United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

Summary of External Peer Review and Public Comments for Asbestos and Disposition for Asbestos Part 1: Chrysotile Asbestos

Response to Support Risk Evaluation for Asbestos Part I: Chrysotile Asbestos

December 2020

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This document summarizes the external peer review and public comments that the EPA's Office of Pollution Prevention and Toxics (OPPT) received for the draft risk evaluation of asbestos. It also provides EPA's response to the comments received from the peer review panel and the public.

EPA appreciates the valuable input provided by the peer review panel and the public. The input resulted in numerous revisions to Part 1 of the Risk Evaluation for Asbestos.

Peer review charge questions[1] and the sections of the draft evaluation are used to categorize the peer review and public comments into specific, issue-related main themes.

1. Environmental Exposure and Release
2. Occupational Exposure
3. Consumer Exposure
4. Human Health Hazard/Derivation of the Inhalation Unit Risk (IUR)
5. Human Health Risk Characterization and Determination
6. Environmental Risk Characterization and Determination
7. Potentially Exposed or Susceptible Subpopulations
8. Overall Content and Organization
9. Systematic Review
10. Physical/Chemical Properties
11. Public Comment and Peer Review Processes
12. Other

Peer review comments on the charge questions are typically presented first, organized by charge question or risk evaluation topic in the following sections. These are followed by the public comments.

Abbreviations

AABL	Aftermarket automotive brakes/linings
AC	Asbestos-containing
ACBM	Asbestos-containing building materials
ACC	American Chemistry Council
ACE	Agency tariff code
ACM	Asbestos-containing material
AHERA	Asbestos Hazard Emergency Response Act
AIAN	American Indians/Alaska Natives
AIC	Akaike Information Criteria
APF	Assigned protection factors
ASHARA	Asbestos School Hazard Abatement Reauthorization Act
ATSDR	Agency for Toxic Substances and Disease Registry
BCF	Bioconcentration factor
BLS	U.S. Bureau of Labor Statistics
BRCA	BReast CAncer gene
CAA	Clean Air Act

[1] These are the questions that EPA submitted to the panel to guide the peer review process.

CASRN	Chemical Abstracts Service Registry Number (referred to as CAS as well)
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control
CDR	Chemical data reporting
COC	Concentrations of concern
COD	Chemical oxygen demand
COPD	Chronic obstructive pulmonary disease
COU	Condition of use
CPF	Cancer potency factor
CQ	Charge Question (to SACC)
CT	Central tendency
CWA	Clean Water Act
DIY	Do it yourself
DQE	Data quality evaluation
EBRI	Employee Benefit Research Institute
EC	Exposure concentration
ELCR	Excess lifetime cancer risk
EMP	Elongate mineral particles
EPA	U.S. Environmental Protection Agency
HEI	Health and Safety Executive in the United Kingdom
HERO	Health and Environmental Research Online
HTS	Harmonized tariff schedule
IARC	International Agency for Research on Cancer
ICD	International Classification of Disease
ILO	International Labor Organization
IRIS	Integrated Risk Information System
IUR	Inhalation unit risk
IURLLT	Less than a lifetime inhalation unit risk
KL	Lung cancer potency factor
KM	Mesothelioma potency factor
LOD	Limit of detection
LMS	Linear multistage (cancer risk model)
LNT	Linear no-threshold (cancer risk model)
MCL	Maximum contaminant level
MLE	Maximum likelihood estimation
MOA	Mode of action (toxicological)
MSDS	Material Safety Data Sheet
NC	North Carolina

ND	Non-detect
NESHAP	National Emission Standards for Hazardous Air Pollutants
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
NPDES	National Pollutant Discharge Elimination System
NY	New York
OCSPP	Office of Chemical Safety and Pollution Prevention
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
OSH	Occupational Safety and Health (Act)
OSHA	Occupational Safety and Health Administration
OSWER	Office of Solid Waste and Emergency Response (renamed Office of Land and Emergency Management)
PAH	Polycyclic aromatic hydrocarbon
PBZ	Personal breathing zone
PCB	Polychlorinated biphenyl
PCM	Phase-contrast microscopy
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
PHS	U.S. Public Health Service
PMN	Premanufacturing notice
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
RACM	Regulated asbestos containing materials
RCRA	Resource Conservation and Recovery Act
RE	Risk evaluation
REA	Risk evaluation for asbestos
RF	Reduction factor
RfC	Reference concentration
RfD	Reference dose
RR	Relative risk
SAB	Science Advisory Board
SACC	Science Advisory Committee on Chemicals
SC	South Carolina
SCR	Silicon-controlled rectifier
SDS	Safety data sheet(s)

SDWA	Safe Drinking Water Act
SEER	Surveillance, Epidemiology, and End Results Program
SMR	Standardized mortality ratio
SNUR	Significant New Use Rule
SOP	Standard operating procedure
STEL	Short-term-exposure limit
TEM	Transmission electron microscopy
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TSCE	Two-stage clonal expansion (model)
TSS	Total suspended solids
TWA	Time-weighted average
TWF	Time-weighting factor
UNARCO	Union Asbestos and Rubber Company
US	United States
USGS	U.S. Geological Survey
UTV	Utility vehicle
WTC	World Trade Center (NY)

List of Comments

#	Docket File	Submitter
SACC	EPA-HQ-OPPT-2019-0501-0113	Science Advisory Committee on Chemicals (SACC)
15	EPA-HQ-OPPT-2019-0501-0015	Richard Haffey, President and Training Director, Mystic Air Quality Consultants, Inc.
16	EPA-HQ-OPPT-2019-0501-0016	ToxStrategies, Inc. on behalf of American Chemistry Council (ACC)
17	EPA-HQ-OPPT-2019-0501-0017	C. Maahs
25	EPA-HQ-OPPT-2019-0501-0025	Brent Kynoch, Managing Director, Environmental Information Association (EIA)
26	EPA-HQ-OPPT-2019-0501-0026	Anonymous public comment
27	EPA-HQ-OPPT-2019-0501-0027	Anonymous public comment
28	EPA-HQ-OPPT-2019-0501-0028	Mark G. Ellis, President, Industrial Minerals Association - North America (IMA-NA)
29	EPA-HQ-OPPT-2019-0501-0029	S. E. Strauss
30	EPA-HQ-OPPT-2019-0501-0030	Kevin Bogue, Platform Environmental, LLC
31	EPA-HQ-OPPT-2019-0501-0031	Michelle Roos, Environmental Protection Network (EPN)
32	EPA-HQ-OPPT-2019-0501-0032	Julie E. Goodman et al., Gradient
34	EPA-HQ-OPPT-2019-0501-0034	David H. Garabrant, Emeritus Professor of Epidemiology and Occupational Medicine, The University of Michigan
35	EPA-HQ-OPPT-2019-0501-0035	Judith Nordgren, Managing Director, Chlorine Chemistry Division, American Chemistry Council (ACC)
38	EPA-HQ-OPPT-2019-0501-0038	John W. Spencer, President, Environmental Profiles, Inc.
39	EPA-HQ-OPPT-2019-0501-0039	G. Mezei, S. Moolgavkar and F. Mowat, Exponent, Inc.
40	EPA-HQ-OPPT-2019-0501-0040	P. R. Williams
41	EPA-HQ-OPPT-2019-0501-0041	V. L. Roggli and T. A. Sporn
42	EPA-HQ-OPPT-2019-0501-0042	Dennis J. Paustenbach, President and David Brew, Toxicologist, Paustenbach and Associates

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43	EPA-HQ-OPPT-2019-0501-0043	M. C. Sharp
44	EPA-HQ-OPPT-2019-0501-0044	R. A. Lemen (corrected version is comment 57, so this comment is not cited in summary)
45	EPA-HQ-OPPT-2019-0501-0045	J. Brent Kynoch, Managing Director, Environmental Information Association (EIA)
46	EPA-HQ-OPPT-2019-0501-0046	A. L. Frank
47	EPA-HQ-OPPT-2019-0501-0047	L. C. Oliver
48	EPA-HQ-OPPT-2019-0501-0048	Jacqueline Moline, Chair, Occupational Medicine, Epidemiology and Prevention, The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
49	EPA-HQ-OPPT-2019-0501-0049	B. Castleman
50	EPA-HQ-OPPT-2019-0501-0050	Raja Flores, System Chairman, Department of Thoracic Surgery, Mount Sinai Health System
51	EPA-HQ-OPPT-2019-0501-0051	Linda Reinstein, President and Co-Founder and Robert Sussman, Counsel, Asbestos Disease Awareness Association (ADAO)
53	EPA-HQ-OPPT-2019-0501-0053	Rebecca L. Reindel, Safety and Health Director, American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)
55	EPA-HQ-OPPT-2019-0501-0055	C. Blake and R. Harbison
56	EPA-HQ-OPPT-2019-0501-0056	Michele Carbone, Cancer Center, University of Hawaii
57	EPA-HQ-OPPT-2019-0501-0057	R. A. Lemen
58	EPA-HQ-OPPT-2019-0501-0058	P. Gottesfeld
59	EPA-HQ-OPPT-2019-0501-0059	Anonymous public comment
60	EPA-HQ-OPPT-2019-0501-0060	Christy A. Barlow, Kimberly A. Hoppe Parr, and Kim E. Anderson, GZA GeoEnvironmental, Inc.
61	EPA-HQ-OPPT-2019-0501-0061	A. M. Langer
62	EPA-HQ-OPPT-2019-0501-0062	Bertram Price, Price Associates, Inc.
63	EPA-HQ-OPPT-2019-0501-0063	J. M. Dement
64	EPA-HQ-OPPT-2019-0501-0064	Bryan D. Hardin, Vice President - Principal Toxicologist, J. S. Held, LLC
65	EPA-HQ-OPPT-2019-0501-0065	Jessica Ryman-Rasmussen, Senior Scientific Advisor, American Petroleum Institute (API)

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66	EPA-HQ-OPPT-2019-0501-0066	Allan Feingold, Medical Director, Occupational & Environmental Medicine, South Miami Hospital
67	EPA-HQ-OPPT-2019-0501-0067	Steve Mlynarek, President, Applied Science Associates, Inc.
68	EPA-HQ-OPPT-2019-0501-0068	B. W. Case
69	EPA-HQ-OPPT-2019-0501-0069	Thomas G. Laubenthal, Technical Chief & Training Supervisor, The Environmental Institute
70	EPA-HQ-OPPT-2019-0501-0070	Judith Nordgren, Managing Director, Chlorine Chemistry Division (CCD), American Chemistry Council (ACC)
71	EPA-HQ-OPPT-2019-0501-0071	Kirk T. Hartley, LSP Group LLC
72	EPA-HQ-OPPT-2019-0501-0072	Robyn Brooks, Vice President, Health, Environment, Safety, and Security, The Chlorine Institute (CI)
73	EPA-HQ-OPPT-2019-0501-0073	Georges C. Benjamin, Executive Director, American Public Health Association (APHA)
74	EPA-HQ-OPPT-2019-0501-0074	Ellen S. Tenenbaum and Craig H. Zimmerman, Attorneys, McDermott Will and Emery LLP
75	EPA-HQ-OPPT-2019-0501-0075	Kelsey Johnson, President, Iron Mining Association of Minnesota (IMA)
76	EPA-HQ-OPPT-2019-0501-0076	Andrey A. Korchevskiy et al, Director, Research and Development, Chemistry and Industrial Hygiene, Inc. (C&IH)
77	EPA-HQ-OPPT-2019-0501-0077	Xavier Becerra, Attorney General of California, California Department of Justice et al.
78	EPA-HQ-OPPT-2019-0501-0078	J. Sahmel
79	EPA-HQ-OPPT-2019-0501-0079	Coreen Robbins, Principal Industrial Hygienist, J.S. Held LLC.
80	EPA-HQ-OPPT-2019-0501-0080	Kevin T. Wyles, Dentons US LLP on behalf of Morse TEC LLC
81	EPA-HQ-OPPT-2019-0501-0081	Harold A. Schaitberger, General President, International Association of Fire Fighters (IAFF)
82	EPA-HQ-OPPT-2019-0501-0082	B. T. Mossman
83	EPA-HQ-OPPT-2019-0501-0083	Michael P. Walls, Vice President, Regulatory and Technical Affairs, American Chemistry Council (ACC)
84	EPA-HQ-OPPT-2019-0501-0084	U.S. Chamber of Commerce et al.

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85	EPA-HQ-OPPT-2019-0501-0085	Randy Rabinowitz, Executive Director, Occupational Safety and Health Law Project and Jonathan Kalmuss-Katz, Staff Attorney, Earthjustice on behalf of American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) et al.
86	EPA-HQ-OPPT-2019-0501-0086	Bob Sussman, Counsel, Safer Chemicals Healthy Families (SCHF) et al.
87	EPA-HQ-OPPT-2019-0501-0087	Nicholas Chartres et al., Associate Director, Science and Policy, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco
88	EPA-HQ-OPPT-2019-0501-0088	Dianne C. Barton, Chair, National Tribal Toxics Council (NTTC)
89	EPA-HQ-OPPT-2019-0501-0089	Linda Reinstein, Cofounder, Asbestos Disease Awareness Organization (ADAO)
90	EPA-HQ-OPPT-2019-0501-0090	Evan M. Beckett et al., Cardno ChemRisk
91	EPA-HQ-OPPT-2019-0501-0091	Richard P. Krock, Senior Vice President, Regulatory and Technical Affairs, Vinyl Institute (VI)
92	EPA-HQ-OPPT-2019-0501-0092	Bruce Stern, President, American Association for Justice (AAJ)
95	EPA-HQ-OPPT-2019-0501-0095	Dennis Paustenbach, Paustenbach and Associates
96	EPA-HQ-OPPT-2019-0501-0096	Nicholas Chartres, Associate Director, Program on Reproductive Health and the Environment, University of California, San Francisco
97	EPA-HQ-OPPT-2019-0501-0097	Bob Sussman, Sussman & Associates on behalf of Asbestos Disease Awareness Organization (ADAO)
98	EPA-HQ-OPPT-2019-0501-0098	Steven P. Compton, MVA Scientific Consultants
99	EPA-HQ-OPPT-2019-0501-0099	Penelope Fenner-Crisp, Environmental Protection Networkâ€‹ (EPN)
100	EPA-HQ-OPPT-2019-0501-0100	Greg Brorby, Senior Consultant, ToxStrategies on behalf of American Chemistry Council (ACC)
101	EPA-HQ-OPPT-2019-0501-0101	J. Brent Kynoch, Managing Director, Environmental Information Association (EIA)
102	EPA-HQ-OPPT-2019-0501-0102	Gabor Mezei, Principal Scientist, Exponent, Inc.
103	EPA-HQ-OPPT-2019-0501-0103	Suresh Moolgavkar, Principal Scientist, Exponent, Inc.
104	EPA-HQ-OPPT-2019-0501-0104	Linda Reinstein, Cofounder, Asbestos Disease Awareness Organization (ADAO)
105	EPA-HQ-OPPT-2019-0501-0105	Tony Tweedale, Rebutting Industry's Science with Knowledge (R.I.S.K.) Consultancy

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106	EPA-HQ-OPPT-2019-0501-0106	David H. Garabrant, Emeritus Professor of Occupational Medicine and Epidemiology, The University of Michigan, Ann Arbor, Michigan
108	EPA-HQ-OPPT-2019-0501-0108	Robyn Brooks, Vice President, Health, Environment, Safety, and Security, The Chlorine Institute (CI)
109	EPA-HQ-OPPT-2019-0501-0109	Chacko Mathew, Environmental Engineering Technology, Director, United Industries Unlimited LLC
110	EPA-HQ-OPPT-2019-0501-0110	Robert M. Sussman, Counsel on behalf of Asbestos Disease Awareness Organization (ADAO)
111	EPA-HQ-OPPT-2019-0501-0111	Comment submitted by Patrick Celestine, Federal Relations Counsel, American Association for Justice (AAJ)

1. Environmental Exposure and Release

Charge Question 1

1.1 Please comment on whether the information presented supports the analysis and conclusion in the draft environmental exposure section (Section 2.2 and Appendix D).

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
1.1	**Water (including wastewater and drinking water)**	
SACC, 47, 51	**SACC COMMENTS:** • Recommendation 1: Provide a stronger statement of uncertainty in the conclusion that environmental receptors are not exposed to chrysotile asbestos in waste or surface waters and reflect this in the DRE's Executive Summary. • Recommendation 2: If COU monitoring data are not available, either make a statement that risk cannot be evaluated, or use surface water measurements as a "worst-case" scenario for comparison to Concentrations of Concern (COC) values. • Recommendation 3: Discuss other COU sources to surface water including laundered clothing and surface runoff following brake pad replacement or washing of chrysotile-containing consumer products. • Recommendation 4: Address exposures to environmental receptors by terrestrial and drinking water pathways. • Recommendation 9: Given the uncertainties of occurrence, measurement, and identification of chrysotile fibers, TEM should be recommended for future monitoring, especially in surface waters. • Relatively high concentrations of asbestos have been found in surface waters (ATSDR (2011) and may be derived from sources other than COUs.	EPA has revised the statement in the document suggesting low risk. Based on the reasonably available literature and information for chrysotile asbestos, the Executive Summary adequately states there is low potential risk of exposure for environmental risk to aquatic and sediment-dwelling receptors, but uncertainty is acknowledged. EPA concluded there is no unreasonable risk to aquatic or sediment-dwelling environmental organisms using reasonably available literature as described in Section 4.1. Use of surface water measurements as a "worst-case" scenario for comparison to COC values would not be relevant to Part 1 of the Risk Evaluation because the surface water data are not specific to chrysotile and are not related to COUs included in Part 1. Because these other sources of asbestos in surface water are not relevant, EPA did not expand this discussion on sources. These surface water measurements may be considered in Part 2 of the risk evaluation to evaluate risk from other uses of asbestos not included in Part 1, as appropriate. EPA is confident that relevant COUs were identified and included in Part 1 of the Risk Evaluation for chrysotile asbestos based on reasonably available information, as described in the Problem Formulation document that was made available for public comment. Legacy uses and other fiber types of asbestos may contribute to surface water contamination, but that will be determined in Part 2 of the Risk Evaluation for Asbestos. Terrestrial exposure and drinking water pathways were excluded from Part 1 of the Risk Evaluation as stated in the

	PUBLIC COMMENTS: • Asbestos in drinking water can result from leaching of naturally occurring asbestos from soil and rock erosion and "loose fibers spreading into the environment from nearby construction sites or landfills. Disposing of older asbestos products in the environment can create toxic runoff that eventually flows into watersheds." • Exceedances of the MCL for asbestos in drinking water (which was set by EPA in 1982) have been detected in some of drinking water systems and are more likely in areas contaminated by erosion from natural asbestos deposits or from mining operations (EWG (2019; Howe et al. (1989; Kanarek et al. (1981; Sigurdson et al. (1981; Kanarek et al. (1980; Craun et al. (1977; U.S. EPA (1976).	Section 4.1 and in the Executive Summary of Part 1; relevant terrestrial pathways, including biosolids, and drinking water pathways are covered under the jurisdiction of the SDWA, CAA, and CWA. Regarding methods used for asbestos measurements, EPA acknowledges the advantages of using TEM, such as providing higher definition for the identification and quantification of asbestos fibers when compared to PCM techniques. In Section 4.3.5, EPA states: "The analytical method used to measure exposures in the epidemiology studies is important in understanding and interpreting the results as they were used to develop the IUR." As provided in more detail in Section 3, the IUR for "current use" asbestos (*i.e.*, chrysotile) is based solely on studies of PCM measurement as TEM-based risk data are limited in the literature and the available TEM results for chrysotile asbestos lack modeling results for mesothelioma. Further, all of the industrial hygiene sampling of chrysotile asbestos associated with the COUs were measured using PCM. With respect to potential water quality implications of asbestos leaching from naturally occurring sources and construction/demolition waste landfill disposal, currently there are no active mining operations of naturally occurring asbestos in the United States. In addition, naturally occurring asbestos is not a COU to be addressed by the EPA in Part 1 of the Risk Evaluation. As mentioned in the asbestos PF document, releases associated with construction sites waste disposal into construction/demolition waste landfills are primarily regulated under authorized state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. Therefore, EPA is not including the construction/demolition waste landfill disposal pathway in Part 1 of the Risk Evaluation. Releases associated with landfill disposal are regulated under landfill special requirements for handling and securing the asbestos-

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
		containing waste regulated under NESHAP to prevent releases of asbestos into the air. This includes sealing regulated asbestos-containing waste material in a leak-tight container, reducing possible environmental releases to ground water. While permitted and managed by the individual states, municipal solid waste landfills are required by federal regulations to implement some of the same requirements as RCRA Subtitle C landfills, generally including leachate collection with the use of a liner system and conducting groundwater monitoring and corrective action when releases are detected. These actions help reduce any potential landfill leachate releases to groundwater. Finally, chrysotile asbestos is a fiber and will likely be entrained in soil and is not likely to be leached out of a landfill. Given these controls, general population exposure to asbestos in groundwater from landfill leachate is not expected to be a significant pathway. EPA has not included these landfill pathways in Part 1 of the Risk Evaluation. EPA acknowledges the documented presence of asbestos fibers in drinking water. However, compliance/non-compliance with statutory requirements outside of TSCA is not a component to consider when conducting Risk Evaluations under TSCA. Compliance/non-compliance issues are addressed under separate enforcement authorities for each statute along with settlement of identified non-compliance issues.
1.2 **Biosolids**		
SACC	**SACC COMMENTS:** • Biosolids are a source of asbestos exposure, as relatively high concentrations of asbestos have been found in biosolids (ATSDR (2011) and may be derived from sources other than COUs.	EPA believes the intended reference in this comment should be the 2001 ATSDR Toxicological Profile for Asbestos, which indicates that asbestos was present in 34 of 51 sludge ash samples at levels ranging from 1-10%. EPA evaluated this report and other reasonably available information as described in Part 1 of the Risk Evaluation and in the Problem

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
		Formulation document. As stated in Section 2.5.3.2 of the Problem Formulation document, EPA expects that concentrations of chrysotile asbestos in biosolids due to relevant COUs is low and that "re-suspension of the asbestos fibers into air following biosolid land application, although possible, will result in exceedingly low airborne concentrations." EPA did not evaluate hazards or exposures from chrysotile asbestos releases to terrestrial pathways, including biosolids, for terrestrial organisms, which was described in Section 2.5.3.3 of the Problem Formulation document.
1.3 **Asbestos containing building materials (ACBM) and waste**		
45, 46, 47, 50, 51, 68, 69, 73, 77, 85, 89, 92, 104	**PUBLIC COMMENTS:** • Asbestos can be released into the air during building repair, modeling and demolition, due to the disturbance of ACBM such as insulation, fireproofing material, dry wall, and ceiling and floor tile and many other materials, which results in asbestos exposure to construction workers, nearby residents, pedestrians and bystanders. • EPA does not estimate the number of buildings that contain asbestos. The most recent data from the US Census Bureau's American Housing Survey indicates that 40% of the nation's 118 million housing units (*i.e.*, 47.2 million) were built before 1970. EPA could also use data from the AHS to estimate the annual number of renovations, repairs, and remodeling in which ACM may be encountered. • Amphiboles from Libby and other asbestos remain in buildings (*e.g*, attic insulation) where ongoing use and eventual disposal create risks for residents and workers, including firefighters.	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), EPA will evaluate legacy asbestos uses including asbestos-containing building materials (ACBM) and associated disposals of those materials in Part 2 of the risk evaluation. Legacy asbestos uses are uses for which manufacture, import, processing and distribution no longer occur but the uses are still known, intended, or reasonably foreseen to occur. EPA will include such uses and associated disposals in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope document. EPA will use reasonably available information to determine the number of buildings that continue to contain asbestos. Libby Amphibole asbestos, which is a mixture of several mineral fibers such as tremolite, winchite, and richterite, was found in vermiculite ore mined near Libby, MT and extensively distributed throughout the United States during the 20th century. Vermiculite from Libby, MT had a range of commercial applications, the most common of which included packing material, attic and wall insulation, spray-on fire proofing, various garden and agricultural products, and

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	• Libby Amphibole is still present at the Libby mining site and other inactive sites. • With the projected increases in severe weather, including droughts, hurricanes, and tornadoes, EPA Draft RE for Asbestos should include an assessment of the likelihood and magnitude of occupational and community exposure from damaged residential and commercial buildings. • Single-family homes, small rental properties, schools, factories, and non-federal public buildings were not addressed. • Demolition of buildings that contain legacy and other asbestos-containing materials can expose construction workers, nearby residents, pedestrians, and bystanders. • Asbestos demolition projects were not addressed under CAA because NESHAP does not apply to residential buildings with 4 or fewer units, projects that involve less than a regulated quantity of RACM, or planned demolitions of any building or unplanned events when buildings are destroyed by fire. • The 'use' of the material does not end at the time of manufacture or installation. For many of these materials, the 'use' only begins at installation. Building 'users' are at risk of asbestos exposure from installed legacy asbestos-containing materials, which can be disturbed by vibration, air erosion, water damage, or which citizens and tradesmen might contact directly (Kynoch (2018).	various cement and building products. The Libby, MT vermiculite mine closed in 1990. EPA will address whether asbestos associated with vermiculite originating from Libby, MT will be included in Part 2 of the risk evaluation, beginning with a draft scope document.
1.4 **Waste disposal sites**		
51, 77, 89	**PUBLIC COMMENTS:** • Asbestos-contaminated waste is prevalent both at inactive waste sites and active landfills and industrial	EPA is aware of asbestos-containing building materials (ACBMs) releases to landfills. The EPA is not including legacy asbestos uses, including ACBMs, in Part 1 of the Risk Evaluation. The EPA will evaluate the legacy asbestos and

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	facilities (ATSDR (2001), where asbestos has been detected in air, groundwater, or surface water. • TRI data demonstrates a relatively large increase in total on-site and off-site disposal or other releases of friable asbestos since 2009, with a vast majority released to land. Poor waste management at landfills and construction sites, as well as after disasters that disrupt ACBMs, poses a significant danger to workers and the public. • The industry accounting for the highest release quantities of friable asbestos is the hazardous waste treatment and disposal sector, followed by the petroleum and other chemical and electric sectors. However, due to the limitations of TRI reporting requirements, it is likely that the amount of asbestos-containing waste managed or disposed of was significantly higher than reported.	the associated disposals of those materials in Part 2 of the Risk Evaluation.
1.5 **Reuse of taconite tailings are sources of asbestos**		
26	**PUBLIC COMMENTS:** • The taconite industry markets the use of taconite tailings for road asphalt, and taconite tailings are being used for road asphalt throughout Minnesota and possibly in other states. Some asbestos is likely released through road wear, but release of asbestos certainly is a concern when the roads are dug up and repaired. Therefore, mining of taconite tailings through the Iron Range should be included in the draft RE.	The Agency will consider whether uses of taconite contain fibers that fall within the definition of asbestos and whether uses of taconite are a COU for asbestos to be included in Part 2 of the risk evaluation. Therefore, this document does not include taconite tailings for road asphalt COU.
1.6 **Taconite mining is not a source of asbestos**		
75	**PUBLIC COMMENTS:** • EPA should state explicitly in the final risk evaluation that non-asbestiform EMPs (cleavage fragments) encountered during taconite mining do not fall within	Part 1 of the Risk Evaluation for Asbestos includes COUs for chrysotile asbestos, and relevant exposure pathways were described in the Scope document. Taconite mining was not included in the Scope, Problem Formulation, or draft Risk Evaluation as a source of exposure to chrysotile asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	the TSCA definition of asbestos and are not covered by the risk evaluation. • Nearly all taconite iron ore produced in the United States is supplied to the US domestic steel industry. It is therefore of national and strategic importance and has major impacts on local economies and jobs where these mines are located. • A survey of the Peter Mitchell Pit located in the Mesabi Iron Range found that "no asbestos of any type was found in the mine pit." Improved analytical techniques have confirmed that taconite mining generates short EMP fragments that are not asbestiform fibers (but rather are non-asbestiform minerals), allowing EPA to come to a definitive conclusion that taconite mining operations do not generate asbestos. In the context of the Clean Air Act asbestos NESHAP regulation (84 Fed. Reg. 50660, 50683 (Sept. 25, 2019); see 40 CFR §61.141; which uses the same definition of asbestos as TSCA), EPA cited the Peter Mitchell Pit study of taconite ore mining and concluded that EMPs encountered during taconite mining do not meet the definition of 'asbestos' found in current EPA regulations and technical documents. • The commercial product produced in a taconite mining operation is a fired iron ore pellet that has been exposed to heat in a furnace in excess of 2,000°F, which would eliminate any fibrous properties. As such, EPA should exclude taconite mining from the scope of its current and supplemental TSCA risk evaluations for asbestos.	EPA deemed it unnecessary to revise Part 1 of the Risk Evaluation to explicitly note exclusion of taconite mining.
1.7 **Talc used in industrial and consumer products**		
48, 50, 51, 77, 86, 104	**PUBLIC COMMENTS:** • Industrial uses of talc are diverse and include the manufacturing of plastics, ceramics, paint, paper,	EPA is aware that talc originating from certain sources and used in consumer and industrial applications may contain asbestos. However, considering the significant scope of evaluating the potential risks posed to individuals from

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	roofing material, lubricants, and insecticides/ fungicides. • Talc-contaminated consumer products include baby powder, makeup products, crayons and children's toys. • The presence of a mixture of asbestos fiber types in talc is well-documented (IARC) (Jehan (1984; Rohl et al. (1976a). • The omission of talc-based consumer and industrial applications from the draft evaluation is a significant gap because of the likelihood that some grades of talc used in these applications are contaminated by asbestos, putting consumers and workers at risk. EPA should include these COUs in its risk evaluation. • While not every talc deposit contains asbestos, talc deposits have been identified in mineral formations that include, or are located near, asbestos deposits. Lung illnesses (scarring, lung cancer, and mesothelioma) have been discovered among NY talc miners in the mid-1900s (Kleinfeld et al. (1967; Kleinfeld et al. (1955; Porro et al. (1942). A recent effort by Finkelstein (2012) to update Honda et al. (2002) provides further evidence that asbestos-containing talc causes mesothelioma (Finkelstein (2012). • The extent to which talc contains asbestos is not always known, but typically industrial-grade talc undergoes less extensive processing than talc used in personal care products and is more likely to contain impurities. • Industrial uses of talc likely expose thousands of workers to talc powder by inhalation and dermal contact. • Exposure to asbestos in talc has been linked to ovarian cancer and mesothelioma. This risk should be addressed by EPA in the asbestos evaluation.	exposure to talc, it would be more appropriate to evaluate talc (and any known or reasonably foreseen co-located asbestos therein) in a separate and subsequent risk evaluation focused on talc.
1.8	**TSCA applies to asbestos contaminants in TSCA-regulated consumer and industrial applications of talc**	

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51	**PUBLIC COMMENTS:** • EPA's assertion that contaminants in consumer and industrial products are outside the scope of TSCA risk evaluations because their presence is "inadvertent" is an incorrect interpretation of the law. EPA's policy has always been to treat contaminants found in materials as manufactured for commercial purposes subject to TSCA, regardless of whether the contaminant is "intended" to be present. EPA's premanufacture notice (PMN) regulations under section 5 require manufacturers of "new chemicals" to notify EPA of "impurities" found in these substances (40 CFR § 720.45(b). EPA has used its authorities under section 5 of TSCA to restrict these impurities where they may present unreasonable risks to health or the environment. • Asbestos that is mined "coincidentally" during the mining of talc and lacks "separate commercial value" is nonetheless "manufactured for commercial purposes" under TSCA and is subject to TSCA authorities. • Impurities that are not "intended" to be manufactured but are "known or reasonably foreseen" to be produced during the manufacture of another substance fall within the definition of "COUs" in Section 3(4) of TSCA. Therefore, inadvertent presence in commercially mined talc is a COU of asbestos which must be addressed in EPA's asbestos risk evaluation.	As stated in the Procedures for *Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, 82 FR 33726, 33730 (July 20, 2017), EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be `de minimis' or otherwise insignificant. In other cases, it may be more appropriate to evaluate potential risks arising from a chemical impurity within the scope of the risk evaluation for the separate chemical substances that bear the impurity. EPA is aware that talc originating from certain sources and used in consumer and industrial applications may contain asbestos. However, considering the significant scope of evaluating the potential risks posed to individuals from exposure to talc, the Agency believes it would be more appropriate to evaluate talc (and any known or reasonably foreseen co-located asbestos therein) in a separate and subsequent chemical risk evaluation of talc.
1.9 **Fabric/textiles are sources of asbestos**		
46	**PUBLIC COMMENTS**: • Asbestos blankets and gloves are still currently used for welding activities, and regular repair work on turbine linings containing asbestos continues to expose workers to asbestos containing textiles.	Following the review of published literature and online databases including the most recent data available from the U.S. Geological Survey's (USGS) Mineral Commodities Summary and Minerals Yearbook and government and commercial trade databases, EPA believes asbestos blankets and gloves are not manufactured in the United States or imported into the country for use. Furthermore, on April 25,

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		2019, EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5 that prohibits manufacture (including import) or processing of discontinued uses of asbestos (such as asbestos blankets and gloves) from restarting without EPA evaluating and making a determination on whether the chemical presents unreasonable risks to health and the environment and to take regulatory action, as appropriate, under TSCA Section 5. As part of developing the supplemental scope document for legacy uses and other fiber types of asbestos (Part 2 of the Risk Evaluation), EPA will address legacy uses, such as asbestos blankets and gloves, that while no longer imported into or manufactured in the United States, may be still in use commercially or by consumers, and therefore, should be included in the supplemental scope document.
1.10 **Cement**		
46, 51, 98	**PUBLIC COMMENTS**: • There are exposures from asbestos-cement piping. • Asbestos enters water supplies primarily from the deterioration of asbestos-cement pipes, which make up between 12 and 15% of drinking water systems in the United States.	EPA determined, after researching and contacting potential importers, that there is no evidence to support that asbestos cement products or packings are COUs of asbestos that continue to be manufactured (including imported), processed, or distributed in the U.S. As part of developing the supplemental scope document for Part 2 (legacy uses and other fiber types of asbestos), EPA will investigate whether asbestos cement products or packings should be included in the supplemental scope document.
1.11 **Treat woven and cement products**		
51	**PUBLIC COMMENTS:** • EPA does not include cement and woven products in the Draft RE for Asbestos because it "has not found any evidence to suggest that woven products (other than those that are already covered under a distinct COU such as brake blocks used in draw works) or cement	EPA determined following further research and after contacting potential importers that there is no evidence to support that asbestos-containing woven products (other than those that are already covered under a distinct COU such as brake blocks used in oil drilling equipment), cement products, or packings are COUs of asbestos that continue to be

	products imported into the United States contain asbestos." The International Trade Commission import summaries, however, have consistently shown substantial incoming shipments of asbestos fabric and cement. EPA stated that it contacted potential foreign exporters of asbestos woven and cement products, and the companies stated that they do not have customers in the US. However, EPA only spoke to two Mexican companies, not all the other listed foreign exporters of these products, and by phone rather than via written statements. • The inclusion of asbestos woven and cement products in its Significant New Use Rule (SNUR) (40 CFR §721.11095) is not an adequate substitute for addressing them in the Draft RE for Asbestos. The SNUR makes no finding of unreasonable risk for these or other asbestos-containing products nor is it a prohibition on their use; instead, it merely requires EPA to be notified before their reintroduction into US commerce. By contrast, the risk evaluation would determine unreasonable risk for all asbestos COUs and lay the foundation for a ban of products subject to that determination. The commenter requested that EPA treat asbestos woven and cement products as COUs under TSCA and add them to the evaluation.	manufactured, imported or distributed in the United States. Data that the commenter references from the International Trade Commission regarding asbestos woven and cement products is likely the result of misreporting (see Appendix C of Part 1 of the Risk Evaluation). The Agency worked with federal partners to better understand the asbestos-containing product import information. In coordination with Customs and Border Protection (CBP), EPA reviewed available import information. CBP provided import data for asbestos HTS codes in CBP's Automated Commercial Environment (ACE) system, which provided information for 26 companies that reported the import of asbestos-containing products between 2016 and 2018. EPA contacted these 26 companies in order to verify the accuracy of the data reported in ACE. Of these 26 companies, 22 companies confirmed that the HTS codes were incorrectly used and the imported articles did not contain asbestos. One company could not be reached when contacted by EPA and three companies confirmed that the asbestos HTS codes entered in ACE were correct corresponding to the uses of asbestos gaskets, brake linings and rubber asbestos sheets used to make gaskets. Furthermore, on April 25, 2019, EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5 that prohibits manufacture (including import) or processing of discontinued uses of asbestos including asbestos woven products (other than brake blocks used in oil drilling equipment) and asbestos cement products from restarting without EPA evaluating and making a determination on whether the chemical presents an unreasonable risk to health and the environment and to take regulatory action, as appropriate, under TSCA Section 5. Since finalization of the asbestos SNUR in 2019, EPA has not received any significant new uses notices that would be required prior to import asbestos woven products (other than brake blocks used in oil drilling equipment), packings and asbestos cement products.
1.12 **Vermiculite**		

