of use to exposure scenarios based on relevant products and articles on the market which were assessed using weight fractions of formaldehyde in formulation along with use and activity patterns from surveyed individuals from the Westat Survey and EPA Exposure Factors Handbook.

Summary: A public commenter (0261) expressed support for the CEM and said that it is an appropriate model to use to estimate acute and chronic inhalation exposures to formaldehyde.

However, the commenter had some additional feedback on the CEM. The commenter said they presume that EPA is relying primarily on steady state emission modeling to generate these exposure estimates because there are few, if any, studies that measured emission rates of formaldehyde or room concentrations of formaldehyde from the consumer product types identified. Additionally, the commenter stated that there may be more recent and more reliable data available to EPA, though likely for a cost. The commenter also said they were surprised that in Table 2-1, there were so few products identified by EPA for each consumer product type. The commenter also stated that it is not clear what "formaldehyde weight fraction" means and asked EPA to provide a definition. Finally, the commenter stated that given the problematic history associated with prior use of Urea Formaldehyde Foam Insulation, which was banned by the CPSC in 1982 for use in residences and schools, the commenter suggested that EPA provide a more detailed explanation for its lack of concern for foam insulation.

EPA Response: EPA appreciates feedback on use of CEM to assess consumer exposures from product and article uses. The commenter is correct in that there was a lack of supporting emission data for all of the relevant consumer articles assessed. Though, for the ones with publicly available emissions data, EPA incorporated that into the indoor air assessment using CEM followed by IECCU. It should be

noted that the list of identified products is not meant to represent a thorough list of formaldehyde consumer products and articles. Instead, it is meant to represent a list of current products and articles (at the time of the assessment) guided by a review of the conditions of use and likely products and articles identified in Scope and Use Report documents for formaldehyde. A definition of weight fraction has been added to Appendix F of the Consumer Exposure Assessment. Additional discussion has been added to Section 1.1.1 of the Consumer Exposure Assessment regarding general reduction of urea formaldehyde foam insulation use since the 1980's.

Summary: A public commenter (0263) stated that EPA's risk characterization found that three consumer conditions of use had cancer risks greater than its stated 10^{-4} benchmark, and chronic non-cancer MOEs less than 1.0: 1) adhesives and sealants; paint and coatings; 2) arts, crafts, and hobby materials; 3) ink, toner, and colorant products; photographic supplies. However, EPA determined that the cancer risk from these conditions of use do not contribute to the unreasonable risk of formaldehyde. In addition to disregarding consumer cancer risks, EPA has likely underestimated consumer risks by not accounting for scenarios in which higher indoor air concentrations may occur by only using central-tendency estimates, according to the commenter. Additionally, the commenter said that EPA used indoor air measurements from the AHHS and estimated that the central tendency cancer risk of formaldehyde in homes exceeded the 10-4 benchmark. And EPA also modeled central tendency chronic indoor air concentrations of formaldehyde from four conditions of use, but then failed to use those estimates to calculate cancer risks to home occupants. EPA did, however, use the same modeled indoor air concentrations to estimate chronic non-cancer risks, and found that three of the conditions of use had MOEs less than EPA's benchmark.

EPA Response: For the final risk evaluation EPA focused its consumer assessment on peak exposures as it does not expect most consumer exposures to be chronic in nature because product use patterns generally tend to be infrequent with relatively short durations of use. Therefore, EPA did not estimate potential cancer risks for consumers.

EPA re-modeled indoor air exposures resulting from use of articles. EPA used IECCU to generate low, medium and high-end exposure estimates which are intended to assess sentinel or PESS exposures based on relatively higher exposure estimates. For the revised assessment of formaldehyde in indoor air EPA estimated acute, chronic non-cancer and cancer risks. The risk characterization for indoor air presents chronic cancer and non-cancer risk estimates based on indoor air monitoring data. The revised assessment also presents acute, chronic non-cancer and cancer risk estimates for specific COUs based on indoor air concentrations modeled using IECCU and/or CEM and discusses the strengths and limitations of each of these analyses.

As stated in the Unreasonable Risk Determination, whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. A whole range of information as stated above is considered in order to make an unreasonable risk determination. A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. It is

important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk.

Summary: The SACC recommended that EPA consider the indoor air data collected in response to the CPSC investigation of the Lumber Liquidators use of flooring from China, which provide an additional source of flooring exposure information.

The SACC also recommended that EPA attempt to normalize data from older literature, taking into consideration the sensitivity and measurement methods (and their limitations) used at that time to derive indoor air concentration of formaldehyde over past decades. The SACC said it is important to distinguish types of structures (i.e., homes, mobile homes, age of structure, insulation, and outdoor air passage, etc.) and as is discussed in the document and tables, and to emphasize greatest sources of risk.

Additionally, the SACC stated that CEM inputs used for consumer product- and scenario-specific parameters should reflect the loss of loaded formaldehyde in consumer products during the transportation and/or the shelf life of consumer product(s). The SACC said that a "retention factor" should be applied in CEM inputs, defining "retention factor" as the mean average concentration of free formaldehyde during the shelf life of a given consumer products.

The SACC recommended that EPA consider using nested approaches such as Multicriteria Integrated Resource Assessment (Stahl and Cimorelli, 2013) to integrate factors influencing levels of exposure associated with potential adverse outcomes.

The SACC recommended that EPA consider several aspects of contributions from wood stoves and other combustion sources.

The SACC suggested that EPA should consider physiological indicators as early warning signs for adverse effects and incorporate them into the assessment of potential risk.

EPA Response: These comments pertain to the indoor air assessment of formaldehyde in certain articles. EPA refined its analysis of wood flooring from the draft to the revised version of the indoor air assessment using IECCU which is a higher tier model compared to CEM. The refined assessment considered recent emission factors from articles on the market (which assumes a consideration of lead time), applied an exponential decay rate and assumed that wood manufacturers adhere to the composite wood emission standards for new wood articles added to the market. EPA considered all submitted data from the public and peer reviewers. The recommended retrospective analysis of sensitivity and measurement methods (and their limitations) used at that time to derive indoor air concentration of formaldehyde over past decades is beyond the scope of this evaluation, especially given EPA's reliance on AHHS II – a robust indoor air monitoring study of formaldehyde. Combustion sources were considered in the indoor air assessment, especially through an analysis of the AHHS II data.

Summary: In response to EPA's request for comment on information or approaches that will increase confidence in long-term exposure estimates and corresponding cancer risk estimate for consumer products, the SACC provided several recommendations:

- Consideration of PESS and fenceline communities is required by TSCA and can be a tool for EPA to build credibility and encourage participation by the public and collaborative information submission by communities, states, unions, and others across the nation;
- Include the broad scope of exposure opportunities, including all required by the TSCA mandate;
- Provide a scope document before the assessment begins and circulate that document widely. Scenarios suggesting PESS and/or fenceline scenarios should be noted with requests for information and suggestions on such situations;
- Compare conclusions reached in EPA assessments (hazard, exposure, risk) with decisions reached by other global regulatory authorities and scientific organizations;
- Present the full distribution of values for parameters used in any part of the algorithms and/or model assumptions, along with key statistical metrics;
- Provide TSCA scientists with competent, probabilistic, and flexible modeling tools capable of aggregate exposure assessment, considering lifetime physiological factors and multiple exposure opportunities, which will enhance the current deterministic models and simplistic approaches used by the EPA;
- Although information for consumers regarding formaldehyde content in products is improving, increase attention to sources of consistent exposure;
- Clarify whether chronic exposure in Table 3-1 refers to periods of time per day or consistent exposure, such as living in an area with ubiquitous environmental pollutants in the air; and
- Provide information to the public.

EPA Response: EPA considered PESS and fenceline in its ambient air exposure and risk analyses. EPA considered all potential exposures based on the best available information. A scope document was published for formaldehyde and included all of the relevant and expected exposures to be assessed. EPA used the published scope to generated its risk evaluation for formaldehyde. EPA considered the best available information and data and associated conclusions from authoritative sources to guide its risk evaluation of formaldehyde. Please see all of the technical support documents including the Human Health Risk Assessment for more specific information. EPA has considered various tools and methodologies to characterize exposures and risks. Some tools (i.e., probabilistic modeling for consumer exposures) and associated approaches have not yet been developed. EPA welcomes any available peer reviewed tools that may be supportive of its consumer and other exposure assessments. EPA uses systematic review efforts to identify the best available data and tools to address any data gaps. EPA used the available literature to identify TSCA COUs with known persistent emissions to indoor air. EPA also considered aggregate exposures in its assessment of indoor air. It is unclear which table the reviewer is referencing. However, if this is referencing Table 3-1 from the Draft Indoor Air Exposure Assessment, then the estimated CEM modeling exposures reflect activity patterns based on the assumed room of use per article. Primary and supplementary data and information have been published for the draft and are being published for the revised Formaldehyde Risk Evaluation.

Dermal assessment

Summary: A public commenter in two submissions to the docket (0220, 0235) stated that the value of 10.3mg/cm2 was the maximum measured value for retention of a mineral oil-based product on the skin following application in the Cinalli et all (1992) study, but the commenter said that the dermal retention values from that study have little relevance to formaldehyde or formaldehyde mixtures. Another public

commenter (0246) stated that very few consumer products are mineral-oil based like the product used in the study, and it may not be appropriate to use the worst-case mineral oil immersion test to represent dermal exposure to all consumer products. The commenter recommended that EPA include exposure to other common solvents in consumer products with different physical-chemical properties and other common consumer habits and practices, such as rinsing and wiping hands following product use.

A public commenter (0219) stated that EPA inflated the consumer dermal exposures by assuming that consumers ignore label recommendations and assume immersion of hands using liquid or spray consumer products. EPA also recognizes that risk estimates are based on modeled exposure estimates, and it is not possible to determine how frequently these exposures may occur. However, EPA still concludes that it has "medium confidence" rather than "low confidence" in its risk estimates for dermal exposures.

A public commenter (0226) stated that the dermal exposure assessment is incorrectly performed because it is based on generic loading factor assumptions and high-end estimates for supplied bulk formaldehyde rather than known concentrations of formaldehyde in formulated products that could come in contact with the skin. The commenter said that assuming routine exposures to liquids containing 30-60% demonstrates a fundamental misunderstanding of formaldehyde toxicity and reflects an overly conservative assessment.

A public commenter (0259) stated that while EPA did not use the results of the CEM dermal exposure model and elected to use the Thin Film Model, the CEM inputs demonstrate that EPA considered alternate dermal contact scenarios when developing the CEM inputs compared to Thin Film, but then used none of them. The commenter said that this likely overestimated actual exposures.

EPA Response: EPA believes the use of 10.3 mg/cm^2 was for skin retention of the identified and relevant liquid products to be protective of exposures where individuals may receive prolonged exposures to the product or exposures where hands may be submerged or similar scenario whereby a thin film remains on the skin before washing or wiping hands. EPA does acknowledge potential uncertainty associated with the skin retention value and associated assumptions. However, the assumptions are assumed to be protective of worst-case exposure scenarios that may occur.

Since the assessment is specifically for formaldehyde, a quantification of additional potential dermal exposures to other chemicals was beyond the scope of the dermal exposure assessment for formaldehyde.

The Thin Film model used is a relatively simple calculation of the Qu (amount retained on skin) by the weight fraction. The medium confidence in the dermal modeling stems from a consideration of weight fractions associated with the products assessed and the Qu which may be as high as 10.3 mg/cm^2. The lowered confidence from high to low is due to the potential that the highs relevant Qu per product may be slightly lower than the assumed 10.3 mg/cm^2.

The dermal weight fractions identified in SDSs, Use Report and CDR ranged from 0.009% up to 30% (please see Table_Apx B-4).

When the input table was generated, it was done so with consideration of all potential routes and pathways of consumer exposure. EPA initially considered using CEM to estimate dermal exposures as it normally does for most TSCA chemical risk evaluations. However, once the dermal endpoint was finalized CEM was no longer appropriate to be used. Instead, the Thin Film (a subcomponent of CEM)

was used to generate dermal exposure estimates to better represent the dermal mode of exposure and endpoint.

Summary: A public commenter (0261) expressed support for the Thin Film Model used to estimate dermal exposures to users of products that contain formaldehyde.

EPA Response: EPA used the Thin Film Model to estimate dermal exposures in the final risk evaluation, consistent with the draft risk evaluation.

Drain and toilet cleaner

Summary: A public commenter (0246) stated that they are unaware of products that contain formaldehyde at 10% concentration, and the references that EPA used do not document or support this value. The commenter said that EPA overestimated the inhalation and dermal exposures associated with the drain and toilet cleaner condition of use in the draft consumer exposure assessment and recommended that EPA update and verify the information to update the consumer exposure assessment accordingly.

EPA Response: EPA found an SDS from Portaloo for a cleaner with reported formaldehyde concentrations up to 10%. The SDS describes the product as the following "PORT-A-LOO is a portable toilet sanitiser and deodorant, designed to emulsify sludge and waste in holding tanks of portable toilets" (Source of publicly available SDS from Minehan Agencies: Port-A-Loo). Generally, EPA exposure assessors assume the highest possible weight fraction for this product was 10%. With a lack of better data or information, EPA assumed that for a high-end assessment a 10% weight fraction was the highest concentration of formaldehyde a consumer may be expected to be exposed to, based on the available data and information. However, this product is no longer in commerce. Hence, EPA did not quantify exposures for this consumer product in the revised formaldehyde indoor air exposure assessment. No further update is necessary.

Wood articles

Summary: A public commenter (0142) stated that the SACC should evaluate the data EPA used in combining multiple uses within one category such as combining furniture, furnishings, and other wood finishes with drain and toilet bowl cleaner in the *Draft Consumer Exposure Assessment*. Additionally, two public commenters (0202, 0205) said that EPA acknowledged that solids such as composite panels are not of concern for dermal exposure and pose no unreasonable risk, which supports one of the commenter's (0202) request to remove these products from the scope of the draft risk evaluation. However, one of the commenters (0205) stated that the conditions of use relevant to board products found to have unreasonable dermal risk for workers were based on worker exposure scenarios that included liquid containing formaldehyde in unloading/loading and cleaning activities. It is not transparent or clearly stated that EPA excluded solid products from the consumer dermal risk assessment, therefore, the specific exposure scenarios responsible for the unreasonable risk should be clearly and transparently stated.

EPA Response: The SACC was able to review the Consumer Exposure Assessment including the modeling assumptions used. Overall, the SACC agreed with the consumer exposure modeling approaches applied. Based on the available data, dermal effects as a result of handling solid articles are unlikely. Though, EPA did qualitatively consider potential dermal exposures from new and unwashed clothing treated with formaldehyde for various reasons including wrinkle reduction. The consumer conditions of use relevant to board products does not contain any unloading/loading activities and it should be noted that the conditions of use may contain a variety of products and articles (see Table _Apx B-1 of the Consumer Exposure Assessment). Each product and article are modeled as individual scenarios, according to relevant TSCA consumer COUs for formaldehyde. Then, one scenario is selected to represent a TSCA consumer COU, typically according to the highest estimated exposures per individually modeled products and/or articles, for data visualization and risk calculation. Regarding a clear statement on the lack of dermal exposures expected from solid articles please see Appendix D of the Consumer Exposure Assessment.

Summary: A public commenter (0205) stated that EPA incorrectly assumed a maximum weight fraction value of 10% formaldehyde board products based on the content of the formaldehyde in adhesives (unreacted resin). The commenter said that based on the chemistry of thermoset resin including phenol and urea systems in board products, there is an expected lack of unreacted resin in a board system.

EPA Response: According to Use Report, OECD identified use of formaldehyde in the components of wood articles with concentrations ranging from 0.1 to 10%. Since the high-end consumer exposure scenarios were assessed, this meant that the highest identified weight fraction of 10% (in addition to highest duration and use amount) was incorporated into the consumer exposure modeling. Nonetheless, EPA performed a refined analysis of solid consumer articles in indoor air using IECCU. This higher tier modeling considered potential reduction in the amount available for exposure from the manufacture to home installation by foregoing the use of the weight fraction in the article and instead relying on the article-specific emission rates per surface area in the expected room of use or an entire home.

Recreational vehicle (RV) industry

Summary: A public commenter (0203) stated that EPA failed to recognize limited exposure to formaldehyde for those in the RV industry. For example, the median annual usage for RV owners is 20 days a year. Though the draft risk evaluation focuses on newer home furniture and building materials, the RV industry expects to be impacted by the risk evaluation, according to the commenter.

EPA Response: In the Indoor Air Exposure Assessment, EPA used real-world monitoring information and data to acknowledge potential mobile home-related exposures. For the purposes of this assessment, EPA considers RVs and mobile homes to be the same and assumes that some people live in their RVs. Though, as the Composite Wood Products final rule continues to be implemented, indoor air concentrations of formaldehyde should generally decrease in RVs over time.

TSCA section 6(c)(2)(E) articles

Summary: A public commenter (0224) expressed that it is challenging to determine where EPA stands on the potential exposure to formaldehyde from articles where formaldehyde may have been in input but is no longer present or present only in minimal concentrations. According to the commenter, one reason that accurately assessing potential exposures from articles is critical is that that statutory language in the Frank R. Lautenberg Chemical Safety for the 21st Century Act directs EPA to take a more focused and narrow approach when identifying articles that EPA believes need to be managed under sections 4, 5 or 6. In the draft risk evaluation, the commenter said that EPA has not identified what exposure(s) are occurring as a direct result of the "exposure to the chemical substance or mixture from the article" nor does it appear to have recognized the distinction between the exposures, risks, and impacts associated with direct chemical exposure versus any potential limited or negligible exposure to a manufactured article. The commenter recommended that EPA clarify its interpretation of the applicability of TSCA section 6(c)(2)(E).

EPA Response: EPA has provided text in Section 1.1.1 of the Consumer Exposure Assessment (technical support document) and Appendix D.2 of the Indoor Air Exposure Assessment, for example, regarding low levels of formaldehyde in formulation for products and articles. For the updated indoor air assessment, EPA used article specific emissions to account for the reduction of formaldehyde from manufacturing to installation into a home, instead of using weight fractions. IECCU results were more comparable to CEM results. Exposure assessed are specifically to the formaldehyde chemical formulated in products in articles – not a mixture of chemicals, per TSCA.

Other comments

Summary: A public commenter (0246) said that this is the first time the language "chronic consumer exposure" has been included in a draft risk evaluation and suggested that EPA discuss and substantiate the evidence to support the inclusion of chronic consumer use for a particular condition of use.

EPA Response: There have been previous TSCA chemical risk evaluations in which long-term or chronic exposures were assessed. One example is the 2019 HBCD risk evaluation in which chronic non-cancer exposures from articles (Docket ID: EPA-HQ-OPPT-2019-0237-0002) were assessed. Nonetheless, EPA determined that the consumer exposures to formaldehyde are expected to be infrequent with relatively short durations of use. Therefore, EPA prioritized acute exposures and risks for the revised risk evaluation.

Section 5.5 – Indoor air exposure assessment

General comments on CEM

Summary: A public commenter (0142) suggested that SACC analyze the limitations on the modeling that EPA has recognized in the draft risk evaluation, such as their chronic exposure scenarios which did not recognize emission decay over time. Additionally, EPA admits in the *Draft Indoor Air Exposure Assessment* that the CEM is a screening approach, and the Agency is investigating other modeling approaches. The commenter said that these limitations are especially critical for furniture, finishings and other interior wood finishes. Several other commenters (0202, 0224, 0270) also discussed how the model did not take into consideration that formaldehyde dissipates over time or decays. Two of the commenters (0224, 0270) stated that if an assessment assumes a steady state of the highest possible

chemical concentration, the resultant risk assessment overestimates the potential risk. One of the commenters (0224) said that the choice to not address dissipation is doubly confusing given that EPA has included a clear dissipation curve that shows a rapid decrease in formaldehyde emissions after initial installation of an article or component. Conversely, a public commenter (0261) stated that though there is uncertainty related to the degree of dissipation of formaldehyde over time, they are not convinced that EPA should have low confidence in their exposure estimates since EPA evaluated this uncertainty in the 1980s.

Another public commenter (0177) stated that the CEM used in the D*raft Indoor Air Exposure Assessment* is suitable for a worst-case analysis to estimate theoretically achievable maximum concentration and is not suitable for making valid statements about real-life exposure to formaldehyde. The commenter said that the model is not sufficiently valid to predict and evaluate risks from indoor formaldehyde exposure, particularly short-term exposures. The commenter, along with another (0202) stated that a full assessment requires a complete mass balance model with reasonable assumptions about sources, decay behavior, surface covering, possible sinks, and realistic assumptions about the time-dependent air change in the building, according to the commenter. The commenter (0177) said that indoor air chemistry is a formaldehyde source that has not been taken into account or is underrepresented in the draft risk evaluation, and suggested that EPA look to Salthammer (2019a,b) for available data. Additionally, the commenter said that when taking in available date, formaldehyde concentrations higher than 10 ppb from gas phase and surface reactions with ozone seem to be possible but unlikely under normal indoor conditions, and concentrations between 1 ppb and 10 ppb seem to be realistic.

EPA Response: It should be clarified that the CEM assessment performed for indoor exposures (yielding 1-year average concentrations) was based on central tendency parameters. Hence, that is not the key reason exposures may have been overestimated for the indoor air assessment. The E5 emission condition used to develop air concentrations in CEM E5 allows the user to input empirically derived emission rate data, but assumes that emissions occur at a constant rate, likely overestimating both short and long terms concentrations of formaldehyde in air. The screening models (Appendix D of the Indoor Air Exposure Assessment) carried out in CEM indicated that Consumer articles with large surface areas may contribute significantly to indoor air concentrations of formaldehyde, prompting a second round of modeling for these items using the higher tier Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model. IECCU allows the user to input both empirically derived initial emission rates and a first order exponential rate of decay for emissions, providing a significant improvement to the models.

The refined models did not include a full mass balance approach as chemical sinks and air chemistry were not included in the models. However, these are expected to result in a relatively small decrease in air concentrations as compared to ventilation, which was included. The primary consideration for formaldehyde chemistry in air is degradation due to photolysis; this is generally accepted as insignificant in indoor environments because of the lack of UV light. Similarly, while formaldehyde has been shown to sorb to indoor surfaces, this effect is expected to be limited partitioning behavior of formaldehyde from air. Thus, despite uncertainties and limitations associated with the new modeling results, the refined models developed in IECCU are expected to provide reasonable estimates of exposure.

Given the high indoor air concentrations observed in CEM models for TSCA conditions of use with large surface areas, EPA carried out additional modeling using IECCU which is peer reviewed and has

been previously used in TSCA risk assessments to model chemical exposures. Modeling formaldehyde exposures for consumer articles with large surface areas in IECCU is expected to have several benefits. First, IECCU allows for the use of an emissions model that includes an exponential decay rate, which is expected to better represent formaldehyde emissions from solid articles and resulting air concentrations. The model may also be run for longer periods of time as compared to the CEM E5 condition and is expected to provide better estimates of chronic exposure. In addition, IECCU models can be configured to include multiple items with individual emission rates in the same space. This allows for the generation of aggregate models for scenarios in which consumers may bring several articles belonging to the same TSCA condition of use into the home simultaneously (e.g., newly built homes and décor change scenarios). A brief overview of the IECCU model is provided in the Indoor Air Assessment.

For the final risk evaluation, EPA has identified and utilized the IECCU model as a higher tier tool to assess formaldehyde in indoor air for solid articles. IECCU addresses the key comments associated with CEM limitations regarding indoor air exposure assessment. A key output of the IECCU modeling is a set of COU/article- specific dissipation curves; showing peak (short-term) concentrations followed by long term dissipation over ~1 year. The modeling is responsive to SACC comments whereby peak exposure estimates (in addition to chronic exposure estimates), for the indoor air exposure assessment, were generated as the SACC deemed it protective of potential effects resulting from chronic exposures. Also, low, medium and high exposure scenarios were modeled using IECCU. Hence, EPA presents a range of exposures, instead of just the worst-case scenarios.

Regarding comments on realistic indoor air concentrations of formaldehyde, please note (as presented in Section 3.1.2) monitored concentrations have been measured much higher than 10 ppb (or 12.28 $\mu g/m^3$) as suggested by the commenter. For American homes, concentrations have been measured as high as ~124 $\mu g/m^3$ per AHHS II; and for unoccupied Federal Emergency Management Agency trailers, as high as ~4500 $\mu g/m^3$ according to the Agency for Toxic Substances and Disease Registry. Though as the Formaldehyde Emissions Standards for Composite Wood Products final rule continues to be implemented, peak indoor air concentrations of formaldehyde should generally decrease in American homes over time.