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
51	**PUBLIC COMMENTS**: • Vermiculite contaminated with amphibole has been used as insulation in some 10-30 million homes and can be released into indoor and outdoor air when there is disruption caused by extreme weather or home remodeling or demolition, exposing residents and construction workers.	As part of developing the scope document for Part 2: legacy uses and other fiber types of asbestos, EPA will consider whether legacy uses of vermiculite orginating from Libby, MT should be included. The scope document will be made available for public comment.
1.13 **Only chrysotile asbestos is being imported, processed, and distributed**		
28, 42, 61, 84	**PUBLIC COMMENT:** • A commenter agreed that only chrysotile asbestos is currently being imported in the raw form or imported in products (Draft RE for Asbestos p. 132, ln. 4864–4865). It is used to create diaphragms for the chlor-alkali industry. • The Draft RE for Asbestos's conclusions that the only form of asbestos known to be imported, processed, or distributed for use in the US is chrysotile is justified. • The fiber consumed in US commerce today (chrysotile) is mostly imported in finished product form. • None of the potent forms of asbestos are imported into the US.	EPA appreciates the comment.
1.14 **More importation data are needed**		
SACC, 42, 51, 68, 80, 97	**SACC COMMENTS:** • Recommendation 67: Actively collect more data on imported products suspected of containing asbestos instead of relying exclusively on voluntary reporting. • The Draft RE for Asbestos states that it is "highly certain" that import of ACM beyond the six product categories does not occur. Given USGS data on imports, the following HTS codes were not specifically addressed in the DRE: 6812.99.0004 (yarn and thread); 6812.99.0004 (crocidolite products except footwear); 6812.91.9000 (clothing except footwear); 6812.99.0025	EPA conducted extensive research and outreach to determine the COUs of chrysotile asbestos and activities that do not qualify as COUs. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR), EPA's Toxics Release Inventory (TRI) program, Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb and government and commercial trade databases. EPA also reviewed company websites of potential

	(building materials). If these have been investigated, then they should also be listed in Appendix C. **PUBLIC COMMENTS:** • The Draft RE for Asbestos repeatedly admits EPA has virtually no information on imported asbestos-containing products, including the quantities, the number of end-users and the sites where asbestos exposure occurs. • According to the USGS, EPA allowed 280,325 metric tons of asbestos to be imported from 1991 to 2018. Based on 2019 [USGS] data, the total amount of raw asbestos imported into the US from Brazil and Russia was 750 metric tons in 2018 (Usgs (2020); however, only a modest amount of documentation supports this claim. • The U.S. Geological Survey for Asbestos 2020 states that "a small, but unknown, quantity of asbestos was imported within manufactured products, including brake blocks for use in the oil industry, rubber sheets for gaskets used to create a chemical containment seal in the production of titanium dioxide, certain other types of preformed gaskets, and some vehicle friction products" (Usgs (2020). EPA is not aware of the volume of those imports (Draft RE for Asbestos ln. 1305-1307). • EPA had the authority and the duty under TSCA to do more to acquire information prior to publishing the Draft RE for Asbestos. The power to compel information from the entities profiting from the manufacture/import of subject chemicals is central to TSCA.	manufacturers, importers, distributors, retailers, or other users of asbestos. EPA also considered comments received on the Scope of the Risk Evaluation for Asbestos, the Problem Formulation of the Risk Evaluation and the draft Risk Evaluation for Asbestos. In addition, EPA convened meetings with companies, industry groups, chemical users, and other stakeholders to aid in identifying COUs and verifying COUs identified by EPA. Although there is some uncertainty regarding the amount and number of exposed individuals for the asbestos COU, EPA believes the remaining asbestos uses that are imported, manufactured, processed and distributed are sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets. These asbestos uses align with what is listed as asbestos products that continue to be imported into the U.S. according to the most recent (2020) USGS Mineral Commodities Summary for asbestos found at https://www.usgs.gov/centers/nmic/asbestos-statistics-and-information. In regards to the referenced HTS codes pertaining to products not evaluated in the DRE: 6812.99.0004 (yarn and thread); 6812.99.0004 (crocidolite products except footwear); 6812.91.9000 (clothing except footwear); 6812.99.0025 (building materials), EPA believes the listing of these products is likely the result of misreporting (see Appendix C of Part 1 of the Risk Evaluation). The Agency worked with federal partners to better understand the asbestos-containing product import information. In coordination with Customs and Border Protection (CBP), EPA reviewed available import information. CBP provided import data for asbestos HTS codes in CBP's Automated Commercial Environment (ACE) system, which provided information for 26 companies that reported the import of asbestos-containing products between 2016 and 2018. EPA

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
		contacted these 26 companies in order to verify the accuracy of the data reported in ACE. Of these 26 companies, 22 companies confirmed that the HTS codes were incorrectly used and the imported articles did not contain asbestos. Furthermore, on April 25, 2019, EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5 that prohibits manufacture (including import) or processing of discontinued uses of asbestos including asbestos woven products (other than brake blocks used in oil drilling equipment) and asbestos cement products from restarting without EPA evaluating and making a determination on whether the chemical presents an unreasonable risk to health and the environment and to take regulatory action, as appropriate, under Section 5.. Since finalization of the asbestos SNUR in 2019, EPA has not received any significant new uses notices that would be required prior to import asbestos woven products (other than brake blocks used in oil drilling equipment) and asbestos cement products. As such, EPA had sufficient information to complete the Part 1 of the Risk Evaluation (Chrysotile Asbestos) using a weight of scientific evidence approach. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, EPA will continue to improve on its method and data collection for the next round of chemicals to be assessed under TSCA. As a result of the court decision in Safer Chemicals Healthy Families v. EPA 943 F.3d 397. (9th Cir. 2019), the Agency

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
		will evaluate legacy asbestos uses and associated disposals of those uses. EPA will include such uses and associated disposals in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope document for Part 2 of the Risk Evaluation for Asbestos.
1.15 **Exposure does not occur during importation**		
72	**PUBLIC COMMENTS:** • The Chlorine Institute agrees with the Draft Risk Evaluation for Asbestos that asbestos exposures are not expected during the import process (ln. 7665–7671) or when handling fabricated diaphragms (Draft RE for Asbestos ln. 2121) because the asbestos is tightly controlled.	EPA agrees with the commenter that exposures to asbestos are unlikely to occur during the importation process for both raw commercial chrysotile asbestos and the asbestos articles evaluated in the Draft Risk Evaluation for Asbestos.
1.16 **Exposure can occur during importation**		
51	**PUBLIC COMMENTS:** • To conclude that no asbestos exposure occurs during importation activities is speculation. Risks of accidental releases and spills exist during importation and distribution of asbestos-containing products.	See response to Comment 2.41 acute exposure events such as spills and accidents.
1.17 **Other sources or releases**		
SACC, 51, 76, 77	**SACC COMMENTS**: • The Draft RE for Asbestos did not include certain exposure sources (drinking water, talc, asbestos-containing building materials, vermiculite, etc. as noted above). • Fugitive emissions associated with disturbing naturally occurring asbestos deposits through activities such as construction should be a COU that is examined in the asbestos risk evaluation under TSCA. • Several SACC members searched online and found information that at least suggests that asbestos-bearing products are in circulation, including chats, how-to	After reviewing reasonably available information, the asbestos uses EPA evaluated for Part 1 of the Risk Evaluation for Asbestos include the import of raw commercial chrysotile asbestos manufactured domestically into chlor-alkali diaphragms, sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets. EPA evaluated the following categories of COUs for chrysotile asbestos: manufacturing; processing; distribution in commerce; occupational and consumer uses; and disposal. EPA does not consider "naturally occuring asbestos" a condition of use in Part 1 of the Risk Evaluation for Asbestos

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	videos, junkyard parts listings, online advertisements of wholesale quantities, etc. **PUBLIC COMMENTS:** • In parts of the country with high asbestos levels in rock formations, air emissions may result from rock mining. • Urban ambient air concentrations of asbestos have been documented by (ATSDR (2001). Asbestos concentrations in excess of 0.0001 f/cc in urban air probably represent loading from point sources. • Over 111,420 metric tons of asbestos were mined in the United States from 1991 until the last domestic mine closed in 2002 (USGS (2006). • Fibrous amphibole asbestos exposure from natural sources is a current potential concern, especially in mining activities as well as earth moving processes such as dam and road construction and other excavations. Maintenance and abatement activities also can result in amphibole asbestos exposure.	because it is not manufactured (including imported) processed, distributed. As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 et al. (9th Cir. 2019), the Agency will evaluate legacy asbestos uses including asbestos-containing building materials (ACBM) and associated disposals of those materials Part 2 of the Risk Evaluation, beginning with a supplemental scope document.
1.18 **Include ingestion route of exposure**		

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
SACC, 31, 51, 89	**SACC COMMENTS:** • SACC recommended that EPA consider including the drinking water pathway in the TSCA asbestos risk assessment. • EPA has not identified publications that measure water releases of asbestos associated with processing, using, or disposing of aftermarket automotive products. • Another potential source of surface water contamination is transport of asbestos-contaminated clothing from the workplace to residence, where laundering the clothing could release asbestos to domestic wastewaters, although the contribution overall is likely small. **PUBLIC COMMENTS:** • Commenters requested EPA to expand its risk evaluation to assess the ingestion route of exposure. • Ingestion of asbestos-contaminated aquatic animals is possible. The Draft RE for Asbestos stated that asbestos is unlikely to bioconcentrate in aquatic ecosystems based on Belanger et al. (1987) finding that BCFs measured in clams in the laboratory were low (slightly >1). However, field-collected clam viscera BCFs of 100 were found, and field-collected whole clam homogenate BCFs ranged from 1,400 to 5,000. Thus, asbestos does bioconcentrate in filter feeders such as clams in aquatic systems. Animals that eat clams (*e.g*, humans) might ingest relatively large loads of asbestos in areas where there is considerable asbestos contamination.	The drinking water pathway for asbestos is currently addressed under the Safe Drinking Water Act (SDWA), therefore it was not included in this evaluation, as described in Section 1.4.4 of Part 1 of the Risk Evaluation for Asbestos. As stated in the PF, EPA decided to focus its evaluation of health hazards to lung cancer and mesothelioma. Because oral exposures (ingestion) are not expected to contribute to the development of these cancers, this route of exposure was not considered critical to the evaluation. EPA believes that for the evaluation of chrysotile asbestos in Part 1 of the Risk Evaluation, that the inhalation exposures are the most critical as this is the exposure route that is associated with mesothelioma, lung cancer, and other cancers that are known to result from asbestos exposure.
1.19 **Acknowledge dermal exposure**		
SACC	**SACC COMMENTS:** • The Draft Risk Evaluation for Asbestos discounts the dermal exposure pathway by stating asbestos will not absorb into the body through the protective outer skin layers (p.108, ln. 3890-3891). However, dermal	EPA acknowledged dermal exposures in the Problem Formulation document released in 2018. Body powders are not included in any of the relevant COUs identified for chrysotile asbestos that is the focus of Part 1 of the Risk Evaluation for Asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
	absorption is assessed for risk assessments involving body powders containing asbestos. In that situation, the primary dermal route of exposure to fibers is reported as being through perineal application of the body powder (see IARC (2012a); p. 232). This route cannot be discounted for exposures from the COUs discussed in this DRE. The DRE should at least acknowledge this potential dermal pathway.	
1.20 **Other environmental pathways of exposure**		
SACC, 51, 77, 89, 92, 104	**SACC COMMENTS:** • The Draft RE for Asbestos does not address take-home exposures associated with the transport of asbestos-contaminated clothing from the workplace to residence. (see for example, Abelmann et al. (2017)). Several articles quantify the airborne chrysotile asbestos fiber levels associated with handling contaminated clothing in the home. The handling can include laundering the clothing at home, which could release chrysotile asbestos to domestic wastewaters, although no studies are reported to have addressed this possibility. Recommendation 24: Explain how contaminated products and articles of clothing will be addressed. Recommendation 25: Add a "take-home" or occupational bystander COU and address exposures associated with the transport of asbestos-contaminated clothing (and other items) from the workplace to the home residence. • Excluding terrestrial pathways based strictly on statutory considerations will result in an incomplete risk assessment for asbestos; EPA should consider including these. **PUBLIC COMMENTS:** • EPA should include other environmental pathways of exposure including in ambient air (*e.g*, from stationary	As described in Part 1 of the Risk Evaluation for Asbestos, EPA ONU assessments evaluate the worker who is not handling the chemical but is nearby, and ONU exposures are already addressed throughout the risk evaluation Regarding the "take home" exposure scenario, scientific literature has reported on this topic through various protocols, like shaking clothing with deposited asbestos fibers and then collecting samples to measure airborne asbestos. However, EPA notes that: The publication cited in the SACC report Abelmann et al. (2017) addresses "take-home" exposures, but the asbestos in cement dust is not relevant to the COUs considered in the Part 1 of the Risk Evaluation. Specifically, this reference considered workers using powered abrasive saws to cut cement pipe over entire shifts, with the pipe containing 35 percent asbestos. The amount of asbestos released during such conditions is likely dissimilar to releases from the COUs that OSHA evaluated. Therefore, the results from this publication (and some similar publications) may significantly overstate "take-home" exposures for the risk evaluation's COU. EPA examined take home exposure for the chlor-alkali industry. This industry's facilities have implemented safe work practices to dramatically reduce "take-home" exposures. Specifically, these facilities' locker rooms and changing areas

	sources, incineration, and energy recovery units, outside chlor-alkali plants), and in solid waste. • "Take-home" exposure to asbestos—someone working with asbestos carries fibers on their clothing to non-occupational settings including home—is a well-documented exposure pathway. • Asbestos is not a hazardous waste regulated under RCRA, and therefore generation, transport, and disposal of asbestos are not adequately addressed under RCRA. These exposure pathways should be part of the TSCA-required risk evaluation for asbestos.	have "clean rooms" separate from "dirty rooms." Outer clothing and footwear used when handling asbestos is removed in the "dirty room" and decontaminated or discarded, thus limiting the amount of "take-home" exposures; and workers are not allowed to store work clothes and personal clothes in the same area. Take-home exposures are possible for other COUs including auto brake and gaskets. However, the frequency and magnitude of take-home exposure and contaminations on clothing and shoes depend on several factors, including personal hygiene and visibility of the chemical on skin or clothing. At this point, EPA has not found and does not have methods to reliably predict take home exposure. EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the risk evaluation for methylene chloride using authorities in TSCA sections 6(b) and 9(b)(1). EPA did not evaluate hazards or exposures from chrysotile asbestos releases to terrestrial organisms or the general population in this risk evaluation, and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to the terrestrial organisms or the general population."

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
1.21	**Potential for co-existing fibrous amphiboles and impurities**	
SACC, 42, 58, 77	**SACC COMMENTS:** • Without extensive testing to indicate otherwise, the aftermarket brake pads, linings, gaskets, and other vehicle friction products could contain some amphiboles, likely in small amounts, that were naturally intermixed with the chrysotile. • Recommendation 6: The potential for co-existing fibrous amphiboles should be mentioned in the document. • Of the "asbestos" in past and current commerce, 95% is chrysotile asbestos; however, the Draft RE for Asbestos acknowledges that commercial chrysotile can include small amounts of amphibole asbestos. Thus, asbestos-containing products in commerce contain both types of fiber in varying proportions. Some SACC members objected to a chrysotile-specific risk evaluation. **PUBLIC COMMENTS:** • Populations exposed to commercial chrysotile asbestos are likely to be exposed to small but variable amounts of amphibole asbestos which strongly dictates mesothelioma hazard and influences the risk of developing an asbestos-related disease. • Imported chrysotile often contains impurities of other forms of asbestos. Many imported products containing talc or vermiculite may also contain amphibole asbestos. • EPA collects no information about asbestos-containing articles or products that could contain impurities.	EPA has included text describing that, as a naturally occurring mineral, chrysotile can co-occur with other minerals, including amphibole forms of asbestos. Trace amounts of these minerals may remain in chrysotile as it is used in commerce. This commercial chrysotile, rather than theoretically "pure" chrysotile, is therefore the substance of concern for Part 1 of the Risk Evaluation for Asbestos. As a result of the court decision in Safer Chemicals Healthy Families v. EPA 943 F.3d 397. (9th Cir. 2019), the Agency will evaluate legacy uses of asbestos and associated disposals as well as other fiber types of asbestos in Part 2 of the Risk Evaluation for Asbestos. The Agency's risk evaluation for asbestos will be comprised of both Part 1 (chrysotile asbestos) and Part 2 (legacy uses and other fiber types of asbestos), and therefore, is not a chrysotile-specific risk evaluation.

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
1.22 **Other comments on environmental exposure and release**		
51, 89	**PUBLIC COMMENTS:** • Both the chemical and oil industries may be large users of asbestos-containing products although EPA lacks information on the full extent of these uses. • EPA no longer funds administration of the AHERA requirements for asbestos in schools, so EPA should evaluate this exposure pathway.	When preparing the chrysotile asbestos risk evaluation, EPA obtained and considered the reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. EPA conducted extensive research and outreach to determine the COUs of chrysotile asbestos and activities that do not qualify as COUs. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR), EPA's Toxics Release Inventory (TRI) program, Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb and government and commercial trade databases. EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos. EPA also considered comments received on the Scope document, the Problem Formulation, the draft Risk Evaluation for Asbestos. In addition, EPA convened meetings with companies, industry groups, chemical users, and other stakeholders to aid in identifying COUs and verifying COUs identified by EPA. Although there is some uncertainty regarding the amount and number of exposed individuals for the asbestos COUs, EPA believes the remaining asbestos uses that are imported, processed and distributed are sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets. These asbestos uses align with what are listed as asbestos products that continue to be imported into the U.S. according to the most recent (2020) USGS Mineral Commodities Summary for

#	Summary of Comments for Specific Issues Related to Charge Question 1	EPA/OPPT Response
		asbestos found at https://www.usgs.gov/centers/nmic/asbestos-statistics-and-information. As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy asbestos uses including asbestos-containing building materials (ACBM), including those that could occur in school buildings, and associated disposals of those materials in Part 2 of the Risk Evaluation for Asbestos.

2. Occupational Exposure

Charge Question 2:

2.1 Please comment on the estimation methods and assumptions used for occupational exposure assessment (including ONUs) in terms of concentration, frequency and duration of exposures, and their use in the risk evaluation. Below are two specific issues in which EPA is particularly interested in feedback from the SACC.

Incorporation of Short-Term Occupational Monitoring Results

EPA received from industry (or obtained from the published literature short-term (*i.e.*, less than a full 8-hour work shift) monitoring data for several of the COUs (chlor-alkali, sheet gaskets/stamping, aftermarket automotive parts, and other vehicle friction products). For these COUs, EPA calculated a separate "full-shift" asbestos exposure estimates as well as a short-term exposure estimate to account for these occasional, short, high-exposure scenarios. Please comment on the method used.

ONU Exposure Estimates

Based on the readily available information, EPA used different methods to estimate ONU exposures. ONU estimates were made for each COU; however, the limited information did not allow the development of ONU exposures for short-term exposure scenarios for chlor- alkali, sheet gasket use, oil field brake blocks, or other gaskets/UTVs. Please comment on the method(s) used (identified below).

Chlor-alkali (Section 2.3.1.3.5): For ONU exposure estimates area samples were used. Two chlor-alkali facilities provided a total of 15 area samples which were all below the limit of detection (LOD). There were two different detection limits in the two submissions. Although true exposure values below any limit of detection may be unevenly distributed from zero to the limit of detection, we assumed that the central tendency exposure concentration estimate is based on one-half of the detection limit for individual samples and the high-end concentration is based on the highest detection limit across the samples.

Sheet Gasket Stamping and use (Sections 2.3.1.4.5 and 2.3.1.5.5): EPA did not identify any ONU exposure measurements for these COUs. However, the literature includes "bystander" exposure studies. Specifically, one publication, Mangold et al. (2006), measured "bystander" exposure during asbestos-containing gasket removal. The "bystander" locations in this study were between 5 and 10 feet from the gasket removal activity, and asbestos concentrations were between 2.5 and 9 times lower than those measured for the worker. Based on these observations, EPA assumes that ONU exposures for these COUs are a factor of 5.75 (*i.e.*, the midpoint between 2.5 and 9) lower than the directly exposed workers.

Oilfield brake blocks (Section 2.3.1.6.5): EPA has not identified specific data on potential ONU inhalation exposures from brake block use. It is assumed that ONUs do not directly handle brake block and drawworks machineries and that this equipment is always used and serviced outdoors close to oil wells. Given the limited information identified in Section 2.3.1.6.4 (*i.e.*, worker monitored values), the lower of the two reported values was used to represent ONU exposures for this COU.

Aftermarket automotive brakes (Section 2.3.1.7.5): EPA has not identified data on potential ONU inhalation exposures from after-market auto brake scenarios. ONUs do not directly handle brakes and the ONU exposure estimates in Table 2-15 were generated by assuming that asbestos concentrations decreased by a factor of 8.4 between the worker location and the ONU location. EPA derived this reduction factor from a publication (Madl et al. (2008) that had concurrent worker and bystander exposure measurements where the bystander was approximately 5 feet from the worker. The value of 8.4 is the average concentration reduction across four concurrent sampling events.

Other gaskets/UTVs (Section 2.3.1.9.4): Paustenbach et al. (2006) includes area sampling results that EPA thought appropriate for ONU exposures. These samples were collected at breathing zone height at locations near the ends of the muffler shop bays where the exhaust system work was performed. The area sample durations ranged from 25 to 80 minutes, and these samples were collected during exhaust system work. Overall, 21 area samples from these locations were analyzed by PCM; and 16 of these samples were non-detects for asbestos. Among the PCM data from this subset of area samples, the authors report that the average asbestos concentration was 0.005 fibers/cc and the maximum asbestos concentration was 0.015 fibers/cc. The study authors did not report 8-hour TWA concentrations for the area sample locations. EPA used these average and maximum asbestos concentrations to estimate potential ONU exposures.

2.2 Please comment on EPA's reasonableness of these assumptions, the uncertainties they introduce, and the resulting confidence in the occupational exposure estimates (Section 4.3.3).

2.3 Please provide specific suggestions or recommendations for alternative approaches, estimation methods, or information sources that EPA should consider for improving the occupational exposure assessment.

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2.1	**EPA's general approach was valid**	
SACC	**SACC COMMENTS:** • Given the relatively high level of uncertainty about chrysotile asbestos exposure levels associated with the COUs, EPA has appropriately selected the high exposure estimates by which to identify risk. • Absent conclusive state-of-the-science data on the absence of biologically active chrysotile asbestos in aftermarket brake drums, the SACC believed EPA's general approach and evaluation was valid.	EPA thanks the SACC for these comments.
2.2	**Support for TSCA definition of asbestos in Draft RE for Asbestos**	
75	**PUBLIC COMMENTS:** • EPA's adherence to the TSCA definition of asbestos in the Draft RE for Asbestos is strongly supported. As defined in TSCA, asbestos is the "asbestiform varieties of chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite, or actinolite." EPA should continue to adhere to the TSCA definition of asbestos in the final risk evaluation.	EPA acknowledges this comment and will consistently apply this definition in the Risk Evaluation for Asbestos.
2.3	**Include legacy and other forms of asbestos in current risk assessment; excluding them underestimates risk**	
SACC, 25, 45, 47, 51, 53, 57, 63, 69, 73, 77, 85, 86, 88, 92	**SACC COMMENTS:** • The Draft RE for Asbestos is focused on current commercial uses of chrysotile asbestos. The SACC encourages EPA to incorporate into the assessment other asbestos and asbestos-like fibers in addition to chrysotile exposure beyond the COUs evaluated. • SACC recommended that EPA include exposure to legacy asbestos to avoid underestimation of risk to workers, ONUs, and consumers. Without a discussion	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019)), the Agency will evaluate legacy asbestos uses and associated disposals of those uses. Legacy asbestos uses are uses for which manufacture (including import), processing and distribution no longer occur but the uses are still known, intended, or reasonably foreseen to occur. EPA will include such uses and associated disposals in Part 2 of the Risk Evaluation (legacy uses and other fiber types of asbestos) beginning with a supplemental scope document.

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	of legacy uses, a reader might conclude that legacy uses do not contribute to population risk. **PUBLIC COMMENTS:** • By not considering exposures to "legacy" asbestos in buildings and elsewhere, EPA leaves out exposures that occur to persons not aware of the presence of asbestos in buildings and other materials and therefore, these persons are not adequately protected. Legacy asbestos poses the greatest potential for exposures to asbestos in the US today. By EPA's own admission, it has undercounted both exposure and likely mortality rates.	
2.4 **Future supplemental evaluation for legacy asbestos**		
SACC, 29, 45, 51, 65, 68, 75, 77, 85, 97	**SACC COMMENTS:** • Recommendation 16: Explain how legacy uses of asbestos will be addressed in the proposed larger asbestos evaluation. **PUBLIC COMMENTS:** • EPA indicates that they will "consider legacy uses and associated disposal in a supplemental scope document and supplemental risk evaluation." However, completing a separate risk evaluation for legacy uses of asbestos, while moving forward with risk management options for chrysotile asbestos is piecemeal regulation that would underestimate risks associated with aggregate worker exposure to both current and legacy asbestos. • Addressing legacy asbestos in a future supplemental evaluation raises several questions, particularly because "exposure to older asbestos is just as dangerous as exposure to newer asbestos." Would EPA need to develop IURs for non-chrysolite fibers? How would those IURs relate to the chrysotile-only IUR?	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy asbestos uses and associated disposals of those uses in Part 2 of the Risk Evaluation for Asbestos. For Part 2, EPA plans to issue the following documents: a draft supplemental scope document for public comment, a final supplemental scope document, a draft risk evaluation document for public comment and a final risk evaluation document. Prolonging finalization of the risk evaluation for chrysotile asbestos (Part 1 of the Risk Evaluation for Asbestos), by expanding the document to also evaluate legacy uses (where only use and associated disposal is present) would significantly delay needed risk management to address COUs where unreasonable risk is present for chrysotile asbestos. Part 2 of the Risk Evaluation for Asbestos will include relevant COUs identified for legacy uses and other fiber types of asbestos that will be described in a scope document that will be made available for public comment. EPA will consider the hazard and risk and appropriate IUR(s) for

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	Presumably the future evaluation would address aggregate or total risk from current and legacy products. • EPA should clarify whether the phrase "supplemental documents" simply means the supplemental scope document and supplemental risk evaluation or whether it includes other documents too. If the latter, EPA should specify in the final REA any such additional documents in which EPA intends to address legacy uses and associated disposal of asbestos. Further, it is not clear if the IURs for chrysotile and/or other types of asbestos will be updated when EPA assesses legacy uses in the future.	cancer and non-cancer to apply in order to address asbestos fibers relevant for legacy COUs.
2.5 **Need to address aggregate risk of exposures to COUs and legacy asbestos**		
53, 69, 43, 45, 51	**SACC COMMENTS:** • Recommendation 60: Include legacy and aggregate asbestos exposures in the calculation of exposure and cancer risk. **PUBLIC COMMENTS:** • EPA should revise the Draft RE for Asbestos to include all uses and forms of asbestos—particularly "legacy" asbestos and disposal—and ensure that it estimates the total [aggregate] risk of asbestos exposure for workers. Many workers perform tasks daily with no knowledge of ACM in their work. Labels and safety data sheets are not present when ACBMs are reused, removed, or repaired, or disturbed during renovation and demolition activities. Such workers would not have been trained in required protection and safety practices. • Workers and consumers exposed to current chrysotile-containing products may also have been exposed to other fibers earlier in their work careers when construction materials containing these fibers were still in active use. Determining asbestos risks to these workers and consumers based solely on their exposure	Section 6(b)(4)(F)(ii) of TSCA requires the EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the COUs were considered and the basis for their consideration. The EPA has defined aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." The EPA defines sentinel exposure as "the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures (40 CFR § 702.33)." For this risk evaluation document (Part 1), the EPA considered sentinel exposure the highest exposure given the details of the COUs and the potential exposure scenarios. EPA considered sentinel exposure for chrysotile asbestos in the form of a high-end level scenario for occupational exposure resulting from inhalation exposures for each COU; sentinel exposures for workers are the high-end 8-hour exposures for sheet gasket stamping without any PPE.

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	to chrysotile in current products would fail to account for all pathways of exposure and understate risks.	EPA considers the reasonably available information and used the best available science to determine whether to consider aggregate or sentinel exposures for chrysotile asbestos. EPA determined that using the high-end risk estimate for inhalation risks separately as the basis for the unreasonable risk determination is a best available science approach. Aggregate exposures for chrysotile asbestos were not assessed by multiple routes of exposure in the Part 1 of the Risk Evaluation for Asbestos (chrysotile asbestos) since only inhalation exposure was evaluated. Although there is the possibility of dermal exposures occuring for the chrysotile asbestos COUs, the only known associated hazard with dermal exposure to asbestos is the formation of skin lesions, as discussed in the Scope and PF documents, the only known hazard associated with dermal exposure to asbestos is the formation of skin lesions. EPA estimated full-shift time-weighted averages (central tendency and high-end) for each COU for the risk calculation. Since these are full-shift exposure and not task-based estimates, aggregate exposure is not relevant for the occupational settings. It is reasonable to assume that the workers are exposed to asbestos from one COU and that the high-end air concentration represents the plausible upper bound of exposure for each COU. Pathways of exposure were not combined in for chrysotile asbestos in Part 1 of the Risk Evaluation. Although it is possible that workers exposed to asbestos might also be exposed as consumers (*e.g*, by changing brakes at home), the number of workers is potentially small. The individual risk estimates already indicate risk for all conditions of use except NASA super guppy; aggregating the pathways would increase the risk. Given all the limitations that exist with the data, EPA's approach reflects best available science.

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		The potential for exposure to legacy uses of asbestos for any populations or subpopulation, due to activities such as home or building renovations, as well as occupational or consumer exposures identified in Part 1of the Risk Evaluation, is possible. EPA will consider these other uses and associated disposal of asbestos in Part 2 of the Risk Evaluation, beginning with a draft scope document.
2.6 **Concerns about reduced involvement/enforcement of worker-related asbestos regulations**		
15, 45, 69	**PUBLIC COMMENTS:** • Excluding legacy ACBMs from the Draft RE for Asbestos appears to be the prelude to less involvement of EPA in efforts enshrined in 40 CFR 763 and all its appendices, including the Asbestos Worker Protection Rule. • EPA and OSHA have significant rules in place for identifying ACM and its management and handling. EPA has a specific rule, known as the asbestos NESHAP regulation (40 CFR Part 61, subpart M), which requires a "thorough inspection" of the building(s) where renovation or demolition activities will occur and the prior removal of RACM; however, this rule is commonly violated.	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy uses and other fiber types of asbestos uses and associated disposals of those uses in Part 2 of the risk evaluation. EPA will proceed to risk management for any unreasonable risks found in Part 2 of the Risk Evaluation (legacy uses and other fiber types of asbestos). NESHAP regulations will be appropriately considered in Part 2 of the Risk Evaluation for Asbestos.
2.7 **Need IUR(s) to address all types of asbestos**		
SACC, 15, 25, 29, 43, 45, 46, 47, 51, 53, 57, 63, 68, 69, 73, 75, 85, 86, 87,	**SACC COMMENTS:** • Recommendation 44: Derive one IUR to apply to all types of asbestos not just chrysotile asbestos. (One Committee member strongly objected to this recommendation in post meeting communications.) **PUBLIC COMMENTS:** • The risk evaluation should not be limited to chrysotile but should encompass all recognized asbestos fibers and amphiboles because (1) evidence suggests that exposure to asbestos-like fibers can also yield unwanted health	EPA is confident that chrysotile asbestos represents the only form of asbestos where manufacture, import, processing and distribution in the U.S. is still known, intended, or reasonably foreseen. The derivation and use of a chrysotile-specific IUR is necessary to address the COUs included in Part 1 of the Risk Evaluation for Asbestos. The IUR derived in Part 2 of the Risk Evaluation for Asbestos will appropriately reflect other fiber types and health hazards, as supported by the best available science.

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89, 101, 104	effects (2) real-world exposure is not limited to only chrysotile. • In addition to the six commercial asbestos fibers, all elongated mineral particles (EMPs) are biologically active in lung and other tissue. Just like commercial asbestiform fibers, both non-asbestiform fibers and other EMPs are deadly and cause pleural disease; asbestosis; other non-malignant respiratory diseases; lung, ovarian, and laryngeal cancers; and mesothelioma and should be included. There is no reasonable basis for EPA to ignore COUs involving occupational talc exposures and other exposures to EMPs. • By only evaluating chrysotile and not including the five forms of legacy asbestos (amosite, crocidolite, anthophyllite, tremolite, and actinolite) plus Libby Amphiboles, EPA has underestimated the risk of exposure to asbestos. Supported by claims of scientists and epidemiologists, Libby Amphiboles cause cancer and death, and they are another legacy material form of asbestos that should be included in any asbestos risk evaluation by EPA.	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy uses and other fiber types of asbestos uses and associated disposals of those uses in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope document. EPA will proceed to risk management for any unreasonable risks found for the legacy COUs evaluated. EPA is aware that talc originating from certain sources and used in consumer and industrial applications may contain asbestos. However, considering the significant scope of evaluating the potential risks posed to individuals from exposure to talc, it would be more appropriate to evaluate talc (and any known or reasonably foreseen co-located asbestos therein) in a separate and subsequent risk evaluation focused on talc. Libby Amphibole asbestos, which is a mixture of several mineral fibers such as tremolite and winchite and richterite, was found in vermiculite ore mined near Libby, MT and extensively distributed throughout the United States during the 20th century. Vermiculite from Libby, MT had a range of commercial applications, the most common of which included packing material, attic and wall insulation, spray-on fire proofing, various garden and agricultural products, and various cement and building products. The Libby, MT vermiculite mine closed in 1990. EPA will consider whether such uses of vermiculite originating from Libby, MT will be included in Part 2 of the Risk Evaluation for Asbestos.
2.8 **Legal requirement to address legacy uses**		
25,31, 45, 68, 77, 101, 73, 53,	**PUBLIC COMMENTS:** • EPA has not addressed requirements imposed by the court in the 2019 Safer Chemicals Healthy Families, et al. v. U.S. EPA decision relating to "legacy uses" of asbestos in the Draft RE for Asbestos. TSCA's	As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy uses and other fiber types of asbestos and associated disposals of those uses in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope

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47, 51, 104, 92	definition of 'COUs' clearly includes uses and future disposals of chemicals; therefore, EPA's exclusion of legacy uses and associated disposals from the definition of "COUs" is unlawful. • In testimony before the US House of Representatives Energy and Commerce Committee in May 2019, EPA's assistant administrator for OCSPP conceded that risk evaluations under TSCA are meant to assess exposures related to disposal. EPA should consider, for example, the evidence of significant asbestos waste in the TRI and the data and reports about active and proposed Superfund sites. Thus, EPA has, without basis in law or fact, eliminated from its risk evaluation many significant sources of chronic exposure to asbestos and failed to fulfill the mandate of Section 6(b)(4)(A) of TSCA and contradicts Congress' clear intent. (15 U.S.C. § 2605(b)(4)(A).]	document. Prolonging finalization of the risk evaluation for chrysotile asbestos (Part 1 of the Risk Evaluation for Asbestos), by expanding the document to also evaluate legacy uses (where only use and associated disposal is present) would significantly delay needed risk management to address COUs where unreasonable risk is present for chrysotile asbestos. EPA's Risk Evaluation regulations explicitly recognize that EPA may reach risk determinations for the chemical substance under the conditions of use "either in a single decision document or in multiple decision documents" (40 CFR 702.47). As explained in more detail in Section 1.4.4. of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for asbestos using authorities in TSCA Sections 6(b) and 9(b)(1). Additional details included in response to Comment 1.1 are additionally relevant to landfill waste/disposal.
2.9 **Methods to estimate past occupational exposures**		
76	**PUBLIC COMMENTS:** • The methods that the EPA used to estimate past occupational exposures to EMPs for specific cohorts	

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	seemed reasonable; however, it appears that the high-end exposure estimations in the analysis represent probable worst-case historical levels. These worst-case levels represent a small fraction of the potential range of exposures for the historical cohorts, which is only minimally applicable to the current situation.	For high-end exposures, EPA used the best information that was reasonably available for its estimates. For most conditions of use, these estimates were based on sampling data that characterize current worker activities. EPA defaulted to historical information in the few instances where current data were not available
2.10 **Focus on modern fiber measurements appropriate**		
46	**PUBLIC COMMENTS:** • The risk assessment for the COUs properly focused on modern fiber measurement assessments and does not rely on historic dust measurements converted to fiber counts, especially as these have never been properly evaluated and verified.	EPA appreciates the comment.
2.11 **EPA should use its authority under TSCA to acquire sufficient information to evaluate exposure**		
77	**PUBLIC COMMENTS:** • EPA conceded that it did not obtain important exposure information, including import volumes of asbestos-containing products, which sites fabricate imported sheet gaskets containing asbestos, number of workers potentially exposed for other non-chlor-alkali plants, and proximity of workers to exposure sources. EPA should obtain that information before issuing its final REA. • EPA should exercise its Section 8 authority to adopt an asbestos information gathering regulation. This will help EPA to fill the data gaps.	EPA did not use its TSCA data collection authorities to gather additional information regarding asbestos because EPA believes it had sufficient information to complete the Part 1 of the Risk Evaluation for Asbestos using a weight of scientific evidence approach. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. To determine the current COUs of asbestos and inversely, activities that do not qualify as COUs, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR), EPA's Toxics Release Inventory

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		(TRI) program, Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb and government and commercial trade databases. EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos. EPA also considered comments received on the Scope, Problem Formulation, and the Draft RE for Asbestos. In addition, prior to the June 2017 publication of the scope document, EPA convened meetings with companies, industry groups, chemical users, and other stakeholders to aid in identifying COUs and verifying COUs identified by EPA. Although there is some uncertainty regarding the amount and number of exposed individuals for the asbestos COUs, EPA believes the remaining asbestos uses that are imported, manufactured, processed and distributed are sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets. Furthermore, on April 25, 2019, EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5 that prohibits manufacture (including import) or processing of discontinued uses of asbestos including asbestos woven products (other than brake blocks used in oil drilling equipment) and asbestos cement products from restarting without EPA evaluating and making a determination on whether the chemical presents an unreasonable risk to health and the environment and to take regulatory action, as appropriate, under Section 5. Since finalization of the asbestos SNUR in 2019, EPA has not received any significant new uses notices that would be required prior to import asbestos woven products (other than brake blocks used in oil drilling equipment) and asbestos cement products.