Summary: Two public commenters (0244, 0283) stated that EPA's reliance on central tendency exposure estimates violates TSCA's requirement to evaluate and address risks to PESS. One of the commenters (0283) said that central tendency risks are based on the 50^{th} percentile of exposure estimates which do not cover the many workers and consumers who experience exposures and risks greater than the median. One of the commenters (0244) stated that by EPA's own estimation, use of the central tendency exposures to calculate cancer risks does not capture real-world exposures to some populations. The commenter said that monitoring data captured in occupational and indoor settings have clearly identified situations where individuals are more likely to be exposed to high levels of formaldehyde which should be captured by the use of high-end exposure values. Additionally, the commenter said that EPA's use of high-end exposure values in the calculation of cancer risk from ambient air exposures but not from indoor exposures is not consistent, and EPA should consider the general population and workers equally. The commenter also stated that EPA failed to aggregate indoor air exposures by only selecting a representative exposure scenario per condition of use according to the highest estimated concentration per duration and route of exposure. At minimum, the commenter

recommended that EPA must aggregate exposures from each modeled condition of use that contributes to indoor air exposure.

The commenter, along with another commenter (0283) also stated that EPA failed to assess indoor air exposures for more than 1 year, and only estimated exposures for an individual who is outside the home for 11 hours, which does not account for people who are unemployed like children and the elderly, or the 22 million Americans that work from home. One of the public commenters (0283) similarly stated that EPA significantly underestimated the number of hours people are exposed to formaldehyde in indoor air by considering only estimates in home and vehicles and ignoring other environments such as schools and workplaces.

The SACC stated that probabilities of occurrence are valuable data to calculate a distribution of exposures in homes that are likely to have air contamination from given sources. The SACC recommended that EPA design parametric distributions for assumptions such as the duration of exposure and values of indoor air concentrations, as well as off-gassing rates for different media, showing a projected decline over 1 year, and report these values along with the entire distribution curve and the rationale behind the curve designs.

Additionally, the SACC said that the public would like to know, even in the absence of aggregate exposure, what could the risk be for at least the single conditions of use for which acute exposure assessments have been fashioned. The SACC concluded that the EPA draft assessment has dismissed too much information and avoided too many difficult aspects of the assessment to inspire confidence. To remedy this, the SACC recommended that EPA conduct exposure assessments for each condition of use and for metrics from all monitoring studies, and use these quantitative exposure assessments to provide a perspective on the relative contributions of individual conditions of use.

The SACC also discussed the automobile monitoring studies (Lawryk et al., 1995 and Lawryk and Weisel, 1996) and suggested that EPA use new studies such as Wang et al 2023. The SACC recommended that EPA use all available indoor air, vehicle, and contained space monitoring studies to fully assess exposures. The SACC also suggested that descriptions of the findings for each of these monitoring studies should be presented in more detail.

EPA Response: EPA ran the IECCU model and generated low, medium and high exposure scenarios. Hence, EPA presents a range of exposures, instead of just the worst-case scenarios. The expanded range should also cover potential exposures for PESS populations. EPA performed and refined its assessments of exposures based upon the relevant activity patterns per populations. Residents are expected to be in the room of use at the time that the article is being used and when the peak exposure is observed. EPA did not quantify aggregate exposures in the draft risk evaluation due to uncertainties noted in the draft indoor air exposure assessment technical support document. However, as part of its refined modeling using IECCU, EPA presented aggregate exposure estimates for a new build and a new décor scenario. EPA has updated its characterization of automobile indoor air exposures. However, there is no record of the Wang study being submitted to EPA to allow it for inclusion during the draft risk evaluation or during SACC peer review. The commenter did not provide sufficient reference for EPA to identify the study. In addition, for the revised indoor air exposure assessment EPA is considering acute non-cancer, chronic non-cancer, and cancer exposure and risk estimates for low, medium, and high-end exposure estimates for individual and aggregate TSCA COUs.

Summary: A public commenter (0259) took issue with the selection of the emissions model used to represent exposure. The commenter stated that EPA chose the E5 model for products placed in a room instead of the E6 model due to the E6 model's inability to specify emissions rates. The commenter stated that this was not an acceptable substitution, particularly without providing substantive data demonstrating the similarity and differences of the given emissions models. The commenter said that the E6 model provides a more accurate representation of emissions directly from an article, which evaluates multiple processes and compartments. It considers parameters such as surface area and surface thickness of the emitting article, as well as article density, and also considers abrasion of the article and particulates as both a sink and source for emissions, more accurately representing the life cycle of an article in the environment. As such, the commenter suggested that the E6 model should be the model used to evaluate article emissions and not a retrofitted E5 model.

EPA Response: For the screening analysis of formaldehyde exposures in indoor air, the E5 model was used as a substitute for the E6 model because CEM does not allow for the refinement of the default emission rate for articles. Nonetheless, EPA used a higher tier model (IECCU), primarily refined by article-specific emission rates and surface areas, to generate a more realistic estimate of inhalation exposures from articles overtime (up to ~1 year from initial use).

Summary: A public commenter (0261) stated that based on the emission rate information gathered by EPA from literature for formaldehyde-emitting products and activities, the commenter agreed that EPA has appropriately focused on the four general conditions of use that are likely to be major current TSCA contributors in homes and vehicles. The commenter also stated that they don't have concerns that CEM cannot or should not be used for estimating long-term concentrations, but did ask why EPA did not use the Formaldehyde Indoor Air Model (FIAM) rather than CEM. The commenter stated that the exposure document would benefit from the addition of a clear explanation as to why CEM rather than FIAM was used, as well as an explanation as to why dated emission rate information using Oak Ridge National Laboratory Formaldehyde Surface Emission Monitoring devices was used to estimate emissions from hardwood flooring for use in the risk assessment rather than chamber emission rate data for actual hardwood flooring products or for particleboard as an analog.

EPA Response: EPA appreciates feedback about the selection of the four conditions of use assessed for indoor air and agreement with the use of CEM, as this is consistent with comments received by the SACC. EPA used CEM as a screening tool allowing for the modeling of various products and articles as necessary. The Formaldehyde Indoor Air Model - pressed wood products FIAM-PWP) was considered but not used because it is limited to pressed wood products and cannot be used for other articles of interest. Instead, for the final risk evaluation, EPA used the IECCU model as a higher tier tool which was parameterized with updated emission factors from the FIND, 2019 study (the most recent data available to EPA at the time of the revised assessment) and incorporated emission standards for compressed wood (assuming compliance). An explanation has been provided in the final Indoor Air Exposure Assessment regarding the use of IECCU following the CEM screening approach for indoor air exposure estimations.

Summary: The SACC suggested that EPA more clearly justify their rationale for grouping the uses into four categories. For example, a wide range of uses were grouped into the first grouping. Additionally, the SACC stated it was not clear how specific metrics were used to select the conditions

of use, such as what emission rate cut-off was applied to highlight the four chosen conditions of use. The SACC said that emission rates themselves may not be sufficient to rank conditions of use. Further, the SACC said that EPA should specify whether CEM results were used to validate the choices of conditions of use. If not, this may be another input to provide confidence that the condition of use choices focus on the greatest exposure risk. Overall, the SACC said that EPA's choices in this area are reasonable and adequate for the analysis of risk from indoor air.

EPA Response: This comment is in reference to the indoor air assessment of formaldehyde. Additional explanation has been provided regarding the identification of the COUs relevant to the indoor air assessment of formaldehyde. CEM results were not used to identify the relevant COUs assessed for indoor air. Updated emission rates and factors were also incorporated following the SACC's review, along with supporting sources and methods used to incorporate them into the new IECCU modeling.

EPA estimated acute non-cancer risks using monitoring data in the indoor air for four consumer COUs via the inhalation pathway in residential, indoor environments. EPA estimated risks for four COUs expected to be significant and persistent emitters of formaldehyde in the indoor air environment. These types of products can include furniture, cabinetry, drywall, plaster, tile, wallpaper, flooring, foam seating, mattresses, clothing, household cleaning supplies, cardboard boxes, plastic home articles, toys, and sporting equipment.:

- *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;*
- *Fabric, textile, and leather products not covered elsewhere (clothing);*
- *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;*
- *Paper products; Plastic and rubber products; Toys, playground, and sporting equipment.*

Regarding the Indoor Air Analysis, EPA considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air, but the monitoring data do not provide information about the relative contributions of each source. EPA also used models to estimate formaldehyde concentrations from TSCA conditions of use that cannot otherwise be distinguished from other sources of formaldehyde reflected in measured indoor concentration data. EPA used the CEM to estimate long-term indoor air exposures and refined the results with IECCU modeling to estimate acute and long-term risks for exposure to formaldehyde in residential indoor air associated with specific TSCA COUs. EPA found that for the four consumer COUs evaluated under an aggregate approach to exposure to the indoor air, there is no unreasonable risk to the general population in indoor environments.

CEM inputs

Summary: A public commenter (0235) stated that EPA's inputs for the indoor air exposure scenario are overly conservative and at best representative of worst-case scenarios. Based on the exposure modeling conducted, as well as the inappropriate and overly conservative human health POD used, EPA should have high confidence that the four conditions of use evaluated do not contribute to unreasonable risk due to formaldehyde exposure, according to the commenter. The commenter agreed with Dr. Salthammer that the AHHS II dataset, which EPA relied on for indoor air formaldehyde levels, is a well-planned and well conducted study, but expressed concern over EPA's inconsistent use

of this data set. For example, the commenter said that on page 82, EPA refers to the 95th percentile as being approximately 40 ug/m^3, while Table 3-4 in the Draft Indoor Air Assessment chapter shows the 90th percentile at 41.8 ug/m^3. Thus, the commenter said that the 95th percentile is likely above 42 ug/m^3. Considering the low levels at which EPA proposes to set an OEV, the commenter recommended that EPA be more precise and consistent when using the AHHS II data.

Other public commenters (0177, 0202, 0261) stated that it can be concluded that the AHHS II study represents the average formaldehyde exposure in the US very reasonably and realistically. However, one of the commenters (0202) said that specifying arithmetic mean values for concentration distributions does not make sense. In some studies, the number of measurements were very small. The commenter recommended that EPA consider studies with a large sample size. One of the commenters (0261) also stated that these data do not provide information about the relative contribution of each source.

Two public commenters (0151, 0202) said that the results of Pickerell et al. (1983, 1984), Matthews et al. (1984), Yu and Crump (1998) and Kelly et al (1999) are no longer representative today, as the requirements for building products regarding the release of VOCs have become significantly more restrictive over the last 40 years. One of the commenters (0151) said that in other studies that were carried out in newly built or renovated buildings, no noticeably high levels of formaldehyde concentration were found.

The SACC discussed the strengths of the AHHS in that it is a reasonable representative of the US population in primary residences in the US, and that very good statistical design and thorough reporting represent a large sample with weighting to show permanent residence representation of the monitored formaldehyde concentrations. On the other hand, the SACC said that only permanent residences were monitored, excluding all other interior building spaces, offices, schools, hotels, retail, warehouses, etc.

EPA Response: EPA has refined its assessments of indoor air conditions of use using IECCU; using the best and most recent available data per article assessed (Mathew et al (1984) and Pickrell (1983, 1984) studies have been replaced by 2017, 2018, and 2019 studies for the IECCU modeling of wood articles); and considering bother peak and chronic exposures, along with low-, medium- and high-end scenarios. Results show a reduction in predicted indoor air concentrations in from use of the articles modeled, even for the high-end scenarios. The IECCU modeling data fits even better with the monitoring data compared to the CEM screening assessment. Confidence in the unreasonable risk is separate from that of the indoor air exposure assessment which is at least a medium. The referenced AHHS II data in the monitoring data summary table has been corrected as there was a typo. Otherwise, the reported data throughout the module is correct and consistent with HUD's reported AHHS II results.

The presented data were the best and reasonably available sources and sufficiently represent current in-home exposures of formaldehyde. Studies of various sizes were presented to provide a compendium of quality monitoring references of indoor air formaldehyde concentrations.

For the draft Indoor Air Exposure Assessment, AHHS II was identified as a cornerstone of the formaldehyde Indoor Air Exposure Assessment due to the reasons highlighted by the commenters including its large sample size and representativeness of American homes. For the revised Indoor Air Exposure Assessment, EPA was able to identify and apply newer emission rates from more recent studies for some articles using IECCU. In addition, residential (including newly constructed homes, such as new FEMA trailers) and non-residential formaldehyde indoor air exposures and risks were

assessed. Regarding the monitoring data, EPA summarized the data from each study as presented which means that if an arithmetic or geometric mean was generated by the original study, this is what was summarized for the final risk evaluation.

Summary: A public commenter (0286) agreed with EPA's conclusions that there is no unreasonable risk for the consumer condition of use related to automobile interiors. The commenter said that the modeled indoor air exposures were consistent with monitoring data.

EPA Response: No further changes will be applied.

Summary: The SACC suggested that EPA construct, validate, and use a probabilistic CEM, and compare the results with existing results. For CEM results to properly estimate long-term indoor air exposures, product specific decay rates need to be incorporated into the model

EPA Response: EPA does not have the tools nor developed an approach to generate a probabilistic model for consumer or indoor air COUs. The application for probabilistic models may be considered in future chemical risk evaluations as such consumer and indoor air COU-specific tools and overall approaches are developed. Article-specific decay rates have been incorporated into the new indoor air exposure assessment for formaldehyde.

Wood articles

Summary: Two public commenters (0142, 0270) stated that EPA must evaluate emissions from wood products under their actual conditions of use today, which includes Title VI of TSCA limits on formaldehyde emissions from composite wood products. The commenters said that instead, EPA used data that predates Title VI and applied modeling to predict emissions. Also, the commenters, along with another public commenter (0194) said that the draft risk evaluation relied on emission studies based on deconstructed furniture items which does not reflect reality. Additionally, the commenters requested that EPA consider the time delay between when a product is produced and when it reaches a consumer, which affects emission rates, which EPA even addresses in the *Draft Indoor Air Exposure Assessment*. One of the commenters (0270) suggested that EPA should rely on chamber testing results from Intrinsik Consumer Report because the results demonstrate conclusively that wood articles in residences do not present an unreasonable risk. Beyond these chamber studies, the commenter said that other published data demonstrates how coverings, coatings, and other barriers impede emissions. Similarly, a public commenter (0177) stated that in the case of wood-based materials, it is not justified to use the results of an emission test to calculate possible indoor air concentrations or to estimate exposure. The commenter said that the chamber concentration does not picture real-life situations, such as raw materials covered with layers.

A public commenter (0283) stated that EPA improperly disregards its own calculations of unreasonable risks from formaldehyde-containing wood products. The commenter said that EPA defers to the Formaldehyde Emissions Standards for Composite Wood Products final rule pursuant to Title VI of TSCA that was enacted in 2018, and that the ongoing implementation of those standards will "reduce formaldehyde emissions from composite wood products." The Title VI standards limit formaldehyde emissions from different types of composite wood products to 0.05 to 0.13 ppm. In contrast, the draft risk evaluation found that chronic inhalation of 0.017 ppm of formaldehyde is associated with reduced

pulmonary function and other respiratory effects. The commenter added that EPA's reliance on the Title VI rule fails to account for exposures from wood products that were sold before that rule took effect. The commenter said that EPA states that "the chronic non-cancer risk estimates for indoor air are based on studies with medium level of confidence regarding the use of the COU-specific emission rates," and EPA's asserted "medium level of confidence" is a reason to adhere to its calculations of unreasonable risk, not to reject them. The commenter said that EPA made unreasonable risk determinations for other conditions of use for which EPA has "medium" confidence (e.g. "commercial use . . . in automotive and fuel products") and they should do the same for wood products.

A public commenter (0261) suggested that relevant trade associations or companies may provide more recent emission rate data for hardwood flooring and furniture as well as other products assessed in the indoor air assessment. Additionally, the commenter said that Third Party Certifiers could be given permission by the companies they represent to provide the data to EPA directly. This data could address shortcomings rather than EPA using limited and very dated emissions data in the current exposure assessment.

The SACC suggested that EPA explain the potential impacts of the recently implemented exposure standards for new composite wood products. For example, the SACC suggested that EPA discuss the uncertainties associated with the following:

- Composite wood types are shown on Table 2-2 and reflect various wood types, including pressed wood, treated wood products, sealed, and other products, etc. Wood types in floors and furniture also vary, both in the pre- 2016 final rule standards and the post new standard implementation.
- There is additional uncertainty from glues, and other products used in the home, in addition to formaldehyde emanating from the wood.
- Products that predate the new emission standards clearly do not currently reflect the emissions for wood products on the market; however, there may be diminution of formaldehyde emission over time according to the specific product constituents and usage.

The SACC also suggested that EPA acknowledge that articles passively used can contribute to chronic exposure, which are key factors in aggregate exposure. Finally, the SACC suggested that EPA discuss estimates of predicted outcomes associated with the new emission standards as summarized in Appendix D.

EPA Response: Wood articles were re-assessed according to the Formaldehyde Emissions Standards for Composite Wood Products final rule, using the IECCU model. This approach is expected to better represent exposures from articles currently being sold on the market. The new modeling does consider formaldehyde peak emissions after it has been manufactured (with a given weight fraction), sits on a shelf before purchase, and is installed in a home after being purchased by a consumer. To best represent realistic peak exposures after the article has been installed into a home, EPA used emission rates based on the most recent and reasonably available studies, instead of the concentration of the formaldehyde in-article formulation reported by the manufacturer. Together, the CEM modeling and IECCU modeling represent potential exposures to formaldehyde in indoor air.

In the draft risk evaluation, EPA utilized wood article emission rates identified from literature published from 2009 and prior. EPA recognizes that these emission rates may overestimate emissions for current composite wood articles because the rates predate implementation of the TSCA Title VI Formaldehyde Emission Standards for Composite Wood Products final rule (40 CFR Part 770). Therefore, in the final risk evaluation, EPA utilized the TSCA Title VI emission limits set for

The risk estimates in the indoor air scenario for the residential COUs included two COUs with wood products: (1) *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*; and (2) *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*. These COUs contain composite wood products, many of which are regulated as finished goods under TSCA Title VI. Finished goods include furniture and cabinetry while other regulated composite wood products include flooring. TSCA Title VI reduces exposure to formaldehyde emissions from certain composite wood products such as hardwood plywood, medium density fiberboard, and particleboard. EPA did not identify risk of from the general population in indoor air environments. This includes wood articles and products that are pursuant to TSCA Title VI.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

Chronic inhalation POD

Summary: In response to EPA's request for comment on the strength and uncertainties associated with their application of the chronic inhalation POD in the context of exposure to formaldehyde through indoor air, the SACC stated that it appears unreasonable and unrealistic that EPA's chronic POD is 21 ug/m^3 (16.8 ppb) when the typical U.S. home concentration of formaldehyde is 23.2 ug/m^3 (18.6ppb). Several SACC members do not think the POD is appropriate, and it may be that EPA is not asking the right question to derive an appropriate POD and explain an adequate MOE. Suitable questions to address would be, how does risk increase above the POD, who is most at risk, and how those risks estimate compare with real- world data on disease prevalence. At least two SACC members suggested that many homes, like schools, have inadequate ventilation, such that emissions of formaldehyde from various sources that are being evaluated by the EPA and those that are not such as releases from gas stoves, can be present in concentrations that are problematic for people living in homes without adequate ventilation (Uchiyama et al; 2024; Kashtan et al, 2024). At least two SACC members stated in regard to rates of disease, tracking and compiling rates of asthma are under-reported, particularly for people who live in places in the US that lack health care infrastructure and access to clinics (Pate et al., 2021). The SACC members agreed with a public commenter that links to asthma can be confounded by many other exposures, and that an observational epidemiology study should not be used to causality or develop a POD.

EPA Response: EPA is using the chronic hazard conclusions and chronic hazard value for formaldehyde inhalation presented in the final IRIS assessment and peer reviewed by NASEM for those indoor air scenarios under TSCA where chronic exposure is expected pursuant to the Indoor Air Exposure Assessment. Since the release of the draft risk evaluation reviewed by peer reviewers and public commenters, EPA has finalized the IRIS assessment for formaldehyde. Discussion regarding study selection is provided in Section 2.1.1 of the IRIS assessment. Discussion regarding the weight of evidence for noncancer respiratory effects is provided in sections 3.2, 4.2, and 5.1.5 of the IRIS assessment. Comments on study selection, weight of evidence for noncancer effects, and sensory

irritation are addressed in Sections F.1 and F.3 in Appendix F of the IRIS assessment supplemental materials.

Cancer IUR

Summary: The SACC stated that EPA's cancer IUR would suggest that formaldehyde exposure in typical homes is hazardous to human health, and that there is no adequate epidemiological estimates for rates of cancer or respiratory disease associated with in-home exposures to formaldehyde.

EPA Response: EPA is using the cancer conclusions and cancer value for formaldehyde inhalation presented in the final IRIS assessment and peer reviewed by NASEM for those indoor air scenarios under TSCA where chronic exposure is expected pursuant to the Indoor Air Exposure Assessment. Based on available human and animal data, the final IRIS assessment evaluated the weight of evidence and performed dose-response analysis for several respiratory and non-respiratory cancer types to derive an inhalation unit risk (IUR).

Many of the scientific issues raised by SACC members and some public commenters on the draft TSCA risk evaluation regarding the approach taken in the draft IRIS formaldehyde assessment were considered during the IRIS process and are addressed in the final IRIS assessment. Further discussion on how IRIS derived the cancer IUR is provided in Section 5.2 of the IRIS assessment.

Based on the IUR and indoor air monitoring data reported in the AHHS II, EPA estimates lifetime cancer risks from typical indoor air exposure to formaldehyde in the 1 in 10,000 range. This is consistent with a relatively rare cancer like nasopharyngeal cancer.

Other comments

Summary: A public commenter (0182) stated that the data used in the review do not accurately characterize indoor exposure, and direct indoor exposure to formaldehyde has a higher risk than ambient exposure from industrial and biogenic sources.

EPA Response: Substantial updates have been incorporated into the Formaldehyde Indoor Air Exposure Assessment. The most substantial change is the use of a second EPA model to better characterize indoor air concentrations of formaldehyde. The *Draft Risk Evaluation for Formaldehyde* relied on the CEM to estimate 365-day average formaldehyde concentrations from articles that may be contributing to long-term indoor air concentrations. This model is commonly used by EPA to estimate exposure to chemicals in consumer products and articles for TSCA conditions of use.
In this revised assessment, EPA used the Simulation Program for Estimating Chemical Emissions from Sources and Related Changes to Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones or IECCU to estimate short-term (15-minute peak), intermediate (3-month), and long term (1-year) concentrations. This model is better parameterized for volatile organic chemicals like formaldehyde. It provides exposure decay curves allowing for better characterization of exposure concentrations over time (i.e., after an article is introduced to the home). However, available data suggest IECCU may underestimate long-term exposure concentrations. As such, modeled concentrations for both CEM and IECCU are presented in the results of this assessment to characterize the potential range of formaldehyde concentrations in indoor air.

In addition to this updated modeling, the indoor air exposure technical support document further characterizes formaldehyde concentrations in trailer homes, athletic fields with tire crumb surfaces, and

government buildings. Furthermore, feedback and resources from data submissions to the docket (Docket ID: EPA-HQ-OPPT-2023-0613) were incorporated throughout this assessment.

It is unclear whether the commenter is referring to modeled or monitoring indoor air data. Nonetheless, EPA's CEM and IECCU modeled concentrations are within the same order of magnitude as indoor monitoring concentrations – including the American Healthy Home Survey II which has been agreed upon by the SACC as a very good study and is representative of American in-home exposures to formaldehyde. Based on a review of the available data, indoor air monitoring concentrations (including those from the AHHSII) were higher than ambient air monitoring concentrations overall.

Summary: A public commenter (0263) discussed EPA's consideration of risk. The commenter stated that EPA does not provide any supportable argument that consumer products in the indoor air scenario do not contribute to unreasonable risk of formaldehyde. EPA said that residential indoor exposure will be reduced by ongoing implementation of these standards. The commenter suggested that EPA should conclude based on the best available science that these conditions of use represent an unreasonable risk.

EPA Response: The consumer articles that may contribute to indoor air exposures have been reassessed. TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified by EPA as relevant to this risk evaluation, under the conditions of use (COUs). Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses on aggregate exposures. The *Unreasonable Risk Determination* explains how the Agency considered these risk related factors in the determination.