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2.12 **Characterize the market share of asbestos containing products**		
SACC	**SACC COMMENTS:** • While the effort to characterize the number of potentially impacted individuals seems thorough, it is also surprising the number of times EPA merely declares that a value is unknown. No attempt is made to characterize even a ballpark estimate. This is important since in several occupational COUs (specifically workers stamping sheet gaskets) the numbers exposed are so small as to suggest that this is a category where less attention is needed. However, for other occupational COUs there is insufficient information to even put bounds on potential numbers of exposed individuals. It seems that some effort to characterize the market share of asbestos containing products is warranted, at least to determine a broad characterization. As another example, while it may not be known how many DIYers service asbestos-containing UTVs, it should be reasonable to estimate this from the fraction of UTVs with asbestos-containing parts (a value which is not provided). • Another concern is the representativeness of the Auto Parts Warehouse online survey. • Recommendation 71: Better characterize the market share of asbestos-containing products and associated exposed workers.	For every occupational exposure COU, EPA estimated the number of exposed workers and ONUs. Some estimates could be made to a high degree of accuracy, while others involved greater uncertainty. In all cases, EPA used the best available information to derive these estimates and acknowledged uncertainties where appropriate. Some comments EPA received (like this one) suggested that some numbers of exposed workers were underestimates, and other comments indicated that some numbers were overestimates. To be responsive to these comments, EPA revisited every estimate made in the draft risk evaluation. Some changes to numbers were made (*e.g*, ONU estimate for the aftermarket brakes COU in Section 2.3.1.7.4) after further reflection on the methods and the input that EPA received. EPA has not indicated the fraction of UTVs with asbestos-containing parts because doing so could potentially result in the release of confidential information. In coordination with Customs and Border Protection (CBP), EPA reviewed available import information. CBP provided import data for asbestos HTS codes in CBP's Automated Commercial Environment (ACE) system, which identified 26 companies that reported the import of asbestos-containing products between 2016 and 2018. EPA contacted these 26 companies in order to verify the accuracy of the data reported in ACE. Three companies confirmed that the asbestos HTS codes entered in ACE were correct corresponding to the uses of asbestos gaskets, brake linings and rubber asbestos sheets used to make gaskets. One of the companies indicated that it used asbestos gaskets in producing UTVs. EPA has limitations on its use of specific information from ACE, including the identities of the companies. Specific ACE information can only be used internally within EPA and cannot be discussed or shared with anyone outside of the

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		Agency. While EPA is not indicating the fraction of UTVs with asbestos-containing parts, EPA was still able to reach a risk determination for the associated COU. For oil field brake blocks, EPA received direct confirmation of U.S. companies importing asbestos-containing oil field brake blocks for domestic use (as explained in Section 2.3.1.6.1 of the draft risk evaluation). However, EPA did not receive information on the market share of asbestos-containing brake blocks. In its comments on asbestos-containing automotive parts, the SAAC stated that "… the availability … is unclear and a default to reasonable worst case taken by the Agency would appear to be warranted" and "The DRE has, like all prudent assessments, traded conservatism when data are unavailable. That is, when the information is not definitive, it has defaulted to reasonable worst-case estimates." EPA has taken a similar reasonable worst-case approach for the market share of asbestos-containing oil field brake blocks. Regarding the representativeness of the Auto Parts Warehouse online survey, EPA does not have other sources of information on DIYers that perform their own brake work. The Agency considers the Auto Parts Warehouse survey to be reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation.
2.13 **Low occupational exposures (multiple COUs)**		
39, 42, 61	**PUBLIC COMMENTS:** • Commenter found no information in the document that oil field brake blocks have contained asbestos over the past 35 years. Even if true, it seems this analysis is not warranted under the Lautenberg initiative. If it were, given the low number of persons who could be	EPA identified the oil field brake block COU in the Scope document and received no comments at the time about the appropriateness of this COU. EPA believes asbestos-containing oil field brake blocks continue to be used for older oil rigs based on consultations with industry representatives with knowledge of the oil field drilling

	potentially exposed and the magnitude of possible exposures, regulatory action is unwarranted, especially considering such a critical use scenario where the failure of such materials can result in multiple injuries to workers. • The majority of the document describes scenarios that will likely rarely occur in the coming years and, if they do, the number of persons potentially exposed is vanishingly small and below regulatory significance. • The exposure concentration data are clear and consistent: mechanics and persons working with and around AABL are exposed only to low levels of short-fiber chrysotile, at concentrations well below even today's PELs (*e.g*, Finley et al. (2007); Boyles et al. (2019)). • There is no exposure to asbestos during the installation of brakes, even if there were asbestos-containing brakes used, as there is no brake grinding needed on a modern car. Additionally, all the new cars would have disc brakes. Since as few as 100 persons may be exposed, no cancer deaths are expected. • Because the demand is so low and because no facility wants asbestos-containing gaskets on their site (except chlor-alkali facilities or a refinery), it is not surprising that only one employee in the US is involved in punching gaskets. • The number of plausibly exposed automobile mechanics is probably less than 30-100 persons in the United States (if any). • Commenter believes that virtually no workers will be handling asbestos-containing clutches in the coming years in the US and recommended dropping the scenario.	industry. As Section 2.3.1.6.1 of the draft risk evaluation notes, EPA received direct confirmation of U.S. companies importing asbestos-containing oil field brake blocks for domestic use. Therefore, EPA is justified in retaining this COU in the final risk evaluation. Part 1 risk evaluation is based on uses of chrysotile asbestos for which there is known, intended, or reasonably foreseen import, processing, or distribution. COUs are not limited based on anticipated future trends. EPA made adjustments to the estimated number of individuals exposed by the limited available information on the potential market share of chrysotile asbestos brakes. Details are provided in Section 4.3.7: Confidence in the Human Health Risk Estimations, but the new estimate for number of both workers and ONUs assumes that asbestos brakes represents approximately 0.05% of aftermarket automotive brakes. EPA estimated potentially exposed individuals (both worker and ONUs) applying this factor (0.05%) to the universe of automotive service technicians and mechanics. EPA identified information to indicate that replacement drum brakes and brake shoes are readily available from U.S. auto parts stores, and there are many popular instructional videos online explaining how to replace drum brakes. Many of the instructional videos deal specifically with cars that are model year 2000 or later, so DIYers are clearly interested in changing drum brakes in more recent vintages, not just antique automobiles. If a small percentage of drum brakes are imports that contain asbestos, there could still be numerous workers and DIYers exposed to asbestos. EPA further notes that the California Air Resources Board found that brakes from 3% of tested vehicles contained chrysotile asbestos in the rear drum brakes (De Vita et al. (2012). The vehicle model years ranged from 1989 to 1998 and based on high mileage and/or confirmation by vehicle

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		owners, all vehicles with asbestos brakes were assumed to have had their brakes replaced at least once, thereby indicating a high probability of an aftermarket source of the brake linings. Several of the vehicle owners indicated they had maintenance performed at a service station or independent garage. While California and Washington state subsequently limited sales of asbestos-containing aftermarket brake parts (California Health and Safety Code sections 25250.50 et seq.; and Revised Code of Washington, Chapter 70.285.), the state laws allow the sale until 2025 of brakes exceeding the concentration limit if they were produced prior to 2015. Also, brake friction material manufactured as part of an original equipment service contract for vehicles manufactured prior to 2015 are exempt. The California and Washington laws also exempt brake friction materials used in: motorcycles; military vehicles; race cars and other off-road vehicles (*e.g*, farm equipment, logging equipment, etc.); collector vehicles (those over 30 years old); parking brakes; and motor vehicles employing internal-closed-oil-immersed motor vehicle brakes or similar contained brake systems. Moreover, certain manufacturers may also apply for an exemption from the state requirements. And while a Memorandum of Understanding (MOU) between EPA and industry stakeholders adopted the California and Washington limitations, the MOU does not cover products that are exempted by California and Washington (https://www.epa.gov/sites/production/files/2015-11/documents/copper_brakepads_mou.pdf). In addition, the MOU is not legally enforceable against the signatories to the MOU, their members, or any other parties. While the California and Washington laws and the federal MOU may have reduced the prevalence of asbestos-containing brakes in the U.S., they do not preclude continued exposures to

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		asbestos from automotive brakes/linings and other vehicle friction products.
2.14 **Calculation of full-shift (8-hour) exposures using short-term, peak occupational exposures**		
16, 41, 42, 70, 79, 90, 100	**PUBLIC COMMENTS:** • Peak exposure data cannot be used to predict full-shift, task-duration, or even short-term concentrations. • The duration of potentially high exposure actions is usually minutes, rather than hours or days; therefore, the 8-hour TWA of these exposures would be diminishingly small. • While not all activities may be performed during a particular shift, it is reasonable to assume that long-term monitoring data, such as is available for the chlor-alkali industry, provides an accurate representation of exposure during a typical shift. Calculating 8-hour TWA concentrations using a combination of short-term exposure data and full-shift data incorrectly assumes that exposures represented by the full-shift data are exclusive of exposures represented by the short-term data. • Additionally, EPA's evaluation mischaracterizes the data in the text and presented in Table 2-7 by focusing on the maximum short-term value from preliminary data submitted by ACC. ACC and member companies have since provided additional information including the specific task descriptions and exposure data as well as full shift exposure data which represents exposures through the entire shift, including short term tasks. • The Draft RE for Asbestos incorrectly compares the short-term data to the OSHA 8-hour TWA of 0.1 f/cc.	EPA used a method to incorporate short-term data into an estimate of full-shift exposures; EPA did not extrapolate the short-term concentration values into an 8-hour shift. The methodology used the appropriate 30-minute value (*i.e.*, central tendency or high-end) and incorporated it into a revised 8-hour value (again, using central tendency or high-end). For example, the first two scenarios show the values for the chlor-alkali scenario and the third row shows the value that would be a true extrapolation of the 30-minute value to an 8-hour value: Scenario: 8-hour Full Shift Central 0.0049 High-End 0.034 Scenario: 8-hour Full Shift with appropriate 30-minute short-term value incorporated into the 8-hour time frame Central 0.061 High-End 0.0639 Scenario: 8-hour Full Shift with appropriate 30-minute short-term value extrapolated to the 8-hour time frame Central 0.024 High-End 0.512 Based on information received during the public comment and peer-review period, EPA updated the chlor-alkali data in Section 2.3.1.3.4. Updates reflect clarifications received from ACC on important details of their original data submission that were not previously available to EPA. EPA agrees that a comparison should not be made between short-term asbestos concentrations and OSHA's 8-hour TWA PEL. It appears this comparison was only made in

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		lines 2247-2248 in Section 2.3.1.3.2 the draft risk evaluation. EPA removed that text from Part 1 of the Risk Evaluation for Asbestos. Additionally, as noted in Section 5.2, "The Agency also considered that the health effects associated with asbestos inhalation exposures are severe and irreversible. These risk-related factors resulted in EPA focusing on the high-end risk estimates rather than central tendency risk estimates to be most protective of workers, ONUs, consumers, and bystanders." In keeping with this decision, EPA concluded that it would be prudent to assume that the short-term samples may not simply represent the high end of the sampling distribution for full-shift sample and thus decided to include the short-term sample concentrations into a revised 8-hour TWA to ensure that the short-term samples were represented in risk characterization and risk decisions. The three observations that: 1) the full-shift and short-term samples are not taken concurrently; 2) the task-specific sampling data are not randomly ascertained; and, 3) the weighted average of the median values of the task-specific short-term samples is almost as large as the 95th% of the full-shift tasks in Table 2-5 (0.03 vs 0.034 f/cc), strongly suggest that these short-term data do not fall withing the sampling distribution of the full-shift samples. While it is possible that these short-term samples could be samples within a full-shift and thus averaging them into a re-weighted 8-hour TWA might be considered inappropriate, the short-term samples were not recorded on the same dates as the full-shift samples according to Occidental Data, see Volume 2, so it is clear that the short-term data were not sampled concurrently within the full-shift samples. Further, the short-term samples appear to represent targeted tasks that do not represent full-shift activities.

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		The short-term sample concentrations from the chlor-alkali industry are higher than the full-shift values. According to Table 2-4 which summarizes the 30-min short-term personal breathing zone samples from two of three companies in the chlor-alkali industry, the median concentration is 0.024 f/cc and the 95th% is 0.512 f/cc. According to Table 2-5 which summarizes the full-shift personal breathing zone samples from all three companies, the median concentration of full-shift samples is 0.0049 f/cc and the 95th% is 0.034 f/cc. Table 2-7 summarizes the ACC Short-Term PBZ Sampling Data by Exposure Group (samples from 2001 to 2016) by task and shows that the tasks are sampled unevenly with the overwhelming preponderance of samples taken from the 'Glovebox Weighing and Asbestos Handling' which accounted for 150 of 326 samples (46%) even though that task was one of seven specific tasks (14%). The weighted average of the task-specific short-term samples from Table 2-7 is 0.03 f/cc – which is higher than the median concentration of short-term samples in Table 2-4 (0.03 vs 0.024 f/cc).
2.15 **Reduction factors used for indoor bystander exposure are reasonable but inconsistent**		
	SACC COMMENTS: • Given the high variability in the bystander exposure, the reduction factors (RFs) in the Draft RE for Asbestos for indoor use appear to be reasonable. Using an outdoor factor of 10, however, would likely produce an exposure estimate that is a substantial over-estimate of bystander exposure. It should be considered as an upper bound estimate and used accordingly. One SACC member suggested that a more accurate estimate could be derived using previous research demonstrating how to estimate airborne concentration fall-off outdoors as a function of air speed (Shade and Jayjock (1997).	EPA received several comments about the approach used for ONU exposure estimates. As a result, EPA reevaluated its approach for each COU. For aftermarket automotive brakes/linings, EPA determined that the NIOSH sampling studies (mostly from the 1980s) include direct measurements that could be used to characterize ONU exposures. EPA updated the ONU exposure estimates for this COU accordingly in Section 2.3.1.7.5. For the other COUs for occupational exposures, only one "reduction factor" is now used. EPA continues to believe this is the best approach in the absence of direct measurements. EPA updated the text in Section 2.3.1.4.5 and 2.2.1.4.6 to

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	• The RF of 10 for bystanders outdoors for brake repair seemed to be rounded up from the value of 6.5 calculated from one data source. Then the Draft RE for Asbestos (p. 114) mentions using a bystander RF of 5.75 for a gasket installation scenario using a value derived from an occupational study. Another statement (Draft RE for Asbestos p. 120) states that EPA did not use an RF for gasket repair/replacement because there were sampling data available. The approach does not show a consistent decision process and as a result the discussion was found to be somewhat confusing. Recommendation 32: Clarify the reduction factor (RF) discussion for bystanders. **PUBLIC COMMENTS:** • With three different approaches for estimating exposure RFs for ONUs and bystanders in the Draft RE for Asbestos, EPA's "consistency" in satisfying the weight of the scientific evidence requirement is unclear. The final REA needs a clear rationale for how the RFs reflect "reliable and unbiased" science. EPA should provide a "pre-established protocol" to…" consistently" identify and evaluate each stream of evidence. commenter recommended that EPA take a more uniform approach and believes that averaging would best capture the available monitoring data. • EPA incorrectly assumes ONUs are exposed for 8 hours per day and 250 days per year for 40 years, which far exceeds reality. ONUs including supervisors/managers and janitorial workers are unlikely to stay near work zones throughout an entire day. Accordingly, EPA must appropriately and significantly reduce the TWF to account for the actual duties of ONUs.	explain this selection and acknowledge the associated uncertainties. The term bystanders is often used in consumer settings whereas ONU is used for occupational settings. For occupational exposures, the most appropriate ONU exposure assessment approach depends on the available information. For each COU EPA reviewed the reasonably available information, including air monitoring and exposure assessment approaches. EPA selected the most appropriate estimation method based on the strength, limitation and the relevance of the data. EPA agrees that in some cases ONU may not be exposed at a full shift, every workday. EPA included statements acknowledging this possibility in all COUs except for the NASA Super-Guppy which EPA assumed 12 hours/year of exposure. ONU exposure is likely to vary depending on COU, sites, and what tasks are assigned to ONUs. The information EPA reviewed since issuing the draft risk evaluation supported revisions to the ONU exposure estimates for aftermarket automotive brake and brakes installed in exported cars. EPA used a consistent hierarchy to derive occupational exposure estimates, whether for workers or ONUs which is described in Section 2.3.1.3.6. EPA's preferred approach was to use representative monitoring data of a known and high quality. When such data were not reasonably available, EPA considered other sources of information, including the extent to which reasonable estimates could be derived. This approach was uniformly applied across the COUs. After applying this hierarchy, the occupational exposure assessment now includes two different approaches for

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		estimating ONU exposures: direct monitoring data (typically area samples) and application of reduction factors. Monitoring data was used to estimate ONU exposures for all COUs except for the two conditions of use pertaining to sheet gaskets, for which reduction factors were used. Specifically, for sheet gasket fabrication and use, EPA relied on literature that measured asbestos concentrations at "bystander" locations that were between 5 and 10 feet from the gasket removal activity; at these locations, asbestos concentrations were between 2.5 and 9 times lower than those measured for the worker. The details of the estimates are in section 2.3.1.4.4 of the risk evaluation.
2.16 **Reliance on industry-reported practices could result in bias**		
31, 73	**PUBLIC COMMENTS:** • EPA determined that several COUs did not constitute an unreasonable risk. However, those conclusions are predicated on information received from the regulated community itself, and the commenters are skeptical about self-reported compliance. They suggested that EPA adjust industry-reported compliance and practices observed during announced site visits to account for the more likely routine practices. For example, during one site visit, a consultant noted in a footnote that: "unused scrap pieces of reportedly ACM were placed in a dumpster with other waste and disposed with normal plant waste," although that practice is not permissible. • EPA should assume that industrial hygiene sampling results represent the best-case scenario in that workplace. If a site visit is announced, employers can modify the usual work environment to reduce the concentration of a contaminant. Many workers report that their worksite is cleanest when an OSHA inspector	When preparing the chrysotile asbestos risk evaluation, EPA obtained and considered the reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. EPA looked at reasonably available information and determined that the monitoring data provided by industry was the highest quality data available. All studies used in the Risk Evaluation, including industry submissions, are evaluated using the same data quality criteria under the TSCA Systematic Review process described in the document, Application of Systematic Review in TSCA Risk Evaluations. In consideration of comments received, EPA is in the process of updating the TSCA Systematic Review protocol to improve the transparency of this review process and further reduce possible bias such that all studies are appropriately considered. EPA is not aware of any scientifically defensible adjustment factor that could be used for this purpose. When using industry-supplied data, EPA sought independent lines of

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	(or an insurance adjuster, safety consultant, corporate official, or investor) is on the premises.	evidence (*e.g*, observations during site visits, concordance with trends reported in the literature) to validate the information provided by industry.
2.17 **General comments on COUs (COUs) for occupational exposure**		
SACC, 42, 51, 53, 65, 68, 74, 83, 92	**PUBLIC COMMENTS:** • EPA grossly overstates the potential number of exposed workers and ONUs in most or all COUs. • The Draft RE for Asbestos lacks meaningful exposure monitoring data for nearly all the COUs it addresses. The sparseness of the monitoring data is surprising considering the longstanding concern about the risks of industrial use of asbestos. • ACC urges EPA to revise the Draft RE for Asbestos to include COU and associated exposure levels that accurately represent realistic conditions, rather than extreme, unrealistic usage. • The number of workers that might plausibly be over-exposed, beyond the OSHA PEL, is virtually zero.	EPA estimated the estimated number of individuals exposed using reasonably available information on the potential market share of asbestos brakes. Details are in provided in Section 4.3.7: Confidence in the Human Health Risk Estimations. The new estimate for number of both workers and ONUs assumes that asbestos brakes may represent only approximately 0.05% of aftermarket automotive brakes. EPA estimated potentially exposed individuals (both worker and ONUs) by applying this factor (0.05%) to the universe of automotive service technicians and mechanics. One comment pertains to the sparseness of occupational exposure monitoring data. EPA took extensive measures to identify the reasonably available information per TSCA section 26(k) to support the risk evaluation. That included obtaining data from the systematic review process and from the affected industries. Additionally, the public comments and peer review comments included several hundred references—all of which EPA reviewed for additional occupational exposure monitoring data for use in the risk evaluation. The last comment pertains to the extent to which today's workers are exposed to chrysotile asbestos above the OSHA PEL. The comment does not provide any supporting information. Evaluation of compliance with OSHA's asbestos standard and the protectiveness of the asbestos PEL is not the purpose of the risk evaluation.

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2.18 **Limited submissions by industry/publicly available information for COUs**		
SACC51, 63, 86	**SACC COMMENTS:** • In the "components of occupational health exposure assessment" that EPA sends to companies with a request for data, EPA does not ask for descriptions of exposure monitoring/surveillance protocols. Thus, sampling/monitoring program plans and/or individual company strategies are not presented in the Draft RE for Asbestos, and it was unclear whether companies having workers engaged in asbestos COUs were specifically requested to submit such descriptive data. Without a description of the sampling strategy and how employee duties were monitored, one cannot determine the completeness and representativeness of facility worker exposure data. The SACC found it difficult and problematic to review the data inclusion/exclusion decisions that are inherent in the Draft RE for Asbestos exposure assessment. • In the descriptions of many of the COUs, the Draft RE for Asbestos mentions studies but did not describe findings from these studies. These studies may have been performed too far in the past or are otherwise inappropriate. These data might be inappropriate for direct use but would provide a comparison to see how results have varied over time and, if current data are not available, could provide a "worst case" source of data that could be used. Some SACC members suggested that international data (from countries that have not yet banned or restricted asbestos) appeared to be underutilized. • The Draft RE for Asbestos used very few studies from the peer-reviewed published literature to estimate asbestos exposure in some COUs. This is especially true of exposure associated with repair and/or replacement	EPA made numerous efforts to gather supporting documentation (*e.g*, sampling plans, sampling reports, etc.) for the occupational exposure data on the identified COUs included in Part 1 of the Risk Evaluation for Asbestos. For some COUs, particularly the studies of auto break mechanics, the underlying literature thoroughly documented study objectives, methods, results, and limitations; and EPA reviewed this information early in the risk evaluation process as part of its systematic review procedures. For other COUs, detailed background information mentioned in the comments such as sampling plans and data handling methods, was not available. For example, for the chlor-alkali industry and for sheet gaskets, the data EPA used in Part 1 of the Risk Evaluation came from employers' worker monitoring, which evidently was conducted in fulfillment of OSHA's asbestos standard. The OSHA asbestos standard has worker exposure monitoring requirements, but that standard does not prescribe development of sampling plans and data handling methods. Accordingly, a complete account of the sampling strategy for some data sets is not available, but EPA did confirm other important details for those data sets (*e.g*, sampling methodology used, type of sample collected, worker activities conducted during the sampling). For 9 Chlor-alkali facilities EPA received the following information in addition to the air samples: representative regulatory compliance controls, representative asbestos handling process flow diagram, and representative asbestos dust collector preventative maintenance process for semiannual annual inspection.

	of brakes where one or two studies are referenced and used in the relevant portions of the DRE. **PUBLIC COMMENTS:** • Once commenter commended EPA's use of industry monitoring data for several COUs; however, for some COUs EPA lacked information about the representativeness of the data it used. For other COUs, EPA's assumptions are not realistic and therefore may not meet the "reasonableness" or "relevancy" requirements of best available science. • The evaluation relies on limited submissions by industry and publicly available information to identify ongoing COUs and to determine the magnitude of current exposure. (86-11) The data for some COUs were very sparse and often did not identify the actual tasks being performed by the workers who were sampled; therefore, it is unclear if 'worst case' or even 'high-end' exposure scenarios were considered. (63-8) • Only two workers were identified for stamping sheet gaskets, and only two US. TiO2 manufacturing facilities were identified that use asbestos-containing gaskets. EPA is not certain if asbestos-containing sheet gaskets are used in other industries and to what extent. For the other COUs, EPA has no estimates of the number of potentially exposed workers. EPA acknowledged that, outside the chlor-alkali industry, there is no information on the market share of AC products available to workers and consumers. Overall, EPA received only a "handful" of voluntary submissions from industry.	The compilation of underlying data is included as a supplemental document and the original submissions are available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0103 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0129 https://hero.epa.gov/hero/index.cfm?action=search.view&reference_id=5352390 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0106 All information received were reviewed in detail and relevant information incorporated in Part 1 of the Risk Evaluation for Asbestos. Another issue suggested that EPA did not fully utilize available data, including those from the international community. For most COUs, EPA intentionally focused on data from the U.S., because OSHA's asbestos standard includes provisions that apply to U.S. workers and worksites—and these provisions do not apply in other countries. Responses to other comments document EPA's recent research into data from European Union chlor-alkali facilities. Given concerns about data representativeness, EPA will not incorporate additional data from foreign countries in the draft risk evaluation (though some text in Sections 2.3.1.3.4 and 2.3.1.7.4 has been revised to acknowledge EPA's awareness of such data for certain COUs). Additional information and why EU information was not used is in the response to Comment 2.20 Chlor-alkali occupational workers exposure estimate. A comment correctly notes that EPA used very few studies from the peer-reviewed literature for aftermarket automotive brakes/linings. As explained in the draft risk evaluation, EPA considered publications since 1980 that were conducted in the U.S. and that presented original compilations of

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		occupational exposure data. Many of the publications in the peer-reviewed literature since that time summarize data presented in earlier publications and do not present original data. A final comment pertains to the estimated number of workers for each COU. As noted in responses to other comments, EPA reviewed all relevant exposure information found for each COU and selected the most relevant information to estimate the workplace air concentrations. The review and selection of references is broadly described in our systematic review process.
2.19 **EPA should use its TSCA information collection authorities**		
SACC, 51, 85, 86	**SACC COMMENTS:** • EPA acknowledged that the data they received voluntarily from various companies might not be representative of all tasks and all facilities and that they were uncertain about the numbers of exposed workers. The direction and magnitude of some of the uncertainties were not described. EPA should use its TSCA powers to obtain missing critical information. • Recommendation 68: Require reporting of numbers of potentially exposed workers and other critical missing data from industrial facilities that process asbestos. (SACC-169) • The Draft RE for Asbestos was hampered by lack of data for specific COUs. For example, in Draft RE for Asbestos section 2.3.1.4., Sheet Gaskets, EPA indicated that there were no surface wipe sampling data "available to characterize the extent of settled dust and asbestos fibers present during this operation." (SACC-77) For the chlor-alkali industry it was unclear if certain high-exposure activities were associated with the air monitoring results. Recommendation 26: EPA should	EPA did not use its TSCA data collection authorities to gather additional information regarding asbestos because EPA believes it has sufficient information to make a reasoned analysis in light of the limited time available under the statute for completing the risk evaluation. EPA had sufficient information to complete the Part 1 of the Risk Evaluation for Asbestos using a weight of scientific evidence approach. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this Part 1 of the Risk Evaluation for Asbestos, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. When reviewing publications specific to aftermarket automotive products, EPA intentionally limited its evaluation to studies that examined exposures at U.S. business establishments. This focus was due to the fact that OSHA's asbestos standard includes provisions that apply to U.S.

	use its statutory authority under TSCA to request additional data on occupational exposures to fill knowledge gaps. **PUBLIC COMMENTS:** • Some commenters agreed with SACC that EPA should use its statutory authority under TSCA to obtain reports from industry on ongoing imports, uses and exposures for asbestos and asbestos-containing products. One commenter laid out the history of the 2018 petition by six organizations to EPA requesting that EPA promulgate reporting requirements for asbestos under the information collection authorities in section 8(a) of TSCA. A similar petition was filed again in 2019 by 18 Attorneys General (AGs) representing 17 states and the District of Columbia. The Draft RE for Asbestos suffers from the exact same information gaps identified in the 2018 petition and expressly acknowledges the gaps, just as the earlier problem formulation did.	workers and worksites—and these provisions do not apply in other countries. Additionally, the profile of brakes and clutches encountered in U.S. vehicles differs from what is seen in other countries. For these and other reasons, EPA scientists read studies of workers in Colombia, Iran, and many other countries, but the risk evaluation focuses on the asbestos measurements specific to conditions in U.S. establishments. Lines 3387-3388 in Section 2.3.1.7.4 of the *Draft Risk Evaluation for Asbestos* explained EPA's approach, which "…focused on post-1980 publications that reported original asbestos PBZ measurements for business establishments in the United States." EPA will expand upon the text in this section in the final Risk Evaluation for Part 1. For the comment on surface wipe data, EPA contends that surface wipe sampling data are not essential for evaluating inhalation exposures. These data, were they available, would only confirm the presence or absence of airborne asbestos—they would not quantify airborne concentrations. One comment indicates that the chlor-alkali sampling data might not have captured certain high-exposure activities. The sampling data do account for certain high-exposure activities (*e.g*, hydroblasting). However, the methods for measuring airborne asbestos are not continuous, and EPA is not aware of any industry that has continuous asbestos monitoring data that would capture every peak exposure event. EPA acknowledges in Section 2.3.1.3.6 of the Risk Evaluation that some high-exposure events might not be reflected in the data. The following sentence was added to Section 2.3.1.7.4 to highlight the focus of EPA's search for exposure data: "EPA focused on U.S. business establishments due to the availability of measurements and the fact that OSHA's asbestos standard mandates controls and other safe work practices that do not apply in other countries."

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2.20 **Chlor-alkali occupational worker exposure estimates**		
SACC, 35, 42, 51, 70, 73, 91, 108	**SACC COMMENTS:** • The chlor-alkali industry is the only COU under evaluation that had considerable air monitoring data, having data for both full shift and short-term exposures. Public comments confirmed what the Draft RE for Asbestos reports, that the ACC-submitted data might have duplicated the individual company submissions (see p. 66, ln. 2347-2349). Despite the duplication concern, the Draft RE for Asbestos rates the data set as excellent and the exposure determination is given a high level of confidence. The SACC recommended that duplicates be identified and be removed, and the analyses be redone. • SACC found that there were chlor-alkali industry asbestos exposure studies conducted historically that are not described or referenced in the Draft RE for Asbestos. The paper by Strokova et al. (1998) referenced in Section 2.1.1.4.4. (sheet gasket stamping inhalation) has sampling data from a "diaphragm electrolysis shop" that might be useful for comparison. While it is understandable that these studies are not used directly, they could provide perspective as to whether exposures have changed or not. International data may also be available as the EU chlor-alkali industry is not expected to replace the use of asbestos until 2025. • Recommendation 18: If EPA has not done so, it should query EU sources to determine if additional asbestos exposure study data are available. • In the chlor-alkali industry, EPA used industry-supplied data to estimate exposures in sheet gasket use even though those data did not include sample duration or how long gasket removal was performed (Draft RE for Asbestos page 79). Recommendation 75: Limit	EPA was made aware that ACC submitted chlor-alkali occupational exposure data that were duplicative of other data submissions. ACC confirmed this duplication after the draft risk evaluation was issued. EPA has since removed the duplicate data, and the final risk evaluation will be based only on original data points. EPA included text in Section 2.3.1.3.4 to explain this issue. Another comment suggested that EPA review the Strokova et al. (1998) publication for relevant data for the chlor-alkali COU. That study documents asbestos sampling from two Bulgarian manufacturing facilities in the mid-1990s. One of the facilities evidently manufactured asbestos-containing electrolysis diaphragms. The paper reports the range of breathing zone concentrations observed, and this range falls within the range of data that EPA compiled from U.S. facilities. Therefore, the paper does not change EPA's assessment. EPA did not add details on this paper to the chlor-alkali section, because the study was conducted in Bulgaria more than 25 years ago, using sampling and analytical methods that differ from those used in the United States. Regarding the recommendation that EPA seek information from the EU on occupational exposures to chrysotile asbestos in the chlor-alkali industry, a limitation in any such comparison is that exposure data from EU facilities may not be representative of the U.S. manufacturing environment, due to differences in process design, production levels, ventilation practices, regulatory frameworks, and other factors. Another complicating factor is that, as of 2014, all but one chlor-alkali facility in the EU had phased out use of asbestos-containing diaphragms (EC, 2014). Nonetheless,

	environmental risk determinations to scenarios/COUs that have available actual exposure data. **PUBLIC COMMENTS:** • One commenter explained the duplicate data identified by the SACC; after removal of those data, approximately 60% of full-shift samples were below the LOD. • The chlor-alkali plant monitoring data might not adequately represent all chlor-alkali facilities. The industry might have selected certain data for submission, and data were not provided for 5 of the 15 plants in the industry. • One commenter believed that practically none of the approximately 400 persons identified in Table 2-7 were exposed above the OSHA PEL (Table 2-4, 2-5 and 2-6; Draft RE for Asbestos pp. 66-68), which the commenter considers applicable. Breathing zone samples were likely even lower. • EPA could have investigated whether the chlor-alkali industry monitoring data addressed all high-exposure activities by using a checklist developed by the industry itself (*e.g*, the Chlorine Institute's Pamphlet 137). • The Draft RE for Asbestos does not include all relevant studies, specifically, Longo et al. (2002) found high airborne exposures to asbestos during gasket removal, including some that were substantially higher than OSHA's PELs. • Some commenters presented arguments as to why importation, handling, storage, and conversion of chrysolite asbestos into diaphragms should not pose an unreasonable risk, with monitoring data registering below OSHA PELs. • Elimination of asbestos, where possible, is the first step in the hierarchy of controls. Since many chlor-alkali plants have eliminated asbestos membrane cell	EPA compiled information from EU facilities. This information came from two EU documents: In 2014, the European Chemicals Agency published its *Background document to the Opinion on the Annex XV dossier proposing restrictions on Chrysotile* (ECHA, 2014). Asbestos sampling data are presented for the one facility that continued to use asbestos-containing diaphragms at the time. However, no personal exposure monitoring data are available. The report explains: "For practical reasons (viz. the type of sample pumps used to sample the required volume of air) it is not possible to perform personal monitoring. All measured data are based on stationary measurement." EPA infers that "stationary measurement" refers to area sampling. Section A2.2 of that report discusses occupational exposures to asbestos for seven specific worker activities involved in "use in diaphragm cells (closed systems)." Three of these worker activities involved area sampling, and asbestos detections were reported in areas where electrolytic cells were assembled and where parts were dismantled and cleaned. The highest 90 percent upper confidence limit concentration reported was 253 fibers/m^3, which occurred in the area where electrolytic cells were assembled. This concentration is equal to 0.000253 fibers/cc—the measurement unit used throughout Part 1 of the Risk Evaluation for Asbestos. Later in 2014, the Joint Research Center of the European Commission published its *Best Available Techniques (BAT) Reference Document for the Production of Chlor-alkali*. Table 3-40 of that report summarizes concentrations of asbestos in workplace air at three chlor-alkali facilities. For two facilities in Germany (one of which has since shifted to non-asbestos alternatives), the asbestos concentration in workplace air is reported as "<1 000" fibers/m^3, which equates to less than 0.001 fibers/cc. For a manufacturing

	technology from the production process, this suggests that other facilities could do so as well. • One commenter found use by the chlor-alkali industry disturbing, with reported high exposure levels, a high potential for accidental release during the shipment of asbestos from ports to plants, and the unjustified assumption that respiratory protection will suffice to mitigate possible exposures. • EPA relies on testimonials by ACC's Chlorine Chemistry Division for information on asbestos exposure in nine chlor-alkali plants. One synopsis of best practices implies that all nine plants operate the same way; that is highly unlikely. A table summarizes asbestos air monitoring data from 1996-2016 without the number of samples collected at each plant for each task, the industrial hygiene procedures and methods used for the sampling, or the laboratory analytical methods used.	facility in Poland, which was shut down in 2012, the asbestos concentration in workplace air prior to shutdown was reported as "5 000–30 000" fibers/m^3, which equates to 0.005 to 0.030 fibers/cc. Further details on the sampling data are not provided. Overall, the full-shift central tendency concentration that EPA used in the Draft RE for Asbestos was 0.0060 fibers/cc. This number is reasonably consistent with the range of values reported above, considering the differences in manufacturing environments and sampling strategies (*i.e.*, EPA compiled personal breathing zone data for workers, whereas the data cited in the EU reports are area samples). To be responsive to this comment, EPA inserted the following text in Section 2.3.1.3.4: "EPA also considered information published by European Union (EU) agencies (EC, 2014; ECHA, 2014). Those data ultimately did not factor into this report's exposure estimates due to differences in sampling strategies, facility processes and production rates, and U.S. versus EU regulatory frameworks." EPA used the most recent data from the facilities that currently handle asbestos. Comparisons with the past exposures data were not included in the risk evaluation. Regarding comment that chlor-alkali workers in the U.S. are not exposed to asbestos above OSHA's PEL, EPA notes that evaluation of compliance with OSHA's asbestos standard and the protectiveness of the asbestos PEL is not the purpose of the Part 1 of the Risk Evaluation for Asbestos. Feasibility of eliminating asbestos from chlor-alkali facilities and other control strategy options will be appropriately considered in risk management for chrysotile asbestos, following the issuance of Part 1 of the Risk Evaluation.

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		EPA acknowledges that it did seek information from ACC, but EPA also sought information from the three companies that currently use asbestos-containing diaphragms in their processes. The responses from those companies included facility-specific information. Additionally, EPA conducted site visits to chlor-alkali facilities, as described in the Problem Formulation document. Therefore, EPA's assessment of the chlor-alkali COU reflects the best information reasonably available to EPA and not just information provided by ACC. Regarding data provided for the chlor-alkali plants, EPA received monitoring data from eleven facilities owned by Axiall, Occidental, and Olin. Data from the three companies were used for the estimates which represent all current chlor-alkali facilities in the US.
2.21 **Chlor-alkali occupational non-user (ONU) exposure estimates**		
SACC16, 35,42, 51, 70, 72, 73, 77, 83, 86, 91, 108	**SACC COMMENTS:** • The chlor-alkali exposure point air concentrations used for the ONU exposure assessment are based on 15 samples (all non-detects) collected at only two facilities (a small subset of the facilities used for worker exposure estimation). representativeness was suspect. • SACC members appreciated the pictures/graphics and site visit descriptions where provided. Duplicate data were identified in the chlor-alkali industry data set [ACC data set] which should be removed from the analyses. Standardized approaches to addressing values less than detection limits should be adopted. While acknowledging data sparsity [especially for occupational non-users (ONUs)], members wanted to see descriptions of sampling plans and methods for available data and a more structured approach to estimation of exposure point concentrations in the	For the chlor-Alkali ONU exposure estimate in Part 1 of the Risk Evaluation for Asbestos, EPA made several assumptions including the assumption that workers not directly handling asbestos may access the work area and ONU exposure concentration is comparable to the area monitoring result. It is possible that workers not related to chlor-Alkali production may be trained on asbestos so that they could access the work area for tasks unrelated to chlor-alkali. EPA used the study by Mangold et al. (2006) to estimate "reduction factors" for ONU assessments for sheet gasket COUs. While the comment correctly points out that the Mangold et al. (2006) publication may not report magnitude of asbestos concentrations consistent with the sheet gasket COUs, EPA did not use the publication for that purpose. Rather, EPA used the publication's data to estimate the decay rate of asbestos levels with distance from the area of

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	absence of data. Concerns were raised over completeness and representativeness of industry data and for inadequate characterization of "off-normal" events. **PUBLIC COMMENTS:** • ONU exposure assessment is based on fifteen (15) area samples at fixed locations at two facilities, all of which were below the LOD –0.004 f/cc in one case and 0.008 f/cc in the other. The samples were taken primarily in the deposit and cell service areas, both of which have restricted access. ONUs are unlikely to "pass through or work near" restricted areas. A downward adjustment using appropriate fugitive emission modeling is necessary to estimate ONU exposures. • EPA's reference to "maintenance and janitorial staff" should also be clarified; they are included the OSHA workplace standard for asbestos. Restricted areas are not attended by non-operator janitors. Housekeeping within a restricted area is performed by operators with designated minimum PPE for the task. • The Draft RE for Asbestos presents conflicting information on the number of ONUs that are present at chlor-alkali facilities. While Chapter 4 suggests that there may be 2,000 to 3,000 ONUs at these facilities, Chapter 2 estimates the number at about 100. Moreover, even 100 would be an overestimate non-operator ONUs in or around restricted areas given procedures in place for restricted area access. • The Mangold et al. (2006) study of asbestos exposure during removal of gaskets relies was generated to assist a gasket manufacturer subjected to lawsuits. It did not consider the dustiest activities associated with removal of old gaskets. EPA selected the midpoint to estimate ONU exposure and stated that might overstate risk	active work. EPA believes use of the data for relative insights (as opposed to absolute exposure levels) is appropriate. EPA reviewed the approach used for handling non-detect in Part 1 of the Risk Evaluation for Asbestos and confirmed that it is consistent with other risk evaluations. EPA reviewed and included all reasonably available and pertinent information in Part 1 of the Risk Evaluation. During the review, EPA did not find any background information on the chlor-alkali monitoring data, such as sampling plans and data handling methods. The data EPA used in Part 1 of the Risk Evaluation came from employers' worker monitoring, which evidently was conducted in fulfillment of OSHA's asbestos standard. The OSHA asbestos standard has worker exposure monitoring requirements, but that standard does not prescribe development of sampling plans and data handling methods. However, EPA did confirm other important details for those data sets (*e.g*, sampling methodology used, type of sample collected, worker activities conducted during the sampling). The last comment states that ONUs monitoring data were not available because ONUs are not exposed, and therefore were not monitored. EPA used area monitoring data (most below the limit of detection but some above) and a decay factor to estimate ONU exposures. The information used to develop the decay factor showed that the asbestos concentration in workplace air decreases as you move farther away from the source. This is an indication that none detect measurements near the source of asbestos do not necessarily mean zero asbestos in workplace air. For multiple conditions of use, EPA has information confirming that ONUs are present during the activity of interest. For instance, EPA observed

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	because the simulation study occurred in an enclosed setting. EPA does not, however, explain that the estimate may understate risk because the simulation does not represent actual workplace conditions (*e.g*, participant bias.) • Industrial hygiene data were not available for ONUs because these workers are not likely to be exposed and therefore are not subject to monitoring. EPA lacks any evidence or data that ONU's are exposed to asbestos, and ND samples do not demonstrate exposure to a substance. EPA cannot make a finding that this COU "presents an unreasonable risk of injury to health or the environment" based on the evidence it presents.	this for sheet gasket stamping, and numerous reports in the literature confirm bystanders are present during auto repair work. Just because no personal sampling data are available for these ONUs does not mean that exposure did not occur. EPA continues to believe that relying on the available data sets, even if they were uniformly non-detect in some circumstances, is the most reasonable approach to characterize these ONU exposure scenarios.
2.22 **Concerns about properties of fibers in air**		
SACC, 42, 61, 70, 78, 79, 82, 95	**SACC COMMENTS:** • Rapid settling implies increased floor load, which is then available for resuspension; air measurements at specific locations reflect countervailing processes (compensating effects). SACC recommended papers investigating fiber dispersion in indoor and outdoor environments. **PUBLIC COMMENTS:** • Research showing "that fibers in the vicinity of 5–40 microns in length" is older and outdated from the 1960s (Hinds (1999; Corn and Stein (1967, 1965). The assertion that fibers will drift from a point source and cause a potential hazard to nearby workers or become a source for resuspension is not often the case, especially for fibers with a length of 5-40 µm that will agglomerate and fall due to gravity. Similarly, fibers in dust are not so easily resuspended. • EPA does not consider many other factors such as the overreliance on ventilation and gravitational settling in	EPA continues to believe that ONU exposures are reasonably foreseen for certain COUs. However, EPA understands that the entire premise of ONU assessments presume that fibers from a worksite can move through the air to other workplace locations, and that EPA did not explicitly state in the Draft RE for Asbestos that asbestos fibers will move long distances—or that previously settled fibers become resuspended into the air. EPA reviewed multiple studies that report data (both measured and modeled) on how asbestos concentrations decay with distance, and none of these publications suggested instantaneous deposition of all airborne fibers. Thus, EPA believes it is plausible that fibers can move through the air. It should be noted that EPA reconsidered ONU analyses for all COUs and made changes in response to comments. EPA used a different data source for the ONU estimates for the aftermarket automotive brakes/linings COU as described in Section 2.3.1.7.5.

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	models, proper ventilation systems, inert properties of most lengths, and other recent research. One commenter pointed out there is "no support that particles from brake repair, gasket replacement, and other processes will emit particles that would remain suspended in air or be resuspended." The half-life for these fibers to settle out is on the order of 5 minutes not hours or days. These commenters urge EPA to revisit the physical settling properties of asbestos fibers. • The EPA assertion of resuspension of asbestos fibers as a plausible and significant contributor for ONU exposure is unfounded.	
2.23 **Age at first exposure and exposure duration**		
70, 72, 100	**SACC COMMENTS:** • One SACC member felt that a starting age of 16 years is too young for tasks typically assigned to experienced workers. **PUBLIC COMMENTS:** • The Draft RE for Asbestos assumption that employment begins at 16 contradicts chemical industry practice which requires persons to be at least 18 years old to work in chemical facilities. EPA's assumption that worker exposure continues for 40 years is also inconsistent with current industry employment data and with Agency assumptions for other programs. The average tenure of workers who handle asbestos is less than 20 years; it is very common for a worker to begin in one production unit and move to another unit where asbestos is not used. • Based on the available information, a more appropriate assumption for the central tendency of exposure duration for the evaluation is in the range of 5 to 10 years (not 40 years), while a more appropriate	There is no evidence supporting that tasks related to handling asbestos require skills and experience. Thus, EPA has not revised the age at first exposure and exposure duration for most analyses conducted for Part 1 of the Risk Evaluation for Asbestos focused on chrysotile asbestos. However, EPA did revise analyses for the COU related to the specialize large NASA transport plan (Super Guppy) to begin at 16 years of age. The draft risk evaluation presented analyses beginning at age 26, but EPA did not find specific information that supported the assumption of a certain level of training and experience for these workers. The occupational exposure assessment made standard assumptions of 240 days per year, 8 hours per day over 40 years starting at age 16 years. EPA notes that the Fair Labor Standards Act of 1938 allows adolescents to work an unrestricted number of hours at age 16 years. EPA retained assumptions made in the risk estimates as Bureau of Labor Statistics data provides statistics for workers beginning at age 16 (for example, see Table 2-32 in Part 1). Furthermore, EPA's approach to cancer risk

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	assumption for high-end exposure duration is 25 years. This is consistent with other EPA risk assessment guidance (*e.g*, EPA Regional Screening Levels) • Second, workers in chlorine production facilities handle friable asbestos on an intermittent basis. The total time spent handling dry asbestos is estimated to be about 76 hours per week (1.6 hours/week per employee). The balance of their time is spent doing other tasks unrelated to handling asbestos, such as warehousing activities, training, and other activities. • To calculate an 8-hour TWA exposure, EPA assumed that brake job-specific exposure occurs throughout the day over a 40-year working lifetime. That is unlikely to be a common occurrence, especially for brakes containing asbestos. • EPA's assumption that a worker is exposed for 40 years for both its central tendency and high end scenarios is far longer than the information available from the Bureau of Labor Statistics, which indicates median employment tenure for workers in the chemical industry is 10 years or less, taking into account all age groups. • Data from the Employee Benefit Research Institute or EBRI show that the median tenure with one employer of all wage and salary workers ages 25 or older has remained steady at approximately five years. EBRI data also show that approximately 80% of older workers (ages 55-64) have tenures at one employer of less than 25 years, and the current trend is consistently toward lower tenures. As such, 25 years, not 40 years, is a conservative estimate for high end exposure duration and should be used for the chlor-alkali scenario.	estimates is based on a 40-year exposure period. EPA does present partial lifetime estimates in Appendix K of the risk evaluation Part 1. For chlor-alkali worker exposure, EPA used the workplace air measurements to estimate the exposure. For the full shift measurements, workers wore sampling devices throughout the entire shift which included time spent away from asbestos handling activities. Therefore, EPA's assessment approach for Chlor-Alkali is appropriate and takes into account the time workers spent for activities unrelated to asbestos. For chlor-alkali worker exposure, EPA used the workplace air measurements to estimate the exposure. For the full shift measurements, workers wore sampling devices throughout the entire shift which included time spent away from asbestos handling activities. Therefore, EPA's assessment approach for chlor-alkali is appropriate and takes into account the time workers spent for activities unrelated to asbestos.
2.24 **Approach for considering non-detect values**		

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SACC, 42, 91, 100	**SACC COMMENTS:** • A sensitivity analysis using alternate non-zero values for ND could allay concerns. Statistical methods for better handling of non-detects are available (2005). Recommendation 19: Create and consistently utilize an SOP for processing data with high levels of non-detect. **PUBLIC COMMENTS:** • When a significant fraction of the sampling data is "ND" (non-detects, *i.e.*, censored data), it is not appropriate to simply substitute ½ the LOD or the LOD divided by the square root of 2 to summarize exposure concentrations. It is even less appropriate to assume the full LOD for those samples, and for the chlor-alkali industry, 60% of the 15 samples were ND. By EPA's approach, absolutely any activity can be determined to present an unreasonable risk because, at best, such activities will return non-detect values if sampled for the presence of asbestos. • Further, in the "All Data" worksheet, it appears EPA also included the full value of the LOD as the proxy non-detect values for the Axiall-Westlake results even though EPA assigned a value of LOD divided by 2 or square root of 2 to non-detect data in the Axiall-Westlake worksheets. This inadvertent mistake should also be corrected.	EPA notes that while developing the Draft RE for Asbestos, the ACC provided exposure monitoring data that included some overlap with the data provided by Occidental, but it also appeared to include other observations. EPA included both data sets in the assessment of chlor-alkali worker exposures and acknowledged the overlap. ACC clarified in a public comment that its entire data set should be viewed as a duplicate of industry submissions and removed from the analysis. Removing these data results in more than half of the observations being non-detects. EPA has updated its chlor-alkali data analyses to reflect this change: refer to Section 2.3.1.3.4 for changes that EPA made when addressing this comment. EPA's approach for non-detects is documented in an EPA report, Guidelines for Statistical Analysis of Occupational Exposure Data, which calls for replacing non-detects with either one-half the detection limit or the detection limit divided by the square root of two, with the preferred approach depending on the skewness of the data distribution (as characterized by the distribution's geometric standard deviation). EPA followed this guidance when processing the chlor-alkali data. After removing the ACC data from the evaluation (see previous bulleted item), more than half the sampling results are non-detect observations. In these situations, the same reference recommends acknowledging potential biases introduced into calculations. Following this guidance, EPA has added text in Section 2.3.1.3.6 to acknowledge uncertainties. EPA conducted a sensitivity analysis for various non-detect replacement strategies and included text in Section 2.3.1.3.6 that discusses the range of central tendency concentrations based on the sensitivity analysis.

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		EPA acknowledges an inadvertent error in incorrectly using the full detection limit when processing the "Axiall-Westlake" data in the Draft RE for Asbestos. EPA corrected this analysis, which had minimal impact on the final asbestos concentrations for the chlor-alkali data set in Part 1 of the Risk Evaluation for Asbestos. EPA has made these additional changes to Part 1 of the Risk Evaluation for Asbestos: • EPA removed the ACC data from its evaluation and recalculated exposure concentrations for the chlor-alkali COU. All tables and text citing these concentrations were updated accordingly. New text was added to Section 2.3.1.3.4 describing removal of the ACC duplicated data. • EPA added text to Section 2.3.1.3.6 to acknowledge uncertainties associated with the dataset, given that more than half of the measurements were non-detect observations. This discussion also addresses the sensitivity associated with different non-detect replacement strategies.
2.25 **Sheet gasket stamping worker exposure estimates**		
SACC, 42, 46, 61, 83, 95, 98	**SACC COMMENTS:** • For the sheet gasket COU, the Draft RE for Asbestos uses data from a simulation (Mangold et al. (2006) that was not conducted in a factory setting and involved automobile gasket removal rather than a sheet gasket making process. One SACC member concluded that the Draft RE for Asbestos underutilizes available data by	EPA clarifies that it did not use Mangold et al. (2006) to derive sheet gasket exposure data. The Draft RE for Asbestos based worker exposure estimates on occupational exposure monitoring conducted at the facilities that fabricated gaskets and that used these gaskets. The only inference EPA drew from the Mangold et al. (2006) study was the rate at which asbestos concentrations decay between exposed workers and ONUs. EPA continues to believe this is an appropriate interpretation of the Mangold et al. (2006) study.

	selecting only this study on which to establish exposure levels to this COU. • Recommendation 23: Collect and provide sampling plans and handling methods for data used to establish COU exposures when possible. **PUBLIC COMMENTS:** • EPA received data from one company that fabricates sheet gaskets and one company that uses sheet gaskets and admitted that the data are unlikely to be representative of practices in their respective industries (Draft RE for Asbestos p. 195, ln. 6904–906). EPA identified one firm that punches out gaskets that contain chrysotile; the commenter does not know of any other firms that punch gaskets with asbestos-containing materials in 2020. • The data presented for the facilities indicate exposures of two to four workers, who might work the press occasionally. The commenter later states that one facility employs four workers. The information presented by EPA about the number of persons who "might" work with asbestos-containing gaskets in the coming years is not accurate. • The COU seems unnecessary to evaluate, given the few numbers of persons exposed, the low levels of airborne asbestos concentrations measured in these facilities, and the lack of potential future exposures to asbestos. • Sheet gaskets contain up to 50% of resin-soaked asbestos, and these fibers are embedded in a resin or other polymeric material. They are not released to a measurable degree during routine cutting procedures. • There are no more than 0.001% of all new gaskets might contain asbestos and virtually no old gaskets being replaced today (they should have been replaced 20-30 years ago).	EPA addressed the compilation of sampling plans for data used to establish COU exposures in the first part of the response to comment category 2.18. EPA confirms that it relied on occupational exposure data from a small number of companies that fabricate and use asbestos-containing sheet gaskets. EPA believes this reflects the fact that only a small number of companies engage in these activities. This is not considered a limitation in the occupational exposure assessment. EPA staff personally observed sheet gasket stamping operations during site visits. Based on those observations and input from the one company known to manufacture these gaskets, EPA believes its estimated number of exposed workers accurately reflects current conditions. Commenters do not expand further on what a revised or alternate number should be. EPA believes that any relevant COU is necessary to consider in the risk evaluation, regardless of number of workers exposed. EPA evaluates circumstances "…under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." There is no minimum threshold of workers below which EPA automatically disregards potential exposures and risks. The best information reasonably available to address release of asbestos during sheet gasket stamping is the exposure data collected at the facility that fabricates these gaskets, and those data showed PCM-detected asbestos in worker breathing zone samples. Therefore, EPA has not revised Part 1 of the Risk Evaluation for Asbestos in sections pertaining to sheet gasket stamping and related exposures. EPA does acknowledge that a relatively small portion of sheet gaskets currently in use contain asbestos, but inclusion of this COU is still warranted.

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	• See original comment for screenshot displaying gasket exposure measurements from specific activities related to cutting, installation, and removal. • The high-end values in Table 2-11 are not consistent with the published literature or the experiences of most of the industrial hygienists in the field for an 8-hour TWA (even 20–30 years ago) due to the infrequency of the worker's contact with these materials. • The exposure assessment studies that EPA used in the Draft RE for Asbestos to quantify worker asbestos exposures as a result of sheet gasket removal and oil field brake block work are missing information (*e.g*, sampling duration and locations, analytic method, number of samples, description of work) that is both fundamental and necessary for assessing asbestos exposures resulting from this work.	EPA explained in the text how exposure estimates were derived for high-end exposure concentration. The magnitude of the concentration (0.059 fibers/cc) was measured during a 30-minute sample at the one company known to manufacture asbestos-containing sheet gaskets. EPA noted in the text that the high-end 8-hour TWA was estimated under the assumption that the activity that occurred during that sample could reasonably be foreseen to occur throughout a full work shift. EPA believes this is an appropriate assumption for reasonably foreseeable worst-case conditions. A comment also notes that sheet gasket removal and oil field brake block measurements are missing some study details. EPA acknowledges the missing details (such as analytical methods and monitored duration.) Nevertheless, EPA believes that these are the most relevant measurements for the report and rationale for the selection is included.
2.26 **Sheet gasket stamping and use ONU exposure estimates**		
42, 61, 65, 83	**PUBLIC COMMENTS:** • EPA's general approach to estimating exposures of bystanders is reasonable. A paper by Donovan et al. (2011) specifically evaluates bystander exposures when working with asbestos-containing materials. That paper and the two letters to the editor regarding that paper are the best available information for estimating these bystander exposures. • EPA did not identify any ONU exposure measurements for sheet gasket stamping and overestimated exposure for this. Mangold et al. (2006) measured "bystander" exposure during asbestos-containing gasket removal; however, EPA assumes the ONU is present in the area	EPA has not revised the "reduction factor" used in Part 1 of the Risk Evaluation for Asbestos but has noted the consistency between the employed approach and that in Donovan et al. (2011) (see Section 2.3.1.4.5). EPA derived a "reduction factor" that estimated asbestos concentrations will decrease by a factor of 5.75 between the worker and an ONU, located up to 10 feet away. EPA's estimate is on the same order of magnitude of the Donovan et al. (2011) estimates. That publication indicated a "reduction factor" of 2.85 for workers 5 to 10 feet away from the worksite and a factor of 10 for workers 10 to 30 feet away. The value EPA used is marginally lower than the midpoint of these two "reduction factors." EPA does not believe that the "reduction factor" for the sheet gasket stamping was overestimated in Part 1 of the Risk Evaluation for Asbestos. Some commenters believe that the

	(5-10 feet) for a full 8-hour shift in the risk characterization. • Exposures are estimated for workers stamping sheet gaskets and for ONUs using an averaging of short-term exposures (assuming 30 minutes) and full shift exposures (7.5 hours per day of the full shift TWA exposure) based on monitoring data. With high-end exposures that approximate ½ the OSHA PEL, how can risk be unacceptable given the few occasions of possible exposure per year? • EPA overestimated exposure for sheet gasket stamping based on its assumption that the ONU exposures were the same for all ONU types and that exposure concentrations based on a factor of 5.75 were representative of all ONUs. Exposures are likely to be lower for many of these ONUs based on (a) the larger distance from asbestos work areas and (b) certain workers (*e.g*, office workers) who may have no asbestos exposures when away from the asbestos work area. • Commenter has investigated the issue of friction products as manipulated during brake maintenance and repair. They also studied service on vehicles and the nature of brake dust, its composition and character as it relates to its biological potential. Their data and conclusions do not support the position put forward by EPA. Gasket studies show the action of gasket change on flanges is associated with exposures that are extremely low. Considering all the factors of gasket change by steam-fitters their risk is barely measurable. • EPA correctly states that the replacement of these gaskets occurs mostly during plant shutdowns and regular workers are not exposed. It is appropriate for EPA to assume at least a 5-fold decrease in exposures for the occasional ONU who might be passing by during the removal/installation operations. Most of the industrial operations are carried out outdoors and	Donovan et al. (2011) is the "best available information", but EPA notes that nearly the same reduction factor would have been calculated had the agency based it on that study. EPA believes it is appropriate, for sheet gasket stamping, to assume the ONUs are present in the same work environment throughout their shifts. During a site visit, EPA observed other workers who do not work with asbestos-containing sheet gaskets in the same open manufacturing space; and these other workers appeared to work in this room for their entire shift (except for breaks, lunch, etc.). EPA does not aim to evaluate compliance with OSHA's asbestos standard and the protectiveness of the asbestos PEL in Part 1 of the Risk Evaluation for Asbestos. EPA has added text in Section 2.3.1.4.3 of Part 1 of the Risk Evaluation for Asbestos to clarify which workers are considered ONUs for the sheet gasket fabrication condition of use. Specifically, the Branham facilities had asbestos-containing sheet gasket activity occur in a warehouse-like space, where other workers (ONU) spent their entire shift doing other tasks. Those other workers were considered ONUs for this condition of use, because they might have been exposed to asbestos fibers released from the stamping operation. On the other hand, Branham facilities had office workers who spend their days in enclosed rooms separate from where the sheet gasket stamping occurred. These office workers were not considered ONUs, because they likely are not exposed to asbestos that might be generated during stamping operations. EPA opted to use the data provided by the one company known to engage in use and removal of asbestos-containing sheet gaskets. These data suggest that asbestos is detected by PCM in the air during this activity, and EPA continues to

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	personnel can avoid passing by regulated areas. ONUs are likely to have sporadic, if any contact with this material in such environments.	believe these measurements are most representative of current uses.
2.27 **Limited scope of industries relevant to sheet gasket stamping**		
42, 51, 65, 85	**PUBLIC COMMENTS:** • The Draft RE for Asbestos indicates that only a limited number of asbestos-containing sheet gaskets rolls are imported each year for one specific use in one industry. That is why they can be produced by one firm on a handful of days per year (involving just two employees). Thus, exposures are insignificant relative to other Agency concerns. • If a pipefitter replaces gaskets older than 30 years, the worker should assume that asbestos might be in the gaskets and use current OSHA practices to limit exposure. Such exposures are generally less than the OSHA PEL and are immeasurable small when the work is conducted outdoors. • EPA acknowledged that other companies might process and use asbestos sheet gaskets, but it had no knowledge of how many. EPA, therefore, lacks information about respirator use beyond the two companies it contacted and has no basis to assume that workers uniformly wear respirators across this COU. • When describing use of sheet gaskets, EPA only considers the use in inorganic manufacturing. The application is much broader and includes chemical and refining industries.	EPA evaluates circumstances "…under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." There is no minimum threshold of workers below which EPA automatically disregards potential exposures and risks. Thus, inclusion of sheet gasket fabricators is warranted. EPA acknowledges that certain workers who remove sheet gaskets must comply with requirements in the OSHA asbestos standard. EPA opted to use the occupational exposure data provided by the one company known to use these asbestos-containing sheet gaskets, and the Agency continues to believe that is the best approach for evaluating this COU. Regarding comparisons to the OSHA PEL, evaluation of compliance with OSHA's asbestos standard and the protectiveness of the asbestos PEL is not the purpose of the risk evaluation. EPA notes in Part 1 of the Risk Evaluation for Asbestos that it was only aware of one company that fabricated these gaskets and another company that used them. All observations presented in Part 1 are based on what occurs at those two companies. EPA continues to believe that it is appropriate to base risks on what is known about respirator use for these companies. EPA acknowledges that sheet gaskets may be used in applications beyond use in titanium dioxide manufacturing, but the Agency could not confirm any additional uses.

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2.28 **Availability of quantitative data, study quality, or external validity for sheet gasket stamping**		
38, 42, 51, 63, 73, 85, 92	**PUBLIC COMMENTS:** • The gasket replacement air sampling data from Chemours are missing critical information (*e.g*, sampling duration, frequency, analytic method, indoor-vs-outdoor, ventilation, number of samples below the LOD, etc.) needed to use the data in an exposure assessment. EPA only assumed the data represented short-term samples. Although not known, it is likely that the samples were collected for either 30 minutes or 8 hours as part of OSHA compliance monitoring and that asbestos concentrations were lower than their respective PELs. • The limited monitoring data from a single processor of asbestos-containing sheet material might not be representative of workers in the COU. The Draft RE for Asbestos states that the facility had only one worker who processed asbestos-containing gaskets (p. 74). That worker is perhaps the only person in the US in this COU. • The gaskets are not new in design; EPA should more fully explore the literature [*e.g*, see two studies Boelter et al. (2011; Boelter et al. (2002) that EPA rated as high quality which provide probative exposure data on removal of old gaskets and cleaning the sealing surface prior to installation of a new gasket.] • EPA apparently did not review data from the 22 states and territories that operate their own OSHA-approved analytical laboratories and maintain their own exposure monitoring data from inspections of workplaces. • Other data are available in the international literature (*e.g*, from the Netherlands, study of workers who	EPA believes the assumptions made when interpreting the data err on the side of precaution (*i.e.*, assuming the data are 8-hour TWA concentrations as opposed to 30-minute TWA concentrations), which the Agency feels is an appropriate approach when further details on the sampling are not available. EPA agrees that the sampling data likely were collected as part of OSHA compliance monitoring. The data were provided by ACC, which submitted multiple public comments—but did not clarify the issues surrounding sampling. EPA does not believe that having data from one facility is a major limitation for the sheet gasket (stamping) COU, and that is because only two facilities (both owned by the same company) account for all known asbestos-containing sheet gasket stamping operations nationwide. EPA reviewed all publications cited in the peer review comments and public comments for further information on worker exposure to asbestos during sheet gasket removal. That literature addresses a broad range of industrial settings. EPA did not find compelling evidence from the literature for changing the exposure estimates for the sheet gasket fabrication condition of use. The two publications cited in this comment (Boelter et al., 2002, 2011) reported asbestos exposures nearly identical to those used in the risk evaluation. EPA has revised Section 2.3.1.5.4 to indicate that the Agency views it most appropriate to base risk evaluation on observations at the one company known to use the asbestos-containing sheet gaskets When preparing this Risk Evaluation, EPA obtained and considered reasonably available information, defined as

	removed braided gaskets and sheet gaskets; Spence and Rocchi (1996). • With data from one manufacturing plant, EPA has no basis to assume "the absence of asbestos exposure" for this COU. • The study on which EPA relied used an inadequate sampling volume. • Some gaskets stick to sealing surfaces very tightly and require hand or power wire brushing to completely remove, resulting in exposure levels much higher than the high-end values summarized in Table 2-11 of the Draft RE for Asbestos.	information that EPA possesses, or can reasonably obtain and synthesize for use in Risk Evaluations, considering the deadlines for completing the evaluation. Federal OSHA implements worker safety and health programs in many states throughout the country, but a few dozen states have their own OSHA programs – and these are called "state plan states. EPA reviewed data provided by OSHA and incorporated the information in the risk evaluation. However, the OSHA data EPA reviewed does not indicate if "state plan states" information is included. It is possible that the current OSHA data system is separate from the state's because it requires considerable effort to integrate the information. EPA acknowledges the limitation in not reviewing occupational exposure data collected by OSHA state plan states. EPA revised Section 2.3.1.1 to reflect this limitation. EPA clarifies that the Spence and Rocchi (1996) study on braided gasket removal was considered as described Section 2.3.1.5.4 of Part 1 of the Risk Evaluation for Asbestos. EPA clarifies that it never assumed the "absence of exposure," from the sheet gasket COU. The data tables in Part 1 of the Risk Evaluation correctly identify the estimated exposures for workers and ONUs at sheet gasket fabricators. In EPA's judgment, the primary exposures for sheet gasket fabricators occur during the stamping operation and not during disposal. A comment refers to "inadequate sampling volume" for the sheet gasket stamping exposure data. OSHA's asbestos sampling method reports "recommended air volumes" between 25 liters and 2,400 liters per sample; and the method suggests a minimum sample volume of 48 liters for assessment of excursion limits (30-minute averages). The personal breathing zone samples for the sheet gasket condition of use were collected at a rate of 2.04 liters/minute. The shortest duration sample was 27 minutes, which would suggest that all samples collected at least 55.08 liters of air.

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		Because this value falls within the recommended range for OSHA's method, EPA does not consider this to be an "inadequate sampling volume" and will continue to use these data to evaluate the sheet gasket fabricator condition of use. Note also that none of the samples from the sheet gasket stamping report were non-detect for asbestos, which is not consistent with "inadequate sampling volume," as the comment suggests. EPA continues to believe that using data provided by the one company known to currently use the asbestos-containing sheet gaskets is appropriate.
2.29 **Assumption that for any specific COU, the ONU exposures were the same for all ONU types**		
51, 65,83	**PUBLIC COMMENTS:** • While the concentration term may be represented by an 8-hour TWA sample, the actual time an ONU may enter areas near asbestos work zones (5-10 feet) is unlikely to be 8 hours per day, 5 days per week, for 40 years. Using those assumptions, EPA has overestimated exposure for ONUs in potentially every exposure scenario and should revisit whether it is appropriate to assume that ONUs (*e.g*, supervisors, managers, maintenance, janitorial, and other workers) access asbestos area work zones at the same intensity/frequency/duration as asbestos workers. • Because ONUs include "supervisors/managers, and maintenance and janitorial workers who might access the work area" (Draft RE for Asbestos p. 56), it is implausible that these ONUs spend 8 hours a day, 240 days/year, for 40 years within 5 feet of a mechanic using imported brakes. • A time weighting factor (TWF) was applied for DIY consumers and bystanders, and this recognition of the importance of exposure duration should also be examined in the context of ONUs.	EPA agrees that ONU may not be exposed for entire full shift, every workday. ONU exposure is likely to vary depending on COU, sites, and what tasks are assigned to ONUs. EPA does not have information to further refine ONU exposures for each COU. EPA searched for the exposure data and was able to find only one source which was used in the risk evaluation. EPA made several attempts to reach out to the industry and public for additional information but was unsuccessful.