Summary: In response to EPA's request for comment on the strengths and uncertainties associated with use of the chronic non-cancer POD from the draft IRIS Assessment for evaluation of formaldehyde risks to indoor air, a public commenter (0261) expressed agreement with OCSPP that the robustness of the data set, selection of the appropriate endpoint, and calculation of a chronic inhalation hazard value as presented in the IRIS Assessment reflects the best use of the available information and provides a suitable basis for assessing the long-term non-cancer inhalation risks to people with exposure to formaldehyde through indoor air. However, the commenter stated that they are is not convinced that EPA should have such low confidence in these long-term exposure estimates that potential cancer risks should not be evaluated.

EPA Response: EPA has reevaluated formaldehyde indoor air exposures from consumer articles, and it currently has a medium to high confidence in its new assessment. For the revised indoor air exposure assessment EPA is considering acute non-cancer, chronic non-cancer, and cancer exposure and risk estimates for low, medium, and high-end exposure estimates for individual and aggregate TSCA COUs.

Summary: The SACC stated that the sentence at lines 186-189 states a rationale for low confidence; however, more explanation is needed for this reasoning. The SACC said there should be a sentence referring to post-implementation emissions estimates in new products.
EPA Response: The weight of scientific evidence section have been updated according to the new higher tier modeling with consideration to the emission rates identified for relevant articles assessed.

Section 5.6 – Ambient air exposure assessment

General comments

Summary: A public commenter (0182) submitted the following observations: • the analysis was overly conservative; • the analysis used short-term monitor samples to represent annual concentrations; • there was no consideration of how much sources not regulated by TSCA impact monitored measurements; • use of site-specific modeling parameters would improve credibility; • the analysis used generic modeling parameters that are not representative; • there was no facility fence lines or building downwash
EPA Response: EPA disagrees with the comment that the analysis is overly conservative. EPA compared the modeled concentrations from IIOAC (TSCA COU specific contributions to ambient air) to those obtained from the AMTIC archive monitoring data (aggregated concentrations in ambient air from all sources) in the draft documents and showed modeled concentrations are generally within the same order of magnitude as modeled concentrations and generally in the lower quartile of the monitored values from AMTIC. EPA included discussions and uncertainties around the use of short-term monitored samples in the revised ambient air exposure assessment for formaldehyde. . EPA also added a case study with short-term monitoring data and its relation to modeling assumptions of continuous releases to the revised ambient air assessment for formaldehyde.. EPA disagrees with the comment that the analysis does not consider how much sources not regulated by TSCA impact monitored values. Throughout therevised ambient air exposure assessment for formaldehyde, EPA consistently and repeatedly acknowledges that EPA considers monitored values to represent a total aggregate concentrations from all sources contributing formaldehyde to the ambient air (TSCA sources and other sources). In response to the remaining three bullet points, broadly speaking, EPA specifically categorized ambient air exposures from facilities under TSCA specific conditions of use based on modeling using EPA's IIOAC model. For a national level assessment, EPA does rely on several default parameters which are based on national averages considered during the development of the IIOAC model and integrated into the IIOAC model. Depending on the specific needs of the risk evaluation, EPA may conduct more granular higher tier analyses which include site specific release data and stack parameters. While certain EPA models like AERMOD can consider building dimensions for downwash effects as part of the modeling, the level of specificity required for geographic information system (GIS) coordinates of every corner of every building around a single release point (nearly 50,000

in NEI and the lack of process level release data in TRI to identify release points, etc.) is not reasonably available and has not been provided by industry to EPA.

Summary: A public commenter (0182) stated that the Draft Ambient Air Exposure Assessment for Formaldehyde analysis does not accurately characterize ambient air exposure resulting from sources that are the focus of the draft risk evaluation, providing various reasoning concerning the monitoring data (e.g., short-term samples being used to represent annual exposures, no consideration for how much biogenic sources impact the measurements, and measurements below detection limits being excluded from the analysis) and modeling analyses (e.g., using release point parameters with no consideration of downwash effects from structures from structures at a facility). The commenter discussed in detail their concerns including:

- HEM did not use the specific source data of the 810 sources modeled;
- Assumptions were unrealistic;
- AirToxScreen modeling shows that industrial point source impacts were 1-2 orders of magnitude lower than non-TSCA regulated sources;
- Direct indoor exposure to formaldehyde has a higher risk than ambient outdoor exposure from industrial and biogenic sources;
- State health-based and NESHAP risk review modeling using more accurate inputs show that there is not an unacceptable ambient risk from industrial formaldehyde emissions; and
- EPA used data to identify the influence of specific facilities on ambient concentrations but needs a more granular review to serve that purpose.

EPA Response: EPA disagrees with the commenters statement that EPA did not accurately characterize ambient air exposures resulting from sources that are the focus of the risk evaluation. Broadly speaking, EPA specifically categorizes ambient air exposures from facilities under TSCA specific conditions of use based on modeling using EPA's IIOAC model. For a national level assessment, EPA does rely on several default parameters which are based on national averages considered during the development of the IIOAC model and directly integrated into the IIOAC model. Depending on the specific needs of the risk evaluation, EPA may conduct more granular higher tier analyses which include site specific release data and stack parameters. While certain EPA models like AERMOD can consider building dimensions for downwash effects as part of the modeling, the level of specificity required for geographic information system (GIS) coordinates of every corner of every building around a single release point (nearly 50,000 in NEI and the lack of process level release data in TRI to identify release points, etc.) is not reasonably available and has not been provided by industry to EPA.

EPA expands discussion on the reasoning behind the use of the AMTIC monitoring data and further characterizes exposures based on AMTIC data in the ambient air exposure assessment for formaldehyde. EPA also derives risk estimates based on AMTIC data to contextualize risks in the Human Health Risk Assessment for Formaldehyde. The AMTIC data captures all formaldehyde in the ambient air from all sources contributing around the monitoring site. However, it is not possible to parse out what part of the measured value is due to individual TSCA conditions of use and what is due to other sources (including mobile sources, biogenic sources, and secondary formation).

EPAconsiders contributions to formaldehyde in ambient air from biogenic sources, and secondary formation through integration of the 2019 AirToxScreen and 2020 AirToxScreen data in the ambient air exposure assessment for formaldehyde.

HEM: While HEM is a higher tier model (compared to IIOAC), EPA utilized HEM for a specific purpose which was to consider aggregate exposures and outputs on population exposures and risks. Additionally, TRI reporting facilities do not include site specific source data (stack parameters, building dimensions, etc.), and individual facilities may have multiple release points, stack parameters, etc. Therefore, EPA did not and cannot incorporate such source data into modeling of the TRI sources.

Indoor vs. Outdoor formaldehyde concentrations: Findings that indoor air has higher formaldehyde exposures (and thus higher risks) for formaldehyde compared to outdoor ambient air is consistent with findings in the literature. Some studies have found indoor air is 10 times more polluted than outdoor air due to multiple factors including tightening of homes and residences, lower air exchange rates when compared to open outdoor air, etc. Regardless of the comparison between indoor and outdoor air, each exposure is independent of the other, and a higher indoor concentration does not negate the potential exposures and risks occurring to populations in the outdoor ambient air.

Other modeling results: While state and NESHAP based modeling may use more specific data, it isn't necessarily more "accurate" input data. Additionally, some State and Federal modeling work still shows exposures of concern, although how "unacceptable exposures" are defined in state and federal statutory language varies and some have higher or lower thresholds against which exposures are considered "unacceptable".

Summary: A public commenter (0224) discussed combustion and secondary sources of formaldehyde and said the draft risk assessment could not practically or reasonably differentiate secondary formation, formation from combustion, and direct releases of formaldehyde with certainty for the draft risk evaluation and, instead, the cumulative impact on the exposure assessment of those background exposures has resulted in a serious overestimation of risk. The commenter added that EPA's exposure assessment assumes that formaldehyde is being released from all the conditions of use regardless of whether there is any demonstrated off-gassing.

Similarly, another public commenter (0226) stated that the draft risk evaluation must view TSCA sources as a relatively smaller addition to an existing and safe baseline of exposure and dismissing major sources (secondary formation and combustion) as "background" exposures does not reflect good science. The commenter recommended the draft risk evaluation be revised to separately account for formaldehyde generation from anthropogenic and non-anthropogenic/biogenic sources and the relative contribution of each source to total exposures.

EPA Response: EPA acknowledges several times in the revised ambient air exposure assessment for formaldehyde that it is not possible to apportion monitored concentrations of formaldehyde to secondary formation, combustion, biogenic, or anthropogenic. EPA does derive risk estimates based on the AMTIC monitoring data in the Human Health Risk Assessment for Formaldehyde, these numbers are not relied upon for risk determination purposes. Rather, EPA relies upon the IIOAC modeling results attributable to TSCA COUs to derive risk estimates and risk conclusions. EPA presents additional lines of evidence of the available data (IIOAC modeled results, AMTIC monitoring results, AirToxScreen,biogenic and secondary formation results) but does not add them together in a cumulative fashion to estimate overall exposures for purposes of risk determination.

EPA's IIOAC modeling presented in the revised risk evaluation and associated Supplemental Files, is relied upon for characterizing exposures to a sub-set of the general population living nearby releasing facilities associated with TSCA COUs The IIOAC modeling results are then used to derive risk

estimates for purposes of characterizing risks. EPA does not define any safe baseline exposure from "background" exposures and does not compare relative contributions from TSCA sources as smaller or larger contributors to exposure. Regardless of the "size of exposure" resulting from TSCA specific condition of use contributions, exposures attributed to TSCA conditions of use are independent from other sources and additive to biogenic and secondary formation contributions if looking at a total aggregate exposure from all sources.

Summary: A public commenter (0261) expressed support for the Agency's level of confidence in exposures, risk estimates, and risk characterizations for ambient air.

EPA Response: EPA appreciates the commenter's support for the Agency's described level of confidence.

Data sources

Summary: A public commenter (0246) stated that the ambient air assessment relied on AMTIC data from 2015 to 2021, AirToxScreen data from 2019, and Toxic Release Inventory data from 2016 through 2021, and suggested temporal alignment of monitoring and modeling data to minimize year-to-year variability when possible.

Another public commenter (0235) did not support adjusting these data to fit them to the health effects benchmarks, and instead, suggested EPA take a more holistic approach and develop human health benchmarks that are representative of the fact that we are all exposed to formaldehyde every day, and not just when using specific products or completing an occupational task.

Another public commenter (0182) said that the data sources, though individually have a high-quality rating, may not be easily comparable without making assumptions that add uncertainty. Also, each approach has a level of conservatism embedded within which compounded may be unrealistically conservative as a whole.

EPA Response: EPA's overall approach with the multiple data sources and multiple years of data was in response to previous SACC recommendations to consider multiple years of data. Each piece of data was integrated into the draft risk evaluation independently to provide a broader holistic picture of exposures. While the data years do vary, all the data sources fall within the same 6 to 7 year window. Even the NEI data modeled was based on 2017 NEI data. Both the NEI dataset and the 2019 AirToxScreen data were the latest available data at the time of writing.

EPA's IIOAC modeling results (which were relied upon to characterize exposures and derive risk estimates), was done at the industry sector level using various statistics from the entirety of the release distribution across all years of TRI reported data and not independently modeled for each year of data.

EPA acknowledges several times in the draft and revised risk evaluation that the general population is exposed to formaldehyde every day from a variety of sources, including secondary formation, biogenic, and anthropogenic sources. However, when characterizing exposures and deriving associated risk estimates from TSCA conditions of use, the resulting exposures are independent of the other sources of exposure at the TSCA condition of use level, and additive to other sources when considering a total aggregate exposure.

EPA acknowledges several times the limitations of considering the multiple data sources and the associated comparability of such data sources. While some assumptions may be more conservative, conservatism generally only applies to modeling assumptions (IIOAC, HEM, AirToxScreen), as monitoring data (AMTIC) is taken at face value and are based on actual measurements in ambient air at the monitoring site. However, results from modeling in AirToxScreen may actually be less conservative because results are averaged over a census tract level (a larger area than finite distances), and that may bias the modeled concentrations low.

Summary: A public commenter (0235) agreed that AMTIC data is a useful ambient monitoring dataset to inform EPA's analysis, but expressed disagreement that the monitored data allows EPA to identify the influence of specific facilities on regional air levels. Without a much more granular review of individual monitors and local sources and emission and meteorological characteristics that may influence the sample concentrations, the commenter said that these data should not be used to evaluate specific facilities.

EPA Response: EPA did not use the AMTIC data to evaluate specific facilities. The data was presented as a piece of the entirety of data considered by EPA for the revised RE. That being said, the commenter is correct that a more granular review at the monitoring site location level would be needed to evaluate specific facilities, although it can only be done if time allows and resources are available.

Summary: A public commenter (0235) said that AirToxScreen overestimates source contributions to ambient air. The results do not consider the variations in the biogenic portion of ambient formaldehyde that might be present in smaller amounts in industrialized areas or larger amounts in more rural sources. The commenter stated that EPA's use of AMTIC and AirToxScreen and the development of the HEM would also be greatly improved through direct engagement with state environmental Agencies and the Agency's Office of Air Quality Planning and Standards.

EPA Response: EPA does not agree that AirToxScreen overestimates source contributions to ambient air because it does not consider the variations in the biogenic portion of ambient formaldehyde. Point source modeling for the 2019 AirToxScreen considers releases reported to NEI (at the process level), and therefore modeled concentrations for each point source are exclusive of other sources contributing formaldehyde to the ambient air.

EPA appreciates the comment about engagement with other offices. Throughout development of the draft and final risk evaluations, OPPT did have direct engagement with multiple Offices within the EPA including the Office of Air and Radiation and Office of Air Quality Planning and Standards.

Summary: A public commenter (0235) said that the HEM would be appropriate if EPA were using appropriate source and emissions data. However, the commenter said that EPA used unrealistic and generic source data for representing point releases, stacks, fugitive releases, and unplanned releases, which leads to inaccurate estimate of community exposure.

EPA Response: While HEM is a higher tier model (compared to IIOAC), as stated in the RE, EPA utilized HEM for a specific purpose which was to consider aggregate exposures and outputs on population exposures and risks at the screening level. Therefore, EPA's use of certain default

parameters from IIOAC in HEM was appropriate and allows direct comparison of the IIOAC and HEM results at a facility level. The commenter is correct, that if additional, higher tier modeling is sought for a fit-for-purpose risk evaluation, HEM does allow more site-specific information to be used as inputs.

Strengths and limitations of AMTIC

Summary: A public commenter (0182) expressed support for EPA's use of AMTIC as the size of the dataset included over 300,000 samples and entries with concentrations below the limit of detection were omitted making results by default higher. However, the commenter discussed multiple issues that impacted the accuracy of the review:

- The data was collected using 5 different collection methods and over several different sample periods ranging from 5 minutes to 24 hours and EPA did not normalize the data by collection duration or methodology.
- 15%, or approximately 46,000 samples, were discarded because they were below that sample method's detection limits.
- Most of the monitors are located near urban or industrialized areas, suggesting that a higher percentage of the formaldehyde concentrations may be anthropogenic than could be the case at monitors located in more rural settings, but that cannot be determined from the data.
- The monitored data does not allow EPA to identify the influence of specific facilities without a much more granular review of the individual monitor and the local source, emission, and meteorological characteristics that may influence the sample concentrations.

The commenter said they are not aware of any other datasets that would provide better data, but recommended EPA more closely look at collection methods and sample periods to make the data more "homogenous."

The SACC stated that there are several strengths of the AMTIC data, including: the high quality of the observations, the representativeness of real-world conditions, and the national coverage of the AMTIC dataset. The SACC also stated that there were several weaknesses of AMTIC, including: the varied measurement methods and observation periods (e.g., 5 min to 24 hours) and the representativeness of all sources, including both TSCA conditions of use and other emission sources.

The SACC suggested that EPA consult with the Office of Air and Radiation on issues related to ambient formaldehyde concentrations and contributions from specific sources. The SACC said that it is important to include information in consultation with the Office of Air & Radiation related to EPA modeling activities related to regulating formaldehyde as a HAP and contributor to ozone and particulate matter under the Clean Air Act. The SACC recommended participation from the Office of Air to the extent that they are included as co-authors on the ambient air documents.

The SACC requested that EPA provide more clarity about the form of the concentrations provided by the AMTIC dataset. The SACC said that it is not clear to the extent that the ambient air quality standards included both a value and form of the standard, which differs by pollutant, and if this format was incorporated by EPA in developing their documentation on formaldehyde. The SACC stated that it was unclear exactly what the form of the measurement provided by the AMTIC data were; are the monitors reporting "average concentration over a specific time interval" or are they reporting "total" or "maximum concentration" over a specific time interval?

The SACC suggested that, while this is out of the scope of the risk evaluation, EPA acknowledge formaldehyde's contributions to ozone and secondary organic aerosol, as these downstream impacts are real and important to acknowledge.

The SACC recommended including descriptions of the distributions of the data to the extent that they may be incorporated in probabilistic analyses.

The SACC stated that it would be helpful for EPA to lay out in a perfect world which modeled or measured output would be sufficient for the risk evaluation. The SACC asked what simplifications/uncertainties are acceptable, and how do those relate to the measurement and modeling tools available?

The SACC requested that EPA provide information on the times of day when the observations were taken. The SACC said that it is unclear how representative the monitoring data are of annual averages and that it would be beneficial to organize the data according to the time of day that the measurements encompass. The SACC suggested that EPA could identify any temporal variability (by using a smoothing temporal filter) in outliers in observations near TRI sites in order to help to identify locations and times when air emissions happened. The SACC said that given the transience of formaldehyde and its different half-life length in the presence of sunlight, it is important to know when, during a day, the 5-minute AMTIC monitors were collecting data. The SACC said that formaldehyde tends to be unstable and react based on meteorological conditions, thus, understanding the spatial distribution of the AMTIC monitors and the timing of the day these measurements are taken is fundamental. The SACC said that information on the AMTIC ambient monitoring data, e.g. how/whether daily average and annual average formaldehyde concentration could be calculated, is not mentioned in the draft report on Ambient Exposure to Formaldehyde and that it would be helpful if that information was reported and if the information regarding the AMTIC monitoring data were consistent across documents. The SACC stated that simply averaging the available measurements reported by an AMTIC monitor over the course of a year without taking into account the confounding factors (e.g. location of the monitor (is it rural versus urban?), the time of the day and the year the measurement is collected, the method of collection and the duration of collection) and creating plots of the distribution that lumps all the values together as in Figure 3.8 of the Draft Ambient Exposure without considering the spatial location of the monitors, and comparing it to the distribution of ambient formaldehyde concentration obtained from IIOAC is not quite fair as the comparison does not consider all the confounding factors that lead to differences between the AMTIC monitoring data and the IIOAC. The SACC said that given the spatial misalignment between the AMTIC monitoring data and the IIOAC data, a different approach would be to: “use the AMTIC monitoring data, assume that the measurement represents a daily average concentration, regardless of the duration of collection, and fit a spatial regression model that regresses the measured AMTIC observed concentration data at a given AMTIC monitor on the various confounding factors (method of collection, duration of collection, time of collection, season of collection, rural versus urban, distance to nearest industrial facility, wind speed, wind direction, etc.) and a spatial random effect to account for the fact that there is also variation from monitor to monitor and concentrations from monitors nearby might tend to be similar.” The SACC said that this approach would allow comparison of estimated ambient exposure from all sources (the “AMTIC” formaldehyde concentration) leveraging the AMTIC monitoring data with the IIOAC modeled concentration relative to the same locations, accounting for all the confounding factors that lead to differences among the AMTIC monitoring values besides the source of formaldehyde. The SACC suggested another option in which EPA could calculate average AMTIC concentration, averaged over all the AMTIC monitor locations that are within a certain distance buffer from a TRI

facility and then these averages could be used to compare the IIOAC modeled concentration 100-1000 meters from a given TRI facility to this more localized average AMTIC concentration. The SACC stated that it does not support assigning zeros as concentration values for data falling below limits of detection for environmental data where the data are being aggregated from methods that have a wide range of detection limits. The SACC said that there is a need to understand the distribution of the limits of detection, because in large data sets that represent large temporal and spatial settings, there is a non-negligible possibility that many limits of detection will fall well into the quantifiable concentration range of other methods. The SACC said that it is improper to assume that below limit of detection values represent the lowest values in a distribution.

The SACC said that EPA mentioned that satellite data have measured formaldehyde concentrations across the United States, providing insights on temporal and geographic trends that help to characterize ambient formaldehyde concentrations, however, it did not appear that this data source was considered in the draft reports. According to some SACC members, use of the remote sensing data would have been useful to understand spatial variability. One SACC member said that while remote sensing data can provide potentially useful information, it was important to acknowledge that remote sensing data are not actual data nor a measurement of formaldehyde concentration, as instruments aboard satellites measure quantities related to refraction of light, not chemical concentrations. This SACC member described the many sources of uncertainties in using satellite data and concluded that, while remote sensing might offer an additional source of information on formaldehyde concentration, it is important to validate the quality of the data and recognize the different sources of uncertainties in these datasets. The SACC commented on the extent to which the Weight of Scientific Evidence (WOSE) narrative is supported by current outdoor ambient air monitoring information for formaldehyde: "The findings derived from the draft report's outdoor ambient air monitoring data are predominantly qualitative, due to the absence of source-specific formaldehyde observations. Regarding the WOSE, although its elements such as AERMOD and AirToxScreen have undergone peer review and received support from prior Committees for different objectives, it does not imply that their application, if not done with great care, would automatically yield valid results when attributing sources of formaldehyde concentrations. Each individual comparison has merits, but there is no inherent merit in each additional comparison."

EPA Response: EPA appreciates the comments provided and incorporated several of the issues highlighted as uncertainties and limitations of the data within the revised ambient air exposure assessment and human health hazard risk assessment for formaldehyde. Given additional time and resources, EPA can consider other ways to improve the way AMTIC data is evaluated and utilized in future risk evaluations, including several considerations recommended by commenters and SACC.

AMTIC representing long-term exposure concentrations

Summary: A public commenter (0182) stated that the AMTIC data is an aggregate of data that is made up of a wide variety of sample times, is not annualized, and none of the data are annual averages. Therefore, AMTIC data cannot be directly compared to the modeled data presented in the assessment. Additionally, the commenter said that using short-term sample data as potentially representative of long-term exposure concentrations is unlikely to be correct. The commenter suggested taking the sample data at a given monitor and normalizing the data to an hourly time frame. Then, then the commenter suggested building annual data sets for each of the 5-years of data reviewed to generate an annual average for that year, and generating a range of annual averages over all monitors that could be used to more accurately assess chronic health effects.

The SACC provided several comments on the conclusion that AMTIC represents long-term exposure concentrations and is better aligned with timeframes associated with human health points of departure, including the following recommendations: include additional data summaries and potential post-processing that would enable considering these data as representative of long-term formaldehyde exposure; expand the discussion on data processing steps undertaken that are related to the limit of detection and perform additional sensitivity analyses; and include additional post-processing to better align calculated exposures with health points of departure.

The SACC stated that while the AMTIC monitoring data can be considered as providing information on the ambient formaldehyde concentration due to all sources, inclusive of industrial releases, biogenic processes, and secondary formation, it is hard to think of the raw data as representative of long-term exposure concentration. The SACC said that the differences in sampling duration and collection methods (each having its own detection limit and reliability characteristics) make it difficult to state with confidence that each monitor provides a reliable estimate of the long-term exposure to ambient formaldehyde concentration experienced by the population living nearby the monitor. One SACC member said that in order to state that, these data need to be statistically post-processed to obtain reliable daily average concentrations. Given that average annual ambient formaldehyde concentration can be estimated only at a very small percentage of AMTIC sites (0.03%), one SACC member believed that stating that the AMTIC data provide estimates of long-term average exposure to formaldehyde is not realistic, at least not under the current sampling scheme. The SACC said that in order to confidently relate AMTIC data to human exposure, it is important to have a better description of the spatial distribution of the AMTIC monitors, including urban/rural representativeness, time of day that the measurements were taken, sampling duration, and a summary of distances from TRI emissions sites.

The SACC said that EPA should expand the discussion on data processing steps undertaken that are related to the limit of detection and perform additional sensitivity analyses. One SACC member requested more clarity on why 15% of samples were excluded for being below the limit of detection as per Section 2.2.1. The SACC recommended that the EPA do at least one sensitivity analysis where they retain the non-detect samples and/or invalid entries but make assumptions about the values of the concentration, for example, by setting the concentration to be equal to of the detection limit. The SACC also said that it would be of interest to see which collection duration bins and geographic regions were more represented among the excluded data in order to identify the risk characterizations most likely to have been affected by this choice. The SACC submitted the following set of questions regarding the "count" information in Table 3-1: Were the Fluxsense frequency distributions similar in 2019 vs. 2020 (data count increased from 77,654 to 121,218, so maybe Fluxsense implementation occurred part way through 2019?)?; Is 2019 versus 2020 an apples-to-apples comparison in terms of sample durations? Or was there a decrease in ambient air formaldehyde correlated to Covid-19 pandemic lockdowns? The SACC stated that Figure 3-7 does not define the term "relative" concentration at each monitoring site and requested that EPA explain what this value is (a median, geometric mean, 95th percentile, or something else?).

The SACC recommended that EPA include additional post-processing to better align calculated exposures with health points of departure, stating that the data could be better aligned with the underlying studies and more realistic exposure scenarios for the acute POD could be derived. One SACC member downloaded an AMTIC data file (for year 2019) to get a sense of the available metadata and noted that sample times are logged. The SACC member said that these data could be aligned to time of the day and weighted in the assessment for the times of the day that people are most frequently outside (e.g., not 3 a.m.). The SACC said that formaldehyde varies in predictable diurnal

and seasonal patterns (higher in summer; higher at mid- day), which is important to take into consideration when calculating an annual average. The SACC suggested that EPA could build seasonal trends (e.g., using the Komogorov-Zurbenko filter, which sufficiently handles missing data, or other methods used by EPA in their trends assessments for criteria pollutants; references provided in the submission) from the available data based on time of the year and predict missing days to create updated annual means and modeled daily concentrations. The SACC said that measurement locations, time of day, and other considerations are highly influenced by EPA regulations and policy, so there should be closer involvement between offices in optimizing observation locations, times of day, and times of year of measurements.

EPA Response: EPA appreciates the comments provided and identified several of the issues highlighted as uncertainties and limitations of the data within the revised ambient air exposure assessment and human health risk assessment for formaldehyde. Given additional time and resources, EPA can consider other ways to improve the way AMTIC data is evaluated and utilized in future risk evaluations, including several considerations recommended by commenters and SACC.

Strengths and uncertainties associated with HEM results

Summary: A public commenter (0182) stated that the HEM is suitable for use in assessing risk to individual communities and census blocks if the appropriate source and emissions data are used. However, for this assessment, the specific source data for the 810 TRI sources that were modeled was not used. Instead, conservative, generic source data for point releases, representing stacks, and fugitive releases, representing leaks and other unplanned releases, were used, as described in Table 2-2 of the Assessment (e.g., a stack diameter of 2 m for a 10-m-high stack, exit velocity of 5 m/s and, and for the fugitive air release source, an assumed release height of 10 feet).

The commenter said that the use of generic source parameters likely results in model-predicted concentrations that do not reflect the impacts from the source. Also, no building data was included for these sources. The commenter recommended engaging with the Office of Air Quality Practices and Standards to better characterize the sources and emissions included in the modeling to improve the accuracy of the results. The lack of inclusion of aerodynamic downwash due to nearby buildings is not only unrealistic (especially for a 10-meter stack) but also likely causes the highest impacts from the source to be farther from the emission point than it should be, thus potentially appearing to affect a larger population than it should.

Another public commenter (0261) asked why there is no mention or use in the ambient air exposure assessment of the 2022 Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0 as HEM and IIOAC are components of the document.

The SACC requested that EPA provide more explanation/justification of using the TRI dataset instead of the much larger NEI dataset. The SACC said that a comparison of releases reported in the two databases shows that the TRI tends to have lower release values, as oil and gas drilling industries tend to have highest releases of formaldehyde, yet that sector does not have to report for TRI. The SACC said that by choosing to use release data from TRI, even if using the maximum release reported by a site, the ambient exposure estimated by the HEM is likely to be an underestimation. The SACC said

that the number of TRI sites for which release data are available is dwarfed by the amount of release data available from NEI.

The SACC recommended that EPA clarify the temporal scale of meteorological data used in AERMOD. The SACC requested that EPA provide clear explanations of how the census block ambient concentrations are derived, as this is fundamental in understanding and interpreting the results presented in Figure 2-8 (e.g. what procedure is used to aggregate the estimated annual exposure from the receptors to obtain the annual average concentration at the census block level?). The SACC said that the text is unclear about what procedure is exactly used to aggregate the estimated annual exposure from the receptors to obtain the annual average concentration at the census block level, and asked the following questions: 1) Did the Agency overlay the boundaries of each census block in a map of the United States and select all the receptor points surrounding TRI sites that fall in the census block?; 2) What approach did the Agency use?; and 3) Was the annual average ambient concentration from the receptor points falling within a census block boundaries averaged or summed together? The SACC suggested that EPA provide ranges of concentrations for each census block, rather than presenting only one estimated annual average formaldehyde concentration. The SACC stated that it is unclear what the benefit of showing whether a census block had an estimated ambient formaldehyde exposure annual concentration that was larger than a US-wide biogenic threshold. The SACC recommended an analysis to understand whether in a specific block the amount of formaldehyde concentration due to TRI releases is greater than the 95th percentile of formaldehyde concentration due to biogenic sources at that location. The SACC reasoned that this would be more protective to the population as it sets a threshold that is location-specific and potentially lower than a nation-wide 95th percentile threshold.

The SACC said that Figure 2-9 attempted to compare the distribution of the ambient exposure concentration at the receptor points and evaluate the contribution of fugitive release versus stack release at different distances from a TRI sites. However, it is unclear how the total, which is assumed to be the sum of fugitive and stack release, has a median that is smaller than the median for one of the two terms that defines it. Secondly, these results do not consider the spatial distribution as the concentrations for all the receptors are lumped together, so for example, there could be a receptor at 10m from a TRI site for which the concentration due to stack release is larger than the concentration due to fugitive release and that might be true for all the receptors in a particular region of the United States because of meteorological conditions and dispersal. Yet one would not be able to identify this type of pattern as described here because the results are collated over space. The SACC said that given the large uncertainty surrounding this estimate, they strongly encourage EPA to discuss the uncertainties and think about providing ranges of concentrations for each census blocks rather than presenting only one estimated annual average formaldehyde concentration.

The SACC said that it is important to note the uncertainties within the Census data that the HEM is based on, especially in the 2020 Census, which has been shown to under-count certain groups.

The SACC said that a limitation of the IIOAC model and AERMOD used in HEM is that daily meteorological conditions (e.g., which way the wind is blowing or an inversion), which might vary concentrations by multiple orders of magnitude, are not considered. The SACC said it was also not clear whether other factors such as building down-washing have been incorporated in the AERMOD modeling. The SACC asked if AERMOD was run with daily meteorology, or some other temporal scale. The SACC stated that it is unclear whether the HEM model uses actual meteorological data, with different meteorological conditions every year, or whether the same fixed meteorological conditions are used for every day in the year (as the Agency has done to derive the modeled concentrations using the IIOAC approach). It is also unclear if the results the Agency are presenting in Figure 2-8 refer to a

specific year or refers to averages across the 6-year worth of data. The SACC said that the level of details provided in the text is so summary and, in certain instances so confusing, that it makes it impossible for somebody to replicate the results the Agency has obtained.

The SACC stated that they are concerned that use of the Toxic Release Inventory dataset will underestimate exposure and that important exposures are not captured in the current assessment given the models, methods and approaches used. The SACC requested more justification for why the concentration contributions from Toxic Release Inventory facilities were presented as a fraction of biogenic contribution from AirToxScreen. The SACC asked what the variability was for the Toxic Release Inventory emissions data used across the six-year period (2016-2021) and if there was a trend. The SACC said that the biggest worry for most of these sites would be whether there was a large accidental (or planned) release that accounts for most of the reported annual emissions. The SACC suggested that there may be information from these facilities' air permits that might add more information about the periodicity and magnitude of non-continuous emissions from these facilities.

The SACC stated that the consideration of only the industrial and consumer product scenarios omits an important array of other exposure scenarios, and several SACC members have challenged the EPA assertion that the calculations they've presented are representative of the US population with no PESS identified. The SACC said that EPA has calculated ambient air concentrations in the IIOAC model to represent exposure farther than 100 meters from the source of contamination, however, there are no football-field sized spaces between the auto body shop's rooftop vents and the homes and a preschool in the photographs shared by the SACC. Therefore, ambient air concentrations of formaldehyde as calculated by EPA with these factors and assumptions are unlikely to represent daily exposures for these urban populations. The SACC said that modeling for this mixed-use urban setting could be estimated with the IIOAC model or preferably the HEM model. The SACC said that literature is available on this issue with a variety of monitoring information studies, and specifically, detailed information about formaldehyde-based products in car repair and painting shops is available in the publication and references therein by Granadero et al., as a start.

EPA Response: While HEM is a higher tier model (compared to IIOAC). EPA utilized HEM for a specific purpose in the ambient air exposure assessment and human health risk assessment for formaldehyde: to consider aggregate exposures and outputs on population exposures and risks at the screening level. Therefore, EPA's use of certain default parameters from IIOAC in HEM was appropriate and allows direct comparison of the IIOAC and HEM results at a facility level. The commenter is correct, that if additional, higher tier modeling is sought for a fit-for-purpose risk evaluation, HEM does allow more site-specific information to be used as inputs. EPA describes the uncertainties associated with the default stack parameters used in both the IIOAC and HEM modeling in the revised ambient air exposure assessment for formaldehyde as it represents a low, slow moving, non-buoyant plume which may be more conservative than actual stack conditions.

While certain EPA models like AERMOD can consider building dimensions for downwash effects as part of the modeling, the level of specificity required for GIS coordinates of every corner of every building around a single release point (nearly 50,000 in NEI for formaldehyde and the lack of process level release data in TRI to identify release points, etc.) is not reasonably available and has not been provided by industry to EPA. Additionally, as stated by the commenter, the impact of building effects like downwash can be highly dependent on the site-specific stack parameters. While a plume from a 10-meter stack height may be more impacted by nearby buildings, a facility has a stack height of 25 meters, or 50 meters, the plume may not be impacted by nearby buildings, especially if the buildings themselves are single-story buildings that are upwind of the release point (where there will be almost

no impact on the plume) or the plume has a high temperature and velocity resulting in much more lift before moving downwind of the release point.

EPA considered and evaluated both the TRI and NEI release datasets for the IIOAC modeling as described in the methodology section of the Draft and revised Ambient Air Exposure Assessment for Formaldehyde (See Section 2.1.1.1, Section 3.1.1 of the revised ambient air exposure assessment, and supplemental files on IIOAC modeling). Results from the IIOAC modeling were used to characterize exposures and derive risk estimates. EPA presents the results from both TRI and NEI datasets in combination when characterizing exposures and associated risks in the revised ambient air exposure assessment and human health risk assessment for formaldehyde.

EPA provides additional explanation/justification around using TRI and NEI release data, additional analysis/comparison around the releases and associated modeled results between TRI and NEI, in the revised ambient air exposure assessment.

EPA provides additional clarification within the revised ambient air exposure assessment for formaldehyde around the temporal scale of meteorological data used in the HEM analysis as well as the procedures used by HEM to obtain the census block level ambient concentrations, to the degree feasible, as the bulk of these methods/procedures are integrated within the HEM inner workings and not post-processing activities as EPA has previously used for past ambient air exposure assessments (*e.g.*, Fenceline analyses, other chemical specific REs, etc.) using AERMOD.

EPA provides the presents the aggregate piece of the HEM results associated with TSCA COUs in relation to the 95th percentile biogenic concentration to contextualize the contributions of industrial sources associated with specific TSCA COUs relative to the natural production of formaldehyde from biogenic sources in the revised ambient air exposure assessment. These results are presented at the census block level..

The HEM outputs providing the census block level concentrations provide a single value within that census block (at the centroid receptor) and therefore the output does not include a range of concentrations within each census block and EPA is unable to provide a range of concentrations as recommended by SACC with the tools and output files used for the formaldehyde risk evaluation.

EPA provides additional clarifying language around the census data used by the HEM, to the extent feasible.

Neither IIOAC nor HEM allow for the directional analysis recommended by SACC. However, the pre-run AERMOD scenarios within IIOAC and the HEM both consider hourly meteorological data obtained from real meteorological stations included within the AERMOD sub module AERMET. Neither IIOAC nor HEM allow for the consideration of building down-washing effects. While running AERMOD directly (which was not done for the formaldehyde risk assessment) would allow for building down-was effects, heights, etc. the data required for EPA to accurately incorporate that consideration is not reasonably available information and would require industry to provide building dimensions of every building in and around every release point (both on and off property) for which air releases are reported to either TRI or NEI across the entire continental US. Therefore EPA did not consider it for the formaldehyde risk evaluation.

EPA did not conduct a site-specific analysis of either TRI or NEI release datasets for the formaldehyde risk evaluation. Due the large number of releases reported to both TRI and NEI, EPA took an industry sector approach (as described in the revised environmental release assessment and revised ambient air exposure assessment for formaldehyde) and therefore did not conduct any trend analyses or multi-year analysis for the TRI dataset. Additionally, while accidental releases may result in higher emissions from a single site-specific analysis, the industry sector approach taken in the formaldehyde exposure assessment evaluates four statistics (max, 95th percentile, median, and minimum) across the entire distribution of releases for each industry sector captured by either TRI or NEI. This approach, while it may capture a random accidental release from a single facility in the maximum release statistic, by looking at other release statistics across the entire release distribution of each industry sector should minimize the impact of such a random accidental release being the sole cause of a high exposure and associated high risk estimate.

Since EPA evaluated and included results for both TRI and NEI datasets EPA expects that it did not miss important exposures within the current assessment of formaldehyde.

Use of AirToxScreen

Summary: A public commenter (0182) said EPA's presentation of HEM results are "broad-brushed" and do not consider the variations in the biogenic portion of ambient formaldehyde that might be present in smaller amounts in industrialized areas or larger amounts in more rural areas. For example, the commenter said that the median contribution from point sources is an order of magnitude lower than that of biogenic sources, and more than 2 orders of magnitude less than the contribution from secondary production. The commenter stated that unrealistic assumptions lead to AirToxScreen impacts from point sources likely to be overestimated. The commenter added that the approach is inconsistent with the HEM modeling, which used the site-specific annual emissions reported to TRI and, according to the most recent NEI data available, biogenic emissions of formaldehyde are by far the biggest contributor, followed by fires; industrial sources contribute less than 10% of the formaldehyde emissions in the NEI.

The SACC requested that EPA describe more clearly the reasoning for using biogenic and secondary formaldehyde as a baseline point of comparison for point-source formaldehyde. The SACC said that it was unclear whether all risk in the ambient air is discounted relative to biogenic or secondary formaldehyde and that the SACC was not convinced this discounting was appropriate. The SACC questioned why EPA selected biogenic and not secondary sources, or why not all sources, as biogenic contributions and secondary contributions vary in space. The SACC recommended that EPA compare each facility's contribution from HEM/AERMOD with the biogenic or total formaldehyde spatially.

The SACC said that the IIOAC results yield concentrations up to 6g/m^3, while AirToxScreen showed contribution of up to only 0.88g/m^3, and HEM with a maximum concentration of 8.9g/m^3. The SACC said that these disagreements were not fully addressed by the discussion of the HEM spatial scale being at census blocks, whereas AirToxScreen generates estimates at census tracts, and IIOAC at a specific distance from sources. However, the SACC believed that there is more going on here to lead to an order of magnitude difference in concentrations, including that AirToxScreen is based on a combination of a chemical transport model (Community Multiscale Air Quality model) to capture "background" contributions and chemistry, and AERMOD, which captures local contributions. The

SACC recommended that EPA harmonize the modeled concentrations and observations in space and time.

The SACC said that Figure 3-3 is helpful to appreciate the range of annual average concentration across the various census tracts in the United States, however, in order to adequately perform source apportionment it is necessary to calculate, at each census tract, the ratios of the estimated formaldehyde concentration that can be attributed to a specific type of source in that census tract (e.g. secondary formation) to the estimated concentration due to all sources at the same census tract. The SACC stated that the current figure does not show these ratios, thus not allowing one to draw any conclusion. The SACC said that EPA's current assessment is incorrect as it completely ignores the fact that these three average annual concentrations (due to point sources, biogenic sources, secondary formation) are not independent of each other. The SACC suggested that EPA discuss the contributions of secondary formation and natural sources of formaldehyde in relation to contributions of formaldehyde from TSCA conditions of use.

The SACC recommended that EPA explore more fully the secondary formation contribution and consider its role in ambient formaldehyde exposure and suggested the reference, Zhang et al. (2013), which noted that 10-30% of secondary formaldehyde comes from industrial sources. The SACC said that it is unclear how well observations reflect total formaldehyde from AirToxScreen and that it would be better to do more direct comparisons (e.g., comparisons made only at areas with IIOAC modeled locations or only at AMTIC monitoring sites).

The SACC suggested that EPA address concerns related to comparing AirToxScreen output and IIOAC, as the concentrations estimated by the IIOAC method and AirToxScreen are not comparable for the following reasons:

- Spatial misalignment – The two estimated concentrations do not refer to the same spatial locations. The IIOAC estimates of formaldehyde concentrations only refer to concentrations at selected locations within a certain distance (100m to 1,0000m) from TRI facilities, while the AirToxScreen concentrations refer to all census tracts centroids.
- Different input sources – The IIOAC method uses as input the formaldehyde releases from TRI facilities while AirToxScreen uses as input the formaldehyde releases provided in the NEI database. There are sizeable differences between the two databases in terms of amount of data and even magnitude of the releases, with the largest releases not included in the TRI dataset.
- Static versus changing meteorology – The estimates of formaldehyde concentration obtained by the IIOAC method are not derived using actual meteorological conditions, but they are derived using a fixed meteorological condition that is maintained constant for every day of the year. Given the high reactivity of formaldehyde and the way it behaves under different meteorological conditions, not allowing the meteorological conditions to change from day to day or even from season to season is not realistic and might yield estimated of formaldehyde concentration due to TSCA conditions of use that are too high or too low.

The SACC said that: "once the above issues are addressed, a calculation of the ratio of the estimated formaldehyde concentration due to TSCA conditions of use at a given location and the estimated formaldehyde concentration due to all sources (and estimated by AirToxScreen) at the same location or at least in a neighborhood of the same location would allow to quantify the percentage of formaldehyde concentration at a given location that is contributed by TSCA conditions of use. Repeating such calculation for each location, it will make evident the variability in the contribution of TSCA conditions of use to the formaldehyde due to all sources across space. This variability is to be expected

given the different meteorological conditions over space as well as the variability in the density of industrial facilities releasing formaldehyde across space."

EPA Response: Neither the HEM modeling nor the 2019 AirToxScreen modeling for point source releases consider the variations in biogenic portion of ambient formaldehyde because the point source releases modeled are independent of the additional contributions of a biogenic source to total aggregate exposure from all sources. While certain point source release contributions to ambient formaldehyde may be less than biogenic source contributions (or secondary formation), it does not impact the overall characterization of exposures from that point source individually.

EPA stated several times in the draft risk evaluation that a direct comparison of the 2019 AirToxScreen results and either the IIOAC or HEM modeling is not appropriate because of the differences in modeling approaches as well as the fact that the 2019 AirToxScreen modeling results are averaged over a census tract, which is a much larger area than the finite distances modelled with IIOAC and HEM, and can bias AirToxScreen modelled results low rather than overestimation.

EPA includes discussion around the reasoning why biogenic and secondary formation concentrations from AirToxScreen were identified and used for comparison to IIOAC modeled concentrations throughout the draft ambient air exposure assessment. Generally, of the 37 source types captured by the 2019 AirToxScreen analysis, the two highest source type modeled concentrations were biogenic and secondary formation of formaldehyde equalling up to 80 to 90 percent of total ambient concentrations according to AirToxScreen. Therefore these two contributing sources in combination with IIOAC modeled contributions specific to TSCA COUs are a good representation of the high majority of all the ambient concentrations of formaldehyde which may be captured by ambient monitoring data.

EPA also describes in the ambient air exposure assessment how the various individual contributors to total ambient concentrations of formaldehyde are additive in nature. EPA derived risk estimates based on the modeled IIOAC concentrations and did not discount those risk estimates based on biogenic risk estimates. Rather EPA contextualizes the risks found by IIOAC modeling relative to biogenic risks.

While EPA appreciates the comments around Figure 3-3 in the Draft Ambient Air Exposure Assessment and recommendations to do a source apportionment of each source type (point source, secondary formation, biogenic, TSCA COU, etc.) at each census tract, the statutory timeframes provided by TSCA and the resource needs for such a detailed analysis is not feasible.

EPA can consider a more site-specific comparison between datasets like AMTIC monitoring sites and industrial monitoring sites to better contextualize the relative contributions of TSCA COU specific releases to total monitored values in future risk evaluations. Since this formaldehyde risk assessment did not conduct a full site-specific analysis for purposes of deriving risk estimates and regulatory decision-making (EPA used an industry sector approach and only modeled specific statistics of releases) such a comparison is not feasible at this time for the formaldehyde risk assessment.

EPA describes the limitations/concerns expressed by SACC related to comparing AirToxScreen outputs and IIOAC outputs in the revised ambient air exposure assessment

EPA provides more description of the meteorological data used in the IIOAC model in the revised ambient air exposure assessment for formaldehyde. The IIOAC model uses hourly meteorological data across 5 years (2011 to 2015) from actual meteorological stations within AERMODs AERMET module.

Threshold for risk

Summary: A public commenter (0263) said that EPA's determination that general population exposure to formaldehyde in outdoor air does not contribute to unreasonable risk is scientifically unjustified. The commenter stated that EPA did not explain how formaldehyde measured in ambient air at concentrations as high as 60.1 g/m^3 leads to a conclusion that any lower concentrations attributable to releases from industrial facilities do not represent an unreasonable risk. The commenter said that 60.1 g/m^3 is a short-term concentration found in a single location under unusual conditions and is inappropriately and unscientifically used as a point of comparison for estimated long-term average outdoor air concentrations. Also, the commenter said that EPA provides no rationale for how biogenic concentrations are relevant to judging unreasonable risks from industrial emissions. Further, EPA disregarded the comparison of formaldehyde levels resulting from industrial emissions to biogenic background when it concluded there is no contribution to unreasonable risk, even for the seven conditions of use with an order of magnitude greater risk than biogenic sources. The commenter recommended the final risk evaluation determination be revised to "contributes to unreasonable risk" for any condition of use whose emissions to ambient air result in modeled 1-in-1,000,000 or greater risks of cancer to fenceline communities.

Similarly, a public commenter, in multiple submissions to the docket (0151, 0178) asked if EPA has preliminarily determined that air with a formaldehyde concentration at or below 60.1 ug/m^3 poses no unreasonable risk of cancer to the general population. The commenter requested the scientific rationale for lowering the values below the method detection limit to zero and how substituting zero for the method detection limit influence the subsequent analysis and conclusions.

Another public commenter (0244) stated that EPA inappropriately dismisses general population risks with the misuse and comparison to "background" exposures or non-TSCA sources, which is scientifically unfounded. The commenter recommended EPA instead contextualize TSCA sources of formaldehyde ambient air risks with non-TSCA sources and not dismiss the risks due to uncertainty. The commenter stated that risk should not be deemed unreasonable based on comparison to other exposures but rather in addition to other exposures. EPA should instead calculate and consider how risks from TSCA sources of formaldehyde contribute to the sum of the formaldehyde risks, including risks from formaldehyde in ambient air from other sources of formaldehyde. The commenter added that the definition of "background" exposures must be clarified, based on the best available science.

Another public commenter (0261) recommended that all ambient exposures, including unreasonable risk, be incorporated into the exposure assessment without regard to sources.

A public commenter (0283) added that EPA dismisses all fenceline community and general population risks across the country based on a single data point - the greatest one-time measurement of formaldehyde in ambient air anywhere in the United States, taken in December 2018 in Fontana, California. Additionally, the commenter said that EPA arbitrarily compares fenceline community residents' lifetime of formaldehyde exposures to the maximum ambient air concentration detected on a single day, and that EPA "utilized the 95^{th} percentile release value" reported by TRI and the 95^{th} percentile modeled annual-averaged air concentrations to calculate fenceline communities' cancer risks, which further skews EPA's comparison against a finding of unreasonable risk, since even if the datasets were otherwise comparable, the 99.999^{th} percentile value would exceed the 95^{th} percentile.

EPA Response: EPA considered short-term acute inhalation risks and long-term cancer inhalation risks of formaldehyde in the ambient air after receiving feedback from the SACC review panel and public comments. For short-term acute inhalation exposures, a calculated MOE that is less than the benchmark MOE of 3 generally supports a determination of unreasonable risk of injury to health. Similarly, for long-term cancer inhalation exposures, a calculated cancer risk estimate that is greater than the cancer benchmark of 1×10^{-6} generally supports a determination of unreasonable risk of injury to health from cancer.