#	Summary of Comments for Specific Issues Related to Charge Question 2	EPA/OPPT Response
2.30 **Oilfield brake blocks worker exposure estimates**		
SACC, 38, 42, 51, 65, 83	**SACC COMMENTS:** • For the oil field brake blocks COU, worker exposure data are sparse, but were at least collected on an oil rig during brake block replacement. Further description of how brake blocks were replaced and how many individuals were in the immediate area would be helpful. While the replacement activity might generate the most likely exposure, individuals who work around the machine when it is operating might also be exposed because of brake block wear. SACC questioned why the Draft RE for Asbestos used the lower of two reported worker air values rather than using a central tendency (mean, median) estimate. **PUBLIC COMMENTS:** • As noted by SACC, the oil field brake block exposure data is missing some critical information (*e.g*, sample duration and frequency, analytic method, number of samples, area versus BZS, description of the work tasks and equipment used, ventilation, PPE.) • While it "is reasonable to assume that wear of the brake blocks over time will release some asbestos fibers to the workplace air," the "magnitude of these releases and resulting worker exposure levels is not known." • Cheng and McDermott (1991) calculated occupational TWA exposures lower than those in the Draft RE for Asbestos. Apparently, EPA assumed that the time not sampled (the unaccounted time) has the same exposure intensity as the time that was sampled (measured), resulting in overly conservative estimates. • Table 2-12 gives the impression that 17,831 firms, with a total employment of about 530,000 people, could be	EPA considered exposures to workers in the vicinity of the brake replacement activity in the ONU evaluation. EPA updated the language in Section 2.3.1.6.2 and 2.3.1.6.5 of Part 1 of the Risk Evaluation to be clearer. Concentrations from Steinsvag et al. (2007) that were included in Part 1 are those for the worker exposure estimate and the ONU exposure estimate. EPA has clarified this point in Section 2.3.1.6 as well. EPA selected the higher of the two reported worker values for the worker exposure estimate. The lower value was selected only for the ONUs. EPA continues to support this approach, as ONUs near the main worksite will likely have lower exposures, when compared to the directly exposed workers. EPA was not able to document the full range of sampling details for the oil field brake block COU because Steinsvag et al. (2007) did not include sufficient documentation of details. EPA reviewed Cheng and McDermott (1992) for Part 1of the Risk Evaluation for Asbestos exposure estimates for the sheet gasket COUs; however, EPA does not find this study to have any bearing on consideration of oil field brake blocks. EPA adequately described information demonstrating asbestos-containing oil field brake blocks in the U.S. EPA spoke directly with the representative of a company that continues to purchase and sell asbestos-containing oil field brake blocks in the U.S., and EPA has added language to acknowledge uncertainties about the amounts of asbestos-containing brake blocks in use. With regard to the estimated number of workers potentially exposed for the oil field brake block COU, EPA acknowledges that these are the high-end estimates based on

#	Summary of Comments for Specific Issues Related to Charge Question 2	EPA/OPPT Response
	exposed to asbestos from these oilfield brake blocks, which is not possible. • Steinsvag et al. (2007) stated that the "samples were analyzed by stationary samples of asbestos fibers on the drilling floor at one installation in 1988." Because there is no need for a worker to be near the brakes, at most those samples might represent a short-term peak exposure for a person who happened to be there, probably for no more than an hour per month. The data are not representative for the COU and would overestimate exposure. One commenter recommended dropping the exposure scenario (or altering Draft RE for Asbestos Table 2-13). • In consideration of the measured 0.02–0.03 fibers/cc, assuming one hour of exposure on any particular day, the 8-hour TWA would be approximately 0.003 fibers/cc. Furthermore, assuming one day a month of such exposure, a 45-year career cumulative exposure would be 0.006 fiber/cc-year. • One commenter was adamant that there is no evidence that the brakes in these rigs have contained asbestos over the past 35 years. The MSDS cited by EPA is 8 to 10 years out of date; the commenter suggested that EPA confirm that chrysotile in oilfield brake blocks applications continues to exist. • EPA identified one company that "imports asbestos-containing brake blocks on behalf of some clients for use in the oilfield industry," but it is not known if other companies fabricate or import asbestos-containing brake blocks or how widespread continued use of asbestos brake blocks in oilfield equipment might be (Draft RE for Asbestos p. 83, ln. 3007–3010). This uncertain statement does not constitute a plausible exposure scenario.	the reasonably available information. Part 1 of the Risk Evaluation for Asbestos describes key assumptions and uncertainties pertaining to exposure estimates for each COU. EPA acknowledged limitations of data from Steinsvag et al. (1998) included in Part 1 of the Risk Evaluation for Asbestos and assigned these exposure estimates the lowest confidence rating. EPA continues to think this is the best approach for this COU and has revised Section 2.3.1.6.6 to further emphasize the uncertainties associated with the exposure estimates for this COU. EPA acknowledges that there is limited information available on chrysotile asbestos for the oil field brake block COU but does not agree that "there is no evidence that the brakes in these rigs have contained asbestos over the past 35 years," as one comment suggests. As noted above, the two main lines of evidence EPA considered to identify this COU are a Safety Data Sheet documenting the presence of asbestos and written and verbal input from a representative of a company that continues to purchase and sell asbestos-containing oil field brake blocks in the US.

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2.31 **Oilfield brake blocks ONU exposure estimates**		
SACC, 42, 51, 65, 77, 98	**PUBLIC COMMENTS:** • Rigs are outdoors, which means that there is nearly infinite dilution in air, so an ONU would have no measurable exposure to brake wear debris. The "holding" brake portion of these brakes would release debris at even the low rate of automobile brakes, and they are washed down prior to being replaced. This COU probably should not be in the document. • Crane brakes are an excellent example of holding brakes. One study, Spencer et al. (1999), in the industrial hygiene peer-reviewed literature found "There were no asbestos fibers detected by the TEM method from air samples collected during the operation of the cranes." In fact, Spencer et al. (1999) found no TEM-detected asbestos fibers in air samples collected during the operation of stationary cranes with brakes, even though crane operators sat within 2 feet of the exposed brake. • The COU of oilfield brake relied heavily upon a Norwegian study which is of limited relevance to the US oil industry. The commenter provided detailed information indicating that EPA has overestimated risk to both workers and ONUs. • Normal activities of workers operating the break handle to control the speed of the drawworks could be considered ONUs, because their exposures are expected to be incidental and no PPE would be required. These workers would be at least 5 feet away from the brake block, and they are not expected to replace the blocks.	EPA included the oil field brake block COU in the Scope document based on the known presence of asbestos in some oil field brake blocks distributed in the U.S. and does not agree that there is "no measurable exposure" for ONUs. Therefore, EPA retain this COU in Part 1 of the Risk Evaluation for Asbestos. EPA reviewed the suggested study on crane brakes when developing the Draft RE for Asbestos. EPA selected the one identified study of oil field brake blocks for evaluating exposure for this COU. Recognizing that crane brakes may be similar in certain regards, EPA has added text to the uncertainty section for oil field brake blocks (Section 2.3.1.6.6) acknowledging that the exposure concentrations used in the risk evaluation may be conservative estimates of actual exposures, based on the study cited in this comment. However, EPA does not feel this one study of a similar—but different—process confirms no exposures among oil field brake block workers. EPA has classified its confidence in exposure estimates as "low," and as noted, and will add language in Section 2.3.1.6.6 of Part 1 of the Risk Evaluation for Asbestos to acknowledge the possibility of overestimated exposures.

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2.32 **Study quality (*e.g*, use of monitoring data from oil rig drilling floors)**		
42, 65	**PUBLIC COMMENTS:** • EPA identified a single US facility that imports asbestos-containing brake blocks (Popik (2018). The number of customers receiving those brake blocks is unknown, as is the number of potentially exposed workers. Rather than "guess" the number of AC brake blocks still in use, EPA should conduct interviews of the appropriate persons. • Currently, most braking on AC rigs is electromagnetic. The disk brakes and friction pads on AC rigs are used as "parking" brakes and wouldn't experience wear unless they were not adjusted properly. Modern SCR rigs would use a Wichita or Eden braking system which does not use friction pads for normal operation; they would likely be equipped with disks and friction pads like the AC rigs. Older SCR rigs would have run drums with asbestos friction pads. Although, generally industry had poor experience with non-asbestos pads glazing over due to high temperatures, so they weren't preferred.	EPA believes asbestos-containing oil field brake blocks continue to be imported, distributed and used for older oil rigs based on consultations with industry representatives with knowledge of the oil field drilling industry. EPA used 2016 Occupational Employment Statistics data from the Bureau of Labor Statistics (BLS) and 2015 data from the U.S. Census' Statistics of U.S. Businesses. EPA used BLS and Census data for three NAICS codes: 211111, Crude Petroleum and Natural Gas Extraction; 213111, Drilling Oil and Gas Wells; and 213112, Support Activities for Oil and Gas Operations. Table 2-13 in Part 1 of the Risk Evaluation for Asbestos summarizes the total establishments, potentially exposed workers, and ONUs in these industries. EPA does not have an estimate of the number of establishments in these industries that use asbestos-containing brake blocks. Therefore, EPA presents these results as bounding estimates of the number of establishments and potentially exposed workers and ONUs EPA has updated the process description text in Section 2.3.1.6.1 to include some of the details raised regarding braking technologies currently used in the oil and gas industry. But, even though part of the industry uses braking technologies that do not involve asbestos, the information available to EPA suggests that a portion of the industry continues to use asbestos-containing brake blocks.
2.33 **Aftermarket automotive brakes worker exposure estimates**		
SACC, 32, 40, 42, 61, 77, 79, 80, 90, 95	**SACC COMMENTS:** • For the aftermarket brake replacement scenario, SACC identified a set of papers not used by the Draft RE for Asbestos based on work in brake shops in Columbia, where asbestos brake pads are currently legally marketed (Cely-García et al. (2016b; Cely-García et al.	EPA intentionally limited its evaluation of studies on aftermarket automotive products to those that examined exposures in the U.S. because OSHA's asbestos standard includes provisions that apply to U.S. workers and worksites—and these provisions do not apply in other countries. Additionally, the profile of brakes and clutches

	(2016a; Salazar et al. (2015; Cely-García et al. (2012). Additional domestic literature was identified that did not appear to have been cited in the Draft RE for Asbestos (Williams et al. (2007; Paustenbach et al. (2004b). The SACC noted that a summary table of published air measurements associated with brake maintenance can be found in Attachment 3 of public comments by Arthur Frank. Recommendation 27: Use the occupational hygiene measurements reported for the brake shops in Columbia. **PUBLIC COMMENTS:** • EPA does not know the actual number of workers in the US who are currently exposed to asbestos from working directly with asbestos-containing brakes or clutches. • EPA presents no information regarding the actual number of vehicles in the US that contain asbestos-containing brakes or clutches. • Further review and discussion of all available datasets for deriving the 8-hour TWA, high-end exposure, the short-term, central tendency exposures, and the 8-hour TWA, central tendency exposures for this COU are needed, including a clearer rationale for why certain studies and data points were included (versus excluded). • EPA used concentrations measured during "unpacking and packing 16 boxes of asbestos-containing brake pads over approximately 30 minutes" for the high-end exposure value for occupational and DIY vehicle brake work (Draft RE for Asbestos p. 94 of 310); this concentration is not a reasonable surrogate for either. Moreover, the short-term sample collected by Madl et al. (2008) was a 15-minute sample (not a 30-minute sample), so the associated exposure concentrations in the Draft RE for Asbestos are overestimated. One generally does not extrapolate measured concentrations for a job or task to another job or task that differs in fundamental ways (*e.g*, materials, handling procedure,	encountered in U.S. vehicles differs from what is seen in other countries. In Section 2.3.1.7 of Part 1 of the Risk Evaluation for Asbestos, EPA explains the focus on post-1980 publications that reported original asbestos PBZ measurements for business establishments in the U.S. EPA reviewed publications suggested in comments from the public and the SACC. EPA has included relevant occupational exposure data to reflect the new information obtained and clarified why some of the suggested references are not cited in the risk evaluation. EPA revised text in Section 2.3.1.7.3 of Part 1 of the Risk Evaluation for asbestos to reflect a market share adjustment based on the dollar value of imported brakes identified as containing asbestos. EPA has been unable to identify reasonably available information to determine the number of potentially exposed workers and the proportion of vehicles with asbestos-containing brakes or clutches. With regard to the inclusion of Madl et al. (2008) which includes the measurements taken during opening and closing boxes, EPA considers opening and closing boxes to be part of the overall brake replacement process and has retained Madl et al. (2008) in Part 1 of the Risk Evaluation for Asbestos. This is consistent with other COUs (chlor-alkali and sheet gaskets) where measurements taken during the handling of packages containing asbestos and asbestos containing articles were included in the exposure estimates. Section 2.3.1.7.4 has been revised to provide the rationale for including this study. The highest concentration was from a 15-minute average sample and therefore might overstate (by no more than a factor of two) the 30-minute concentration. EPA included data from Blake et al. (2003) for arc grinding of brakes, a practice common decades ago, but noted that the concentrations were likely overestimates of current

	processes, durations, frequencies, etc.) without at least recognizing and adjusting for such differences. • Moreover, the maximum value obtained from a single study is unlikely to represent high-end exposures for an entire population of workers. In the Madl et al. (2008) study, the 30-minute asbestos concentrations ranged 13-fold, while the 15-minute asbestos concentrations ranged 40-fold. • EPA based its high-end exposure on data collected during arc grinding of brakes without dust control; arc grinding has not been a common practice since the 1960s (NIOSH (1989). • EPA used the maximum value from Madl et al. (2008) even though elsewhere in the Draft RE for Asbestos, EPA states that the Agency uses "95th percentile" estimates to represent high-end exposures for COUs" unless not available" (p. 57). Table 1 of Madl et al. (2008) presents the data by which the 95th percentile value (*i.e.*, 0.366 f/cc) can be calculated. • EPA selected the highest 8-hour TWA personal breathing zone result [0.094 f/cc, reported by Blake et al. (2003)] as one of the bases of their "high-end" 8-hour TWA exposure for occupational brake repair work. This sample, however, was collected for 103 minutes during the arc grinding of drum brake shoes. Arc grinding stopped mid 1980s and is unlikely today. Moreover, Blake et al. (2003) conducted a simulation study to recreate historical airborne asbestos concentrations, which is not appropriate for predicting future exposures. • Moreover, Bernstein et al. (2015); Bernstein et al. (2014) showed that samples of dust from arc grinding are not biologically active. • Currently, one car manufacturer imports asbestos-containing brakes for use in a single model of vehicle which is manufactured domestically, but only exported	conditions (Section 2.3.1.7.4). EPA believes this study warrants inclusion because it also received feedback from commenters (see next comment and EPA response) that arc grinding of brakes still occurs today. EPA used the highest exposure concentration from Madl et al. (2008) in the risk evaluation. A comment recommended that EPA instead calculate the 95th percentile concentration using data reported in Table 1 of this article. However, Table 1 does not present all individual sampling results, which would be needed to calculate the distribution percentiles. Regarding asbestos-containing brakes for car manufacturing, EPA did not include an estimate of the number of workers who install asbestos-containing brakes at the one domestic car manufacturer still known to install them. Regarding clutches, EPA is not aware of any car manufacturers that import asbestos-containing clutch assemblies. EPA has revised Section 2.3.1.7.1 accordingly. EPA acknowledges that it received some comments suggesting that exposures were underestimated and others suggesting that exposures were overestimated. EPA evaluated the full range of data sources submitted in comments from the public and SACC, but no additional studies were identified for inclusion related to over- or underestimation of exposures. EPA has revised Section 2.3.1.7.4 to acknowledge that the suggested literature did not meet EPA's selection criteria. EPA revised Section 2.3.1.7.1 to indicate the information available to provide further historical context, but EPA did not find it necessary to add this context in Part 1 for the Risk Evaluation for Asbestos. EPA does not have information on what fraction of dust from arc grinding is "active" asbestos. However, there is information indicating that dust from brake repair contains 30 to 55% unaltered chrysotile fibers.

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	and sold outside of the US (Draft RE for Asbestos ln. 3120-3121, 3126-3127), and EPA presents no information regarding the number of workers involved in this activity. • EPA presents no information that any US automotive manufacturer is currently importing or installing asbestos-containing clutches on any vehicles. • One commenter disagreed and stated that repair of automotive friction products (brakes and clutches) has been documented to cause extremely high asbestos exposures, many times the current OSHA PEL. In the Draft RE for Asbestos, understanding the difference between the materials and processes used for a disc brake versus a drum brake job, and the difference between the use of a grinder versus an arc grinder, and how / when these tools are used or if they are used at all, is critical to interpreting historical sampling data to develop reasonable exposure scenarios.	https://beta.regulations.gov/comment/EPA-HQ-OPPT-2019-0501-0040 EPA believes that the assessment approach used for replacement auto brake COU is appropriate and reasonable.
2.34 **Aftermarket automotive brakes ONU exposure estimates**		
SACC, 40, 42, 51, 80, 90, 95	**SACC COMMENTS:** • In the automotive brake repair COU, the studies used for estimating ONU exposure are simulated surrogate (unpacking) activities rather than actual brake repair in a working establishment. In one study, the surrogate exposure involved unpacking boxes of brake pads, shoes etc. (Madl et al. (2008). Whether the exposures seen in that study mimic those in actual car repair facilities is unclear. The SACC suggested other studies that might be superior. • Casual online searches by SACC members found that arc grinding of brake shoes is likely occurring in 2020 (see YouTube®, eBay®). Moreover, brief searches on eBay produced multiple listings for new asbestos brake pads for both automobiles and motorcycles. Some	EPA's response to Comment 2.33 addresses the inclusion of Madl et al. (2008), which has been retained in Part 1 of the Risk Evaluation for Asbestos. EPA has retained the study on arc grinding of brakes (Blake et al., 2003) in the exposure assessment because there is information indicating that this activity still occurs. EPA does appropriately note in Part 1, however, that this is not a common activity. EPA has identified and described evidence of one car manufacturer using asbestos-containing brakes, however, the extent to which asbestos remains in aftermarket replacement parts is difficult to characterize. EPA evaluated epidemiologic studies of lung cancer and mesothelioma in auto mechanisms and did not find those studies sufficient for

	sellers list wholesale quantities while others list "new old stock." Given ongoing commerce in asbestos pads in many foreign countries, it is unlikely that all asbestos brake pads are counterfeits. **PUBLIC COMMENTS:** • Other commenters stated that EPA ignored relevant studies and overestimated exposure. The five NIOSH studies cited by EPA contain both personal and area sampling data that could be used to assess potential bystander exposures during brake repair work should be considered. • The number of workers or consumer DIY users of imported chrysotile-containing aftermarket automotive brakes/linings are unknown. Import volumes and the number of asbestos-containing brakes purchased online and installed in classic or new cars is unknown (p. 17-18, 22). EPA's "best current estimate" of 749,900 auto mechanics in the US is from 2016 BLS (p. 92). If each mechanic performs multiple brake jobs in a day, few could possibly use imported chrysotile-containing brakes daily. • Far less than <1% of brakes imported from other countries might contain asbestos, and virtually all of those should be brake pads (rather than drum brakes) for which there should be no exposure during installation or removal. • Few older or antique model vehicles that might have asbestos-containing parts are still in operation. The Draft RE for Asbestos (p. 3121-3124) provides no evidence that there are asbestos-containing brakes installed by consumers. • Finley et al. (2013); Finley et al. (2012) provides reasonably accurate descriptions of the number of mechanics who might be exposed to asbestos from brakes and describes limitations of Dr. Lemen's analysis.	use in deriving in IUR to develop risk estimates. The evaluation of these studies and their limitations is described in a Supplemental File for this Response to Comments document. EPA used the NIOSH "bystander" measurements to derive updated ONU exposure estimates for this COU, as described in Section 2.3.1.7.5. EPA made adjustments to the estimated number of individuals exposed using reasonably available information on the potential market share of asbestos brakes. Details are in provided in Section 4.3.7, but the new estimate for number of both workers and ONUs is based on the assumption that asbestos brakes may represent only approximately 0.05% of aftermarket automotive brakes. EPA EPA estimated potentially exposed individuals (both workers and ONUs) by applying this factor (0.05%) to the universe of automotive service technicians and mechanics. Regarding the suggested publications by Finley et al., the first publication compared reported to expected cases of mesothelioma for automotive mechanics—and had to estimate the total number of mechanics to do so. Bureau of Labor Statistics data were used for this purpose, which is the same data source that EPA used in the risk evaluation. The second publication is a letter to the editor, which is a response to a criticism of the first publication. The letter to the editor does not include further detail on the estimated number of workers. Regarding the assertion that asbestos-containing brake materials purchased in 2008 does not imply they are available in 2020, EPA does not make contradictory statements. However, EPA clarifies that asbestos containing brakes are still available online for purchase. EPA has updated Section 2.3.1.7.5 to clarify how central tendency exposure estimates were derived for the

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	• The fact that asbestos-containing replacement brake materials and clutch discs were purchased in 2008 from an auto parts facility (Draft RE for Asbestos pp. 3201-3203, pp. 3248-3251) does not indicate availability or actual use of such parts in 2020. • How EPA derived the 0.006 f/cc value is not clearly explained in the Draft RE for Asbestos. EPA should outline the calculation steps and identify the location of the "central tendency" data for each study. • Inherent in the use of the 0.006 f/cc value is the assumption that every brake job performed over the course of a brake repair mechanic's 40-year career will involve the removal/installation of asbestos-containing brakes. These are obsolete and extreme scenarios that are not "reasonable" for present and future brake repair work. The commenter suggested that EPA consider incorporating a factor that accounts for the small fraction of brakes currently present on vehicles or in commerce that contain asbestos.	aftermarket automotive parts condition of use. That text reads: "The central tendency short-term TWA exposure value for workers is based on the seven studies found to include relevant measurements…For each study, EPA identified the central tendency short-term exposure, which was either reported by the authors or inferred from the range of data points, and the value in Table 2 15. (0.006 fibers/cc) is the median of those central tendencies from those seven studies. Thus, three of the studies reported central tendency concentrations lower than 0.006 fibers/cc, one reported a central tendency concentration of 0.006 fibers/cc, and the other three studies reported higher exposure concentrations."
2.35 **Worker exposures for brake installation on export vehicles unlikely to match aftermarket brake installation ONU**		
42, 79	**PUBLIC COMMENTS:** • EPA exposures for installing brakes and clutches in exported cars from an 8-hour TWA exposure (from Draft RE for Asbestos Table 2-15) before consideration of PPE and any relevant APF. Since those exposures were assumed to be the same as for repairing or replacing brakes, the resulting risks appear to be identical despite the different work environment for installing new brakes or new brake assemblies on new cars for export and for "repairing or replacing brakes with asbestos-containing aftermarket automotive parts." • One commenter recommends a paper by Donovan et al. (2011) for bystanders, although it is unlikely a worker	EPA did not identify reasonably available information on the exposure associated with installing brakes and clutches in new cars and used the data used for aftermarket auto brake replacement COU. The aftermarket auto replacement brake and clutch estimates include monitoring data from the following worker activities: packing and unpacking boxes, cleaning, removal of old parts, and installation of new parts. The air measurements indicate asbestos is present in the workplace air during all activities. Although there are differences between new car installation and old car replacement, there are similarities in worker

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	would install an asbestos-containing brake (that might release dust).	activities: packing and unpacking boxes, cleaning, and installation of new parts. EPA believes that the assessment approach used for the new car installation is appropriate and reasonable. EPA has revised the ONU derivation such that it is based on sampling data that NIOSH collected at bystander locations during brake repair activity. Section 2.3.1.7.5 in Part 1 for the Risk Evaluation for Asbestos describes how EPA derived the ONU exposure estimates from the NIOSH data.
2.36 **Workers engaged in clutch repair have lower exposures than brake mechanics**		
90	**PUBLIC COMMENTS:** • Clutch wear debris has historically contained approximately 10-fold less asbestos than brake wear debris (Draft RE for Asbestos, p. 91); newly manufactured clutches have not contained asbestos for the last several decades; and only one clutch needs replacement compared with four brakes. Thus, exposure data from brake repair environments does not apply and would overestimate clutch repair exposure. • Moreover, "a common clutch repair method is to remove and replace the entire clutch assembly, rather than the clutch disc component" (Draft RE for Asbestos p. 92), which eliminates potential asbestos exposure. • There should be negligible exposures to brake dust released during drum grinding or brake wear debris (due to historical braking) in the coming years. • The vast majority of vehicles undergoing clutch maintenance today and in future will have automatic transmissions, rather than manual transmissions. Automatic transmission bands and clutch plates are considered wet parts, bathed in transmission fluid throughout the lifetime of the transmission. Thus,	EPA revised Section 2.3.1.7.2 in Part 1 of the Risk Evaluation to address additional details on clutch replacements and asbestos exposure (*e.g*, vehicles having just one clutch assembly). In Section 2.3.1.7.2, EPA originally noted that asbestos exposures for clutch repair are known to be lower than the exposures for brake repair. EPA determined that the asbestos air concentrations during clutch repair are comparable to those during brake repair. EPA clarified the text accordingly. Furthermore, EPA has considered the studies and updated Section 2.3.1.7.4 of Part 1 of the Risk Evaluation for Asbestos. EPA did not add language to forecast future exposures to brake dust as "negligible", given that asbestos in automotive parts is not banned at the federal level, and foreign suppliers face few restrictions when selling asbestos-containing brake products to business establishments and individuals in the United States. Finally, EPA acknowledges the comment asserting that worker 8-hour TWA asbestos exposures to aftermarket automotive brakes "ranged from 0.004 f/cc to 0.008 f/cc (for

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	potential exposure of workers to asbestos in air should be much lower. • A comprehensive review of asbestos exposure associated with brake repair work conducted in the 1980s (in the absence of compressed air use) reported that the mean 8-hour TWA exposures for car and light truck brake repair ranged from 0.004 f/cc to 0.008 f/cc (for garages with a "low" level/frequency of service) (Paustenbach et al. (2003), while mean 8-hour TWA exposures for clutch repair ranged between 0 f/cc and 0.0016 f/cc (Blake et al. (2008; Cohen and Van Orden (2008). Given the availability of clutch repair exposure data in the peer-reviewed literature, any health risk assessment for clutch repair activities should rely on these data.	garages with a 'low' level/frequency of service)." EPA notes that its central tendency estimate (0.006 f/cc) falls within this range.
2.37 **Other gaskets/utility vehicles (UTVs) worker exposure estimates**		
SACC	**SACC COMMENTS:** • The study used for other gaskets/UTVs is a research simulation study on automobile exhaust systems rather than actual UTV maintenance data. • The relevant UTV work is not adequately described regarding the state of the UTV components at replacement/repair and difficulty of their removal. Given the Draft RE for Asbestos estimate of the large number of UTV sales and service facilities, the SACC recommended using unannounced site visits to observe the processes. • Discussion of motorcycle brake pads led to further consideration of other vehicles or equipment that might contain asbestos brake or clutch pads such as tractors or other farm equipment, construction equipment, buses and commercial trucks, forklifts, cranes, etc. One SACC member reported that one of the public commenters had provided data that included some asbestos content	EPA clarifies that the principal data source for the UTV gasket servicing COU was data from Paustenbach et al. (2006). While the title of the Paustenbach et al. (2006) paper does refer to "a simulation study," the paper documents a field sampling program at an operating muffler shop, while workers repaired vehicle exhaust systems. This paper was selected as the principle data source because the UTV COU also pertains to asbestos-containing components in exhaust systems. In short, the study data are direct measurements from relevant work activities. Part 1 of the Risk Evaluation focuses on the COUs for which EPA could determine the presence of chrysotile asbestos in friction materials is intended, know, or reasonably foreseen to occur. When developing the risk evaluation, EPA reviewed several publications noting that asbestos was previously found in various other types of vehicles, but EPA has no evidence of its current use in other types of vehicles.

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	analysis and air fiber concentration data for non-passenger car products.	Accordingly, EPA did not revise the COUs for the risk evaluation.
2.38	**Consideration of additional studies on gasket use identified by SACC**	
SACC	**SACC Comments** • Recommendation 79: Discuss and incorporate findings from the additional studies on gasket use identified by SACC (numbers 1 through 5 below): • 1. Cowan et al. (2015) as cited in the Draft RE for Asbestos (p. 91-92) noted results of 19 samples taken by OSHA during inspections of auto repair facilities between 2000 and 2011. One SACC member commented that this number of inspections is barely adequate to support any conclusions about asbestos exposure and the tasks performed during sampling were not reported. Draft RE for Asbestos Table 2-14 showing data from Cowan et al. (2015) can be summarized in text, if retained. • 2. The five reports published by NIOSH in 1987 and 1988 and the associated summary cited by EPA on page 92 demonstrated that asbestos exposure in brake repair facilities can be lowered by specific dust-lowering work practices. However, without knowing the actual prevalence of these practices in auto repair facilities at present, the relevance of these findings is unclear. • 3. The risk evaluation relies heavily on a few publications on brake-related exposures, especially Blake et al. (2003), which was a simulation of brake repair work. It cited Madl et al. (2008) which did not pertain to actual brake repair but to dust levels associated with packing and unpacking dozens of boxes	EPA will retain its review of Cowan et al. (2015) paper (and the summary table) in Part 1 of the Risk Evaluation for Asbestos. However, EPA does acknowledge that this paper includes a relatively small number of sampling events, which is why EPA did not base the COU evaluation on this paper alone. EPA used this paper to provide context for OSHA sampling activities in recent years. EPA agrees that the NIOSH studies were performed to assess the effectiveness of different types of controls. EPA has added language to Section 2.3.1.7.6 in Part 1 of the Risk Evaluation for Asbestos to note that it is unclear how many brake mechanics currently use those techniques (though these workers would still be required to use dust control methods as required by the OSHA asbestos standard). EPA notes that it reviewed all relevant publications in the systematic review process. However, when deriving exposure estimates, EPA focuses only on publications that (1) present asbestos exposure data for U.S. establishments, (2) review sampling data collected from 1980 to the present, and (3) present original data (as opposed to summarizing previously reported results). EPA reviewed every reference mentioned in the public comments and peer review comments. None of those studies meet the three selection criteria that EPA notes here. (Note: The NIOSH (1982) and Rohl et al. (1976b) studies are based on samples collected prior to 1980.) EPA acknowledges that sampling data from earlier years reported higher asbestos concentrations, but those data were also collected before OSHA promulgated asbestos standard requirements specific to brake repair work.

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	of new brakes. It mentioned a Weir and Meraz (2001) study but rejected use of its data for lack of details. • 4. EPA failed to cite other highly relevant studies (page 92) including the NIOSH (1982) and Rohl et al. (1976b) studies which represented sampling performed at active repair facilities. Both studies showed higher levels of asbestos exposure for brake mechanics and others in the area of brake mechanic work. These studies may also more accurately reflect working conditions in current marginal repair shops that use asbestos-containing brakes. • 5. The Draft RE for Asbestos stated that PCM may overstate asbestos fiber concentrations (citing Blake et al. (2003) and Weir and Meraz (2001)) but ignored Rohl et al. (1976b) and failed to cite NIOSH (1982) and Sheehy et al. (1989), which both show that asbestos fibers counted by TEM are greater than those counted by PCM. • The Draft RE for Asbestos (pp. 78-79), cited just two published studies of gasket removal and used Chemours sampling data (which lack critical documentation). SACC suggested EPA consider four additional studies with respect to gasket use including Cheng and McDermott (1991), Longo et al. (2002), Mckinnery and Moore (1992) and Millette et al. (1995).	EPA has added text in Section 2.3.1.7.4 explaining how the Agency arrived at its final list of publications for review. EPA revised Section 2.3.1.5.4 to acknowledge the broader range of literature available on sheet gasket removal that the Agency considered. However, EPA ultimately decided to base its assessment on worker exposure data collected in the one industry that was known to continue using asbestos-containing sheet gaskets.
2.39 **Other gaskets/utility vehicles (UTVs) ONU exposure estimates**		
SACC, 42, 51, 61, 69, 79	**SACC COMMENTS:** • The Paustenbach et al. (2006) study is a research simulation rather than actual UTV maintenance data. **PUBLIC COMMENTS:** • Even though there are some asbestos-containing gaskets still in UTVs, removal of them under any plausible	Refer to EPA's response to comments in Section 2.36 for more information regarding the use of Paustenbach et al. (2006). EPA will continue to base its exposure estimate for the UTV COU on the values cited in the draft risk evaluation. One suggestion in this comment was to use measurements from removal of a gasket from a flange seal and cutting asbestos-

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	scenario produces low airborne concentrations of chrysotile. • There is no information from OSHA, NIOSH, or the scientific literature by which to estimate the number of persons possibly exposed or their exposures with installing and servicing gaskets in UTVs. • One commenter tested removal of chrysotile-impregnated elastomeric matrix (styrene butadiene rubber) gaskets from a flange seat and reported their results. The cutting of chrysotile packing with "snippers" resulted in a PCM measurement of < 0.01 f/cc of air and TEM measurement less than the LOD (< 0.001 f/cc of air). • EPA did not find relevant data from OSHA or NIOSH. The Paustenbach et al. (2006) study involved replacement of exhaust gaskets. In that study, 17 of 23 personal samples and 16 of 21 area samples were ND. The study calculated an 8-hour TWA exposure concentration of 0.01 fibers/cc based on a worker performing four exhaust system removal tasks in one shift. EPA could use these data instead of extrapolating from short task or sampling intervals.	containing packing with "snippers." The exposure estimates in the draft risk evaluation are expected to be comparable or high than any "low airborne concentration" exposure scenarios commenter mentioned. EPA clarifies that, as stated in the Draft RE for Asbestos, no data from OSHA, NIOSH, or the scientific literature report the number of workers involved in servicing UTVs and their asbestos exposures. In such cases, EPA seeks alternate data to characterize these values. Part 1 of the Risk Evaluation for Asbestos documents all assumptions related to the use of alternate data. EPA does not believe the information provided for asbestos concentrations associated with removal of asbestos-containing gaskets from a "flange seal" using "snippers." is directly relevant to the UTV COU. In contrast, the Paustenbach et al. (2005) publication has greater relevance, as that is the only study EPA identified that evaluated asbestos releases from the removal or repair of vehicle exhaust systems with asbestos-containing gaskets. While the Paustenbach study pertains to motor vehicles, EPA believes this data set has the greatest relevance to repair of ATVs/UTVs known to have asbestos-containing gaskets in their exhaust systems
2.40 **Requirement or assumption of use of personal protective equipment (PPE)**		
SACC, 6, 31, 43, 51, 63, 65, 70, 72, 85, 86, 91, 92	**SACC COMMENTS:** • SACC was concerned about the unrealistic inclusion of respiratory protection and associated assigned protection factors (APFs) for risk estimation for workers (Draft RE for Asbestos Table 4-55, p. 208). Respiratory protection programs, as established and operated by some employers, are inadequate. Citation by OSHA for inadequate respiratory protection programs is one of the	EPA agrees that there are challenges associated with use of PPE; they are described in Section 5.1. By providing risk estimates that account for use of PPE, EPA is not recommending or requiring use of PPE. Rather, these risk estimates are part of EPA's approach for developing exposure assessments for workers that relies on the reasonably available information (including information from the industry) and expert judgment. When appropriate, EPA will develop exposure scenarios both with and without

	five most common OSHA violations nationally over the past several years. • Even when PPE may be used, it is sometimes incorrectly used, or a lower PPE standard is used (*e.g*, use of N95 respirators in the sheet gasket stamping operation which OSHA considers inappropriate) (Draft RE for Asbestos p. 161). • Given the uncertainty around availability, use, and effectiveness of appropriate respirator protection, some SACC members recommended deleting the APF's in the exposure estimates and risk calculations (remove from Table 4-55). Another member, however, considered it appropriate to present risk with and without PPE because there are industries and individual facilities that comply with respiratory protection protocols. Recommendation 61: Clarify in Table 4-55 that risks under PPE use are potentially unachievable lower bounds that assume a comprehensive respiratory protection program is always in place everywhere. • Most of the airborne asbestos concentrations used to estimate worker exposures in Draft RE for Asbestos do not exceed OSHA action levels and therefore would not trigger enforcement of a proper respiratory protection program. • As noted in the Draft RE for Asbestos (p. 64–67), ACC documentation from chlor-alkali plants reported respiratory protection is not used in certain tasks even when air sampling shows asbestos fiber concentrations that approach the OSHA STEL, *i.e.*, cell assembly, hydro-blasting. • Small businesses are unlikely to have a respiratory protection program, either because they believe that they are not covered by OSHA or because they do not have the resources to establish such a program. Draft RE for Asbestos Table 2-7 (p. 68) summarizes the short-term sampling results from industry.	engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. EPA did assess the risk to workers in the absence of PPE, and those risks are presented in Section 4 Risk Characterization under Table 4-55, Summary of Risk Estimates for Inhalation Exposures to Workers and ONUs by COU. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a COU presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each COU, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1 in addition to 5.2 In the case of sheet gasket stamping, EPA did take into account in Section 5.2 the ineffectiveness of N95 respirators for reducing asbestos fiber exposure and assumed an APF of 1 (or no reduction in the risk estimate) to reflect this consideration. EPA also took into account that ACC documentation reported respiratory protection was not used in certain worker tasks even when monitoring data showed the presence of airborne asbestos fibers. Section 5.2 also reflects this and assigns an APF of 1 when considering risks to chlor-alkali workers. Further, other COUs presented in Section 5.2 take into the account the absence of PPE where EPA had information to make this determination.