In order to determine risk for the general population in ambient air, the IIOAC model was used as the results represent a risk estimate between 100 to 1,000 m from the release point from industrial facilities that report air releases of formaldehyde attributable to its domestic manufacturing, import, processing, and industrial COUs. The population living or working within 100 m to 1,000 m of the facilities (or fenceline population) are considered PESS and would represent the highest general population exposed to formaldehyde.

Short-term risk estimates for ambient air in this assessment are based on the maximum release scenario and the 95th percentile modeled daily average exposure concentrations at 100 meters from a releasing facility as described in Section **Error! Reference source not found.** and the *Ambient Air Exposure A ssessment for Formaldehyde*. None of the risk estimates were below the acute benchmark MOE of 3 for exposures primarily attributable to the COUs, indicating that acute risk is not expected.

Long-term risk estimates for ambient air are based on the 95th percentile release scenario and the 95th percentile modeled annual average exposure concentrations within the area distance of 100 to 1,000 meters from a releasing facility as described in Section 2.4.2.1.2 and the *Ambient Air Exposure Assessment for Formaldehyde*. The population living or working within 100 m to 1,000 m of the facilities (or fenceline population) are considered PESS and would represent the highest general population exposed to formaldehyde. None of the non-cancer risk estimates were below the benchmark MOE of 3 for exposures primarily attributable to the TSCA COUs, indicating that non-cancer risk is not expected. The highest risk estimate for cancer is 5.85×10^{-5}. The risk evaluation indicates risk for general population due to formaldehyde concentration in ambient air; however, formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde, and there is uncertainty in the geographic and temporal nature of the cancer risk estimates.

Based on the non-cancer risk estimates from acute and long-term exposures, coupled with the uncertainties around the precision of the cancer risk estimates and the magnitude of the cancer risk estimates above the benchmark, EPA found that general population exposures from ambient air emissions under the conditions of use of formaldehyde do not contribute to the unreasonable risk from formaldehyde.

More information on EPA's confidence in exposures, risk estimates, and risk characterization for ambient air can be found in the *Human Health Risk Assessment for Formaldehyde,* Section 4.2.4.7.

Fenceline communities

Summary: Several public commenters (0283, 0263, 0244) stated that EPA underestimated ambient air exposures and risks to formaldehyde in fenceline communities, discussing at length multiple reasons including:

- Limited use of formaldehyde release data (0244);

- Ignoring reported releases that exceed the 95th percentile value from the TRI dataset for each industrial sector evaluated, despite the fact that the maximum reported releases are often many orders of magnitude higher than the 95th percentile value (0283);
- Failing to integrate emission data from NEI; ultimately only presenting results from and relying on TRI data only, but TRI does not reflect major emitters who emissions are reported in NEI (0283);
- Ignoring emissions from multiple categories of industrial facilities that are major sources of exposure to fenceline communities (e.g., petroleum refineries, electricity generation facilities, compressor stations, and sources in the oil and gas drilling, extraction, and support activities sector) (0283);
- Use of only one type of modeling (0244);
- Lack of accounting for aggregate exposures from multiple nearby facilities in fenceline communities either within or across condition of use (0244, 0283);
- Disregarding exposures from secondary formation of formaldehyde attributable to TSCA condition of use which is an important contributor to total exposure (0283);
- Unlawfully discounting risk by comparing exposures from industrial releases to the maximum ambient air concentrations (0283);
- Dismissing risk based on comparison to "background exposures" which is unsupported by the record and contrary to TSCA (0263); and
- Incorrectly asserting that correcting the flaws in the assessment "would not matter" because EPA ultimately chose to determine the reasonableness of fenceline community risk by comparing just two data points: the maximum modeled ambient air concentration of formaldehyde attributable to a condition of use and the maximum monitored national ambient air concentration (0283).

A commenter (0244) discussed in detail how underestimations in exposure can be seen when comparing modeled and monitored data and recommended that EPA use monitoring data to calculate risks as individual experiences then use modeled data to understand how TSCA uses contribute to those risks.

Two commenters (0263, 0244) said that it is unclear and scientifically unjustifiable to solely use the IIOAC model inputs in risk calculations. One commenter (0263) cited the Agency's draft TSCA methodology for fenceline analysis which says IIOAC is used for prescreening and AERMOD "provides a more thorough analysis, and allows EPA to fully characterize identified risks." The other commenter (0244) said EPA should use HEM ambient air exposure estimates for use in risk calculations which is more representative of real-world risks. Utilization of HEM modeling allows EPA to visualize the effects on real fenceline populations, even though without multiple facility aggregation incorporated in the population estimates, these reported effects are likely underestimated.

Two public commenters (0283, 0244) stated that EPA did not account for elevated formaldehyde exposures from reasonably foreseen, but unplanned, excess emission events. Citing the number and impacts from recent releases of chemicals, one of the commenters (0244) stated that EPA did not include reasonably foreseeable accidental or peak spills and releases from extreme weather events or reasonably foreseeable occurrences that should be considered in the risk evaluations. The commenter further added that accidental and start up, shut down, and malfunction releases are common particularly in black and brown and low-income communities where the releasing facilities are disproportionately concentrated, as determined in EPA's analysis of risks for various races/ethnicities using HEM.

Another commenter (0263) said that EPA failed to consider whether any fenceline communities are in proximity to multiple facilities with formaldehyde emissions, which could result in greater risk.

Conversely, a public commenter (0261) commended EPA for giving a significant degree of attention to fenceline communities, pointing to Tables 4-2 and 4-3 showing the disparate burden of pollution that black, brown, and marginalized populations and other disadvantaged communities bear.

EPA Response: EPA disagrees with the commenters' suggestions that EPA underestimated ambient air concentrations. EPA's ambient air exposure assessment (both draft and revised)use all formaldehyde release data from two separate datasets (TRI and NEI) under multiple exposure scenarios and include all results in the supplemental files.. EPA used all the release data to develop industry sector level release number statistics (maximum, 95th percentile, median, and minimum releases within each industry sector) which were then modeled to estimate exposures for each industry sector. EPA also modeled all source categories that reported releasing formaldehyde in the NEI dataset in the same manner as the TRI dataset.

EPA also uses multiple modeling approaches (IIOAC, HEM, 2019 AirToxScreen), each with a specific purpose in the Draft and revised RE, rather than a single model. IIOAC modeled results were relied upon for characterizing exposures and deriving risk estimates in the Draft RE. HEM was used to consider aggregate exposures (in particular multiple facilities in proximity to each other and releasing formaldehyde to the ambient air) as well as certain population and demographic impacts. 2019 and 2020 AirToxScreen results was used to consider other sources contributing to the overall exposures to formaldehyde via the ambient air pathway, including biogenic sources and secondary formation of formaldehyde.

Use monitoring to calculate risk: EPA derives risk estimates based on the monitoring data from the AMTIC dataset in the revised human health risk assessment for formaldehyde. However, these risk estimates are not used for risk determination purposes since monitored values are a total exposure from all sources of formaldehyde, and EPA cannot apportion what part of a monitored value is due to TSCA conditions of use vs. all other sources of formaldehyde.

While the Fenceline write-up used IIOAC for pre-screen and screening, that is not the only use for IIOAC as it also is based on pre-run AERMOD runs under a variety of scenarios and meteorological conditions. IIOAC can also be used for more targeted modeling based on regional meteorological data, populations, and several other inputs can be revised. EPA acknowledges that both HEM and AERMOD are higher tier models which have a wider variety of user defined inputs like site-specific stack parameters, and more localized meteorology, when necessary for each fit-for-purpose risk evaluation. While all three models provide results which can help visualize the effects of releases to fenceline communities, the commenter is correct the HEM has some additional capabilities incorporated into the model outputs which present specific local effects like population and demographics which can be visualized more specifically for fenceline communities, and this is how EPA used HEM for formaldehyde. However, the commenter is incorrect stating that HEM does not include multiple facility aggregate exposures as that is how the population analysis presented in the draft and revised assessments is derived. HEM outputs provide populations exposed and associated risks at the centroid of each census block and is an aggregate exposure from multiple facilities in proximity.

While EPA did not specifically target accidental releases in its assessment, EPA did model and assess all releases reported to TRI and NEI which may include certain reportable releases which occurred due to accidental releases, leaks, or other similar releases.

A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark is a starting point for informing a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk.

Short-term risk estimates for ambient air in this assessment are based on the maximum release scenario and the 95th percentile modeled daily average exposure concentrations at 100 meters from a releasing facility as described in Section **Error! Reference source not found.** and the *Ambient Air Exposure A ssessment for Formaldehyde*. None of the risk estimates were below the acute benchmark MOE of 3 for exposures primarily attributable to the COUs, indicating that acute risk is not expected.

Long-term risk estimates for ambient air are based on the 95th percentile release scenario and the 95th percentile modeled annual average exposure concentrations within the area distance of 100 to 1,000 meters from a releasing facility as described in Section 2.4.2.1.2 and the *Ambient Air Exposure Assessment for Formaldehyde*. The population living or working within 100 m to 1,000 m of the facilities (or fenceline population) are considered PESS and would represent the highest general population exposed to formaldehyde. None of the chronic non-cancer risk estimates were below the benchmark MOE of 3 for exposures primarily attributable to the TSCA COUs, indicating that chronic non-cancer risk is not expected. The highest risk estimate for cancer is 5.85×10^{-5}. The risk evaluation indicates risk for general population due to formaldehyde concentration in ambient air; however, formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde, and there is uncertainty in the geographic and temporal nature of the cancer risk estimates.

Based on the non-cancer risk estimates from acute and long-term exposures, coupled with the uncertainties around the precision of the cancer risk estimates and the magnitude of the cancer risk estimates above the benchmark, EPA found that general population exposures from ambient air emissions under the conditions of use of formaldehyde do not contribute to the unreasonable risk from formaldehyde.

Rubber products manufacturing

Summary: A public commenter (0266) stated support for EPA's determination that the rubber products manufacturing condition of use does not contribute to unreasonable risk in human health through ambient air exposure and discussed how this determination was well supported by the Agency's final residual risk assessment of the rubber tire manufacturing sector, finalized in 2020. The commenter reiterated that formaldehyde rarely emerged as one of the top drivers of cancer or non-cancer risk caused by emissions from rubber tire manufacturing facilities.

EPA Response: EPA appreciates the commenter's support expressed in this comment.

Composite panel mills

Summary: A public commenter (0202) discussed in detail the numerous factors that influence ambient air levels in composite panel production facilities, including wood contributing to both ambient and mill formaldehyde levels, combustion byproducts from mill equipment, and resins, and that TSCA

Title VI recognizes the ubiquity of formaldehyde in wood products, reflecting natural conditions from the wood fiber itself.
EPA Response: EPA recognizes the ubiquity of formaldehyde in wood products both from natural conditions from the wood fiber itself as well as the other conditions mentioned in this comment. EPA is only able to assess the reported releases, however, and not able to apportion a certain percent of the total reported release to any one condition.

Section 5.7 – Other comments

Methods for measuring formaldehyde in fertilizer substrates

Summary: A public commenter (0245) stated that the ability to detect free (un-reacted) formaldehyde at levels proposed by EPA in the presence of full-reacted "aldehyde moieties" has not been vetted in fertilizer substrates with rigorous scientific review. The commenter discussed efforts to establish standards for the measurement of free formaldehyde in urea and said that in May 2024, the New Work Item Proposal would be presented to the International Organization for Standardization Technical Committee 134 to seek authorization to accelerate the validation process for urea free formaldehyde methods, ultimately paving the way for standardized and reliable protocols for assessing formaldehyde levels in fertilizers worldwide.
EPA Response: EPA appreciates the status update on ongoing efforts to standardize measurement of formaldehyde in fertilizers.

Section 6 – Unreasonable Risk Determination

Comments associated with this issue are summarized in the subsections below.

Section 6.1 – Unreasonable risk to human health

General comments

Summary: A public commenter (0235) said that EPA states that formaldehyde presents an unreasonable risk of injury to human health under the conditions of use, but does not clarify which conditions of use actually present an unreasonable risk, only those that *contribute* to unreasonable risk. Without transparency regarding conditions of use, there is no way for stakeholders to understand which conditions of use are actually leading to health concerns or unreasonable risks, according to the commenter. Additionally, the commenter stated that EPA has piled multiple conservative measures on top of each other to reach its unreasonable risk determination. The commenter wrote that EPA's approach seems to be driven by a policy decision to be irrationally protective, rather than implementing an approach that would be predictive of actual risks. The public commenter added that EPA is seeking to eliminate all risks, not just unreasonable risks, which is not consistent with TSCA. The commenter said that EPA is conflating acceptable risk with unreasonable risk.
EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the TSCA

conditions of use (COUs). EPA has determined in the risk evaluation that formaldehyde as a chemical substance presents unreasonable risk under the COUs. EPA identified in the risk evaluation the COUs that significantly contribute to the unreasonable risk based on a number of factors including, the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. This risk determination is presented in the Unreasonable Risk Determination document, including a breakdown by COUs in Tables 2-1 and 2-2. The Unreasonable Risk Determination is based on the information in previous sections of the technical support documents that comprise the risk evaluation for formaldehyde and the appendices and supporting documents in accordance with TSCA section 6(b), as well as (1) the best available science (TSCA section 26(h)), (2) weight of the scientific evidence standards (TSCA section 26(i)), and (3) relevant implementing regulations in 40 CFR part 702. As explained in the final rule amending the *Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)* (89 FR 37028, May 3, 2024) at 40 CFR 702.39(f)(3), EPA will determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under the conditions of use and, where EPA makes a determination of unreasonable risk, EPA will identify the conditions of use that significantly contribute to such determination.

This approach reflects a plain reading of the TSCA statutory text and structure, is consistent with Congressional intent, and will enable the Agency's risk determinations to better reflect the potential for combined exposures across multiple conditions of use. A single determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses—or even a majority of uses—presents an unreasonable risk. Where one or more conditions of use for the chemical present an unreasonable risk, the chemical substance itself necessarily presents an unreasonable risk.

Summary: A public commenter (0261) stated that the more responsible and health-protective approach would be to use high-end estimates and that it is far better to be overprotective than under protective for worker inhalation risks. Additionally, the commenter stated that the Occupational Exposure Assessment was well-done, well organization, and the assumptions and data used were thoroughly documented.

EPA Response: EPA agrees with the commentor that the risk estimates based on high-end exposure levels (e.g., 95th percentile) are generally intended to cover individuals with sentinel exposure levels, such as PESS, whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. The high-end and central tendency exposures may show large variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. EPA generally relies on high-end exposure levels to make an unreasonable risk determination to capture vulnerable populations that are expected to have higher exposures. For occupational based conditions of use (COU), worker risks were evaluated using the high-end estimates to account for workers that may have high exposure or sentinel exposure at the workplace. In a majority of the COUs, non-cancer risks were found for both central tendency and high-end exposures, while cancer risks were mainly found for high-end exposures.

Summary: A public commenter (0241) agreed with EPA's finding that there is no unreasonable risk to the general public from formaldehyde releases to ambient air related to use of formaldehyde in manufacturing, including conditions of use pertaining to asphalt roofing and fiberglass mat manufacturing. The commenter also stated that the finding is in keeping with other recent EPA reviews. For example, in 2020, EPA completed its residual risk and technology review for asphalt

roofing manufacturing facilities subject to NESHAP, and found that risks due to emissions from asphalt processing and roofing manufacturing were acceptable.

EPA Response: EPA considered short-term acute inhalation risks and long-term cancer inhalation risks of formaldehyde in the ambient air after receiving feedback from the SACC review panel and public comments. EPA's risk determination for COUs pertaining to asphalt roofing and fiberglass mat manufacturing have not changed.

EPA did not identify risk due to acute inhalation exposures and cancer inhalation exposures to the general population, including people living or working near facilities (fenceline populations) from the ambient air for certain COUs that would contribute to the unreasonable risk of formaldehyde. The COUs included asphalt roofing and fiberglass mat manufacturing that would be included in the COUs, *Processing, incorporation in an article - adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing* and/or *Processing, incorporation into a formulation, mixture, or reaction product- Asphalt, paving, roofing, and coating materials manufacturing.*

Summary: A public commenter (0141) stated that three conditions of use that received preliminary unreasonable risk determinations are related to fertilizer manufacturing or its commercial use. However, the commenter said that these preliminary determinations do not, however, fully reflect the chemical process through which formaldehyde is used, the actual risk levels in the fertilizer manufacturing process, or a comprehensive evaluation of peer-reviewed studies and international assessments that is required pursuant to TSCA.

EPA Response: EPA utilized reasonable available information to identify the formaldehyde conditions of use, including CDR reported data and other sources. Reasonably available information indicates that formaldehyde's functional use in the manufacture of pesticides and fertilizers is as an intermediate for processing (as a reactant) and as an agricultural chemical for processing (incorporation into formulation, mixture, or reaction product. There may be different processes in which formaldehyde is incorporated into fertilizer – either directly as a reactant in which formaldehyde is used as feedstock in the production of another chemical product via a chemical reaction in which formaldehyde is consumed to form the product or incorporation into a formulation, mixture, or reaction which occurs when formaldehyde is added to a product (or product mixture), after its manufacture, for distribution in commerce.

EPA determined that fertilizer based COUs under the processing, industrial, and commercial categories significantly contribute to the unreasonable risk of formaldehyde. EPA presented the draft risk evaluation to the SACC for an independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA, fulfilling the requirements of TSCA. In addition, the draft risk evaluation was also available for public comment. EPA has taken in consideration the SACC review and all the public comments received in the final risk evaluation.

Summary: A public commenter (0232) stated that the unreasonable risk determinations would likely prohibit all conditions of use of formaldehyde.

EPA Response: EPA disagrees with this submitter's comment that the unreasonable risk determination would likely prohibit all COUs for formaldehyde. As reflected in the Risk Determination for

Formaldehyde, there are fifty-eight COUs that significantly contribute to the unreasonable risk of formaldehyde and five COUs that do not significantly contribute to the unreasonable risk. EPA will initiate risk management rulemaking to apply one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents an unreasonable risk. There are a variety of risk management tools available to EPA under TSCA section 6(a), and in accordance with TSCA section 6(c)(2), EPA will factor in, to the extent practicable, a number of considerations when selecting among prohibitions and other restrictions for any proposed or final rule. For example, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific COU of a chemical substance, EPA considers, to the extent practicable, 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 when the proposed prohibition or other restriction takes effect (TSCA section 6(c)(2)(C)).

EPA will undertake a separate public notice and comment period as part of the proposed TSCA section 6(a) risk management rulemaking for formaldehyde and will consider public comments and any additional information before finalizing the rulemaking.

Summary: A public commenter (0263) stated that EPA's inappropriate use of central tendency (as opposed to high-end estimates) chronic exposure estimates for its unreasonable risk determinations does not consider whether there is unreasonable risk to individuals with greater exposures, disregarding the exposure levels of 50% of the population and failing to meet its obligation under TSCA to identify any unreasonable risks to PESS.

EPA Response: As stated in the Unreasonable Risk Determination, in developing the exposure and hazard assessments for formaldehyde, EPA analyzed reasonably available information to ascertain whether some human populations may have greater exposure and/or susceptibility than the general population to the hazard posed by formaldehyde. The Agency identified as potentially exposed or susceptible subpopulation(s) (PESS) people who are expected to have greater exposure to formaldehyde, such as workers exposed to formaldehyde, those who frequently use consumer products containing high concentrations of formaldehyde, people living or working near facilities that emit formaldehyde, and people living in mobile homes and other indoor environments with high formaldehyde concentrations. Additionally, EPA identified as PESS people who may have greater susceptibility to the health effects of formaldehyde, including, infants and children, developing embryos and fetuses, people of reproductive age, and people who have pre-existing health conditions, such as asthma, allergies, nasal damage.

Risk estimates based on high-end exposure levels (e.g., 95th percentile) are generally intended to cover individuals with sentinel exposure levels, whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. As a result of public comments for the draft and further Agency review, EPA used high-end risk estimates to inform the risk determination for each occupational and consumer COU.

For occupational COUs, EPA provided a high-end and a central tendency risk estimate for the final risk evaluation – a change from the draft evaluation based on further Agency review. The high-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. The distributions may show large variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. Providing the central tendency (50th percentile) in addition to the high-end (95th percentile) of the dataset shows a more complete picture of the worker exposure scenarios that may result in unreasonable risk. For acute effects, the use of the high-end risk

estimate was used to make a risk determination as the hazard effect can occur after experiencing the exposure only once and no additional assumptions on frequency are needed. For long-term cancer risks, the risk determination was also based on the high-end risk estimates, unless otherwise noted, since EPA generally used monitoring data (i.e., workplace measured concentrations) that represents a range of exposure scenarios across workers and, in most cases, cannot be tied to specific worker exposure groups.

For consumer COUs, EPA only provided a high-end risk estimate to account for PESS populations using consumer-based products.

Summary: A public commenter (0283) stated that EPA's risk determinations arbitrarily and unlawfully disregard EPA's own calculations of unreasonable risk after EPA calculated unreasonable risk from virtually every condition of use that it considered. The commenter said that EPA concluded that: formaldehyde presents no unreasonable risks to the general population or to any fenceline community, not based on the risks that EPA calculated in those communities, but rather based on a comparison of estimated fenceline exposures from individual conditions of use to the maximum level of formaldehyde detected nationwide in the ambient air; that formaldehyde presents virtually no unreasonable cancer risks to workers because EPA characterizes those risks using less-protective median exposure values, as opposed to its typical practice of relying on "high end" exposure estimates; and discounts risks to workers and consumers by comparing their exposures to maximum detected indoor air concentrations and by assuming, without any support, that other TSCA regulations will address any unreasonable risks from formaldehyde in building materials.

EPA Response: As stated in the *Unreasonable Risk Determination*, whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA's calculations of exposure estimates are not calculations of unreasonable risk as the commentor states. Rather, a whole range of information as stated above is considered in order to make an unreasonable risk determination.

As a result of public comments on the draft and further Agency review, EPA revised both the ambient air assessment and the related discussion in the *Unreasonable Risk Determination*, and reduced the reliance on biogenic sources as comparison point. Short-term risk estimates for ambient air in this assessment are based on the maximum release scenario and the 95^{th} percentile modeled daily average exposure concentrations at 100 meters from a releasing facility. None of the risk estimates were below the acute benchmark MOE of 3 for exposures primarily attributable to the COUs, indicating that acute risk is not expected.

Long-term risk estimates for ambient air are based on the 95th percentile release scenario and the 95th percentile modeled annual average exposure concentrations within the area distance of 100 to 1,000 meters from a releasing facility as described in Section 2.4.2.1.2 and the *Ambient Air Exposure Assessment for Formaldehyde*. The population living or working within 100 m to 1,000 m of the facilities (or fenceline population) are considered PESS and would represent the highest general population exposed to formaldehyde. None of the non-cancer risk estimates were below the benchmark MOE of 3 for exposures primarily attributable to the TSCA COUs, indicating that non-cancer risk is not expected. The highest risk estimate for cancer is 5.85×10^{-5}.

The risk evaluation indicates risk for general population due to formaldehyde concentration in ambient air; however, formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde, and there is uncertainty in the geographic and temporal nature of the cancer risk estimates.

Based on the non-cancer risk estimates from acute and long-term exposures, coupled with the uncertainties around the precision of the cancer risk estimates and the magnitude of the cancer risk estimates above the benchmark, EPA has not identified risk to the general population from exposure to ambient air that would contribute to the unreasonable risk of formaldehyde.

Tables 2-1 and 2-2

Summary: A public commenter (0261) recommended a note at the top of both Tables 2-1 and 2-2 reminding readers what blank boxes mean. The commenter also requested to have the tables include the numerical estimates for each condition of use/endpoint/duration as was done in most of the first ten risk evaluations and the document where they can be found cited with the tables. The commenter asked why no subacute column was provided in Table 2-1 given that risk estimates were derived for this duration of inhalation exposure.