	• The Draft RE for Asbestos concludes that "even with every worker wearing (a) respirator, some of these workers would not be protected" (p. 60, ln. 2098–2099) and SACC agrees. • For risks to workers that assume use of PPE, the Draft RE for Asbestos uses the APF (assigned protection factor) for the respirator as though it were a limit. OSHA sets APF for a respirator, however, based on whether 95% of the samples in the studies achieved that APF. That does not address personal differences (*e.g*, Crump (2007)), for example a worker whose respirator does not fit well may receive far less protection from the respirator than indicated by the assigned APF. • SACC described various limitations associated with the use of the APFs in some detail, citing the National Personal Protective Technology Laboratory as a resource for realistic protection factors. Recommendation 88: Consider visiting facilities where asbestos is processed to increase EPA understanding of the worker conditions, including PPE use. • SACC members were of mixed opinions regarding the specific APFs in Section 2.3.1.2 as stated in their review (response to CQ 6.2) and as noted by SACC in prior reviews of chemical DREs. It asked EPA to reconsider or defend the default assumptions regarding PPE/APF after reviewing Riala and Riipinen (1998) results and practical limitations in PPE programs. • Recommendation 20: Reconsider or defend the default assumptions regarding PPE and APF use after considering the Riala and Riipinen (1998) results and practical limitations in PPE programs. **PUBLIC COMMENTS:** • Given the uncertainty in PPE use and appropriate APFs, commenters appreciated EPA presenting risks assuming no PPE. Evaluating risk without regard to respirator use	In addition, as explained in Section 2.3.1.2, for asbestos, nominal APFs presented in **Error! Reference source not found.** may not be achieved for all PPE users. Riala and Riipinen (1998) investigated performance of respirators and HEPA units in 21 different exposure abatement scenarios; most involved very high exposures not consistent with COUs identified in this RE. However, for three abatement scenarios, exposure concentrations were below 1 f/cc, which is relevant to the COUs in this draft risk evaluation. In the three scenarios, actual APFs were reported as 50, 5, and 4. The strength of this publication is the reporting of asbestos samples inside the mask, use of worker's own protection equipment, and measurement in different real work conditions. The results demonstrate that while some workers have protection above nominal APF, some workers have protection below nominal APF, so even with every worker wearing respirator, some of these workers would not be protected. Regarding Recommendation 61 to clarify that the risks in Table 4-55 using PPE are potentially unachievable where respiratory protection is not comprehensive was addressed in the DRE using footnote c in the columns where PPE was applied. Footnote c to Table 4-55 says: "As shown in Table 4-3, EPA has information suggesting use of respirators for two COUs (chlor-alkali: APF of 10 or 25; and 7430 sheet gasket use: APF of 10 only). Application of all other APFs is hypothetical."

	is consistent with prevailing industrial hygiene practices and OSHA asbestos regulations. • OSHA and NIOSH emphasize that respirators are not always properly worn for a variety of reasons. OSHA inspection data show that the respirator standard is the fourth most often cited violation even in situations where respirators are required. • Assertions in the Draft RE for Asbestos about PPE should include a discussion on the extent and frequency that the PPE is used according to requirements. • The nominal APFs in Table 2-3 may not be achieved for all PPE users. Riala and Riipinen (1998) found some workers have protection above nominal APF while others have below nominal. Even the ACC submissions for chlor-alkali production indicated that PPE is not worn throughout an entire shift. • If the two chlor-alkali facilities had advanced notice of EPA's 2017 site visit, they might have "cleaned up" for it. Moreover, EPA did not verify wearing of respirators or evaluate whether the 2 facilities were representative of the 15 in the industry. • The general public might believe that product safety data sheets exaggerate hazards of asbestos or may not keep the data sheets for future reference. • The assumption of respirator use does not change EPA's conclusions on some COUs, but it does reduce risk estimates significantly and might justify exposure restrictions that are insufficiently protective. • EPA assumed respirator use for three COUs based on reports by industry, which might not be representative. EPA also lacked information on the type of respirator used except for chlor-alkali production and sheet gasket use. Thus, EPA used largely "hypothetical" APFs of 10-25. • EPA considered respirator use either in the entire shift or not at all. Failure to incorporate current practices	

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	regarding respirators will lead to an overestimate of risks to chlor-alkali workers.	
2.41 **Acute exposure events such as spills and accidents**		
51, 86	**PUBLIC COMMENTS:** • Particularly for asbestos imports for the chlor-alkali industry, accidents or improper handling could rupture shipping containers and bags, releasing raw asbestos powder in quantities that put workers or bystanders at risk. The Draft RE for Asbestos acknowledges that damaged shipping containers have arrived in the US and port and warehouse workers manage and remediate damaged containers. Spill exposure scenarios include losses from torn sacks in shipment, unloading and storage of asbestos sacks, and waste from vacuuming areas where torn sacks are discovered and patched. • Thus, it is not appropriate to assume that spills, leaks and accidents during importation and distribution in commerce never happen and pose no risk. • EPA also cautioned that "it is uncertain if certain high-exposure activities are captured in this dataset, such as exposures when cleaning spilled asbestos within a container from damaged bags." EPA had little ability to verify the completeness of the chlor-alkali data because it made site visits to only 2 of the 15 plants using asbestos diaphragm cells, these visits were announced in advance, and EPA was not accompanied by knowledgeable experts from OSHA and NIOSH.	EPA gathered frequency of exposure information from the chlor-alkali industry, both through observations and discussions during site visits and through written inquiry. Section 2.3.1.3.2 in Part 1 of the Risk Evaluation for Asbestos was updated to clarify that industry informed EPA that facilities receiving damaged bags containing chrysotile asbestos is a "very rare" event. In addition, Section 2.3.1.3.2 has been updated to include task-specific (*e.g*, hydroblasting) data provided by ACC. EPA believes Section 2.3.1.3.6 pertaining to data assumptions, uncertainties, and level of confidence for the chlor-alkali COU in the occupational exposure assessment is sufficient. As noted above, asbestos spilling from damaged bags is an infrequent occurrence in this industry. There is not currently available information available to conduct quantitative evaluations of this uncertainty for this COU. EPA does not believe that conducting additional site visits would not have provided further quantitative insights on worker exposures during extremely rare events. Accidents, spills and leaks generally are not included within the scope of a TSCA risk evaluation because in general they are not considered to be circumstances under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of. To the extent there may be potential exposure from accidents, spills and leaks, EPA is also declining to evaluate environmental exposure pathways addressed by other EPA-administered statutes and associated regulatory programs.

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		First, EPA does not identify asbestos accidents, spills or leaks as "conditions of use." EPA does not consider accidents, spills or leaks to constitute circumstances under which asbestos is manufactured, processed, distributed, used, or disposed of, within TSCA's definition of "conditions of use." Congress specifically listed discrete, routine chemical lifecycle stages within the statutory definition of "conditions of use" and EPA does not believe it is reasonable to interpret "circumstances" under which asbestos is manufactured, processed, distributed, used, or disposed of to include uncommon and unconfined accidents, spills or leaks for purposes of the statutory definition. Further, EPA does not generally consider accidents, spills and leaks to constitute "disposal" of a chemical for purposes of identifying a COU in the conduct of a risk evaluation. In addition, even if accidents, spills or leaks of asbestos could be considered part of the listed lifecycle stages of asbestos, EPA has "determined" that accidents, spills and leaks are not circumstances under which asbestos is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, as provided by TSCA's definition of "conditions of use," and EPA is therefore exercising its discretionary authority under TSCA section 3(4) to exclude accidents, spills and leaks from the scope of the asbestos risk evaluation. The exercise of that authority is informed by EPA's experience in developing scoping documents and risk evaluations, and on various TSCA provisions indicating the intent for EPA to have some discretion on how best to address the demands associated with implementation of the full TSCA risk evaluation process. Specifically, since the publication of the Risk Evaluation Rule, EPA has gained experience by conducting ten risk evaluations and designating forty chemical substances as low- and high-priority substances. These

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		processes have required EPA to determine whether the case-specific facts and the reasonably available information justify identifying a particular activity as a "condition of use." With the experience EPA has gained, it is better situated to discern circumstances that are appropriately considered to be outside the bounds of "circumstances… under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" and to thereby meaningfully limit circumstances subject to evaluation. Because of the expansive and potentially boundless impacts that could result from including accidents, spills and leaks as part of the risk evaluation (*e.g*, due to the unpredictable and irregular scenarios that would need to be accounted for, including variability in volume, frequency, and geographic location of accidents, spills and leaks; potential application across multiple exposure routes and pathways affecting myriad ecological and human receptors; and far-reaching analyses that would be needed to support assessments that account for uncertainties but are based on best available science), which could make the conduct of the risk evaluation untenable within the applicable deadlines, accidents, spills and leaks are determined not to be circumstances under which asbestos is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, as provided by TSCA's definition of "conditions of use." Exercising the discretion to not identify accidents, spills and leaks of asbestos as a COU is consistent with the discretion Congress provided in a variety of provisions to manage the challenges presented in implementing TSCA risk evaluation. See *e.g*, TSCA sections 3(4), 3(12), 6(b)(4)(D), 6(b)(4)(F). In particular, TSCA section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA risk evaluations "the likely duration,

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		intensity, frequency, and number of exposures under the conditions of use….," suggesting that activities for which duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated based on reasonably available information, including spills and leaks, were not intended to be the focus of TSCA risk evaluations. And, as noted in the preamble to the Risk Evaluation Rule, EPA believes that Congress intended there to be some reasonable limitation on TSCA risk evaluations, expressly indicated by the direction in TSCA section 2(c) to "carry out [TSCA] in a reasonable and prudent manner." For these reasons, EPA is exercising this discretion to not consider accidents, spills and leaks of asbestos to be COUs. Second, even if asbestos accidents, spills or leaks could be identified as exposures from a COU in some cases, these are generally not forms of exposure that EPA expects to consider in risk evaluation. TSCA section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Agency "expects to consider" in a risk evaluation. This language suggests that EPA is not required to consider all conditions of use, hazards, or exposure pathways in risk evaluations. EPA has chosen to tailor the scope of the risk evaluation to exclude accidents, spills and leaks in order to focus analytical efforts on those exposures that present the greatest potential for risk. In the problem formulation documents for many of the first 10 chemicals undergoing risk evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA...." This

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		approach is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the risk evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. As a result, EPA believes it is both reasonable and prudent to tailor the TSCA risk evaluation for asbestos by declining to evaluate potential exposures from accidents, spills and leaks, rather than attempt to evaluate and regulate potential exposures from such accidents, spills and leaks under TSCA.
2.42 **Generalization of occupational exposure based on similar job title and working condition**		
67, 68	**PUBLIC COMMENTS:** • Generalization from certain types of materials, job titles, work practices, etc. to other workers in similar jobs but with different exposure profiles based on those variables, is not appropriate. • Application of any risk assessment of a given exposure situation (such as those to which this draft is being applied, for example theoretical chlor-alkali work exposures) must consider similarities and differences between those industrial processes and the differing processes incorporated in the risk model and resulting differences in fiber concentrations, types, and dimensions.	EPA was mindful of this comment when preparing Part 1 of the Risk Evaluation for Asbestos. However, for all COUs, the data collected were from workers engaged in the activity of interest; and if not, limitation and uncertainties associated with use of surrogate data were noted.
2.43 **Suggestions for alternative information**		
16, 34, 51, 69, 65, 73, 82	**PUBLIC COMMENTS:** • Should Bureau of Labor Statistics and other available data on chemical industry worker tenure be used in	EPA has employed a consistent approach for exposure scenarios for multiple recent risk evaluations conducted under TSCA. EPA is not aware of specific data for each COU to allow for application to specific asbestos-related jobs. EPA received a wide range of comments on over- and underestimation of occupational exposures, which have been

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	developing central tendency and high-end worker exposure durations? • The draft risk evaluation lacks meaningful exposure monitoring data for nearly all the COUs it addresses. • EPA should review inspection data from OSHA and the OSHA-approved state plans for employer violations of the agencies' asbestos standards. In any given year, less than 1% of all workplaces will be inspected by federal or state OSHA compliance officers.	addressed for relevant COUs in previous responses to public and SACC comment in this Response to Comment document. EPA carefully considered all input received and reviewed all publications that were provided in comments from the public and the SACC. Through this effort, EPA believes the Part 1 of the Risk Evaluation for Asbestos is based upon the best available science. EPA clarifies, again, that evaluation of compliance with OSHA's standards and the protectiveness of the PELs is not the purpose of risk evaluations conducted under TSCA.
2.44 **Requirements for maximum number of "worst case" input parameters for a given use**		
83, 91, 100	**PUBLIC COMMENTS:** • The risk estimates presented for chlor-alkali workers are not "central tendency" or "high-end" estimates. Instead, several worst-case assumptions are used as exposure assessment factors, which results in a significant overestimate of exposure and risk. EPA needs to redefine the combination of exposure factors for the central tendency and high-end scenarios such that they better represent worker exposures in the chlor-alkali industry. • One commenter recommended probabilistic exposure assessment to comply with best scientific practices. Given that multiple conservative assumptions can skew a model or monitoring data to high-end exposure scenarios that do not represent realistic possibilities, a commenter suggested that EPA draft guidance on best practices for high-end exposure estimates, including guidance on the maximum number of "worst case" input parameters for a given use.	EPA does not believe it is appropriate to view the exposure estimates as "worst-case." EPA believes it has sufficiently characterized the key assumptions, uncertainties and confidence for occupational exposure estimates for each occupational COU. Risk Evaluations for the First 10 Chemicals completed under TSCA are based on deterministic risk assessment. EPA will consider the feasibility and appropriateness of using probabilistic risk assessment for future documents. EPA will consider the need for guidance for evaluating worst-case conditions when conducting future risk evaluations under TSCA

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2.45 **Revisit assumptions and data for realism of high-end exposures**		
SACC, 65, 79, 90, 91, 100	**SACC COMMENTS:** • SACC appreciated the segregation of full-shift and short-term estimates presented in Table 2-24 (Draft RE for Asbestos p. 106). However, full interpretation of exposures requires information on how frequently individual workers participate in specific tasks, and knowledge of the facility monitoring program strategy, including how activities are selected for monitoring and how frequently they are sampled. The absence of this information increases uncertainty regarding "high end" exposure characterization. Capturing "off-normal" events is a continuing problem in occupational hygiene measurement, and it is not clear that the data sets available for asbestos COU exposures are fully representative of actual work conditions. • Use of area samples is also questionable when worker/ONU exposures are disproportionately due to specific but sporadic point source activities. The short-term sample results provided in the Draft RE for Asbestos show that specific activities could produce elevated short-term exposures. ONU exposures might occur closer to the source than indicated by general environment area monitoring results. • Recommendation 21: Identify the frequency of high exposure activities (*e.g*, cleaning asbestos from damaged bags). **PUBLIC COMMENTS:** • One commenter disagreed and suggested that area monitoring does not generally yield lower airborne concentrations than personal monitoring; area monitors	EPA believes its approach relied upon the best available science, while acknowledging uncertainties and limitations of available data. Moreover, EPA evaluated all data sources suggested in comments by the public and the SACC and updated its evaluations where appropriate. The fact that the data may be missing rare, peak exposures or "off normal" events is not viewed by EPA as a critical data gap for Part 1 of the Risk Evaluation for Asbestos, given that the focus of the evaluation is on health risks associated with chronic exposures to chrysotile asbestos. Generally, EPA used representative worker exposure monitoring data for ONU analysis, whenever those data were reasonably available. In all other cases, EPA investigated the range of alternate data sources and selected the ones that offer the most reasonable insights into potential ONU exposures—and this included review of area sampling studies. Part 1 of the Risk Evaluation for Asbestos will continue to follow this approach but acknowledges the limitations of using area sampling data. EPA gathered frequency of exposure information from the chlor-alkali industry, both through observations and discussions during site visits and through written inquiry. EPA updated Section 2.3.1.3.2 to indicate that the frequency of receiving damaged bags of chrysotile asbestos is a "very rare" event. Section 2.3.1.3.2 was also updated to reflect task-specific data provide by ACC, of which hydroblasting has the highest 50th percentile asbestos PBZ concentrations of all worker activities. EPA clarifies that calculations in the Draft RE for Asbestos are not based solely on studies involving techniques used from approximately 1940 to 1980. In fact, by excluding publications with samples collected before 1980, EPA

	are usually placed in locations with the highest expected concentrations, and where workers rarely spend time. • EPA states that it assumes modern era control technologies for brake changes. However, all the calculations in the Draft RE for Asbestos are based on studies involving techniques used from approximately 1940 to 1980. • Some of the assumptions for those working with gaskets and brakes are not reasonable. Instead, in asbestos-containing brakes and gaskets, the asbestos is not friable; old gaskets are unlikely to still be in any active industrial factory; and gaskets are removed as a single unit or in large chips, making respirable airborne fibers unlikely. • Cowan et al. (2015) (page 627) indicates that OSHA compliance measurements are not random samples of workplace conditions, nor do they represent an industrial hygiene risk management strategy. The OSHA compliance sample is a snapshot in time, providing a yes or no answer to the question of whether a specific worker exposure scenario complies with the regulatory standards over an 8-hour shift. • EPA assumes for the indoor scenario that a consumer might use compressed air to clean brake assemblies; however, no mechanic would want to blow the dust out in a garage. • Use of PCM analysis throughout the risk assessment at such low levels biases the risk assessment because non-asbestos fibers, which exist in background air, cannot be distinguished from asbestos fibers. For example, one study found that most fibers from removal of asbestos gasket material in good condition (group A) as determined by PCM originated from glass fiber insulation as determined by TEM Spence and Rocchi (1996).	purposefully did not include data "based on techniques used decades ago." More specifically, EPA notes that the NIOSH studies on aftermarket automotive brakes examined techniques (engineering controls and work practices) specified in OSHA's asbestos standard for automotive brake and clutch inspection, disassembly, repair, and assembly operations. EPA identified sampling events for brake repair and gasket replacement that detected release of respirable fibers. Thus, despite the factors that can limit release of asbestos during brake repair and gasket replacement, EPA did not find reasonably available information to conclude those factors eliminate the releases. EPA agrees that Cowan et al. did not include measurements from a random sample of workplace conditions, but EPA clarifies that it did not rely solely on the Cowan et al. (2012) publication when evaluating aftermarket automotive brakes. In fact, most of the data for this COU is from NIOSH studies that were designed to characterize actual workplace conditions. Therefore, the limitations of Cowan et al. (2012) do not warrant revision to EPA's characterization exposure. EPA agrees that compressed air blowdowns should not factor into the occupational exposure assessment for aftermarket automotive parts. Section 2.3.1.7 of the draft risk evaluation explained why the occupational exposure assessment did not include any exposure data collected during compressed air use. However, compressed air use did factor into the consumer/DIY exposure assessment. Section 2.3.1.7 notes that for occupational exposure for this COU, the use of compressed air as a work practice will not be considered because, in addition to the EPA current best practice guidance (EPA-747-F-04-004), there is a provision in the OSHA Asbestos Standard: 29 CFR §1910.1001(f)(1)(ix): *Compressed air shall not be used to remove asbestos or materials containing asbestos unless the*

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	• Regarding the exposure point concentration, one commenter recommended EPA use the mean concentration instead of the 95th percentile for the high-end scenario, consistent with EPA's 2008 Framework for investigating asbestos contaminated Superfund sites.	*compressed air is used in conjunction with a ventilation system which effectively captures the dust cloud created by the compressed air.* EPA acknowledged limitations in using PCM measurements in that may count non-asbestos fibers and report them as asbestos in Section 2.3.1.7.6. EPA believes PCM measurements are suitable and the IUR derived in Part 1 of the Risk Evaluation for Asbestos is based on PCM measurements. EPA does not believe the commenter interpreted the Framework accurately. It clearly encourages (see Section 5.2 of Part 1 of the Risk Evaluation for Asbestos) using upper 95th (UCL) concentration. Based on the totality of information in the Framework and established TSCA risk evaluation approaches, EPA will continue to use the 50th percentile concentration as an estimate of central tendency exposures and the 95th percentile concentration (and sometimes the maximum concentration) as an estimate of the high-end exposures.
2.46 **Select one method and apply it uniformly to calculate reduced exposure levels for bystanders and ONUs**		
SACC, 83	**SACC COMMENTS:** • SACC members noted that the various methods used to estimate ONU exposures with limited data were not consistent across COUs. The results are unlikely to accurately represent actual ONU exposures because most rely on surrogate data from unrelated studies or are of questionable representativeness and reliability. SACC noted that in prior chemical DREs reviewed, when data concerning specific COU ONU exposures are not available, EPA used the worker central tendency exposure as the estimate for ONU exposure. That approach is not used in this Draft RE for Asbestos. The	EPA will consider the formalization of an SOP ONU exposure assessments. However, as noted in Section 2.3.1.1, EPA attempts to base exposure point air concentrations on direct measurements, as gleaned from the systematic review process. This section also notes that, in cases where such data are not available, EPA will use similar occupational data and professional judgment when estimating exposure concentrations. For Part 1 of the Risk Evaluation for Asbestos, the available sampling data is primarily for workers expected to have highest exposures and locations expected to have highest concentrations, with limited insights on ONUs.

#	Summary of Comments for Specific Issues Related to Charge Question 2	EPA/OPPT Response
	various approaches taken in this Draft RE for Asbestos appear more ad hoc. Multiple SACC members suggested the need for an SOP for ONU exposure assessment, specifically establishing a hierarchy of methods to be applied in future assessments. • Recommendation 22: Develop an SOP for selection of ONU exposure point air concentrations when primary data are limited or unavailable. **PUBLIC COMMENTS:** • The Draft RE for Asbestos uses three methods to calculate reduced exposure levels for bystanders and ONUs—midpoint, averaging, and rounding up. Absent a rigorous selection process, these approaches may be prone to bias. Rather than the ad-hoc approach in the Draft RE for Asbestos, EPA should select and use one method throughout the assessment.	EPA followed the same methodology throughout the occupational exposure assessment in Part 1 of the Risk Evaluation for Asbestos, which is reliant on direct observational data, when available—and use of surrogate information otherwise. EPA did revise the approach for estimating ONU exposures for aftermarket automotive brakes but retained all the ONU exposure estimates. In Part 1 of the Risk Evaluation for Asbestos, EPA refined the applied decay factor for aftermarket automotive breaks, as described in updates to Section 2.3.1.7.5, which is now based on data collected by NIOSH during its field studies of this activity. This section of Part 1 of the Risk Evaluation (Section 2.3.1.7.5) has been updated accordingly. EPA retained its approach to estimating ONU exposure for gasket fabrication, which employed a decay factor derived from Marigold et al. (2006). However, EPA revised Section 2.3.1.4.6 to better explain the approach in the risk evaluation, and more prominently acknowledge the associated uncertainties.
2.47 **Seek input/increase transparency regarding coordination with OSHA and NIOSH**		
15, 29, 42, 65, 67, 83	**PUBLIC COMMENTS:** • EPA should seek OSHA's input and monitoring data for its risk evaluation of workplace exposures to asbestos. EPA and OSHA operate under a memorandum of understanding to coordinate on issues where their jurisdictions overlap. • EPA cited OSHA's 1994 RIA for information on process and exposures for some COUs but not others, without explanation. While it may be in the purview of EPA to make recommendations related to occupational exposures, this seems to be more appropriately done by NIOSH and OSHA.	In the 2017 Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017), EPA committed to, by codifying, interagency collaboration to give the public confidence that EPA will work with other agencies to gain appropriate information on chemical substances. This is an ongoing deliberative process and EPA is not obligated to provide descriptions of pre-decisional and deliberative discussions or consultations with other federal agencies. In the interest of continuing to have open and candid discussions with our interagency partners, EPA is not intending to include the content of those discussions in the risk evaluation.

#	Summary of Comments for Specific Issues Related to Charge Question 2	EPA/OPPT Response
2.48 **OSHA regulations**		
15, 17, 30, 42, 51, 57, 65, 73, 83, 92	**PUBLIC COMMENTS:** • One commenter stated that OSHA's asbestos regulations are robust, far reaching, and protective of workers and ONUs. • OSHA has acknowledged, however, that asbestos exposures below its PEL may still pose unreasonable risks to workers. The PEL is the lowest feasible level that can be achieved by engineering or work practice controls in most operations, most of the time. • OSHA set the PEL at a level that is reliably measurable and imposed additional work practices and ancillary provisions for operations regardless of measured fiber levels (59 FR 40981-82: Aug. 10, 1994). OSHA conceded that the PEL could result in 6-7 workers per 1,000 developing lung cancer. At the PEL of 0.1 f/cc, a lifetime risk of death from asbestos-related cancer would be 3.4 per 1,000 workers and a 20-year exposure risk would be 2.3 per 1,000 workers (OSHA (1999); 29 CFR Parts 1910, et al. Occupational Exposure to Asbestos; Final Rule 1994 pg.40978). • OSHA standards are by law limited by considerations of economic and technical feasibility; TSCA is not. • Another limitation is that the OSHA PEL applies to chrysotile, amosite, and crocidolite as if they were equally potent carcinogens. The OSHA PEL of 0.1 fibers/cc might be acceptable for chrysotile but would not protect workers exposed to crocidolite. • EPA could foster "across-Agency" action to lower PELs in ACBM-laden occupational settings. This was a primary future vision held out by the Lautenberg Act. • Once commenter requested that if EPA's final risk determination for this COU reflects the conclusions of the Draft RE for Asbestos, EPA could exercise its	As noted in comments and EPA responses above, evaluation of compliance with OSHA's asbestos standard and the protectiveness of the asbestos PEL is not the purpose of the risk evaluation. There are important differences between OSHA standard development process and the risk evaluations that EPA prepares under TSCA. For instance, OSHA standards consider technological and economic feasibility, while a TSCA risk evaluation does not. The various observations about OSHA's asbestos standard are acknowledged but they do not have direct bearing on EPA's risk evaluation for asbestos. Actions that EPA could take are relevant to the risk management phase of the overall assessment, which EPA will commence after the risk evaluation is completed to address unreasonable risks identified in Part 1 of the Risk Evaluation for Asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 2	EPA/OPPT Response
	discretion under TSCA Section 9(a)(1) and find that regulation by OSHA would be sufficient to address any unreasonable risks under the COU in the chlor-alkali industry.	
2.49 **Other occupational exposure comments**		
39, 42, 46, 51, 53, 68, 70, 72, 73, 80, 83, 92, 100	**PUBLIC COMMENTS:** • Explain how the combination of exposure concentration, exposure frequency, and exposure duration used in the risk evaluation (are) representative of a central tendency and reasonable high-end exposure scenario. • One commenter thinks that it is unlikely that EPA missed other significant potential users in Table 2-2. • Many of the studies referenced by the EPA include quantitative or qualitative data that pre-date the 1994 PEL. Not all data reviewed by EPA after 1994 are robust enough to make accurate risk determinations on worker or occupational nonuser exposures. In addition, some of these studies used data and observations that were outside of the US and therefore may not accurately portray the exposure to our US worker which has been controlled by OSHA.	EPA has sufficiently described how central tendency and high-end exposure estimates are derived based on exposure concentrations, exposure frequency, and exposure duration in Section 2.3.1.1 of Part 1 of the Risk Evaluation for Asbestos. EPA has previously described its approach to identifying all reasonably available information in the Scope document as well as Supplemental Files to the Scope document that detailed the literature search strategy. Additionally, EPA followed the process described in the Application of Systematic Review in TSCA Risk Evaluations document. Data from the peer-reviewed literature and provided by industry was subject to data quality evaluation, which is documented in Supplemental Files to Part 1 of the Risk Evaluation for Asbestos. EPA is confident that analyses and conclusions are based up the best available science and information that was reasonably available to EPA.

3. Consumer Exposure

Charge Question 3:

3.1 Please comment on the estimation methods and assumptions used for consumer/DIY exposure assessment (including bystanders) in terms of concentration, frequency and duration of exposures; and their use in the risk evaluation. Please include your thoughts on the reasonableness of the estimated age at start of exposure and duration and frequency of exposure for the consumer (DIY and bystander) (Section 4.2.3).

3.2 Please comment on EPA's approach to developing consumer/DIY exposure estimates for aftermarket automotive brakes/linings (Section 2.3.2.1). Please include your thoughts on the reasonableness of the estimated age at start of exposure and duration and frequency of exposure for the consumer (DIY and bystander) (Section 4.2.3).

3.3 Please comment on EPA's approach to developing bystander exposure estimates (specifically the use of reduction factors [RFs] (Sections 2.3.2.1 and 2.3.2.2).

3.4 Please comment on EPA's approach to develop consumer/DIY exposure estimates for other gaskets (UTVs) (Section 2.3.2.2).

3.5 Please comment on EPA's reasonableness of the assumptions used, the uncertainties they introduce, and the resulting confidence in the consumer exposure estimates (Section 4.3.4).

3.6 Please comment on the methods and assumptions used in approaches for the sensitivity analysis for the consumer (DIY and bystander) risk estimates for both aftermarket automotive brakes and UTV gaskets (Appendix L).

3.7 Please provide any specific suggestions or recommendations for alternative approaches, estimation methods, assumptions, or information that should be considered by the Agency for improving the consumer exposure assessment.

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
3.1	**Aftermarket automotive brakes/linings and UTV gaskets consumer DIY and bystander exposure estimates approach: General support**	
SACC, 42	**SACC COMMENTS:** • Overall, methods and explanations for estimating DIY consumer and bystander exposures straightforward and understandable. • Overall, assumptions for DIY consumers (including age at start of exposure and duration of exposure) and bystanders reasonable for both outside and inside scenarios. • SACC was in general agreement that most consumers are "low-frequency" users of potentially asbestos-	EPA thanks the SACC and public commenters for these acknowledgements.

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
	containing consumer products, including UTV gaskets, and brake shoes. • SACC was in general agreement that there is no direct or compelling evidence that asbestos is no longer used or found in imported after-market products. **PUBLIC COMMENTS:** • Assumptions regarding air exchange rates (facility versus. garage) are reasonable.	
3.2 **EPA analysis not necessary**		
42, 61, 80	**PUBLIC COMMENTS:** • One cannot rule out that brakes purchased online by an individual might contain asbestos. However, <1% of the brakes sold in the United States in 2013 had asbestos and >99% of those would have been disc brakes, for which no exposure during installation or repair occurs. • Likelihood of serious disease among workplace employees, bystanders, and persons in the general population, is remote, particularly given marked reduction in airborne fiber concentrations over distance and time. • The Draft RE for Asbestos lacks important information, empirical data, and precision; it makes unreasonable and unreliable assumptions, contains critical deficiencies, inaccuracies, and uncertainties, and seeks to address an issue that no longer exists. • The EPA analysis is not warranted for the post-2020 era. EPA is investing a significant number of hours in performing calculations about exposure scenarios that are not remotely plausible to exist in the United States today. • EPA assessed chrysotile exposures for the DIY (consumer) and bystander UTV gasket repair/replacement scenario based on aggregated	The draft risk evaluation specifically mentions the potential availability of asbestos containing brakes online for purchase and installation by DIY consumers (manufactured and sold outside of the United States). That availability is the basis for EPA's decision to consider potential exposure to asbestos from brake replacements (as well as UTV gaskets). EPA recognizes there are uncertainties associated with assumptions made for this evaluation, but those assumptions are based on available information identified and evaluated as part of EPA's systematic review process. TSCA requires EPA's risk evaluations determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the COUs, with COUs being defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. 2602(4). As such, EPA, based on reasonably available information identified and reviewed as part of EPA's systematic review process, evaluated two COUs where there is a potential for asbestos exposure to consumers and bystanders, even if there is a limited number of exposed individuals.

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
	exposures resulting from recurring episodic exposures from active use of chrysotile asbestos related to DIY brake-related activities. The commenter doubts one could find an asbestos-containing gasket for a car in the coming years. Even if one were found, there is no exposure associated with installing a pre-cut gasket.	Part 1 of the Risk Evaluation for Asbestos bases the evaluation of exposure to DIY consumers and bystanders replacing UTV gaskets on the replacement of automobile gaskets within the engine and not brake related activities. Exposures resulting from DIY UTV gasket replacement work is expected to occur more during the removal of an old gasket (potentially containing asbestos) rather than installation of a new, pre-cut gasket (also potentially containing asbestos). However, exposure could continue during installation due to residual fibers remaining (or re-entrained during installation) from the removal of the old gasket.
3.3 **EPA does not incorporate the products and processes involved in vehicle repair**		
32, 74, 79	**PUBLIC COMMENTS:** • EPA misstates the current state of scientific understanding about brakes manufactured with asbestos in developing the COU. • The Draft RE for Asbestos suggests a misunderstanding of vehicle repair, including brake work, and the tools available and used by vehicle mechanics (*e.g*, workers and DIY consumers would not arc grind brake drums). Thus, EPA uses inaccurate assumptions about exposure potential that magnifies risk.	EPA discusses the uncertainties of a DIY consumer performing arc grinding of brake pads/drums within the draft risk evaluation. While there is uncertainty associated with arc-grinding activities it is still a potential and foreseeable activity expected to result in potential exposure to asbestos and therefore considered in Part 1 of the Risk Evaluation for Asbestos.
3.4 **EPA does not consider aggregate/cumulative exposures**		
31, 51, 86, 88	**PUBLIC COMMENTS:** • To fulfill the intent of Congress, EPA must consider aggregate and cumulative exposures, and not just for workers. • EPA estimates 31,857,106 consumer DIYs replace brake pads but do not include the millions of workers and consumers exposed to "legacy" asbestos in U.S. homes, businesses, and schools.	Section 2605(b)(4)(F)(ii) of TSCA requires the EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the COUs were considered and the basis for their consideration. The EPA has defined aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." The EPA defines sentinel exposure as "the exposure to a single chemical substance that represents the plausible upper bound of

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
	• There was no aggregate assessment conducted for individuals who might be exposed in an occupational setting as well as a consumer. • The accumulated data suggest that the excess risk of death from lung cancer from asbestos exposure is proportional to cumulative exposure (the duration times the intensity) and the underlying risk in the absence of exposure as with lung cancer, the risk [of mesothelioma] appears to be proportional to the cumulative exposure to asbestos over a given period.	exposure relative to all other exposures within a broad category of similar or related exposures (40 CFR § 702.33)." EPA considered the reasonably available information and used the best available science to determine whether and how to consider aggregate or sentinel exposures for chrysotile asbestos. EPA determined that using the high-end risk estimate for inhalation risks separately as the basis for the unreasonable risk determination is a best available science approach for sentinel exposure. EPA recognizes it is possible that workers exposed to chrysotile asbestos at work might also be exposed as consumers (*e.g*, by changing asbestos-containing brakes at home) or may cause unintentional exposure to individuals in their residence due to take-home exposure from contaminated clothing or other items. While adding such exposures could increase risks to the worker, ONU, consumer, or bystander, which individually exceed the cancer benchmarks in virtually every scenario evaluated, these additional pathways are not evaluated together because EPA did not identify or receive information which could inform developing such an exposure scenario and does not have models which could adequately evaluate and address such combined scenarios. Aggregate exposures for chrysotile asbestos were not assessed by routes of exposure in Part 1 of the Risk Evaluation for Asbestos since only inhalation exposure was evaluated. Although there is the possibility of dermal exposures occuring for the chrysotile asbestos COUs, it is unlikely that dermal exposures would contribute to mesothelioma and lung cancer. As discussed in the scope and PF documents, the only known hazard associated with dermal exposure to asbestos is the formation of warts which is not associated with mesothelioma or lung cancer.