EPA Response: EPA has made clear what the blank boxes indicate in the Unreasonable Risk Determination for Formaldehyde and have implemented the recommendations for clarity. The blank boxes indicate that the particular exposure pathway and human health effect are not the basis to determine if a COU significantly contributes to the unreasonable risk. Because there are other considerations when making an unreasonable risk determination for each COU, EPA only utilizes a check-mark to indicate when a particular exposure route was the basis for the unreasonable risk determination. In addition, certain exposure routes for some COUs were not assessed because it was determined that there was no viable exposure pathway. These exposure routes are grayed out in Tables 2-1 and 2-2 of the *Unreasonable Risk Determination*. The exposure routes relevant to the risk determination are provided in Table 2-1 and Table 2-2 of the *Unreasonable Risk Determination*. With respect to the non-cancer chronic effects, the POD used is based on pulmonary function response in children, however, several SACC members had concerns with determining risk to workers based on health effects observed in children. See page 56 of the Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Public Virtual Meeting "Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde." Therefore, EPA did not use non-cancer effects on workers from chronic exposures risk estimates as basis for the formaldehyde unreasonable risk determination.

Occupational conditions of use

Summary: A public commenter (0214) expressed concern for EPA's determination that most occupational conditions of use contribute to the unreasonable risk presented by formaldehyde due to acute dermal exposures in the workplace, warranting its preliminary determination that formaldehyde presents an unreasonable risk. The commenter said that the lack of scientific basis for this determination demands that EPA re-issue the draft after EPA's risk assessment approaches have received SACC review.

EPA Response: As pointed out by the commenter, EPA determined a majority of the COUs under the manufacturing, processing, industrial, and commercial categories significantly contribute to the

unreasonable risk of formaldehyde due to acute dermal exposures. However, the draft also indicated that the unreasonable risk is due to acute inhalation exposures in the workplace. EPA presented the draft risk evaluation to the SACC for an independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA, fulfilling the requirements of TSCA. In addition, the draft risk evaluation was also available for public comment. EPA has taken into consideration the SACC review and all the public comments received in the final risk evaluation. EPA is issuing the final formaldehyde risk evaluation that revises the draft risk evaluation after considering the input received during the SACC review. The occupational COUs still significantly contribute to the unreasonable risk due to the acute inhalation and dermal, and also due to cancer risk to workers.

Summary: A public commenter (0263) stated that EPA's determinations of unreasonable risk in occupational settings discount and disregard EPA's own occupational risk estimates for cancer and non-cancer effects, without scientific justification. The commenter said that EPA's statement in the risk determination indicating that only one condition of use had cancer risks greater than 1-in-10,000 is a factually incorrect summary of the findings of the occupational risk characterization, and that the vast majority of occupational conditions of use had risk estimates exceeding the 1x 10-4 cancer risk benchmark. Furthermore, the high-end cancer risk estimates for almost all occupational conditions of use are greater than 1 x 10-4. Of the 49 conditions of use evaluated, 48 conditions of use have chronic risk estimates below an MOE of 3, and 47 conditions of use have chronic risk estimates below an MOE of 1. The commenter stated that an MOE below 1 indicates that the exposures are greater than the POD which, for formaldehyde chronic exposure, is the level observed in a human study where people experienced adverse reductions in lung function. In EPA's previous risk evaluations, these results would have translated into a determination that 48 occupational conditions of use contribute to unreasonable risks from formaldehyde based on chronic non-cancer risks. However, EPA instead divides the formaldehyde occupational conditions of use with MOEs lower than 3 into separate tiers, finding that 11 conditions of use contribute to unreasonable risk with a high level of certainty, and 36 condition of use are less certain to contribute to unreasonable risk. The commenter added that EPA provides no explanation for why the occupational condition of use "Finishing agents in textiles, apparel, and leather manufacturing" is considered less certain to contribute to unreasonable risk, and that EPA should revise its determination on the "paper products" condition of use to recognize that its risk estimates indicate that it does contribute to unreasonable risk for chronic non-cancer inhalation effects.

EPA Response: As stated in the *Unreasonable Risk Determination*, whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. A whole range of information as stated above is considered to make an unreasonable risk determination. A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark is a starting point for informing a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk.

Based on public comments and further Agency review, EPA amended its risk determination for occupational COUs to include high-end exposure estimates. For COUs assessed, worker risks were evaluated using the high-end estimate to account for worker exposure groups that may have high exposure or sentinel exposure at the workplace. In a majority of the COUs, non-cancer risks were found for both central tendency and high-end exposures. For a majority of the COUs, the cancer risk estimates for workers indicate risk, and for four COUs cancer risk estimates for ONUs indicated risk. There were no COUs assessed qualitatively for the occupational analysis. Based on the occupational risk estimates and related risk factors, EPA has determined that formaldehyde presents unreasonable risk due to:

- non-cancer risks from worker, including ONUs, acute inhalation exposure;
- non-cancer risks from worker acute dermal exposure; and
- cancer risk from worker, including ONUs, long term inhalation exposure.

With respect to the non-cancer chronic effects, the POD used is based on pulmonary function response in children, however, several SACC Committee members had concerns with determining risk to workers based on health effects observed in children. See page 56 of the Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Public Virtual Meeting "Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde."

In the risk determination, the COUs *Processing, incorporation into an article - Finishing agents in textiles, apparel, and leather manufacturing* significantly contribute to the unreasonable risk due to acute dermal exposure risks, acute inhalation exposure risks, and cancer inhalation risks for workers. EPA found that the Commercial COU, *Paper products; plastic and rubber products; toys, playground, and sporting equipment,* does not significantly contribute to the unreasonable risk.

Summary: A public commenter (0266) said that EPA has determined that there is an unreasonable risk of injury to workers for the rubber product manufacturing condition of use, in terms of acute non-cancer risk, but did not find that the condition of use contributes to an unreasonable risk of injury to human health through either chronic inhalation exposure or ambient air inhalation exposure pathways. The commenter strongly recommended that EPA reconsider its determination that this condition of use contributes to an unreasonable risk of injury to workers, in terms of acute non-cancer risk.

EPA Response: EPA determined that the COU *Processing into an article – additive in rubber product manufacturing,* significantly contributes to the unreasonable risk of formaldehyde due to workers acute inhalation risks and cancer inhalation risks. EPA has high confidence in this assessment based on a robust data set.

Summary: A public commenter (0244) expressed that EPA should not use different risk benchmarks for workers. The commenter stated that EPA discounted risks to workers in the Human Health Risk Assessment by using a less protective cancer benchmark for workers than for any other subpopulation. Specifically, the commenter said that EPA used a benchmark of 1 in 10,000 for workers, while EPA uses a benchmark of 1 in 1,000,000 for the general population. The commenter stated that EPA impermissibly used non-risk factors to downgrade the protection of this PESS.

EPA Response: A calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that the benchmark is not considered a "bright-line" and other risk related factors were considered such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration,

magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

For workers, EPA used a cancer benchmark of $1x10^{-4}$ consistent with 2017 NIOSH guidance (NIOSH Current intelligence bulletin 68: NIOSH chemical carcinogen policy). The $1x10^{-4}$ value is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks as appropriate.

Consumer conditions of use

Summary: Several public commenters (0286, 0205, 0229) stated that reporting unreasonable risk by consumer condition of use categories and subcategories requires that all conditions of use within the category or subcategory have similar risk profiles. The commenters said that if categories are defined too broadly, EPA risks regulating or banning products that do present an unreasonable risk, and suggested that EPA assign unreasonable risk to the specific consumer exposure(s) in the subcategory, rather than the entire category. For example, one of the commenters (0286) said that Figure 2.1 in the *Draft Consumer Exposure Assessment* should clearly show that all acute consumer exposures from automobile interior plastics and rubbers are below risk levels that could be classified as unreasonable risk. The commenters (0286, 0205, 0229) added that each consumer condition of use is compounded by subcategories which include multiple consumer exposure scenarios to both liquid and solids, even though solid products are excluded from the consumer product category for dermal risk assessment. As a result, the commenters suggested that EPA should specify the consumer exposure scenario driving/not driving the risk and the not be assigned to the broader condition of use category or subcategory. One of the commenters (0229) added that EPA should develop multiple consumer exposure scenarios for most conditions of use and apply separate CEM modeling to each in order to develop more refined, product/article-specific exposure assessments. The commenter (0229) stated that EPA used "worst-case" exposure scenarios for each condition of use, despite calling them "representative."

EPA Response: As mentioned in the unreasonable risk determination, since EPA has determined that formaldehyde presents an unreasonable risk under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. The risk management will consider the different risk estimates from the products and articles included in each category and subcategory.

In response to commentor (0229), EPA developed multiple exposure scenarios for COUs in which multiple products could potentially be included. While CEM modeling was used for each exposure scenario assessed, only the most conservative, worst-case scenario was used in order to identify whether each COU significantly contributes to the determination of unreasonable risk for formaldehyde. This approach ensures that any unreasonable risk to a potentially exposed or susceptible subpopulation is integrated in the risk evaluation and captured in the risk determination, as required under TSCA section 6(b)(4)(A) and (F)(i).

Summary: A public commenter (0230) stated that fiberglass and mineral wool insulation present limited exposure to formaldehyde for consumers. For example, insulation products in which formaldehyde is a component of the binder are cured at high temperatures causing a chemical reaction

that virtually eliminates the free-formaldehyde content in the finished product. Additionally, the commenter said that the CPSC found that emissions from fibrous glass insultation and ceiling tiles would have little impact on in-home formaldehyde levels. The commenter also discussed a 1991 NIOSH study that found extremely low formaldehyde concentrations observed in classrooms insulated with fibrous glass. Finally, the commenter said that their member companies rely on certification to verify their products have low formaldehyde emissions. Thus, the commenter concluded that exposures and potential releases of formaldehyde from fiberglass and mineral wool products are well controlled and do not support being deemed a condition of use presenting an unreasonable risk.

EPA Response: TSCA § 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA must apply fact and professional judgment in determining whether or not a particular circumstance is known, intended or reasonably foreseen—and should not select among those circumstances for inclusion or exclusion. EPA must evaluate all COUs to determine if the chemical presents unreasonable risk, and, where EPA makes a determination of unreasonable risk, EPA will identify the COUs that significantly contribute to such determination regardless of other federal statutes regulating fiberglass materials.

Based on the information presented, fiberglass and mineral wool insulation would be considered a COU under *Processing 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* because formaldehyde is used in the manufacture of this product. For consumers, fiberglass and mineral wood insulation would be considered a COU under *Consumer use - 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.* As stated in the Occupational Exposure Assessment, fiber glass and mineral wool building insulation products typically contain 3 to 6 percent by weight cured formaldehyde binder with a maximum concentration range of 30 to 60 percent for processing –incorporation into article – construction per the 2020 CDR (U.S. EPA, 2020a). Other sources indicate the resins, which are used in fiberglass composite material manufacturing, contain up to 13 percent of free formaldehyde (NICNAS, 2006). EPA did consider the submitters comments, including the additional information that during fiberglass or mineral wool insulation manufacturing, virtually all free formaldehyde content is eliminated during the curing process of these materials. However, EPA has determined that the *Processing 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* COU, which contains a wide range of products including fiberglass and mineral wood insulation, significantly contributes to the unreasonable risk of formaldehyde to workers, including ONUs, due to acute and dermal inhalation exposures and cancer inhalation exposures.

For the consumer COU, *Consumer use - 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*, EPA has also determined that this COU significantly contributes to the unreasonable risk of formaldehyde due to acute inhalation and dermal exposures to consumers.

Summary: Several public commenters (0162, 0174, 0188, 0196, 0184, 0194, 0198, 0217, 0228) stated that they agree with EPA's conclusion that conditions of use related to exposure in residences from wood articles do not contribute to an unreasonable risk of formaldehyde, nor do the other conditions of

use evaluated. The commenters added that given that the majority of emissions from wood products are biogenic and should be excluded from the draft risk evaluation, EPA has failed to explain how the small amount of emissions attributable to non-biogenic sources in wood products contributes to an unreasonable risk under any conditions of use. The commenters said that emissions are mitigated by barriers on wood products and formaldehyde's rate of decay, this there is no unreasonable risk to consumers and bystanders from wood articles based on acute, non-cancer effects from dermal and inhalation exposures. The commenters stated that there is no distinction between inhalation exposures from wood products to consumers in residential and non-residential settings, nor is there evidence of a meaningful risk of dermal exposures to consumers or workers from wood, therefore, wood products do not contribute to an unreasonable risk in indoor air for consumers in all situations.

Several public commenters (0202, 0205, 0227, 0233) stated that EPA should make clear that wood and wood articles, including composite wood products, do not pose an unreasonable risk through dermal exposure. A public commenter (0205) added that cleaning, unloading and loading, and other worker activities associated with contact with formaldehyde in liquid form are the basis for the dermal unreasonable risk, based on the 47 conditions of use that EPA specified in having an unreasonable risk due to dermal sensitization from exposure to liquids containing formaldehyde. Another public commenter (0227) added that EPA has acknowledged that composite wood products do not contribute to unreasonable risk in residences, but for the same products in commercial and institutional settings, EPA concluded that they contribute to unreasonable risk. Finally, a public commenter (0233) added that this determination (i.e. "does not pose an unreasonable risk") should expressly apply to all types of risk (acute, chronic, and cancer), all exposures (occupational, consumers, and the general population), and across all potential pathways (dermal, inhalation).

EPA Response: EPA disagrees that a vast majority of wood products are considered biogenic sources and should therefore be excluded from the risk evaluation. EPA does not consider biogenic formation of formaldehyde, such as emissions from trees, plants, and soil microbes, to be conditions of use under TSCA section 3(4). The biogenic formation can significantly contribute to total formaldehyde concentration in ambient air. For purposes of the risk evaluation for formaldehyde, EPA estimated biogenic exposures for context in the ambient air exposure assessment. TSCA section 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" and wood articles were considered as intended, known, or reasonably foreseen uses of formaldehyde.

EPA has specifically addressed these concerns and has clarified which wood product COUs contribute significantly to risk via dermal, inhalation, and indoor air exposures within the Unreasonable Risk Determination for commercial uses, consumer uses, and the aggregate indoor air analysis.

For two commercial COUs that contain wood products, *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 product* and *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* the exposure scenario is based on monitoring data of installation and demolition of building and construction materials. EPA does not expect that the monitoring data reflects articles covered under TSCA Title VI as explained in further detail in the *Indoor Air Exposure Assessment for Formaldehyde*, Section 4.2.3.

For two consumer COUs that contain wood products, *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* and *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*, EPA found acute inhalation risks. Both COUs contain composite wood products regulated under TSCA Title VI. However consistent with EPA's findings as part of the Indoor Air Exposure Assessment for Formaldehyde and as explained in Section 2.1.6. of the Unreasonable Risk Determination, EPA 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.

Summary: A public commenter (0244) stated that EPA inappropriately dismissed consumer risks from its misuse of monitoring data and uncertainty. The commenter said that EPA found chronic non-cancer risks to consumers below a benchmark MOE of 3 for 3 of 8 conditions of use, indicating adverse chronic non-cancer effects due to formaldehyde exposure from these consumer conditions of use. However, EPA dismissed risk due to both uncertainty and comparison to indoor air values, which is not scientifically justifiable, as neither of these approaches are common in risk assessment.

EPA Response: As stated in the *Unreasonable Risk Determination*, EPA does not expect most consumer exposures to be chronic in nature because product use patterns generally tend to be infrequent with relatively short durations of use. Therefore, EPA did not consider risks for consumers due to long-term exposures, but EPA considered chronic exposures to the general population from many sources of formaldehyde within homes and vehicles under the *Indoor Air Exposure Assessment for Formaldehyde*.

Summary: Two public commenters (0263, 0283) stated that EPA does not provide any supportable argument that consumer products in the indoor air scenario do not contribute to unreasonable risk of formaldehyde. The commenters said that EPA first states that four consumer conditions of use are contributors to unreasonable risks due to exposures in homes and automobiles, however, just two pages later, EPA says that the four conditions of use assessed for the indoor air scenario do not contribute to unreasonable risk. One of the commenter (0263) added that EPA attempts to justify the finding of no unreasonable risk by referencing the TSCA Title VI standards for formaldehyde emissions from composite wood products, arguing that residential indoor exposure will be reduced by ongoing implementation of these standards, however EPA provided no analysis to support this statement. The commenter said that EPA should revise its determination for the conditions of use associated with elevated indoor air concentrations of formaldehyde to "contributes to unreasonable risk."

EPA Response: There are many sources of formaldehyde within homes and vehicles. These include sources from articles such as building materials, wood flooring, paint, and fabrics as well as combustion sources like candles, fireplaces, or stoves. Additionally, consumer products containing formaldehyde may also add to indoor concentrations of formaldehyde. EPA considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air, but the monitoring data do not provide information about the relative contributions of each source. EPA also used models to estimate formaldehyde concentrations from TSCA conditions of use that cannot otherwise be distinguished from other sources of formaldehyde reflected in measured indoor concentration data. EPA used the Consumer Exposure Model (CEM) to estimate long-term

indoor air exposures and refined the results with IECCU modeling to estimate acute and long-term risks for exposure to formaldehyde in residential indoor air associated with specific TSCA COUs.

The CEM is commonly used by EPA to estimate exposure to chemicals in consumer products and articles for TSCA conditions of use; however, the model tends to over-estimate indoor air concentrations since it has a constant rate of formaldehyde emissions. Previous studies have demonstrated that articles generally exhibit an initial period of high emissions, followed by a rapid, non-linear decline in the emission rate. To address the uncertainties for the CEM, EPA modeled indoor air concentrations using the IECCU model. However, based on studies conducted in residential homes, it is possible that air concentrations resulting from emissions from articles may remain elevated longer than the IECCU models indicate. In general articles with large surface areas may contribute significantly to formaldehyde concentrations measured in homes. Though, the extent of this contribution is variable, depending on the article, consumer preferences, room of use, home size and configuration, ventilation rates, and relevant meteorological parameters (*i.e.*, temperature and humidity). Using both models provides the potential range of formaldehyde concentrations in indoor air given the uncertainties of both models. The lowest long-term non-cancer risk estimate calculated with CEM is 0.59 (for construction materials) and with IECCU all the risk estimates are greater than the benchmark MOE of 3. The highest cancer risk estimates calculated with CEM was $3.6X10^{-4}$ (for construction materials), and with IECCU was $7.03X10^{-5}$ (for construction materials). Beyond the scope of the models were other variables involved during the production of composite wood products subject to TSCA Title VI, such as resin chemistry, core type, and curing process.

Summary: A public commenter (0270) stated that EPA should find that foam, fabric, and other covers in home furnishings do not contribute to an unreasonable risk determination, which is supported further by the fact that many furniture and mattress foams are manufactured without formaldehyde through the CertiPUR-US program. The commenter added that EPA should retain its finding that there is no unreasonable risk associated with furniture seat covers. Both of these conclusions are supported by the submitted data from chamber tests conducted to identify the potential "worst case" formaldehyde emissions from common foam, textiles, and raw materials used in constructing furniture products in the U.S.

EPA Response: While not intentionally added to the polyurethane foam, because formaldehydye is formed due to the degradation of a foam product, formaldehyde is therefore reasonably foreseen to be present. As such, the use of polyurethane foam becomes a condition of use (COU) under which EPA must evaluate. There are a number of general categories of circumstances that are considered conditions of use that generally must be included within the scope of TSCA risk evaluations, including and the presence of a chemical as an impurity or within an article.

Polyurethane foam is considered a COU and falls under these two categories:

- *Commercial use - 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.*
- *Consumer use - 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.*

The commercial use of foam was evaluated under the Occupational Exposure Scenario (OES), *Installation and demolition of formaldehyde-based furnishings and building/ construction materials in residential, public and commercial buildings, and other structures.* EPA determination is that the commercial COU significantly contributes to the unreasonable risk of formaldehyde due to acute inhalation and dermal exposures, and cancer due to long-term inhalation exposures.

The consumer use of foam was evaluated under two Consumer Exposure Scenarios (CES): *Foam insulation (automobile) and Foam insulation (living room).* . EPA found that the COU significantly contributes to the unreasonable risk of formaldehyde due to acute inhalation and dermal exposures.

Summary: A public commenter (0244) stated that EPA should not dismiss workers risks by comparison to indoor air values. For example, the commenter said that EPA compared its OEV of 14 g/m^3 to the indoor air levels of 20-40 g/m^3 and did not explain how indoor air values measures for residential spaces is appropriate for occupational spaces given the differences in sources that would contribute to the "background" indoor air levels. Rather, the commenter suggested that EPA should consider how TSCA sources of formaldehyde exposure contribute to the overall risk from all sources of exposure.

Similarly, another public commenter (0283) stated that EPA downgrades its confidence in its risk calculations for occupational and consumer conditions of use based on a comparison between the calculated exposure from a condition of use and the monitored concentrations in the indoor air. The commenter said that this comparison fails for multiple reasons. First, the total levels of formaldehyde in indoor air do not diminish the risks from formaldehyde's conditions of use or make EPA's calculations of such risks any less reliable. Second, EPA improperly reduces its confidence in occupational chronic risk estimates based on a comparison to total formaldehyde levels in residential homes, as opposed to workplaces. The commenter suggested that EPA should eliminate these comparisons and their associated characterizations of level of certainty from the final risk evaluation.

EPA Response: Based on public comment and further Agency review, in the final *Unreasonable Risk Determination*, EPA did not compare risk estimates to indoor air or ambient air levels. EPA provided a high-end and a central tendency risk estimate based on the worker exposure data. The high-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. The distributions may show large variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. Providing the central tendency (50th percentile) in addition to the high-end (95th percentile) of the dataset shows a more complete picture of the worker exposure scenarios that may result in unreasonable risk, including those worker exposure groups that may have greater exposure and could represent a sentinel exposure at the workplace. For acute effects, the use of the high-end risk estimate was used to make a risk determination as the hazard effect can occur after experiencing the exposure only once and no additional assumptions on frequency are needed. For long-term exposures leading to potential cancer risks to workers, the EPA considered the high-end risk estimates, unless otherwise noted, since EPA generally used monitoring data (*i.e.*, workplace measured concentrations) that represents a range of exposure scenarios across workers and, the high-end would represent sentinel exposure at the workplace.

Based on the occupational risk estimates and related risk factors, EPA has determined that formaldehyde presents unreasonable risk due to:

- non-cancer risks from worker, including ONUs, acute inhalation exposure;
- non-cancer risks from worker acute dermal exposure; and
- cancer risk from worker, including ONUs, long term inhalation exposure.

Regarding the *Indoor Air Exposure Assessment*, EPA presented monitoring concentrations of formaldehyde from occupational and residential settings. Occupational indoor air exposures were not dismissed and were discussed in Section 3.1.5 (Commercial and Other Buildings). EPA presented a supplemental summary of formaldehyde concentrations identified from several well-established residential and nonresidential indoor air monitoring studies to provide additional context to the TSCA formaldehyde indoor air exposure assessment. These data highlight the various indoor environments from which an individual may receive total daily formaldehyde exposures. These monitoring data do not differentiate between TSCA and other sources of formaldehyde. This means that EPA is unable to determine what portion of the reported indoor air concentrations are from TSCA vs other sources.

For the final *Indoor Air Exposure Assessment*, EPA has medium confidence that the exposure scenarios evaluated in this assessment are reasonable and representative of people who spend most time indoors. And EPA did not identify risk from general population exposure to the indoor air in homes and automobiles for common household products and automobile interiors that would contribute to the unreasonable risk of formaldehyde.

Section 6.2 – Unreasonable risk to the environment

Comments in support of EPA's unreasonable risk determination for the environment

Summary: A public commenter (0230) stated that the Agency made a sound case for concluding there is no unreasonable risk posed by formaldehyde to the environment. The commenter agreed with the multiple lines of evidence supporting the Agency's high level of confidence in concluding there is: (1) no risk to aquatic organisms relative to toxicity endpoints; (2) no risk to terrestrial organisms relative to toxicity endpoints via the land pathway; (3) no risk to terrestrial organisms via the dietary pathway; and (4) no risk to terrestrial organism via the air pathway.

EPA Response: EPA appreciates the comment. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde..

Section 6.3 – Other comments

Comments seeking additional information/clarification

Summary: Two public commenters (0247, 0202) said that EPA must explain what is meant by the term "unreasonable," and specifically how certain risks were found to be "unreasonable." One of the commenters (0202) said that "unreasonable risk" is not defined in TSCA and that the draft risk evaluation contained no discussion of reasonableness (or non) of risk for occupational conditions of use. The commenter stated that EPA assumed that the reported risks it developed through repetitive, worst-case scenarios were unreasonable and then ascribed higher or lesser certainty depending on the inputs.

A public commenter (0244) stated that EPA must use monitoring data and non-TSCA exposure to contextualize risks rather than dismiss them. The commenter said that unreasonable risk is not defined in TSCA and, as acknowledged by EPA, there is a need for EPA to make the determination of unreasonable risk on a case-by-case basis. The commenter said that EPA should consider the combination of risks from TSCA conditions of use and risks from other sources of formaldehyde, in order to calculate and consider how risks from TSCA sources of formaldehyde contribute to the overall risks faced by an individual. The commenter said that EPA must not dismiss risks due to unfounded uncertainty and follow an aggregate and holistic approach to assessing risk and determining whether risk is unreasonable.

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified by EPA as relevant to this risk evaluation, under the conditions of use (COUs). Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses on aggregate exposures. The *Unreasonable Risk Determination* explains how the Agency considered these risk related factors in the determination.

For example, for COUs evaluated quantitatively, to determine if a COU contributed significantly to unreasonable risk, EPA compared the risk estimates of the scenario used to evaluate the COUs and considered whether the risk from the COU was best represented by the central tendency or high-end risk estimates.

In the formaldehyde unreasonable risk determination, EPA reviewed risk estimates with an overall confidence rating of slight, moderate, or robust and the Agency considered COUs with indeterminate exposures and COUs with limited reasonably available information. In general, EPA makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of moderate or robust—because those confidence ratings indicate the scientific evidence is adequate to characterize risk estimates despite uncertainties or is such that it is unlikely the uncertainties could have a significant effect on the risk estimates.

As required by TSCA, this risk evaluation determines whether formaldehyde presents an unreasonable risk of injury to health or the environment under the conditions of use, and identifies the conditions of use that significantly contribute to such determination.

Comments with suggested revisions to the draft risk determination

Summary: A public commenter (0283) stated that where the risk evaluation presents multiple risk calculations for a particular condition of use using both central tendency and high-end exposures, it is often difficult to determine what exposure scenario was used in EPA's unreasonable risk determinations. The commenter said that EPA failed to distinguish between conditions of use for which EPA calculated risks below its unreasonable risk benchmarks and conditions of use for which EPA calculated risks above those benchmarks but still found no unreasonable risk for reasons unrelated to those calculations. EPA also fails to say whether its findings of "less certainty" in specific risk determinations were due to concerns about the reliability of the underlying data, a comparison to

ambient or indoor exposure concentrations, or both, according to the commenter. The commenter said that EPA provided no summary table of its risk calculations and unreasonable risk determinations, as it has for past evaluations, and instead, the public must locate the supporting documents in order to identify EPA's risk estimates. The commenter added that EPA should replace the box and line charts used to depict risks and instead provide a narrative description of the risks associated with individual conditions of use. Finally, the commenter requested that EPA make that summary document available, along with fact sheets that clearly explain EPA's calculations of elevated risks to workers, consumers, and fenceline communications (with the latter risks broken down by facility and geographic location), as well as share those materials with impacted labor unions as well community organizations in areas where EPA has calculated heightened risks from formaldehyde releases. The commenter requested that EPA find that all conditions of use which exceed EPA's accepted benchmarks, individually or in combination with other conditions of use, contribute to unreasonable risk.

EPA Response: EPA considered the suggested changes and, to the extent practical, implemented them. EPA lists each COU that significantly contributes to the unreasonable risk in Tables 2-1 and 2-2 of the *Unreasonable Risk Determination*. EPA also lists and shows the relevant exposure scenarios in each respective technical support document through various figures as a way to supplement the harder to read risk calculators. Where EPA found necessary, certain exposure scenarios and EPA's rationale are explained in the *Unreasonable Risk Determination*.

As stated in the *Unreasonable Risk Determination*, whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark is a starting point for informing a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk. The *Unreasonable Risk Determination* explains how the Agency considered risk related factors beyond the MOES in the determination.

Additional comments

Summary: A public commenter (0263) stated that EPA should make the following revisions to the risk determination before it is finalized:

- "EPA should revise the unreasonable risk determination to clearly present the risk estimates used in making the determination for each COU.
- EPA should clearly state the rationale for its unreasonable risk determination for each individual condition of use.
- EPA should delete irrelevant comparisons of formaldehyde exposure concentrations estimated for the conditions of use to measured background, indoor air and outdoor air formaldehyde concentrations from the risk determination.
- EPA should remove the two-tiered approach to unreasonable risk determination, deleting the label 'EPA has less certainty of the contribution to the unreasonable risk,' and instead state that each condition of use with high risks 'contributes to unreasonable risk.'

- EPA should use high-end exposure and risk estimates, representing the 95th percentile or higher exposure, for unreasonable risk determination for all conditions of use.
- The determinations for any condition of use with a central tendency or high-end exposure estimate that is greater than the chronic non-cancer POD for adverse reduction in lung function should be 'contributes to unreasonable risk;' this determination also applies to conditions of use with lower exposure estimates that also represent high non-cancer risks.
- EPA should revise its determination to 'contributes to unreasonable risk' for any condition of use whose emissions to ambient air result in modeled 1-in-1,000,000 or greater risks of cancer to fenceline communities. Ambient concentrations from combinations of facilities/conditions of use, rather than just individual facilities, should be accounted for in calculating risks used for the determination. EPA should use estimated ambient air concentrations of formaldehyde from HEM in addition to IIOAC in the risk determination for general population exposure.
- EPA should estimate cancer risks for the indoor air scenario and use these risk estimates for the risk determination. EPA should revise its determination to 'contributes to unreasonable risk' for any condition of use whose emissions to indoor air result in modeled 1-in- 1,000,000 or greater risks of cancer; it should also make this determination based on the high non-cancer risks based on modeled and monitored indoor air concentrations. EPA should not discount high cancer and non-cancer indoor air risks based on anticipated exposure reductions from TSCA Title VI composite wood standards without a clear and compelling demonstration that those standards have eliminated the unreasonable risk.
- EPA should incorporate the following considerations into its unreasonable risk determinations: underestimation of cancer and non-cancer risks from a failure to evaluate aggregate exposure; underestimation of cancer risks due to unquantified leukemias and other tumors; and underestimation of non-cancer risks due to the use of an insufficient human variability adjustment factor and a scientifically unsupported non-cancer risk characterization method (i.e., the MOE approach)."

EPA Response: In the final *Unreasonable Risk Determination*, EPA is presenting its final conclusion regarding the unreasonable risk presented by formaldehyde. Risk estimates are presented in the *Human Health Risk Assessment*. The *Unreasonable Risk Determination* presents the rationale for EPA's determination as to whether a risk is unreasonable and identifies the COUs that significantly contribute to a determination that a chemical substance presents an unreasonable risk. EPA explains how the risk estimates were used in making the determination and whether other risk-related factors were considered. EPA revised the language in the *Unreasonable Risk Determination*; however, it is important to note that there are many sources of formaldehyde and the formaldehyde sources in the risk evaluation involve the manufacturing, processing, distribution in commerce, use, and disposal of formaldehyde and formaldehyde-containing products and articles that are subject to TSCA.

EPA's use of a two-tiered approach in the Draft Risk Evaluation was a recognition of uncertainties. Due to the magnitude of available scientific information on formaldehyde coupled with the complex toxicology and exposure profiles for formaldehyde, EPA acknowledged that the evaluation of formaldehyde hazard and exposure is challenging. Following the peer review process and the public comment period, EPA issued a final evaluation that includes a final determination of whether, under its TSCA conditions of use, formaldehyde presents an unreasonable risk of injury to health or the environment.

For each occupational COU, EPA provided a high-end and a central tendency risk estimate. The high-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. The distributions may show large variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. Providing the central tendency

(50th percentile) in addition to the high-end (95th percentile) of the dataset shows a more complete picture of the worker exposure scenarios that may result in unreasonable risk, including those worker exposure groups that may have greater exposure and could represent a sentinel exposure at the workplace. For acute effects, the use of the high-end risk estimate was used to make a risk determination as the hazard effect can occur after experiencing the exposure only once and no additional assumptions on frequency are needed. For long-term exposures leading to potential cancer risks to workers, the EPA considered the high-end risk estimates, unless otherwise noted, since EPA generally used monitoring data (*i.e.*, workplace measured concentrations) that represents a range of exposure scenarios across workers and, the high-end would represent sentinel exposure at the workplace.

For each consumer COU, EPA considered high-end risk estimate to account for PESS populations using consumer-based products.

In this final risk evaluation, EPA has refined the ambient air analysis and has included risk estimates based on IIOAC and HEM models.

As stated in the *Unreasonable Risk Determination*, whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. A whole range of information as stated above is considered in order to make an unreasonable risk determination. EPA also considered, where relevant, the Agency's analyses on aggregate exposures. A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark is a starting point for informing a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk. The *Unreasonable Risk Determination* explains how the Agency considered risk related factors beyond the MOEs in the determination. For the final *Indoor Air Exposure Assessment*, EPA has medium confidence that the exposure scenarios evaluated in this assessment are reasonable and representative of people who spend most time indoors. EPA considered monitoring data and the CEM and IECCU models. As explained in the *Unreasonable Risk Determination*, EPA did not identify risk from general population exposure to the indoor air in homes and automobiles for common household products and automobile interiors that would contribute to the unreasonable risk of formaldehyde.

Summary: A public commenter (0219) stated that, in rendering this unreasonable risk determination, EPA clearly failed to assess potential risk from conditions of use of formaldehyde "within the broader context of all sources of formaldehyde, some of which people have been exposed throughout the course of human existence."

EPA Response: TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use (COUs). Formaldehyde sources in this risk evaluation involve the manufacturing, processing, distribution in commerce, use, and disposal of formaldehyde and formaldehyde-containing products and articles that are subject to TSCA.

Summary: A public commenter (0219) stated that EPA has unlawfully interpreted "unreasonable risk" as "zero risk" and stated that TSCA demarcates risk evaluation from risk management (an unreasonable risk determination is the purview of risk evaluation, and the role of risk management is to eliminate that unreasonable risk).

EPA Response: EPA disagrees with the commenter's assertion that the Agency is interpreting "unreasonable risk" as ensuring "zero risk." EPA's determination of unreasonable risk depends on risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses of aggregate exposures. While the commenter may disagree with EPA's application of uncertainty factors, or otherwise disagree with what level of risk is reasonable (which is commonly understood as "appropriate in a particular situation," *see, e.g.*, OXFORD ENGLISH DICTIONARY), EPA's approach for formaldehyde has not looked to find unreasonable risk unless there is no risk from formaldehyde. Instead, as with other risk evaluations, EPA has conducted its risk assessment consistent with the best available science, including by applying uncertainty factors where appropriate.

As part of the risk evaluation process, EPA must (1) evaluate both hazard and exposure, (2) exclude consideration of costs or other non-risk factors, (3) use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and (4) ensure decisions are based on the weight-of-scientific-evidence. EPA has conducted its risk evaluation for formaldehyde consistent with these obligations, and ultimately determined that formaldehyde presents unreasonable risk. Following the final risk evaluation, EPA will initiate risk management for formaldehyde by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents an unreasonable risk.

Summary: A public commenter (0219) stated that under EPA's "single risk determination" approach for formaldehyde, states could take the position that preemption only applies to those conditions of use that are included in a section 6(a) rule, or that are the subject of a "no unreasonable risk" determination under section 6(i). This approach would exclude from the scope of preemption those conditions of use that are included in a risk evaluation, but are not ultimately included in a section 6(a) rule or section 6(i) order. The commenter added that the draft risk evaluation further determines that four of the conditions of use are not expected to contribute to the unreasonable risk at all. However, under EPA's approach to risk evaluations, none of these conditions of use which are unlikely to present an unreasonable risk by EPA's own criteria will benefit from preemption because these conditions of use are unlikely to be addressed in a section 6(a) rulemaking (to prevent the unreasonable risk) or a section 6(i) order (a "no unreasonable risk" determination). Thus, states will inevitably argue that they are free to regulate these uses even though they have been evaluated by EPA. The commenter said that EPA's vague "contribution" approach to the conditions of use also casts doubt on the Agency's overall determination that formaldehyde, as a whole chemical, presents an unreasonable risk.

EPA Response: As EPA explained in the final rule, *Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)*, 89 FR 37028, 37036 (May 3, 2024), "Commenters have a fundamental misunderstanding of EPA's interpretation of TSCA section 18 as it relates to preemption. ... Permanent preemption is triggered under section 18(a)(1)(B)(ii) if EPA issues first a scope of the risk evaluation under section 6(b)(4)(D) and then a section 6(a) final rule or section 6(i)(1) determination based on the risk evaluation. The scope of this preemption is addressed in section 18(c)(3) and EPA reads this provision to apply permanent preemption to any condition of use within

the scope of the risk evaluation which is the support document for any resulting section 6(a) rule or section 6(i)(1) determination. In the context of a section 6(a) rule, this is the case irrespective of whether those uses contribute to the unreasonable risk and/or are targeted for risk management." Thus, all conditions of use addressed in the risk evaluation which supports the risk management options addressed in a TSCA section 6(a) rule are subject to TSCA section 18 permanent preemption even if a condition of use for a chemical substance does not significantly contribute to the unreasonable risk.

Consistent with the final procedural rule (89 FR at 37035-36; codified at 40 CFR 702.39(f) (2024)), after considering the risks posed under the conditions of use of formaldehyde, EPA determined in the final risk determination that formaldehyde presents an unreasonable risk of injury to health under the conditions of use, and identified the conditions of use that significantly contribute to such determination.

Summary: A public commenter (0178) stated that making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with existing regulations that may be applicable to formaldehyde. Rather, it reflects the Agency's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards. The commenter added, "will EPA be subsequently publishing its judgement on appropriate PPE for the labeled conditions of use, i.e. will use of PPE as labeled mitigate unreasonable risk?"

EPA Response: EPA estimated risks without assuming that personal protective equipment is in place because EPA cannot guarantee, absent reasonably available information confirming that, in all cases, personal protective equipment is provided and worn, and effective at reducing exposures. Formaldehyde is subject to a wide range of federal and state regulations and reporting requirements, including requirements by the Occupational Safety and Health Administration (OSHA). EPA recognizes that there are subpopulations of workers who are not covered by Occupational Safety and Health Administration (OSHA) standards. However, EPA also is aware that many employers are subject to OSHA standards and do take measures and provide equipment to protect the safety of workers in their facilities that can reduce risk if fitted and worn properly.

To ensure the Agency is adequately accounting for potential effects to all potentially exposed or susceptible subpopulations, and based on the reasonably available information, EPA did not assume that such personal protective equipment is always used and effective at reducing worker exposures when making its unreasonable risk determination. However, where the reasonably available information indicates that, for some companies or facilities, personal protective equipment is in use for certain conditions of use and is adequate to address the unreasonable risk, EPA can consider that in risk management, as appropriate.

Section 7 – Systematic review

IRIS Assessment

Summary: A public commenter (0230) stated that the methods for systematic review under the IRIS program differ from those applied under TSCA, therefore, conclusions regarding the review of studies on hazard and dose response assessment may not have aligned through both programs. Most notably, the commenter said that their approaches to assessing quality/risk of bias of the underlying evidence are not consistent. The commenter listed studies for consideration regarding health outcomes in

insulation workers and other formaldehyde-exposed workers, which EPA did not consider. The public commenter expressed that, by solely relying upon the draft IRIS Assessment, EPA ignored valuable studies.

A public commenter (0161) stated that the underlying draft IRIS Assessment did not use a pre-established systematic review protocol. Similarly, another public commenter (0260) stated that the draft IRIS Assessment for formaldehyde is the *only* IRIS Assessment undergoing development for which no pre-established systematic review protocol was released for public comment.

EPA Response: Sections 2.2 and 2.3 of the IRIS assessment describes the approach used for searching and screening literature and evaluating study quality in that assessment. As described in Section 5.5.2 and Table 5-4 of the TSCA Systematic Review Protocol for formaldehyde (included as a supplemental file to the risk evaluation), EPA performed a crosswalk comparison of IRIS and TSCA domains, metrics and criteria considered in data quality evaluation of each study. EPA used this to develop a new harmonized data quality evaluation form for the TSCA risk evaluation that incorporates key elements of both programs. This approach facilitates efficient integration of information previously evaluated by IRIS without duplicating work.

TSCA systematic review

Summary: A public commenter (0260) stated that EPA has failed to integrate past peer review advice on its approach to systematic review. In February 2021, the NASEM committee released its study report and concluded that EPA's 2018 systematic review document did not meet the criteria of "comprehensive, workable, objective, and transparent" and EPA stated publicly that it would not use its 2018 systematic review documents again. However, the Agency used this document in the August 2020 Final Scope of the Risk Evaluation for Formaldehyde but did not revise or replace the 2020 Final Scope after NASEM's report. Additionally, the commenter said that EPA failed to integrate direction from its 2021 Systematic Review Protocol for certain streams of evidence. Finally, the commenter said that EPA failed to request SACC feedback on its systematic review.

EPA Response: For the formaldehyde risk evaluation, EPA applied a fit-for-purpose approach to systematic review that incorporates existing systematic review performed by the IRIS assessment and employed 'further filtering' steps to focus more resource-intensive steps (data quality evaluation and data extraction) on studies that are most informative to the assessment. The Systematic Review Protocol for formaldehyde describes this fit-for-purpose approach and describes the updates made to the systematic review approaches implemented to reflect the formaldehyde assessment data needs as well as those that resulted from the NASEM peer review of the 2018 draft systematic review protocol. EPA continues to explore iterative refinements to systematic review approaches in TSCA with every new assessment.

Summary: A public commenter (0263) said that EPA made some improvements in its approach to systematic review in the draft risk evaluation, but additional improvements are required. Important improvements identified include:

- not using the quantitative scoring method previously used in TSCA systematic reviews to assess study quality;
- substantially revising the number and content of the domains used to assess study quality, aligning the TSCA approach with the better approach that has been used in EPA's IRIS program;

- not using the inappropriate metric regarding statistical power; and
- needing an updated study quality evaluation method that is more scientifically defensible and easier to apply.

The commenter stated that critical deficiencies to study quality evaluation included:

- not adhering to best practices; retaining the practice of deriving an "overall quality determination" for each study instead of implementing the domain-based approach of the Navigation Guide recommended by the National Academies for TSCA systematic review;
- continued use of the term "uninformative" as an overall study rating (*e.g.*, chronic studies by Til et al. and Tobe et al. of gastrointestinal effects) instead of recognizing that studies with low ratings for a single study quality metric may be very useful in the risk evaluation. Labeling studies as "uninformative" is not only misleading but could erroneously lead to disregarding studies that constitute the best available science;
- not publishing a chemical-specific systematic review protocol for public comment before completing the draft risk evaluation as recommended by the Institute of Medicine and NAS as a best practice for systematic review;
- excluding non-apical effects such as cellular-level outcomes from the PECO statement for identifying relevant health effects studies, which is contrary to the advice of the SACC;
- not clearly explaining the scope of inclusion/exclusion of health effects studies not previously incorporated in the draft IRIS Assessment of formaldehyde. For example, not explaining the purpose and implementation of the further filtering step. EPA should clearly explain how and when the search was conducted, why the "further filtering" beyond the determination of PECO-relevance was necessary, and how that filtering was conducted;
- continued use of unclear terminology regarding evidence synthesis and integration (i.e., the term "evidence integration" for both steps). The NASEM has recommended the use of the term "evidence synthesis" for assembling the evidence and drawing conclusions from a single evidence stream (e.g. toxicology, epidemiology), and "evidence integration" for the subsequent process of drawing conclusions considering all evidence streams;
- not providing any clear indication of how integration of hazard evidence is conducted. For human health effects, the protocol section on evidence integration provides Table 6-2; however, this table does not address evidence integration and is instead concerned with the selection of studies for dose-response analysis; and
- applying inconsistent approaches to evidence integration.

In conclusion, the commenter recommended EPA prepare a new TSCA systematic review handbook that is aligned with the best available scientific methods and issue updated draft systematic review protocols for all risk evaluations currently in development, including those recommended by the NASEM and SACC. The commenter said that EPA has failed to implement the more than 200 recommendations issued by the SACC in its review of the 2021 Draft TSCA Method.

EPA Response: The Systematic Review Protocol for formaldehyde describes a fit-for-purpose approach tailored to the needs of this particular assessment to capture available information while still meeting aggressive statutory timelines. It was informed by the unique data landscape and existing assessments for formaldehyde as well as lessons learned through previous assessments and feedback from NASEM peer review of the 2018 draft systematic review protocol. EPA continues to explore iterative refinements to systematic review approaches in TSCA with every new assessment.

Section 8 – Formatting and editing

Improve clarity and accessibility of the draft risk evaluation

Summary: A public commenter (0283) discussed in detail how the draft risk evaluation is structured and written in a way that makes it hard to follow and is not transparent, citing various examples including:

- dividing the document into 14 separate "modules", many with their own appendices and supporting files, which complicates efforts to examine for key terms throughout the risk evaluation and follow EPA's reasoning across sections;
- the modules cross-references or overlap each other, so to understand one document requires constant reference to several others. Additionally, the risk evaluation is EPA's longest to date;
- written with jargon too technical for members of fenceline communities to understand; and
- no mention of a single facility where formaldehyde is released or incorporated in a product, making it impossible for people who are exposed to identify their interest in the draft risk evaluation and comment on EPA's analyses. Releasing facilities are identified only in multi-tab spreadsheets that supplement the draft risk evaluation and EPA has not disclosed the risks associated with any specific facility.

The commenter concluded by requesting EPA make a single, non-technical summary document of each risk evaluation available, along with fact sheets that clearly explain EPA's calculations of elevated risks to workers, consumers, and fenceline communications, with the latter risks broken down by facility and geographic location. The commenter requested EPA share those materials with impacted labor unions and community organizations in areas where EPA has calculated heightened risks from formaldehyde releases.

EPA Response: EPA appreciates this feedback and has tried to improve clarity and transparency of documents where possible. The Human Health Risk Assessment aims to summarize key points from the exposure and hazard assessments provided in more detailed technical support documents. With the revised assessment, EPA is releasing a non-technical summary. EPA aims to continue making iterative refinements to clarity and accessibility in future assessments.

Inconsistent terminology across all documents in the docket

Summary: A few public commenters (0151, 0178, 0211, 0221), stated that the terminology and assessments are not harmonized across all EPA documents in the docket. For example, one of the commenters, in multiple submissions to the docket (0151, 0178), stated that Tables 2-2 and Table 2-3 of the Revised Subcategory of the 2024 Draft Risk Evaluation indicate removal of "agriculture, forestry, fishing, and hunting", but the phrase occurs on page 20 twice, page 22, and page 141. The other public commenters (0211, 0221) stated that, although they were able to reconstruct the majority of the values, the use of inconsistent terminology used in spreadsheets versus the texts description made the review process challenging and burdensome.

EPA Response: EPA appreciates this feedback and has tried to improve consistency across documents where possible.

Appendices

Summary: A public commenter in multiple submissions to the docket (0151, 0178) said the manuscripts listed in Appendix A were not referenced in either the human hazard assessment or risk assessment documents and asked if they were reviewed by EPA and found not relevant or were they not considered by EPA.

Another public commenter (0157) said that under state laws and regulations, CARB's composite wood products regulation needs to be corrected to be listed as an Air Toxic Control Measure and not as a VOC regulation as it currently is in Appendix A-2, p.28.

EPA Response: The sources listed in Appendix A of the Human Health Hazard Assessment were risk assessments performed by other authoritative sources. While EPA considered information available through those assessments, EPA primarily relied on primary sources for formaldehyde.

EPA appreciates the correction regarding CARB's composite wood products regulation and has updated the Appendix in the document named Conditions of Use of the Risk Evaluation for Formaldehyde.

Specific corrections

Summary: Another public commenter (0157) stated that the link for Aerosol Coating Product in California (VOC regulation) is broken and the correct link is: https://ww2.arb.ca.gov/our-work/programs/consumer-products-enforcement/aerosol-coating-product-regulation.

Another public commenter (0261) recommended the following text in Section 2.1.3, p.10 be changed to cite the document after the last sentence where one can find the outputs of the aggregation of exposures:

"*Risk estimates based on high-end exposure levels (e.g., 95th percentile) are generally intended to cover individuals with sentinel exposure levels whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. EPA aggregated exposures across certain routes and exposure scenarios for consumers and bystanders for conditions of use with quantitative risk estimates."*

The commenter also suggested both the median and the high-end value be provided along with reconsideration of which provides the most accurate assessment of reality.

EPA Response: The link has been corrected as pointed out by commentor (0157).

As stated at the end of the paragraph, *"More information on how EPA characterized sentinel and aggregate risks is provided in the Human Health Risk Assessment, Section 4.3."* The commentor will be able find more information on the location in the overall risk evaluation for each specific output within Section 4.3 of the Human Health Risk Assessment.