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
		In addition, the potential for exposure to legacy uses of asbestos for any populations or subpopulation, due to activities such as home or building renovations, as well as occupational or consumer exposures identified in Part 2 of the Risk Evaluation for Asbestos, is possible. EPA will consider these other uses and associated disposal of asbestos in Part 2, beginning with a draft scope.
3.5 **Prioritization of real-world data and use of unpublished data**		
SACC, 42, 83	**SACC COMMENTS:** • Studies that were done in real-world settings for purposes such as establishing compliance with regulatory limits should be prioritized over simulations that were conducted in support of litigation. • Recommendation 36: Include data from all credible but unpublished sources in the set of monitored data discussed and utilized **PUBLIC COMMENTS:** • Exposure scenario assumptions are not based on real-world observations • Unpublished studies would offer credible data on DIY consumer exhaust system gasket repair/replacement.	EPA utilized reasonably available data from published references in the Draft RE for Asbestos and this Part 1 of the Risk Evaluation for Asbestos. These data went through EPA's systematic review process to identify and evaluate the data considered. These procedures are described in EPA's Application of Systematic Review in TSCA Risk Evaluations document. EPA considered multiple sources of data during its systematic review process, including published literature, gray literature, databases, risk assessments, and other reasonably available information. However, unpublished data which was not identified or reasonably available during our searches and which was not provided during public comments is not included in the risk evaluation.
3.6 **EPA's selection of studies to support analysis of aftermarket brake consumer COUs**		
SACC, 40, 42, 55, 60	**SACC COMMENTS:** • Studies used to estimate exposure concentrations for DIY activity limited to two studies: Blake et al. (2003) and Sheehy et al. (1989). The narrowness of the set of references used in making some of the exposure estimates reduced confidence in the estimates. In addition, Blake et al. (2003) was a study on a professional auto mechanic, not a DIY consumer. **PUBLIC COMMENTS:**	EPA used reasonably available information which was identified and evaluated as part of EPAs systematic review process in the Draft RE for Asbestos and Part 1 of the Risk Evaluation for Asbestos for DIY consumer exposure activities. The limited data set and representativeness of the studies to a consumer DIY setting is discussed in the uncertainties section of the draft risk evaluation. EPA provided clarifying narratives around the uncertainties of the studies used in Part 1 of the Risk Evaluation for Asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
	• EPA only used one study, Sheehy et al. (1989), that provided exposure data for consumer DIY activities. • EPA should not have relied on occupational studies to assess consumer DIY exposure; the two groups use different equipment and procedures. • Use of the Blake et al. (2003) study to estimate indoor and outdoor exposures was not appropriate. It does not reflect modern-day practices and overestimates exposure. • Sources used to support the consumer exposures approach and methodology for DIY gaskets in UTVs (Blake et al. (2006; Paustenbach et al. (2006; Liukonen and Weir (2005) are more relevant to exposures that occurred 40+ years ago. • Better sources are available for the handling ND samples for DIY gasket work.	While the Blake study involved a professional auto mechanic in an automotive garage, EPA believes the conditions under which the Blake study was conducted is more representative of a DIY consumer setting than other studies identified by EPA. The basis for this is discussed in the draft risk evaluation and expanded upon in Part 1 of the Risk Evaluation for Asbestos. The DIY gasket studies used in the draft risk evaluation were based on a limited data set found on gasket replacement (and the absence of data on UTV specific gasket replacement). This is discussed in the draft risk evaluation and expanded upon in Part 1 of the Risk Evaluation for Asbestos. Data from the gasket work which were non-detect were considered at half the non-detect value in accordance with EPA practices on utilizing non-detect data when averaging.
3.7 **Data gaps regarding asbestos levels in U.S. or imported products**		
SACC, 74, 80	**SACC COMMENTS:** • Recommendation 28: Better describe the efforts made to ascertain whether asbestos-containing brake shoes and UTV gaskets are available to U.S. consumers and consider additional efforts to reduce remaining uncertainty. • Paucity of information about the actual availability and quantity of imported asbestos-containing products (especially brakes and UTV gaskets) could have been addressed by the purchase of samples of these items at various locations in the US and testing the products for their asbestos content. At a minimum, an estimate of the upper bound of frequency of asbestos-containing products and a more realistic estimate of the population at risk of brake and UTV gasket exposure might have been obtained.	As stated in the draft risk evaluation, EPA reviewed published literature, online databases, government and commercial trade databases. EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos. EPA consulted with USGS and Customs and Border Protection (CBP) staff. EPA reviewed data from CBP's Automated Commercial Environment (ACE) system, which provided information for 26 companies that reported the import of asbestos-containing products between 2016 and 2018. EPA contacted the importer of record pertaining to gaskets and confirmed that chrysotile asbestos gaskets are still imported for use in UTVs. EPA also confirmed that chrysotile brakes and still imported and installed on vehicles that are then exported. Based on internet searches performed by EPA staff, the Agency also believes that consumers can still purchase

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
	• Recommendation 37: Use an independent market research group to sample and analyze for asbestos automotive brake pads, brake shoes and UTV gaskets coming into the U.S. from overseas. • Recommendation 33: Confirm and incorporate the latest information from the USGS on manufactured products including auto parts containing asbestos that are imported into the US. **PUBLIC COMMENTS:** • Asbestos imported into the United States currently is "unknown": in other words, it could very well be "zero." • EPA fails to provide any empirical data regarding the composition of asbestos-containing brakes and/or clutches.	aftermarket brakes online that are advertised as containing asbestos. EPA does not plan to undertake a market survey to obtain, sample, and analyze automotive brake pads, brake shoes and UTV gaskets imported into the U.S. for asbestos. The level of effort and time to develop a full and comprehensive market survey, obtain products, develop and implement a sampling and analysis plan, consolidate all findings, and publish the findings is time prohibitive under the statutory deadlines for timely completion of the Risk Evaluation for Asbestos (Part 1 and Part 2). Additionally, it would provide little to no added benefit to the overall outcome of the risk evaluation and risk findings. EPA believes there is sufficient evidence that aftermarket brakes and UTV gaskets containing chrysotile asbestos continue to be imported into the US and used by consumers for DIY brake/gasket replacement activities. EPA has consulted with the USGS on manufactured products including auto parts containing asbestos that are imported into the US. In the USGS's most recent 2020 Mineral Commodity Survey for Asbestos, the uses of asbestos listed are identical to the COUs in the chrysotile asbestos risk evaluation. The USGS states, "In addition to asbestos minerals, a small, but unknown, quantity of asbestos was imported within manufactured products, including brake blocks for use in the oil industry, rubber sheets for gaskets used to create a chemical containment seal in the production of titanium dioxide, certain other types of preformed gaskets, and some vehicle friction products." See https://pubs.usgs.gov/periodicals/mcs2020/mcs2020-asbestos.pdf

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3.8 **Data gaps regarding number of exposed consumers**		
SACC, 51, 74, 80	**SACC COMMENTS:** • Number of consumers utilizing aftermarket brake shoes and UTV gaskets containing asbestos is unknown, and it is unclear what efforts were undertaken to better ascertain these values. **PUBLIC COMMENTS:** • EPA estimated number of potentially exposed consumers based on market estimates with no information on the market share for asbestos containing products. • Number of asbestos-containing products unknown, so number of impacted consumers unknown, requiring extrapolation from occupational data of uncertain relevance.	EPA consulted with USGS and Customs and Border Protection (CBP) staff. EPA reviewed data from CBP's Automated Commercial Environment (ACE) system, which provided information for 26 companies that reported the import of asbestos-containing products between 2016 and 2018. EPA contacted the importer of record pertaining to gaskets and confirmed that chrysotile asbestos gaskets are still imported for use in UTVs. EPA also confirmed that chrysotile brakes and still imported and installed on vehicles that are then exported. Based on internet searches performed by EPA staff, the Agency also believes that consumers can still purchase aftermarket brakes online that are advertised as containing asbestos. However, due to the limitations to the data that is reasonably available to EPA there is uncertainty on the number of consumers who are exposed to aftermarket brakes and UTV gaskets. This uncertainty is discussed in the Draft RE for Asbestos and expanded upon in Part 1 of the Risk Evaluation for Asbestos. Nonetheless, EPA provides an estimate of the maximum potential number of consumers involved with DIY activities like brake changes in the Draft RE for Asbestos and Part 1 of the Risk Evaluation for Asbestos. The bases for the estimate include manufacturer recommendations for brake change frequency (per miles driven) and Department of Transportation estimates of average miles driven per year. Uncertainties surrounding these estimates is further discussed in the Part 1 of the Risk Evaluation for Asbestos
3.9 **DIY consumer exposure scenarios not appropriate or not considered**		
SACC, 31, 42, 43, 46, 55, 61,	**SACC COMMENTS:** • Recommendation 62: Develop and discuss more likely exposure scenarios on the use of asbestos-containing brakes and gaskets by consumer and bystander. For	EPA discusses both the assumptions made when developing the DIY consumer brake repair/replacement activities and DIY consumer UTV gasket repair/replacement activities and the uncertainties associated with each scenario in the draft

#	Summary of Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
77, 79, 80, 83	example, "shade tree mechanics" who replace the brakes of their own vehicles often also replace brakes of cars of family members, friends and neighbors. • One SACC member noted that drum brakes in other types of vehicles were not considered and may be more prevalent than drum brakes in cars today: motorcycles, farm equipment, snow mobiles. There may be a higher propensity of owners of those vehicles to do their own repair work. • It is possible that significant amounts of chrysotile asbestos could be in the breathing zone of people sanding drum brakes. • For Consumer/DIY exposure estimates for other (primarily UTV) gaskets, the workforce engaged in UTV gasket replacement is different from the workforce engaged in automotive brake repair/replacement, so a separate COU for is UTV gasket replacement is needed. **PUBLIC COMMENTS:** • The consumer DIY exposure assessment used unrealistic exposure scenarios that result in exposure estimates that are not accurate. • Exposure scenarios used in the Draft RE for Asbestos represent historical, not current, exposures. • EPA has not established a basis for assuming that there will be "known, intended, or reasonably foreseen" exposures to asbestos from aftermarket automotive brakes/linings and other vehicle friction products. • EPA has selected a scenario that assumes use of aftermarket automotive asbestos-containing brakes; however, the commenter could not find retailers of such products. • EPA assumes consumer purchase and installation of foreign-made aftermarket parts that contain asbestos and indicates that <1% of imported brakes from China	risk evaluation. EPA provided additional narrative in the final Part 1 of the Risk Evaluation for Asbestos to further clarify assumptions and uncertainties used, including the uncertainty associated with the number of brake changes done by an individual DIY consumer, potential shade-tree mechanics and the potential for over or underestimating exposures depending on the number of repairs/replacements done, potential for multiple cars, or fewer miles actually driven therefore reducing the overall number of brake repairs/replacements needed in a three year period. The limited data identified and evaluated through EPA's systematic review process is prohibitive to expand into other types of vehicles like motorcycles, farm equipment, or snow mobiles. While EPA did not identify consumer specific information on other vehicle types (outside of automobiles and trucks (light and heavy duty)) and was not provided information on such other vehicles as part comments, EPA provided some discussion on the potential exposure resulting from other vehicles repair/replacement activities. However, EPA will not be able to extrapolate exposure results from automobile activities to other vehicle types due to the absence of data to inform such extrapolations. EPA considered potential exposure to asbestos from arc grinding/sanding of brakes in the Draft RE for Asbestos and carried this into Part 1 of the Risk Evaluation for Asbestos (chrysotile asbestos). EPA did evaluate UTV gasket repair/replacement activities as a separate COU. The studies relied upon for the UTV gasket repair/replacement activities did involve "gasket" work although it was on an automobile exhaust system rather than a UTV exhaust system since EPA did not identify any UTV specific studies and was not provided any UTV specific data during comments.

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	or Canada allegedly contain asbestos. This is an unlikely and unsubstantiated scenario. • If true, brakes sold online would likely be disc brakes. Installing or removing a new disc brake and its degradation during use should not pose an exposure concern. • Repair of drum brakes is an unlikely exposure scenario. Consumer DIYs would more likely use/repair disk brakes. • Commenter disagrees that asbestos fibers for DIY mechanics and bystanders outdoors would be similar to indoors.	EPA provided further clarification on the DIY consumer scenarios evaluated, bases for selecting these scenarios, assumptions/uncertainties surrounding the scenarios and brake types in Part 1 of the Risk Evaluation for Asbestos in Section 2.3.2.1. EPA evaluated exposure to DIY consumers in the outdoor environment based on a study which measured breathing zone concentrations outdoors. EPA did utilize indoor exposure data to estimate the outdoor exposure to a bystander observing the brake repair/replacement work, but applied a reduction factor of 10 to the indoor values to account for the higher volume and ventilation rates of an outdoor environment as well as discussing uncertainties associated with this decision and reduction factor.
3.10 **Consumer scenarios not considered by EPA**		
	• EPA did not develop a scenario that included clutch work. • EPA did not consider asbestos from brake pad dust produced while in use. • EPA should consider an upper-bound estimate of exposure that assumes consumers work on multiple vehicles. • EPA has concluded with insufficient basis that it need not evaluate "general population exposures" and other COUs because such exposures might fall under the coverage of other environmental statutes administered by EPA. • Homeowners are consumers that can be exposed to asbestos. The commenter cites a physician affidavit that there are many case reports of mesothelioma in individuals with brief or low dose 'environmental' or home exposure. Another expert believes that asbestos	EPA does not intend to evaluate a separate COU for clutch replacement. EPA did not identify any data on asbestos exposure from clutch repair/replacement and did not receive information to consider during comments. EPA is unclear what the commenter means by "brake pad dust produced while in use." If the commenter is referring to exposure to a DIY consumer when brakes are used during driving, EPA would not expect exposure to a DIY consumer under this circumstance since the dust would not get inside the car environment of the car while driving. Similarly, if the commenter is referring to a scenario involving exposure to a separate car driver (for example a car driving with its windows open behind a car with asbestos containing brakes), this is not an exposure pathway EPA could evaluate due to lack of data to inform such a scenario and the unrealistic assumptions and extreme uncertainty associated with the mechanics of such a scenario.

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	exposure in industrialized countries could account for 20% of all mesotheliomas (Goldberg et al. (2010).	As explained in more detail in Section 1.4.4 of the risk evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the Risk Evaluation for Asbestos using authorities in TSCA sections 6(b) and 9(b)(1). Similarly, EPA did not evaluate exposure to "homeowners" which may receive background exposures to chrysotile asbestos outside of the DIY consumer user or bystander or due to environmental exposure in Part 1 of the Risk Evaluation for Asbestos since background exposures via ambient air would fall under jurisdiction of the Clean Air Act.
3.11 **DIY consumer exposure levels overestimated**		
42, 74, 79, 80	**PUBLIC COMMENTS:** • Estimated exposure levels are unreasonably high given EPA's selected exposure scenario. EPA has little evidence of the current of brake linings manufactured using chrysotile as a raw material and grossly overestimates potential exposures. • There is no evidence that asbestos-containing clutches are currently being imported or are available in the	EPA's draft risk evaluation and Part 1 of the Risk Evaluation for Asbestos for chrysotile asbestos use exposure data from published studies to estimate exposure for both brake repair/replacement work and UTV exhaust system gasket repair/replacement work. As a result, the concentrations used are actual measured values used to estimate potential exposures.

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	aftermarket. Evaluation of automotive clutches should be removed from its analysis. • EPA acknowledges that historical asbestos exposures from clutch repair are lower than comparable brake repair exposures but treats brakes and clutches the same for the purposes of its risk evaluation and exposure analysis. • The estimated exposure concentration for DIYs and their bystanders are higher than for occupational vehicle mechanics, which is nonsensical and unsupported by any data.	EPA did not evaluate clutch repair/replacement work as an independent COU in the draft risk evaluation and does not intend to evaluate such work in Part 1 of the Risk Evaluation for Asbestos (chrysotile asbestos) due to the absence of data to inform such a scenario. EPA removed the single reference to "clutch repair/replacement work" from the consumer section to eliminate the confusion. Occupational settings are likely to be larger than DIY settings and are likely to employ engineering control and building design to enhance air exchanges (ventilation system, larger openings, etc) for the work areas. This is to reduce occupational exposure to volatile chemicals often present in auto repair facilities.
3.12 **Exposure frequency/duration assumptions for DIY consumer exposure not supported**		
SACC, 39, 42, 60, 78, 79, 83	**SACC COMMENTS:** • Some SACC members believed that exposure might be overestimated at older ages because of exposure frequency assumptions. • The estimation model of 35,000 miles per three years is based upon a yearly average number of miles driven and DIY activity from ages 16-78 years. It might be prudent to use a distribution as the mileage driven varies depending upon sex and age. **PUBLIC COMMENTS:** • Exposure duration of 62 years (16-78 years) is not reasonable and borders on absurd. • EPA's approach for estimating consumer DIY and bystander exposure is overly conservative for brake repair and UTV gasket repair given EPA's implausible persistent airborne fiber concentrations and DIY activity frequency and duration. • The high-end consumer indoor exposure level assumes 3 hours of asbestos disc or drum once every 3 years for	EPA used standard exposure age brackets for cancer over a lifetime in accordance with EPA policy. However, EPA also considered the uncertainties associated with assuming a full 78 years (lifetime) where brake work (or gasket work) would occur and be done by a DIY consumer every three years. To address this uncertainty, EPA also evaluated exposure from a single brake repair/replacement activity in a lifetime and still found unreasonable risk. This evaluation will be pulled into the body of Part 1 of the Risk Evaluation for Asbestos from the appendix where it currently resides to address this comment. EPA does not believe a distribution of mileage is necessary based on the finding that a single brake repair/replacement activity still results in unreasonable risk. That being said, EPA already discusses the assumptions related to miles driven and uncertainties associated with such an assumption in the draft risk evaluation. Further clarification on the

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	62 years. Similar assumptions were made for consumer UTV gasket replacement. These are overly conservative assumptions. • EPA's assumption about asbestos fiber removal rate in a home garage over a 3-year interval is not supported by scientific principles of air dilution or available measured data. Actual removal rate would be faster.	uncertainties were provided in Part 1 of the Risk Evaluation for Asbestos. EPA provided clarification on its interpretation of the study data where arc grinding occurred in Part 1 of the Risk Evaluation for Asbestos. The 3-hours associated with brake repair/replacement activities is not intended to assume arc grinding occurs for the entire three hours, and EPA does not believe the study is based on 3-hours of arc grinding. Rather arc grinding occurs for a portion of the total brake repair/replacement activity and sampling time. EPA's assumption on removal rate is based on limited to no localized ventilation in a garage through which asbestos fibers may be removed. It also considers the potential re-entrainment of fibers due to disturbances from walking or even driving on garage surfaces where asbestos fibers may reside.
3.13 **Task/activity assumptions for DIY consumer exposure not supported**		
SACC, 31, 40 42, 55, 60, 74, 79, 83	**SACC COMMENTS:** • Recommendation 34: Better document current uses by consumers of compressed air to clean drum brakes. **PUBLIC COMMENTS:** • EPA uses many unreasonable assumptions for an activity that has not been performed by many persons in the last 35 years. It is unlikely a DIY consumer would use the practices of an occupational mechanic such as brake filing, sanding, arc grinding, and cleaning with compressed air. • Exposure data should more adequately represent the tasks that would be performed at this time (not	EPA did not identify reasonably available information and was not provided information describing current consumer practices related to use/non-use of compressed air to clean drum brakes. The uncertainty around the use of compressed air is discussed in the draft risk evaluation and was expanded upon in the final risk evaluation. Given that DIY videos still show the use of compressed air and readily available cans of compressed air (or home air compressors), EPA believes the use of compressed air is a reasonably available method which can be used by DIY consumers (even with warnings that compressed air should not be used) and therefore evaluates exposure based on such practice. EPA discusses the uncertainties regarding various assumptions made in the Part 1 of the Risk Evaluation for Asbestos. Generally, while arc grinding may not be a

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	historically) in a DIY situation. It is unlikely that indoor arc grinding would be used by DIY consumers. • It is unlikely that consumer DIYs would sand brake pads to remove glazing. Glazing occurred more often in the 1950s–1970s than it has since 1985 due to the better design of automobiles, the lack of brake drums on modern cars, and the adoption of disc brakes. • Consumer DIY use of compressed air in residential garages not supported. • Shade-tree mechanics typically work outdoors, so those exposures would be de minimis (if they occur at all).	common practice for all DIY consumers, DIY videos do show consumers how to grind brakes and pads. Additionally, as an example, while modern day cars may not require grinding/sanding of brakes and pads, those DIY consumers working on classic cars which no longer have perfect fit brakes and pads may require grinding/sanding to fit the modern brake or pad into the classic car brake housing. Work practices across all shade-tree mechanics is unknown. While some shade-tree mechanics may work on another individual's car outdoors, they are just as likely to work on another individual's car inside the individual's garage (as an example if it is raining outside when the work is occurring) and therefore exposures would be similar to the indoor scenarios evaluated by EPA. Since it is reasonably foreseeable to assume shade-tree mechanics could work on multiple cars inside a garage, it is appropriate to consider exposures from such work based on indoor concentrations.
3.14 **DIY consumer exposure underestimated**		
SACC, 31	**SACC COMMENTS:** • Some SACC members believed that exposure might be underestimated in younger ages and in lower income groups. **PUBLIC COMMENTS:** • EPA should consider an upper-bound estimate of exposure that assumes consumers work on multiple vehicles.	EPA conducted a sensitivity analysis on various ages to estimate exposures. This analysis is discussed in Section 4.3.7 and Appendix L and includes younger ages. EPA did not conduct such analysis for various income groups as the conditions under which brake work would be performed is relatively independent of income and assumptions made and uncertainties associated with this risk evaluation are similar across income brackets. EPA did not include an upper-bound estimate of exposure for multiple cars since EPA did not identify or receive data which could inform how many DIY consumers may work on multiple vehicles. EPA expanded the discussion on uncertainties associated with the potential for DIY consumers working on multiple vehicles (as well as shade-

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		tree mechanics) in Part 1 of the Risk Evaluation for Asbestos.
3.15 **Bystander exposure levels overestimated**		
SACC, 39, 42, 79	**SACC COMMENTS:** • There is some concern that estimates of outdoor bystander exposure were overestimated. **PUBLIC COMMENTS:** • Bystander exposure is overestimated based on evidence from Donovan et al. (2011) and Williams et al. (2007). • Egilman and Schilling (2012) would be useful in estimating bystander exposures. • EPA assumes that the DIYs and their bystanders spend time every day, 365 days per year, for 40 to 60 years in the COU. That is implausible for most, if not all, DIYs and bystanders. In addition, bystanders are aged "0" (zero) and onward, and this would appear to be impossible. • The estimated exposure concentration for DIYs and their bystanders are higher than for occupational vehicle mechanics, which is nonsensical and unsupported by any data. • The risk to bystander section of the document is irrelevant due to near impossibility of exposure.	EPA expanded narrative in the uncertainties section associated with the outdoor bystander exposure estimates. EPA acknowledges the use of indoor data, even with a reduction factor, is a more conservative estimate of bystander exposure for the outdoor scenario. However, given the absence of bystander monitoring data in an outdoor environment during brake repair/replacement activities in a consumer setting, EPA believes the assumptions made, data used, and reduction factor provide a reasonable estimate of bystander exposure. EPA does not assume DIY consumers and bystanders spend every day doing the brake repair/replacement work. Brake work is assumed to occur once every three years in a residential garage, not every day. However, it is feasible to assume consumers are in their garages every day (whether getting in a car to go to work, return home after work, run errands, etc.). So, while brake work is not done every day, residual dust is expected to remain in the residential garage for many years and can be re-entrained repeatedly as a consumer or bystander drives into or walks across the floor of the residential garage. In addition, the draft risk evaluation and Part 1 of the Risk Evaluation for Asbestos defines the bystander to be of any age which ranges from newborn (in essence age zero) to elderly. While a newborn that is only a few days old is not likely to be placed in a garage during brake or UTV gasket repair/replacement work, exposure is still possible during motion in and out of the garage where a newborn may be brought in from the car after running some errands or an infant doctor appointment and could be exposed to asbestos if that activity occurs during work or at

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		least to residual asbestos (which could be re-entrained) if work had occurred in the garage at some time. While it seems unlikely a consumer is exposed to higher concentrations than an occupational vehicle mechanic, there are several factors which cause this exposure. Consumers are assumed to be exposed continuously for a lifetime (rather than 40 working years 8 hours per day, 5 days per week). Consumers are not expected to wear PPE or utilize localized ventilation/engineering controls while workers may wear PPE and utilize localized ventilation/engineering controls. DIY consumer practices may vary considerably from worker practices which could cause higher emissions and therefore higher exposures.
3.16 **Bystander reduction factors not appropriate or require clarification**		
SACC	**SACC COMMENTS:** • One SACC member recommended two papers to better address reduction factors related to indoor vs. outdoor exposures: Donovan et al. (2011) (listed in Draft RE for Asbestos references but does not appear to be utilized) and Shade and Jayjock (1997). • Reduction factors applied might not closely estimate outdoor bystander exposures, overestimating that exposure.	EPA appreciates the recommendations for the papers. While EPA did not revise the reduction factor used for the consumer bystander, EPA did expand its discussion on uncertainties associated with the use of indoor area sampling concentrations and a reduction factor for an outdoor bystander scenario. The discussion includes acknowledging the potential overestimation due to the data used and other factors which could affect exposure like outdoor volume and air flows.
3.17 **Bystander exposure level underestimated**		
31, 58	**PUBLIC COMMENTS:** • The risk evaluation underestimates asbestos exposure levels and should rely on real-world data, not simulated data from two studies. • The bystander is more actively engaged in the activity than would be observed in a professional setting and, therefore, would be assumed to be exposed to the same	EPA utilized reasonably available information which was identified and reviewed under EPA's systematic review process to develop and evaluate the specific consumer scenarios associated with the two consumer COUs evaluated. EPA defines the bystander, for purposes of this evaluation, as an individual observing the brake or UTV repair/replacement activities (not actively involved with such activity). The commenter is correct that if a bystander was

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	level of asbestos fibers as the consumer. Using a RF of 10 underestimates exposure for bystander.	actively involved in a given activity then exposure would be expected to be higher, however, such exposure would then be represented by the consumer (user) exposure and therefore not require a separate analysis. The use of a reduction factor of 10 is designed to address some uncertainty associated with using indoor monitoring data for an outdoor bystander scenario where volumes and air exchanges could be considerably different (depending on how close to the work a bystander is observing). However, the indoor data used was area monitoring obtained at a defined distance from the work being performed and therefore would not in itself require adjustments using a reduction factor to extrapolate from a DIY consumer exposure to a bystander.
3.18 **Sensitivity analysis/quantification of uncertainties**		
SACC	**SACC COMMENTS:** • The methods and assumptions used in the deterministic sensitivity analysis for consumer and bystander risk estimates appeared to be well thought out and complete. The assumptions used for the analysis seemed reasonable. • For many of the uncertainties, EPA did not quantify the direction and magnitude. These uncertainties could be better documented (*e.g*, summarized in a table) and judgments made about the direction and magnitude of the bias that might result from the assumptions applied. • To further evaluate true sensitivity, SACC recommended that EPA use a Monte Carlo simulation in which known or assumed distributions of values for the critical drivers or exposure determinants such as: age at start, age at end, airborne exposure concentration, hours of exposure per incidence, number of incidences per year are used individually for both indoor and	EPA did not quantify the direction and magnitude of uncertainties due to the possibility that the direction could be either an overestimate or underestimate of exposure depending on specific factors. Quantifying the effect of uncertainties on magnitude of an exposure would require more quantitative evaluation using, as also suggested by commenters, a Monte Carlo type simulation. However, for an effective and accurate Monte Carlo type simulation, EPA would need considerable data in several areas to derive a true distribution for such a simulation. While distributions can be estimated or assumed using certain techniques (triangular, linear, log normal), these assumptions could increase uncertainties or raise questions about the representativeness of such distributions on the actual affected population without supporting data.

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	outdoor scenarios and combined with cancer target(s) to provide an output distribution of cancer risk in which the percentage of the exposed population that occurred above and below the target risk were displayed. • Recommendation 35: Use a Monte Carlo or similar simulation methodology to identify inputs that most impact model-estimated cancer risk variability or uncertainty and use this analysis to focus efforts to improve risk estimates.	
3.19 **Text clarifications/other**		
SACC, 42, 43, 55, 79, 109	**SACC COMMENTS:** • EPA references a "specific type" of utility vehicle that uses an asbestos-containing exhaust system gasket. Clarify these types of vehicles and better discuss associated exposures. Recommendation 29: Clarify the types of vehicles potentially utilizing asbestos-containing gaskets and better discuss associated exposures. **PUBLIC COMMENTS:** • Creating Tables like 2-26 seems unnecessary; airborne concentrations will be well below the OSHA PEL for asbestos. • Text description regarding brake drums on lines 4133 and 4134 of the risk assessment document is not accurate. • EPA states that consumers wishing to avoid exposure should ask retailers if products contain asbestos and consider not using products that do contain asbestos. This inappropriately puts the onus for protecting oneself on the individual, rather than the EPA, the manufacturer, or the retailer. • EPA does not discuss the basis for "professional judgment"-based exposure estimates.	EPA provides clarifying narratives, where appropriate, in the Part 1 of the Risk Evaluation for Asbestos. EPA uses the term utility vehicle (UTV) as a general description to be inclusive of multiple vehicles in use by DIY consumers. Depending on the manner in which a particular vehicle is used, a UTV, for purposes of this evaluation, may include an all-terrain vehicle, a dune buggy, a snowmobile, or other utility type vehicles. EPA did not identify or receive UTV specific information which could better demonstrate which UTV types may or may not utilize asbestos containing gaskets. Table 2-26 is not intended to provide a comparison of values to the OSHA PEL. Rather, Table 2-26 summarizes the data extracted from the listed studies which was used in the risk evaluation. EPA is unable to address the comment regarding brake drums because the comment does not include any context regarding "why" any text description regarding brake drums is not accurate. While some aspects of certain statements, like the one raised by this commenter, may seem to shift the burden of avoiding exposure to a consumer, the intention is to inform consumers

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		of potential actions they can take to minimize or avoid potential exposure to asbestos independent of any risk management action by EPA to address COUs found to present unreasonable risk through its risk management and regulatory process.
3.20 **Other**		
SACC	**SACC COMMENT:** • Recommendation 38: If asbestos is found in automotive brake pad, brake shoe, or UTV gasket market research samples, then a subsample should be measured for amount and types asbestos.	EPA does not plan to undertake a market survey to obtain, sample, and analyze automotive brake pads, brake shoes and UTV gaskets imported into the U.S. for asbestos. The level of effort and time to develop a full and comprehensive market survey, obtain products, develop and implement a sampling and analysis plan, consolidate all findings, and publish the findings is time prohibitive under the statutory deadlines for timely completion of the Risk Evaluation for Asbestos (Part 1 and Part 2). Additionally, it would provide little to no added benefit to the overall outcome of the risk evaluation and risk findings. EPA believes there is sufficient evidence that aftermarket brakes and UTV gaskets containing chrysotile asbestos continue to be imported into the US and used by consumers for DIY brake/gasket replacement activities.

4. Human Health Hazard/Derivation of the Inhalation Unit Risk (IUR)

Charge Question 4:

4.1 Please comment on EPA's choice of focusing modeling on only lung cancer and mesothelioma.

4.2 Please comment on the appropriateness of the approach to derive the commercial chrysotile-based IURs, including the underlying assumptions, strengths and weaknesses of the choice of study cohorts used, the key calculation decisions and the modelling used to derive the IUR (Section 3.2.4).

4.3 Please comment on EPA's approach to characterizing the implications of the assumptions and uncertainties for the confidence associated with the derivation of the IURs (Section 4.3.5).

4.2 Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in deriving the commercial chrysotile-based IUR.

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4.1 **Focus on only lung cancer and mesothelioma is too limited**		
SACC, 31, 46, 47, 50, 51, 53, 57, 63, 68, 73, 77, 85, 86, 89, 92, 99, 104, 109	**SACC COMMENTS:** • SACC recommended adding more justification as to why only lung cancer and mesothelioma are considered in this occupational risk assessment. • Ingestion of asbestos can lead to other types of cancers. • It also requested justification for the assumption that lung cancer and mesothelioma effects induced by exposure to chrysotile asbestos among textile workers are comparable to lung cancer and mesothelioma effects induced in users of other asbestos products. • Health assessment should focus on all health endpoints, both cancer and non-cancer, and not just mesothelioma and lung cancer. • Recommendation 42: Include other cancer sites beyond lung cancer and mesothelioma as the key cancer endpoints. **PUBLIC COMMENTS:** • The draft risk evaluation is based solely on the carcinogenicity endpoints of lung cancer and mesothelioma. It does not address other types of tumors (like ovarian, laryngeal cancers, colorectal cancer, cancers of the stomach, esophagus, and pharynx) and serious non-cancer lung diseases (like asbestosis and pleural diseases) known to be caused by asbestos. These omissions result in a substantial underestimation of risk • If the EPA lacked quantitative evidence of the risks of cancers of the larynx and ovary from chrysotile asbestos (Draft RE for Asbestos 3.2.4.8, ln. 5695, 5696), how	Following SACC recommendations, EPA now explicitly considers other cancers identified by IARC (2012) as being caused by asbestos exposure. The quantitative derivation of the IUR has been revised to address additional risks associated with ovarian and laryngeal cancers by using a specially derived adjustment factor. See Section 3.2.3.8.1 and Appendix M for details. EPA has noted in Appendix M of the risk evaluation: The IARC (2012) also noted that "positive associations have been observed between exposure to all forms of asbestos and cancer of the pharynx, stomach, and colorectum." However, the evidence for an association between these cancers and asbestos exposure is mixed and IARC did not view it as sufficient for a determination of causality. The EPA concurs with the IARC's evaluation and has limited its effort to estimating the additional risk of ovarian and laryngeal cancer from exposure to chrysotile asbestos. EPA did not find sufficient data that showed chrysotile asbestos effects experienced by textile workers would be different from the exposure to the chrysotile asbestos in other asbestos products. EPA added to the risk evaluation a new section (3.2.2.1) on non-cancer effects of chrysotile asbestos, but there were no quantitative non-cancer data appropriate for derivation of chrysotile asbestos RfC.

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	can the EPA state with confidence that the IUR selected compensates for this risk? Does this compensation lie solely in the selection of the upper bound IUR? • The IARC conclusion that ovarian cancer is causally associated with asbestos has not been supported by peer reviewed literature and other US agencies.	
4.2 **Consider the noncancer health endpoints**		
SACC, 31, 47, 63, 105	**SACC COMMENTS:** • Recommendation 43: Include asbestosis in the discussion and analysis of non-cancer endpoints. **PUBLIC COMMENTS:** • Morbidity and mortality risks of non-malignant respiratory diseases linked to chrysotile such as pneumoconiosis (asbestosis) and COPD were not considered. • Immune activation endpoint must be part of any asbestos risk assessment since such evidence have been found in mice. • Although the noncancer toxicity of chrysotile may be different from Libby amphibole asbestos, the Draft RE for Asbestos IUR for chrysotile asbestos may not fully encompass possible noncancer health risks associated with chrysotile exposure. • Several of the COU-related exposures evaluated for human health risks in Draft RE for Asbestos section 4.2 are at or greater than the POD for non-cancer effects associated with exposure to Libby amphibole asbestos, which is 0.026 fibers/cc (U.S. EPA (2014b).	EPA included asbestosis, nonmalignant respiratory disease, and immune effects in discussion of other non-cancer effects on chrysotile asbestos in Section 3.2. There is no reference concentration (RfC) for these non-cancer health effects specifically for chrysotile asbestos and a new RfC was not derived in Part 1. Additionally, while asbestosis is a relevant non-cancer health effect, EPA does not have a precedent of using mortality data for derivation of a RfC and the only quantitative data available for chrysotile is data on mortality from asbestosis.
4.3 **Clarify how plural and/or peritoneal mesothelioma were considered**		
42	**PUBLIC COMMENTS:** • When EPA corrects for the actual background incidence of both pleural and peritoneal mesothelioma, this will	EPA offers clarification on the commenter's assertion. For example, a peritoneal mesothelioma was observed in North Carolina cohort. See Section 2.3.4.5. The Balangero, Italy

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	affect their derived cancer potency factor. It is noteworthy that peritoneal mesothelioma has never been associated with chrysotile only cohorts, and few persons, if any, over the last 40 years have had exposures to amphiboles that would have increased their risk or caused peritoneal mesothelioma. It is unclear to me where EPA was adding plural and/or peritoneal mesothelioma in their calculated cancer potency factor.	chrysotile asbestos miners also observed several peritoneal cases.
4.4 **Concerns about the use of mortality rather than incidences**		
SACC, 25, 42, 45, 51, 63, 64, 101	**SACC COMMENTS:** • Modeling using cancer mortality outcome rather than cancer incidence might bias the IUR estimate. In recent years, survival times for lung and mesothelioma cancers have been increasing, allowing time for more deaths to be recorded as owing to other causes (*e.g*, road accident), with the result being undercounting of deaths associated with lung and mesothelioma cancers. The Committee suggested that background rates that are currently derived from life table estimates could instead be derived from incidence data as one way of accommodating this concern. • Recommendation 47: Base health outcomes on incidence rates of lung and mesothelioma cancers rather than mortality rates. • The SACC did not agree that using lung cancer mortality as a proxy for incidence inserts a low level of uncertainty. Currently, lung cancer screening detects a large proportion of stage I lung cancer, which are 80% curable. These workers are candidates for lung cancer screening because of their exposure and work history.	As suggested by SACC, EPA stopped using lung cancer mortality as a proxy for incidence and used background incidence rates in lifetables instead of mortality to address incidence of cancer explicitly. The revised methodology is described in Section 3.2.4.4.4.