Because calculated risk estimates alone are not bright-line indicators of unreasonable risk, EPA does not provide each central tendency or high-end risk estimate in Tables 2-1 and 2-2 of the Unreasonable Risk Determination. However, both these values in the case of the occupational COUs, and high-end values for consumer COUs are reflective in each respective risk calculator.

Summary: The SACC said that there is an error for the reference source on lines 398 and 782.
EPA Response: EPA has revised the indoor air exposure technical support document including relevant sources referenced.

Section 9 – Other comments on the draft risk evaluation

Comments on the draft risk evaluation overall

Summary: A public commenter (0161) stated that contrary to TSCA, EPA has inconsistently evaluated drivers of risk, and the draft risk evaluation provides an inconsistent approach to evaluate the dominant sources of formaldehyde exposure.
EPA Response: Every TSCA risk evaluation is written fit-for-purpose. The formaldehyde risk evaluation considers all reasonably available information and identifies confidence and uncertainties in its assessment. These are presented throughout the risk evaluation supporting documents.

Impacts of risk management to industry

Summary: A public commenter (0176) stated that they produce over 70% of the metalworking fluids utilized in North America and that many of these fluids are classified as "water miscible". Water miscible metalworking fluids are highly susceptible to bacterial contamination which can endanger the health and safety of users. According to the commenter, formaldehyde-donor biocides can protect against these health risks by inhibiting bacterial growth. The commenter stated that EPA and the SACC must understand that if the final risk evaluation limits or eliminates the ability of metalworking fluid manufacturers to use formaldehyde-donor biocides, it will endanger the health and safety of workers and users. Two public commenters (0214, 0232) stated that if EPA bans, sets unachievable and scientifically unsupportable exposure standards, or severely restricts the manufacture, import, distribution, and the use of formaldehyde as a reactant, the devastating effects will be felt throughout the value chain. The commenter said that these regulatory actions will eliminate the ability of its members to supply their customers with chemicals critical to product formulation, manufacturing, or application, and will cause severe unintended consequences for the health, safety, and well-being of the public. Two public commenters (0249, 0277) described the potentially critical economic impacts if formaldehyde were restricted for conditions of use such as the use of formaldehyde in MDI production used in the manufacture of adhesives and sealants, in adhesives for wood products, and use in adhesives and sealants used in electronic, automotive, and defense application. Additionally, the commenters said that their members expressed that there are no alternatives for these conditions of use. Two public commenters (0267, 0277) also stated that the proposed OEV could hinder the continued manufacturing of MDI, impacting critical sectors of the economy such as the construction and transportation industries. Another public commenter (0260) said that many formaldehyde-based products lack viable cost-effective or technically feasible alternatives. Another public commenter (0088) said that the proposed standard threatens key industries in Michigan, such as automotive manufacturing and the healthcare system. The commenter said that EPA's proposed evaluation misaligns with international safety standards and risks disrupting supply chains for all of

these products. The commenter requested that EPA reevaluate formaldehyde using trusted science and ensuring that those from impacted industries have a chance to share their thoughts.

Another public commenter (0089) said that formaldehyde is a necessary product for a myriad of construction products like plumbing pipes, roofing, insulation, flooring, and more. If the draft risk evaluation were to be finalized, it would lead to the shutting down of facilities that manufacture formaldehyde, which would stop the production of construction products and threaten nearly one million formaldehyde related jobs and over $550 billion in annual sales. The commenter added that under this restrictive standard, the economic impacts would be worsened by the supply chain delays that ensue.

Another public commenter (0090) said that the draft risk evaluation will lead to an overly restrictive workplace standard and have catastrophic consequences for the American economy. The commenters (0090, 0280) said that formaldehyde plays a key role in the production of countless American-made products ranging from vaccines to seat belts to construction materials, and products that are based on formaldehyde technologies support nearly 1 million American jobs and over half a trillion dollars in annual sales. One of the commenters added (0280) that the resulting disruption to supply chains would profoundly affect consumers, producers, and workers across various sectors, including construction, housing, agriculture, transportation, energy, and beyond. Additionally, it could lead to businesses shifting jobs or operations abroad to more favorable regulatory environments.

A few public commenters (0128, 0150, 0257) described many essential uses of formaldehyde across a variety of industries, such as automotive, aerospace, agriculture, national defense, and many more. The commenters said that all of these important supply chains would be disrupted if EPA proceeds with a regulation that will make it difficult, if not impossible to manufacture and use formaldehyde in America. One of the commenters (0257) added that the draft risk evaluation overestimates the risk to workers by not considering the highly developed safety procedures, protocols, and PPE used throughout industry, and incorrectly infers that neither manufacturers' safety commitments nor OSHA standards are enforced.

Several public commenters (0134, 0209, 0210, 0253, 0281) said that formaldehyde-based feed additives are an essential product that countless farmers rely on to protect livestock (poultry, swine and feed operations) against diseases and infections. Formaldehyde products are resource efficient, provide high functionality at an affordable price, and are not easily replaceable. The commenters (0134, 0210) stated that if EPA moves forward with an overly restrictive formaldehyde risk evaluation, it could lead to an essential ban on the use of these products and in turn inflict significant economic harm on the farmers who form the backbone of our nation's food production, as well as increased risk of pathogen outbreaks within the U.S. meat industry.

Several public commenters (0141, 0245, 0251) said that formaldehyde is essential to the production of fertilizer, specifically urea, and there are no viable alternatives available for its production. The commenters said that the restriction on formaldehyde in fertilizer formulations would necessitate a substantial overhaul of equipment and infrastructure for both production and application processes (costing billions of dollars) and that the existing infrastructure is ill-prepared to adapt to this change which could lead to cascading impacts on the national food supply. Another commenter (0215) added that nitrogen fertilizer sources are important products within the lawn and landscape industry and that EPA's inaccurate conclusions that are not based on current industry practices and may lead to unnecessary restrictions or bans on products that industry relies upon to maintain the health of plants in the landscape. Another commenter (0216) said that formaldehyde-based fertilizers are essential to the

grain and oilseed cropping systems, and if fertilizer manufacturers are not able to use formaldehyde and supply urea-based options domestically, this will shift demand to other, less efficient options for corn production, creating more disruption within an already unpredictable market.

Two public commenters (0160, 0242) said that formalin is the only FDA-approved therapeutant for control of external parasites of catfish and for the control of fungi of the family Saprolegniaceae on catfish eggs. The draft risk evaluation could result in significant economic impacts to producers of the nation's leading aquaculture product, formalin. Another commenter (0268) requested that EPA implement changes that allow the continued use of formaldehyde in aquaculture operations until effective alternatives become identified and available for use.

Another public commenter (0174) said that an OEV of 0.011 ppm would consequently require dramatic change in adhesives and even complete substitution of formaldehyde-based resins within the wood products industry, causing a colossal impact on the value chain of their businesses. Severa; commenters (0174, 0183, 0194, 0228) said that formaldehyde is both naturally present and safely used in wood products, therefore, they have significant concerns about the implications if EPA were to finalize the draft risk evaluation as currently drafted, given the many flawed assumptions that sit behind the evaluation. Another commenter (0233) added that an incorrect unreasonable risk determination for the use of formaldehyde in the production of wood products would significantly impact the International Wood Products Association's members and their industries.

Another public commenter (0207) said that the economic footprint of the methanol industry is vast, as methanol is one of the world's most heavily traded and shipped chemical commodities. The largest application of methanol is in the production of formaldehyde, with 39% of domestic methanol demand being driven by formaldehyde. The commenter sated that an unreasonable risk determination would have significant negative impacts on the domestic methanol industry, hurting the U.S. economy and potentially causing significant job losses.

A public commenter (0169) stated that formaldehyde is the single largest downstream derivative of methanol and that an unreasonable risk determination for formaldehyde impacts the domestic methanol industry (39%, or roughly 3 million tons of the 7.6 million tons of domestic methanol demand being accounted for by formaldehyde).

A public commenter (0151) stated that formaldehyde has many uses in veterinary medicine and animal husbandry. Several commenters (0151, 0268, 0242) described the essential role that formalin (37% formaldehyde) plays as the active ingredient in approved treatments for aquatic organisms. The commenters stated that these drugs are critically important, and in many instances the only drug approved in the United States, for control of external parasites, or fungi, of several aquatic organisms and their eggs. One of the commenters (0268) added that the TSCA evaluation and resulting risk management determinations will likely result in impacts to the manufacture of formaldehyde, thus decreasing the supply and increasing the cost of formalin for hatcheries in the Pacific Northwest, despite the 2017 report from EPA's Region 10, Washington Department of Ecology, the Washington Department of Fish and Wildlife, and the U.S. Fish and Wildlife Service, which found no threat from formalin-containing effluent to endangered salmonids.

EPA Response: As explained in the unreasonable risk determination, TSCA section 6(b)(4) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the TSCA conditions of use (COUs). EPA understands and is

aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. TSCA section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that: the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety (15 U.S.C. 2605(g)(1)).

EPA understands the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. Such specialized uses will be considered during any risk management phase. Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risks may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0156) stated that TSCA requires EPA to consider the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health. Section 6(g) allows EPA to grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the specific condition of use is a critical or essential use for which no technically and economically feasible safe alternative is available. Citing formaldehyde's importance in controlling disease in the animal food industry, the commenter requested that the SACC seriously consider the public health consequences if formaldehyde containing feed additive products would no longer be available for use in the United States as a result of its review. The commenter also asked the committee to have meaningful discussions with the FDA's Center for Veterinary Medicine about the importance of formaldehyde as an approved feed additive in animal food as part of its review.

EPA Response: TSCA section 3(2) excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." However, EPA did not list specific examples regarding animal feeds or animal drugs. Therefore, EPA is explaining that the use of formaldehyde in animal feed or as an animal drug meets the definition of a "food, food additive, [or] drug," respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (Formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004.

EPA understands and is aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: Several public commenters (0152, 0194, 0228) said that wood products support wide-ranging environmental, health, and related objectives and the socioeconomic value of the wood products industry is critical to the U.S. economy - the wood products industry directly employs over 450,000 people in manufacturing alone and provides over $28 billion in payroll income to American workers. The commenters added that the Biden-Harris Administration has recognized this by investing nearly $34 million under the Bipartisan Infrastructure Law to strengthen the wood products economy and to promote sustainable forest management. Two public commenters (0183, 0193) said that the forest products industry is an important part of many state economies and contributes to these state's tourism industry, help maintain sustainable forests that contribute to clean water, air, and wildlife habitat, and act as a natural carbon sequestration method.

Another commenter (0202) said that composite wood products provide important environmental benefits which should not be impeded by undue regulation. The commenter added that composite panels are superior when considering their low-embodied and high-embedded carbon content, and that the manufacturing processes for these products also have a much lower carbon footprint and, in some instances, have negative net carbon emissions.

Another commenter (0218) said that the toy industry is a downstream user of a number of formaldehyde-dependent materials; the individual companies are not able to revise or affect the supply of materials needed for safe and reliable toys other than by selecting from what is already available, and rely on the availability of those appropriate materials from upstream suppliers. The commenter added that the majority of Toy Association members are small business entities who will face significant adverse effects from the implementation of the draft risk evaluation as currently presented.

EPA Response: EPA understands and is aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. Following issuance of a final risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As

required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

De minimis

Summary: Several public commenters (0246, 0269, 0286, 0199, 0218) stated that EPA must ensure that the risk management rule allows for a de minimis concentration in products that may contain formaldehyde, and a few of the commenters (0269, 0286, 0199, 0218, 0277) suggested the threshold be set at 0.1%. Further, two of the commenters (0246, 0199) stated that manufacturers have rigorous internal quality controls designed to identify, monitor, and control potential contaminants or formation of unwanted chemicals, such as formaldehyde, and will disclose presence of known impurities on SDSs.

EPA Response: EPA will consider whether a threshold or de minimus amount is appropriate as part of any risk management actions.

Other comments on risk management

Summary: A public commenter (0234) said that an outright ban on the use of formaldehyde-based foundry resins would have a devastating effect on the domestic foundry industry, and that a more thoughtful approach to risk management is needed. The commenter suggested that a feasible option would be for EPA to restrict the free formaldehyde content of foundry binder resins or limit the amount of formaldehyde that is evolved from these systems. Additionally, the commenter suggested that EPA consider incentives for binder suppliers to provide a wider array of technical approaches in managing potential worker exposures.

EPA Response: EPA understands and is aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0249) stated that workplace protections are already implemented, and their member companies meet and exceed the current OSHA standards, including the OSHA formaldehyde standard. The commenter also expressed that they do not support EPA not assuming PPE use nor do they support the lack of coordination with other federal agencies under section 9 of TSCA.

Similarly, another public commenter (0151) stated that their industry is accustomed to adherence with caution or warning statements on the label or labeling, such as use of appropriate PPE, as being part of

the safe and effective conditions of use for that article. The commenter said that they understand some articles regulated by EPA also have caution or warning statements on labels or labeling.

A public commenter (0158) stated that all current equipment in both human and veterinary diagnostic laboratories are designed to work with formal-fixed tissues, and that the banning of formalin would require the modification or replacement of this equipment, which would be cost-prohibitive for many University and state diagnostic laboratories. The commenter added that formalin is used in controlled conditions with workers required to use PPE and engineering controls to minimize exposures, therefore, it is requested that EPA allow diagnostic laboratories and medical practices to continue their use of formalin until a suitable alternative becomes available.

EPA Response: EPA understands and is aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk, including workplace controls. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0260) suggested that EPA seek public comment on the follow topics related to risk management:

- how to consistently evaluate whether economically or technically feasible alternatives exist for a use;
- health, safety, security, economic, and infrastructure tradeoffs associated with uses subject to "unreasonable risk" determinations, including whether non-cost-based or health-health tradeoffs justify a "reasonable risk" determination;
- the extension of any use exemptions upstream (including manufacturing, import, and processing) to enable the continuation of that use;
- the extension of formaldehyde-based exemptions that have been deployed by EPA or other federal agencies. For example, EPA should consider:
- exempting amino-phenolic resins classified as non-HAP resins under EPA's 2023 National Emissions Standards for HAPs for the Plywood and Composite Wood Products Sector rulemaking (including for resins containing less than 0.1% percent formaldehyde);
- exempting products, uses, or volumes not required to be reported under TRI de minimis reporting thresholds;
- exempting products with formaldehyde levels below which are required to be included in SDSs consistent with OSHA's Hazard Communication Standard;
- exempting products and uses not affect by the CPSC's strong sensitizer interpretation for the Federal Hazardous Substance Act.

EPA Response: EPA understands and is aware of the ubiquitous nature of formaldehyde and the lack of viable alternatives in certain industry specific uses. Such specialized uses will be considered during any risk management phase. The commentor provides valid and useful suggestions to the Agency when

considering proposed risk management actions. Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0262) recommended that EPA consider the quality of data in establishing realistic exposure concerns to assist the risk management team during the next phase.

EPA Response: EPA is required to meet the scientific standards in TSCA for best available science, utilizing a weight-of-scientific-evidence approach when conducting risk evaluations. The application of these standards are documented throughout the risk evaluation process.

Summary: A public commenter (0277) submitted a highly detailed descriptions of Covestro LLC's industrial use of formaldehyde, outlining their strict adherence to comprehensive processes to control exposure, such as engineering controls, administrative controls, PPE program, exposure assessment program, and industrial hygiene monitoring. The commented said that Covestro's industrial hygiene monitoring data show compliance with EPA's proposed OEV (for the short-term samples, five of the samples were below the proposed acute/short-term OEV of 50 ppb and below the limit of quantification (44 ppb)). The commenter stated that, while Covestro can maintain and measure workplace exposure levels below the proposed OEV, we support the science-based OEV of 300 ppb that is proposed in comments from the Diisocyanates and Formaldehyde Panels of the American Chemistry Council.

EPA Response: Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk, including workplace controls. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: Two public commenters (0151, 0178) asked if EPA will publish its judgement on appropriate PPE for the labeled conditions of use.

EPA Response: Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde

under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk, including workplace controls. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0261) stated that when designing a risk mitigation strategy for a specific unreasonable risk scenario, it should be assumed that those unidentified sources are TSCA-related and should be combined with the confirmed condition of use-related exposure when setting an exposure value that reflects an "acceptable" level.

EPA Response: TSCA § 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA evaluated these COUs that were originally identified and described in the *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0*. These COUs focused on the manufacturing, processing, industrial, commercial, and consumer uses of formaldehyde as required under TSCA. As explained in the final rule amending the Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA) (89 FR 37028, May 3, 2024), EPA will not exclude conditions of use from the scope of the risk evaluation. EPA must apply fact and professional judgment in determining whether or not a particular circumstance is known, intended or reasonably foreseen—and should not select among those circumstances for inclusion or exclusion. Therefore, EPA cannot assume that unidentified formaldehydye sources are TSCA related.

Following issuance of the risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Requests for EPA to reevaluate formaldehyde

Summary: Several public commenters (0088, 0089, 0090, 0092, 0093, 0094, 0096, 0100, 0101, 0102, 0103, 0105, 0108, 0109, 0110) requested that EPA reevaluate formaldehyde (specifically the current OEL) citing impacts to various industries, supply chains, local and national economies, and domestic jobs. The commenters said that the draft risk evaluation is scientifically flawed and out of alignment with the findings from the WHO and the EU. The commenters described the importance of formaldehyde and formaldehyde-based products to various industries, including medical supplies, automotive, construction, agriculture, clean energy, lumber, funeral services, etc., and suggested that

EPA to engage with industry stakeholders, revisit the science, and consider the broad economic impacts.
EPA Response: The occupational exposure values for formaldehyde presented in Appendix E of the Human Health Risk Assessment document are calculated values "derived based on standard occupational scenario assumptions of 8 hours/day, 5 days/week exposures for a total of 250 days exposure per year, and a 40-year working life" using the PODs that were subject to peer review. By including this calculation in Appendix E, EPA has provided an opportunity for comment on the calculations. EPA has considered SACC and public comments on hazard values, uncertainty factors and exposure assumptions and made appropriate revisions to Appendix E. For example, EPA revised the uncertainty factor applied to the acute inhalation value from 10 to 3 based in part on SACC feedback and this change has been incorporated into the revised occupational exposure values. The OEVs presented in Appendix E are not workplace standards. As further clarified in Appendix E, "TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus these occupational exposure values represent risk-only numbers. In risk management rulemaking for formaldehyde following the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses." EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Comments regarding the IRIS Assessment

Summary: A public commenter (0128) said that EPA's IRIS Assessment of formaldehyde has long been the subject of congressional scrutiny and that a bipartisan coalition of Members of Congress has repeatedly urged EPA to conduct a more thorough review of this risk assessment, citing its potential impacts on supply chains across several sectors. Additionally, serious concern has been expressed about how the IRIS program, never specifically authorized by Congress, informs the EPA's regulatory decisions. The commenter said that Congress and the U.S. Government Accountability Office (GAO) have repeatedly questioned the IRIS program's effectiveness as part of the EPA's mission of protecting human health and the environment and that IRIS has been on GAO's "High-Risk Series" since 2009. The commenter added that EPA's IRIS Assessment of formaldehyde is likely to provide the basis for forthcoming EPA regulations under TSCA, FIFRA, and the Clean Air Act, with these new standards potentially conflicting with or superseding formaldehyde regulations from other agencies.
EPA Response: Since the public comment period and SACC peer review, EPA has finalized the IRIS assessment. Drafts of the IRIS formaldehyde assessment underwent multiple rounds of internal EPA review, as well as external review by other federal agencies. The assessment was also made available for public comment and submitted for external peer review by (NASEM). NASEM provided an opportunity for the public to nominate committee members, an opportunity for public comment on the proposed committee, and provided three opportunities for the public to comment directly to the study committee throughout the duration of the review. Additionally, NASEM accepted written public comments throughout the duration of the external peer review. In August 2023, the NASEM released its Review of EPA's 2022 Draft Formaldehyde Assessment (NASEM, 2023). Subsequently, IRIS released the final Toxicological Review of Formaldehyde – Inhalation in August of 2024 {U.S. EPA, 2024, 11854950} (also referred to as the IRIS assessment or final IRIS assessment throughout this document). IRIS provided responses to NASEM and public comments on the draft in Appendix F of the Supplemental Information document.

Multiple federal advisory committees—including the NASEM, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC), and the Human Studies Review Board (HSRB)—have provided review of various aspects of the formaldehyde assessment. EPA recognizes that the HSRB, SACC and NASEM provided feedback on several overlapping issues; some peer review feedback was consistent across panels whereas some feedback was inconsistent, providing divergent views. OPPT's final TSCA risk evaluation and supporting documents have been revised with consideration of public, SACC, NASEM, and HSRB peer review comments.

EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Supplemental information

Summary: A public commenter, in multiple submissions to the docket (0106, 0107, 0113, 0114, 0115, 0116, 0117, 0126, 0127, 0129), provided dozens of supplemental materials in support of their public comments.

Another public commenter (0288) provided a list of documents cited in the comments of Boundless Community Action et al. on the draft risk evaluation of formaldehyde.

EPA Response: EPA appreciates this supplemental information and has considered it in revising the risk evaluation and responding to comments.

Other comments on the draft risk evaluation

Summary: A public commenter (0175) extended an invitation to the members of SACC and ad hoc experts reviewing the draft risk evaluation to tour a formaldehyde manufacturing or processing facility at their convenience. The commenter stated that EPA's exposure assessments are more reflective of Agency policy decisions and inaccurate modeling than actual practice at these facilities.

EPA Response: For each COU, EPA's occupational exposure assessments are intended to capture a diverse range of facilities and tasks. Where possible, EPA has described the full distribution of exposures that may occur under particular COUs and has described the strengths and uncertainties of that analysis. EPA expects that while some facilities with greater controls in place to reduce exposure may fall on the lower end of that distribution, those facilities may not be representative of the diverse scenarios captured across the whole COU.

EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment for any proposed rules.

Summary: A public commenter (0243) requested that EPA bring all stakeholders together and review all current scientific data, in order to make an informed decision that recognizes existing compliance with formaldehyde regulations to limit the impact of the draft risk evaluation going forward.

EPA Response: EPA encouraged stakeholders to submit additional available exposure data or address incorrect assumptions through the public comment period. EPA reviewed the submitted data and integrate based on the approaches detailed in the Occupational Exposure Assessment for Formaldehyde.

Summary: A public commenter (0178) asked if EPA has communicated with USDA, FDA, Centers for Disease Control and Prevention (CDC), Department of Labor, and the American Association of Veterinary Laboratory Diagnosticians (AAVLD) regarding potential impacts of this risk assessment on animal health, human health, and food security. The commenter requested that EPA ask USDA Animal and Plant Health Inspection Service about the potential impact on food safety, affordability, and security if formaldehyde is not available for these uses, and if any economically viable alternatives exist. The commenter requested that EPA communicate with FDA Center for Veterinary Medicine regarding potential adverse impacts on the availability and affordability of formaldehyde used in new animal drugs and feed additives and whether any economically viable alternatives exist. The commenter requested that EPA communicate with CDC regarding the potential adverse effect on public health associated with Salmonellosis if formaldehyde is not available for fumigation or as a feed additive, and requested that EPA communicate with the AAVLD regarding the adverse effects on animal health and food security if formaldehyde is not available.

EPA Response: The use of formaldehyde in animal feed or as an animal drug meets the definition of a "food, food additive, [or] drug," respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA section 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, as noted by the commenter, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004. EPA intends to consider the potential for incidental downstream impacts on such specialized uses during any TSCA risk management proceeding. Following issuance of the final risk evaluation for formaldehyde, the Agency will initiate risk management rulemaking to address the unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA considers many factors when developing any proposed risk management activities for COUs that are determined to significantly contribute to unreasonable risk. As required with any Agency rulemaking subject to the notice-and-comment requirements of the APA, EPA will provide opportunity for public comment on any proposed rule.

Summary: Several public commenters (0172, 0184, 0217) said that they endorse the American Wood Council's and American Chemistry Council's comments on the draft risk evaluation for formaldehyde.

EPA Response: EPA has considered and addressed comments from American Chemistry Council and American Wood Council throughout this response to comments

Summary: A public commenter (0178) requested that EPA consider industries that may be indirectly impacted by its findings of unreasonable risk by communicating with other federal agencies prior to engaging in rulemaking for formaldehyde, particularly about any adverse impacts on availability or

affordability that may lead to greater adverse effects on human health, including food security that may outweigh anticipated benefits to human health from proposed rulemaking for formaldehyde.
EPA Response: EPA will follow Agency guidelines for proposed risk management rules under TSCA 6(a) which includes intra-Agency review and multiple public comment periods.