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	Therefore, the SACC expects a large proportion of early stage lung cancers in these populations. **PUBLIC COMMENTS:** • EPA's risk evaluation is based solely on mortality rates instead of incidences of cancer associated with exposure to asbestos. This results in an underestimate of the total risks associated with exposure to asbestos. • Based on recent trends toward longer survival for lung cancer and mesothelioma, by using mortality data, EPA failing to account for disease incidence. The commenter recommends that EPA adjust the IUR upward by an amount that reflects the projected number of missed cases of cancer and mesothelioma corresponding to the latest data on survival rates. • Lung cancer mortality is not a straightforward outcome. Other potential confounders such as duration of chrysotile of exposure should be considered. • Contrary to what is stated in the Draft RE for Asbestos, survival is improving, and patients with mesothelioma and their family members should be aware of this. An increasing number of patients with mesothelioma are experiencing median survivals of 5-7 years. These are typically the patients that develop mesothelioma because of germline mutations of BAP1 or other genes. Moreover, the prognosis for peritoneal mesothelioma has also improved significantly in recent years.	
4.5 **Concerns about combining lung cancer and mesothelioma for the CPF and IUR**		
SACC, 42, 47, 65, 95, 109, 70	**SACC COMMENTS:** • The approach to combining the IUR estimates from the two endpoints seemed reasonable to the SACC. Nevertheless, some SACC members expressed concern with the approach used in the DRE that uses endpoint information from distinct cohorts for the two outcomes,	EPA followed the SACC recommendation and based the chrysotile asbestos IUR solely on data from North Carolina cohort, rather than combining endpoints from different cohorts. The revised derivation of the IUR is now the combined risk of all cancers as recommended by SACC.

	namely combining the lung cancer endpoint from the SC cohort with the mesothelioma endpoint from the NC cohort. **PUBLIC COMMENTS:** • Although an IUR for lung cancer and mesothelioma combined was calculated by IRIS in 1988, the rationale for combining the individual IURs in the current Draft RE for Asbestos is not clear. There are reasons to calculate separate IURs for these two malignancies. Cells of origin are different (epithelial vs. mesothelial). Exposure variables are different, with longer latency and lower dose more characteristic of mesothelioma. Difference in potency by fiber type is alleged for mesothelioma but not for lung cancer. Disease behavior is different, with different clinical presentation. The only thing these two diseases have in common is that both are caused by asbestos. • Other commenters agreed that EPA should not calculate a single CPF for chrysolite by combining lung cancer and mesothelioma because they result from different MOAs with different thresholds. The approach also is not consistent with the current (U.S. EPA (2005) Cancer Guidelines. • One commenter asked if it is appropriate to combine IUR estimates when one was based on a relative risk model and one was based on an absolute risk model. (Draft RE for Asbestos p. 151, Section 3.2.4.6.1) • If the reason for combining the two IURs is regulatory simplicity, consideration should be given to weighting the IUR for lung cancer based on the greater risk of lung cancer mortality and incidence, and the greater number of additional risk factors that render subsets of the population susceptible, compared to mesothelioma. Although mesothelioma is more specific for asbestos, lung cancer is the greater public health problem.	

#	Summary of Comments for Specific Issues Related to Charge Question 4	EPA/OPPT Response
	• The commenter agreed with EPA's decision to base the IUR on lung cancer and mesothelioma, as sufficient data are not available to develop toxicity values for other tumors types that have been associated with asbestos exposures. EPA has not derived a reference concentration (RfC) for potential non-cancer risks associated with exposure to chrysotile asbestos. As evidenced in previous assessments, moreover, lung cancer and mesothelioma are the most significant risk drivers when evaluating exposure to asbestos.	
4.6 **Doses potentially causing mesothelioma are in the vicinity of doses that cause asbestosis**		
42	**PUBLIC COMMENTS:** • If chrysotile could produce mesothelioma (which remains in dispute), it could do so only at doses that are in the vicinity of those causing asbestosis (50-400 f/cc-year) (Pierce et al. (2016; Churg et al. (1993; Churg (1988).	The public comment conflicts with accepted models for cancer and EPA cancer guidelines (U.S. EPA, 2005). In addition, SACC did not recommend threshold modeling for cancer.
4.7 **Discuss wider context compared to other IRIS IURs**		
42, 51, 57, 76, 97	**PUBLIC COMMENTS**: • Currently, IRIS contains two IURs for asbestos. For comparison, the Draft RE for Asbestos should include the central tendency estimation of asbestos unit risk and the upper bound value for each endpoint. The original IUR was developed by summing up the estimated IURs for lung cancer and mesothelioma, whereas the current DRE uses the upper 95% bounds, an approach that inflates the reported IUR for chrysotile. • EPA departed from the well-established scientific and regulatory framework for estimating asbestos risks and calculates an IUR considerably lower than the long-standing IUR adopted by IRIS in 1988. This has significant implications for current and future exposure limits since the new IUR suggests lower risks.	The central estimates and their upper bound for each cancer are provided. EPA clarifies that the 1986 general asbestos IUR is a central estimate of the sum of the two cancer-specific unit risks, whereas the Libby Amphibole asbestos and the chrysotile asbestos IUR (as all IURs in EPA) are upper bound estimates. EPA reviewed the available literature since adopting the 1988 IUR for general asbestos and derived a new IUR specifically for chrysotile asbestos. EPA conducted an intra-agency review as part of the review process. EPA/OPPT has consulted with EPA epidemiologists in the IRIS program and elsewhere to ensure methods and approaches are not contradictory, whilst recognizing different program objectives and statutory requirements.

#	Summary of Comments for Specific Issues Related to Charge Question 4	EPA/OPPT Response
	• Some commenters believe that derivation of a new CPF for chrysotile and this proposal should have been run through the IRIS process, and the dose-response assessment should be viewed in the wider context of other EPA risk assessment efforts. Though the TSCA proposal was not a formal risk assessment of chrysotile asbestos for the purposes of IRIS, it plays a similar role in issuing an updated IUR for chrysotile.	
4.8 **Justify why a separate IUR for chrysotile asbestos is needed**		
SACC, 70	**SACC COMMENTS:** • The Draft RE for Asbestos does not adequately justify why a separate IUR for chrysotile asbestos is needed, or why the Draft RE for Asbestos IUR is better than the one proposed in the comprehensive 1988 EPA IRIS Assessment on Asbestos (U.S. EPA (1988b). The 1988 IRIS asbestos IUR is based on a richer set of 14 studies including the two occupational chrysotile-only studies used in this assessment. Recommendation 91: Provide more justification for the development of a chrysotile-asbestos-specific IUR and include more discussion on the limitations and relative level of confidence associated with the proposed IUR. **PUBLIC COMMENTS** • One commenter supported EPA's decision to move ahead with its evaluation of the identified COUs for asbestos, while it begins to evaluate legacy uses of asbestos. They further support EPA's decision to develop an IUR estimate specifically for chrysotile asbestos, rather than use EPA's previous estimates for all types of asbestos. Chrysotile is the only form of asbestos used to produce diaphragms for the chlor-alkali industry.	EPA developed an IUR specifically for chrysotile asbestos because the COUs evaluated for Part 1 of the Risk Evaluation for Asbestos are for chrysotile asbestos only. In Part 2 of the Risk Evaluation for Asbestos, EPA will consider the hazard and risk of cancer and non-cancer for asbestos fibers that continue to be present in legacy COUs.

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4.9	**Textile industry does not represent the exposures of interest**	
SACC, 34, 39, 41, 42, 60, 64, 68, 76, 79, 90, 103, 106	**SACC COMMENTS:** • SACC suggested that there should be a discussion of the relationship of the airborne asbestos fibers in the textile environment to the fibers in the airborne dust produced when replacing brakes. Furthermore, the degradation from using brakes may result in shorter fibers overall than those in the original asbestos material, so the risks from removing old brakes may be different than the risk in installing new brakes, particularly since installing new brakes can involve some grinding activities. • Some SACC members were concerned that the carcinogenic risk of fibers used in textile manufacturing may not align with the carcinogenic risk of fibers in current uses. Recommendation 46: Better justify the assumption that lung cancer and mesothelioma effects induced by exposure to chrysotile asbestos among textile workers are comparable to lung cancer and mesothelioma effects induced in users of other asbestos products. **PUBLIC COMMENTS:** • EPA relied upon the data from asbestos textile plants, which historically processed longer chrysotile fibers compared with other applications, such as in the friction products, cement, and joint compound manufacturing industries. The exclusive use of textile industry-based longer chrysotile fibers in the EPA assessment is not representative of typical chrysotile fiber lengths used in general industry. The textile data is largely irrelevant for AABL where potential exposures are to low levels of short-fiber chrysotile. • Vehicle mechanics, whether professional or DIYs and their bystanders, are not comparable to workers in asbestos mining and textile milling operations. Textiles	EPA's review of the available data concluded that the best data on which to base the chrysotile asbestos IUR came from the textile industry. EPA did not find sufficient data that showed chrysotile asbestos effects experienced by textile workers would be different from the effects of exposure to chrysotile asbestos in other asbestos products. There was no quantitative exposure data of adequate quality to derive cancer potency values for chrysotile asbestos based on studies of automobile mechanics; they were all unsuitable for use in quantitative risk assessment (see also response to 4.13). In response to the comment on longer vs shorter fibers, the Bayesian analysis by Hamra et al. (2016) shows that shorter fibers also have cancer risk. As SACC noted in other comments (See Section 4.12) "The SACC notes that most asbestos fibers in textile plants were, in fact, short fibers, *i.e.*, less than 5 microns in length." Chrysotile asbestos is a regulated fiber, which is measured by PCM units in the absolute majority of cases, so chrysotile asbestos exposures in textile plants are counted by the same methods as the chrysotile asbestos in other products.

	use a very different form and amount of chrysotile asbestos in different work processes and products which ultimately result in very different exposure concentrations and potential for individual exposure and risk of disease. • The textile workers are an inappropriate cohort to derive an IUR to be used with workers exposed to asbestos in gaskets, brakes, and packing because the fibers are different. Asbestos in gaskets, brakes, and packing are shorter, encapsulated, and have been soaked in a hard-phenolic resin. Textile fibers are longer and not encapsulated. See the Garabrant et al. (2016) meta-analysis to understand the epidemiology of the cohorts relevant to gaskets, brakes, and packing. • By using only the textile industry to derive an IUR for chrysotile asbestos, EPA discarded much of the available literature on chrysotile potency including data relevant to other industries and other environmental exposures (Garabrant and Pastula (2018; Pierce et al. (2016; Bernstein et al. (2013; Berman and Crump (2008a, b; Pierce et al. (2008; Berman (2003; Hodgson and Darnton (2000). • The studies chosen to reflect asbestos textile work and exposure in that industry acceptably. The Draft RE for Asbestos and calculated IUR is only reflective of exposures in that industry, not of other asbestos industries or exposure situations, including environmental exposures. It is a particular problem for a Draft RE for Asbestos meant to be applied to given occupational exposures which are dissimilar. • It is inappropriate to base the risk evaluation of aftermarket brakes on studies of long-fiber chrysotile in textiles, but not consider studies of workers exposed to short fiber chrysotile in brakes. • There is a divergence of risk between the textile cohorts in North and South Carolina and all other	

	predominantly chrysotile-exposed cohorts (Hodgson and Darnton (2010). Per fiber risk of mesothelioma from chrysotile in textile plants is greater than it is in the mines likely due to a high proportion of longer fibers. • No amount of modeling of epidemiology data can make up for the serious differences in what is being inhaled by the textile workers compared to auto mechanics or millwrights 50 years ago. One must consider the differences in fiber length, aspect ratio, purity of the chrysotile, and other factors before grouping them and considering them equivalent. • Consider the paper by Korchevskiy et al. (2019) which can help in understanding of the determinants for chrysotile cancer potency. • The chrysotile mining and milling studies clearly show the risks for lung cancer and mesothelioma in Quebec miners and millers due to chrysotile (with tremolite). It seems equally obvious that – for lung cancer but not for mesothelioma – the chrysotile textile data best represents chrysotile textile risk. Thus, industrial process must be considered in any specific assignment of risk to any other industry which uses – or used – chrysotile. • A significant fraction of fibers found in those textile mills exceeded 20 microns in length, which mechanistically might or might not possibly be responsible for some increased risk for lung cancer or mesothelioma. Berman and Crump (2008a), working under an EPA funded study, suggested that for chrysotile, potency may only be present for fibers in the vicinity of 25-40 microns. • The need to consider the chemical and physical properties of chrysotile and other types of asbestos must be paramount when considering the potential cancer risk	

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	because majority of chrysotile fibers are embedded in resin.	
4.10 **Address heterogeneity between North Carolina and South Carolina textile worker cohorts**		
SACC, 34, 39, 40, 42, 59, 60, 65, 68, 79, 90, 102, 103, 106, 112	**SACC COMMENTS:** • It appeared to the SACC that the NC and SC data sets are of roughly equal quality, albeit with multiple sources of heterogeneity as noted in Elliott et al. (2012). • The SACC concurred that the North Carolina and South Carolina cohorts had the best exposure data and that this was a good reason to focus on these cohorts. • The NC and SC data sets are of about equal quality. Therefore, SACC recommends that the data for calculating an IUR for chrysotile asbestos exposures from the Carolina textile mills be the combined data from the NC and SC mills, rather than selecting data as a means of overcoming biases. Such a pooled analysis can reduce statistical variability. Elliott et al. (2012) contains a pooled analysis of data from NC and SC for lung cancer. Berman and Crump (2008a) and Loomis et al. (2019) contain analyses of the individual level mesothelioma data from SC and NC, respectively and results from these analyses could be combined to evaluate the risk of mesothelioma. **PUBLIC COMMENTS:** • It is inappropriate that Loomis et al. (2010) and Elliott et al. (2012) combined results across the NC and SC textile cohorts without addressing the heterogeneity of pleural cancer and mesothelioma risks across plants. • Even after adjusting for cumulative exposure (f/ml-years), the mesothelioma plus pleural cancer rate in Plant 4 (Marshville) is about 3.5 times higher than the rate in Plant 3 (Charlotte). This is consistent with a conclusion that there is a difference in the potency of	SACC did consider all these limitations raised in public comments to the SACC and this and other SACC recommendations establish that NC and SC datasets have the best exposure data and are appropriate to use for chrysotile asbestos IUR derivation. "The SACC concurred that the NC and SC cohorts (Lenters et al. (2012; Burdorf and Heederik (2011) have the best exposure data and that this was a good reason to focus on these cohorts." (see 4.13 for more detail on this SACC recommendation). The submitted comments provided undisputed information that UNARCO owned the NC Marshville plant for a period of time. They also provided evidence that some other plants from the several that UNARCO owned, did produce amosite products in those other plants. EPA did not find evidence in the comments or court depositions that the Marshville plant was using amosite in its productions and was ever anything other than a textile plant that used commercial chrysotile asbestos. In response to another SACC recommendation, EPA stopped combining data from NC and SC and based the chrysotile asbestos IUR on the North Carolina cohort only, as EPA was not able to locate data to conduct a pooled analysis.

	the fibers between plant 4 and all other NC plants (1, 2, and 3). • It is unexplained how EPA regarded the NC plant exposure data to be "of higher quality than those utilized in other studies of occupational cohorts exposed to chrysotile" (page 141 lines 5200-5201), when Loomis and Dement were completely unaware of the evidence of amphibole asbestos use in plant 4 (Marshville), failed to recognize the heterogeneity in pleural cancer and mesothelioma risks among the NC plants, and failed to recognize that the mesothelioma risk in the Marshville plant was incompatible with all other evidence from occupational cohorts exposed to only chrysotile. • A small amount of crocidolite suggests a strong effect on mesothelioma risk (Szeszenia-Dąbrowska et al. (2015). Because of the possibility of confounding by crocidolite exposure the relationship between mesothelioma and chrysotile exposure, the NC and SC textile cohorts should not be used in the Draft RE for Asbestos. • Several commenters critically reviewed the strengths and weaknesses of the NC studies. • Strengths include reasonably thorough exposure assessment. • Limitations include: – Exposures to asbestos forms other than chrysotile – Fiber count estimates in plants 3 and 4 are not reliable. – Small number of informative deaths – Concerns about quality of mesothelioma ascertainment – Lack of control of smoking	

#	Summary of Comments for Specific Issues Related to Charge Question 4	EPA/OPPT Response
	– Lack of complete occupational history (and length of employment at textile plant) for the cases of lung cancer or mesothelioma • Several commenters pointed to evidence, including depositions and records Johns Manville record repository, that amosite and crocidolite products were manufactured in the Marshville, NC textile plant. • Based on most recent IARC monograph for asbestos, there is reason to suspect that some other potential asbestos types were present in the studies used for the IUR. • If EPA wishes to include the NC textile plants in this risk assessment, it must restrict itself to plants 1 (Davidson, NC) and 2 (Charlotte, NC), where there is no record of commercial amphibole asbestos use. All the cases of lung cancer, pleural cancer, and mesothelioma arose where commercial amphiboles were used, and no cases arose in plants 1 and 2, where only chrysotile was used. • Because roughly 96% of the person-time experience of the NC textile cohort was derived from plants 3 and 4, where chrysotile, amosite and crocidolite were used, the papers by Loomis, Elliott, and Dement (Loomis et al. (2019; Elliott et al. (2012; Loomis et al. (2012; Dement et al. (2009; Loomis et al. (2009) are essentially uninformative on the risks of lung cancer and mesothelioma among textile workers exposed to only chrysotile (34-14). Basing the IUR on plants 3 and 4 violated EPA's own rule that when "the available information does not allow exposures to chrysotile and amphibole forms to be separated" the data is "judged to be uninformative with respect to the cancer risks from exposure to commercial chrysotile and [is] excluded	

	from further consideration." EPA's final IUR selection violated this rule and is not valid by EPA's own rules. • Workers with less than 30 days of employment contributed 42% of the total person years of observation. If the 8 cases of pleural cancer and mesothelioma arose in workers with < 30 days of employment this would substantially affect the interpretation of the findings from these papers. Among short-term workers (<30 days of employment), most spent the majority of their careers in jobs elsewhere, about which nothing (including asbestos exposure) was known. • As noted by Pierce et al. (2016); Pierce et al. (2008) and many others, the lifetime cumulative dose is critical to understand the increased lifetime cancer risk. Tables 2 and 3 from Dement et al. (2009), used for the IUR derivation, include a "considerable amount of uncertainty," and some information seems to be missing. A "key element of Table 3 is the number of None Detected samples that were observed for each exposure zone. As noted previously, this can be important; although for this cohort, it appears that there was an ample number of samples with detectable concentrations." • EPA properly considered studies from the NC and SC textile cohorts to be of particular importance because the exposure data and exposure assessment methods are exceptionally detailed compared to most asbestos studies. EPA provided an excellent rationale for the inclusion or exclusion of each cohort carried forward for the final unit risk determination. • The Carolina plants can still be considered in a comprehensive risk assessment including a wider range of chrysotile (and possibly mixed fiber) industrial processes if a true estimate of overall risk is sought, but only for lung cancer.	

	• NC textile workers were exposed to mixed fibers (amphibole and chrysotile) and were not chrysotile-only cohorts. This makes these cohorts unacceptable for mesothelioma risk assessment for commercial chrysotile because low levels of amphibole have a disproportionate effect on risk. • The SC textile workers' cohort is not the appropriate cohort for a chrysotile risk assessment. SC textile workers were exposed to mixed fibers (amphibole and chrysotile) and were not chrysotile-only cohorts. The use of crocidolite asbestos is well documented in the SC Asbestos Textile plant. Both mesothelioma cases reported by Dement et al. (1994) worked in the spinning area of the plant and possibly were exposed to amphiboles. • Several commenters critically reviewed the strengths and weaknesses of the NC studies. Strengths include reasonably thorough exposure assessment. Limitations include: – Exposures to asbestos forms other than chrysotile – Small number of informative deaths – Concerns about quality of mesothelioma ascertainment – Lack of control of smoking – Lack of complete occupational history for the cases of lung cancer or mesothelioma • The NC Department of Health and Environmental Control documented an excess of pleural cancer in the tri-county region of Charleston, SC, over the twenty-year period from the late 1970s to the late 1990s: 12 of 19 mesothelioma cases diagnosed in 1996-1997 had worked at the Charleston Naval Shipyard. Thus, the Charleston Naval Shipyard was responsible for a high proportion of the mesothelioma cases in the Charleston, SC, area.	

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	• Lung burden analyses have shown that members of the SC textile cohort, thought to be exposed predominantly to chrysotile, had amphiboles in their lungs. Since between 28 and 32% of the mesothelioma cases from the SC Textile plant cohort had excessive amosite and/or crocidolite in their lungs, this cohort cannot be regarded as being exposed only to chrysotile. • The exposure experience of SC textile workers—to the degree this sample of 64 deceased workers is representative—is clearly unique and should not be used to assess risk of lung cancer (or especially, mesothelioma) in miners, millers, cement workers, friction product workers, or any other non-textile group of workers, including those assessed in the current Draft RE for Asbestos. • This cohort is not suitable for inclusion for estimation of risk for mesothelioma, based on the small numbers of cases and the lack of detail noted. • If the asbestos-exposed population being studied has a smoking contribution that is slightly greater than the comparison population, then the risk of lung cancer from chrysotile may be overestimated. There is evidence that this was exactly the case for the analysis of lung cancer risk for the SC textile cohort.	
4.11 **Limitation of basing IUR on only two studies**		
51, 57	**PUBLIC COMMENTS:** • The idea of separating out studies that "isolate" the effects of chrysotile and basing risk estimates on these studies alone is inherently flawed because of the uncertainty in the exposure levels in these studies and the difficulty of using limited data (*i.e.* the two textile	EPA clarifies that 5 cohorts exposed to commercial chrysotile asbestos were identified with dose-response information and considered all of them for deriving the chrysotile asbestos IUR (NC; SC; Quebec, Canada; Italy; China)

#	Summary of Comments for Specific Issues Related to Charge Question 4	EPA/OPPT Response
	studies) to attribute specific potency factors to individual fibers. • Because EPA decided on a chrysotile-specific risk analysis, the Agency screened out all studies for which exposures were not solely to chrysotile; thus, only two studies remained by which to calculate the IUR. Unnecessarily limiting the studies increases uncertainty for the IUR, because all asbestos studies have limitations (*e.g*, how exposure was measured, how death and disease was tracked), and the smaller the database, the greater likelihood that particularities of individual studies will drive risk calculations. • Reliance on two studies – out of the large number of epidemiological studies on asbestos – greatly magnifies uncertainties since different studies have shown different levels of risk and all studies (including the North and South Carolina studies) have limitations in tracking exposure levels, deaths and other inputs that weaken their reliability standing alone. • The earlier EPA approach took advantage of the large number of studies for different fibers and industries by determining an appropriate weighted average of the exposure-response relationships found in different studies, considering observable differences in exposure circumstances. This is a more defensible approach than using only two studies from a single industry for dose-response analysis, as EPA did in the draft risk evaluation.	
4.12 **Phase contrast microscopy (PCM) vs. transmission electron microscopy (TEM) for fiber counts impact the IUR**		
SACC, 31, 42, 47, 60	**SACC COMMENTS:** • The SACC expressed varying perspectives on fiber counts. While the comparison of results using PCM vs. TEM appeared reassuring, suggesting that this is not an	EPA agrees with the SACC regarding the comparison of results using TEM vs PCM "suggesting that this is not an important source of uncertainty in the IUR estimation." EPA disagrees with the public commenter who said "The adoption

	important source of uncertainty in the IUR estimation, some SACC members were not convinced. Very thin, short chrysotile fibers are commonly missed by PCM analyses but are visible by TEM. Many studies are showing that very thin asbestos fibers (including those from chrysotile asbestos) may have an important influence on lung diseases. Also, PCM counts all fibers longer than 5 microns the same, regardless of their length. Textile production presumably requires fiber grades that contain longer fibers, but these longer fibers may be less relevant to the exposures under consideration in this Draft RE for Asbestos. The SACC notes that most asbestos fibers in textile plants were, in fact, short fibers, *i.e.*, less than 5 microns in length. • The argument that direct comparison of TEM vs. PCM is impossible seems reasonable (p. 198, ln. 7060-7066). Would a comparison based on cancer incidence be possible in order to derive "equivalent" increments of exposure regarding their impact on incidence? Uncertainty in converting mass measurements to fiber counts (p. 198, ln. 7068-7077) could be evaluated by using a range of conversion factors and assessing impact. The argument that the impact is not different does not help with this uncertainty, it only implies no additional bias due to association with the outcome. However, EPA's argument that exposure uncertainty should not be a major factor in the NC and SC cohorts is reassuring. • EPA should include text providing the pros/cons of methods of microscopy used to measure fibers. **PUBLIC COMMENTS:** • The Draft RE for Asbestos stated "In developing a PCM-based IUR in this risk evaluation, several TEM papers modeling risk of lung cancer were found, but because there was no TEM-based modeling of mesothelioma mortality, TEM data could not be used to	by the EPA of a new statistical model to calculate an IUR for asbestos should be left until a time when the exposure analyses using TEM have reached a point of practical scientific and regulatory application" because exposures to COUs have been measured in PCM units and the only way to assess risks is to use a PCM-based IUR. When COU exposure data are measured in TEM units and data are available to derive a TEM-based IUR for cancer, then EPA can revisit this issue.

	derive a TEM-based IUR." (p. 30, ln. 1229 - 1231). This is a reasonable assumption at this time. • EPA properly relied upon epidemiological studies using PCM directly measured in fibers per cubic centimeter rather than speculative conversions of historic dust measurements to calculate unit risk. • One could perform a TEM-based assessment for lung cancer and a PCM-based assessment for mesothelioma and still find a way to combine the two into a single value. • Since TEM detects much smaller fibers than PCM, it would be informative to compare the PCM lung cancer model with the TEM model. • EPA does not identify TEM papers mentioned in the Draft RE for Asbestos or compare the TEM models of lung cancer to the PCM model of lung cancer, which EPA used for the risk evaluation. The decision to ignore the TEM studies seems unjustified because the "Systematic Review Supplemental File on Data Quality Evaluation of Human Health Hazard Studies: Mesothelioma and Lung Cancer Studies" indicates on pages 10 and 21 that studies using PCM or TEM analyses are appropriate for use. • Commenter provided detailed findings that indicate a similar fit to the risk models of TEM and PCM fiber counts, but the number of fibers and the range of fiber sizes counted by TEM is much greater than that of PCM. The adoption by the EPA of a new statistical model to calculate an IUR for asbestos should be left until a time when the exposure analyses using TEM have reached a point of practical scientific and regulatory application. • EPA's risk evaluation relies solely on studies using PCM measurements of fibers; however, many EPMs cannot be identified reliably using PCM. Fibers below the resolution of PCM represent the largest contribution	

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	to exposure. EPA must evaluate cumulative exposure to all fiber sizes. Studies show that fibers less than 5mm in length were highly statistically significant predictors of lung cancer and asbestosis mortality. • The long, thin fibers present in the textile facilities from which EPA selected exposure data may not have been counted using contemporaneous standard methodologies for PCM. As such, the exposure data in the Draft RE for Asbestos is likely to underestimate actual exposure concentrations experienced by members of the textile cohorts.	
4.13 **Additional epidemiologic evidence is available for persons working with and around aftermarket automotive brakes/linings (AABL)**		
SACC, 34, 39, 40, 42, 59, 67, 68, 74, 79, 102, 103, 106	**SACC COMMENTS:** • The Draft RE for Asbestos focuses on cohorts occupationally exposed to chrysotile asbestos in the manufacture of textiles. The SACC concurred that the NC and SC cohorts (Lenters et al. (2012; Burdorf and Heederik (2011) have the best exposure data and that this was a good reason to focus on these cohorts. The SACC identified other studied occupational populations that should be given more consideration and possibly used in the analysis. These included studies from Italy (Ferrante et al. (2020; Pira et al. (2017) China, (Wang et al. (2013b; Wang et al. (2013a) and Canada (Liddell and Armstrong (2002; Liddell et al. (1997). • Some SACC members were not convinced that Table 3-8 is adequate to support the conclusion that there are no major differences in risks from chrysotile asbestos exposures between mining and textiles COUs. The SACC agreed that given the constraints necessary for IUR modeling, it was appropriate to focus on the SC	EPA agrees with SACC that NC and SC cohorts have best exposure data and it is appropriate to focus on these cohorts. Following SACC and public comments recommendations, EPA evaluated the quality of studies of auto-mechanics suggested by SACC and public comments for both mesothelioma and lung cancer and found deficiencies in exposure assessment and other aspects of the design of these studies. (see Supplemental File to this Summary of Comments and Disposition). Therefore, those studies (and published meta-analyses based on these studies) are not appropriate to be included in the risk evaluation of chrysotile asbestos (See also response to 4.17 with respect to cohort from Italy. Cohorts from China and Quebec were included in the evaluation already.)

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	and NC cohorts because of their higher quality exposure data. • Regardless, the SACC recommended adding discussion of the exposure assessment and epidemiology studies of mechanics and the rationale for why they were not used. Among the COUs considered in the Draft RE for Asbestos, brake mechanic is the occupation with the highest number of workers with potential for exposures from chrysotile-bearing products, specifically workers who replace old or install new aftermarket brake pads and shoes. Due to the high friction environment in vehicle braking, asbestos fibers in used brake material degrade both chemically and physically. Additional asbestos exposure occurs in the brake environment when new brakes are sanded or ground prior to installation. Several epidemiological studies involving workers involved in brake replacement have been conducted. These studies have been cited in several public comments in the asbestos Draft RE for Asbestos docket and are summarized in two meta-analysis publications (Garabrant et al. (2016; Goodman et al. (2004). • Many of these studies report no association between asbestos brake part replacement and mesothelioma and lung-cancer. For asbestos associated mesothelioma, these include 12 case-control studies (Aguilar-Madrid et al. (2010; Rolland et al. (2010; Rake et al. (2009; Welch et al. (2005; Hessel et al. (2004; Hansen and Meersohn (2003; Agudo et al. (2000; Teschke et al. (1997; Woitowitz and Rödelsperger (1994; Spirtas et al. (1985; Teta et al. (1983; Mcdonald and Mcdonald (1980); and five cohort studies (Van Den Borre and Deboosere (2015; Merlo et al. (2010; Gustavsson et al. (1990; Hansen (1989; Järvholm and Brisman (1988). For	

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	asbestos associated lung cancer, these studies include twelve case-control studies (Corbin et al. (2011; Guida et al. (2011; Consonni et al. (2010; Macarthur et al. (2009; Richiardi et al. (2004; Matos et al. (2000; Swanson et al. (1993; Morabia et al. (1992; Benhamou et al. (1988; Vineis et al. (1988; Lerchen et al. (1987; Williams et al. (1977), and two cohort studies (Veglia et al. (2007; Hrubec et al. (1992). • SACC members acknowledged the weaknesses of the brake work epidemiological studies, including poor exposure assessment and lack of large cohort studies. Many of these studies do not mention whether cancer cases or workers performed brake replacement. Also, none of the studies were specifically designed to study brake replacement (Kanarek and Anderson (2018; Teschke (2016; Vermeulen (2016; Welch (2007; Egilman and Billings (2005; Lemen (2004). The Draft RE for Asbestos should review these studies and consider whether they can be used to evaluate the risk from chrysotile asbestos exposure stemming from brake replacement. If appropriate, the data from exposure assessment and epidemiological studies on workers and consumers exposed to asbestos from motor vehicle brake replacement should be included in the weight-of-evidence narrative for the hazard assessment and risk determination of lung cancer and mesothelioma. • Recommendation 48: Justify exclusion of the studies of mechanics in the IUR estimation. • Recommendation 49: Include studies of workers and consumers exposed via brake replacement in the lung cancer and mesothelioma weight of evidence narratives. **PUBLIC COMMENTS:** • It is inappropriate to use an IUR based on high exposures to long fiber asbestos fibers used in textile	

	manufacturing to estimate risks to workers engaged in brake and clutch repair who have only low exposures to short fiber asbestos. There are 33 publications that provide information on the risks of mesothelioma and 22 publications that provide information on the risks of lung cancer among motor vehicle mechanics and brake repair workers (Aguilar-Madrid et al. (2010; Agudo et al. (2000; Coggon et al. (1995; Finkelstein (1995; Benhamou et al. (1988; Dubrow and Wegman (1984; Enterline and McKiever (1963) (see full comment for full list). In addition, there are two meta-analyses of these papers: first in 2004, regarding risks of mesothelioma and lung cancer, Goodman et al. (2004), and then in 2016, updating the risks of mesothelioma, Garabrant et al. (2016). • The above meta-analyses concluded that (a) employment as a motor vehicle mechanic did not increase the risk of developing mesothelioma and (b) although some studies showed a small increase in risk of lung cancer among motor vehicle mechanics, the data on balance did not support a conclusion that lung cancer risk in this occupational group was related to asbestos exposure. The Draft RE for Asbestos should not ignore the evidence from epidemiology studies of motor vehicle mechanics and brake repair workers who were exposed to low levels of short fiber chrysotile. • In addition to the literature on motor vehicle mechanics, there are 13 studies on the mesothelioma and lung cancer risks in manufacturing of friction products (brakes, clutches) for motor vehicles, none of which supports a conclusion that work in brake manufacturing industries is associated with increased risk of mesothelioma (Szeszenia-Dąbrowska et al. (2015; Clin et al. (2011; Finkelstein (2010; Pang et al. (1997; Kogan et al. (1993; Finkelstein (1989; Newhouse and Sullivan (1989; Mcdonald et al. (1984; Berry and Newhouse	

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	(1983; Browne and Smither (1983; Skidmore and Dufficy (1983; Mcdonald and Fry (1982; Newhouse et al. (1982). • The Draft RE for Asbestos ignores a large body of relevant epidemiologic evidence on workers working with and around AABL which show no increased risk of mesothelioma. • Multiple Studies Show Vehicle Mechanics and Users of AABL Have No Increased Risk of Mesothelioma, Lung Cancer [See original comment for the figure of a list of studies showing no increased risk of mesothelioma, studies indicating no increased risk of lung cancer, and figure showing quality of studies evaluating association between mesothelioma risk and motor vehicle mechanic employment]. • Since nearly all of the epidemiology studies of merit show no increased risk of mesothelioma in the auto mechanics during that period, it is reasonable to infer that four fibers/cc-years for chrysotile did not pose a significant health risk for mechanics who worked from 1940-1975. The obvious caveat to using the experience of mechanics to estimate the risk to those exposed to pure chrysotile is that the fibers associated with braking appear to have lost their biologic activity due to conversion to forsterite or being filled with phenolic resins (Bernstein et al. (2018; Bernstein et al. (2003).	
4.14 **Consider data from epidemiology studies and meta-analyses pertaining to exposures to asbestos-containing brakes**		
39, 42, 59, 59, 60, 64, 74, 76, 82, 90, 99, 103	**PUBLIC COMMENTS**: • EPA should have relied on an important project that it funded almost 20 years ago (Berman and Crump (2008a; Berman (2003). Also, for assessing the risk of exposure to phenolic encapsulated materials, like brakes, packing, and gaskets, EPA should have relied	Following the SACC recommendation, EPA evaluated the quality of the studies of auto-mechanics for both lung cancer and mesothelioma and found deficiencies in exposure assessment and other aspects of the design of these studies. (see Supplemental File to this Summary of Comments and Disposition). Therefore, those studies (and published meta-

	upon the meta-analyses studies of auto mechanics by Garabrant et al. (2016), Goodman et al. (2004), Wong (2001), and Pierce et al. (2008). They are more relevant to the Draft RE for Asbestos than the textile workers' exposure cohorts in the Carolinas (Elliott et al. (2012; Dement et al. (2011; Loomis et al. (2009). • EPA should have considered multiple studies of vehicle mechanics and users of AABL that showed no increased risk of mesothelioma or lung cancer. • EPA did not include a discussion of cement manufacturing cohorts (Albin et al. (1990; Neuberger and Kundi (1990; Lacquet et al. (1980) or friction product manufacturing cohorts. Mcdonald et al. (1984) discussed in other analyses of potency factors stratified by fiber type. • Very few, if any, historical asbestos-exposed cohorts (Bernstein et al. (2013; Berman and Crump (2008a, b; Hodgson and Darnton (2000) have resulted from those purely exposed to chrysotile. A mesothelioma mortality study on an asbestos product manufacturing cohort (Szeszenia-Dąbrowska et al. (2015) demonstrated that use of even minimal quantities of amphibole asbestos demonstrably impacted the risk of mesothelioma in a predominately-chrysotile cohort. Szeszenia-Dąbrowska et al. (2015) reported that mesothelioma occurred only in the plants where amphibole asbestos had previously been used during manufacturing. • Given that this EPA document focuses on brake wear debris (in no small measure), the cancer potency factor should be based on the epidemiology studies for brake mechanics who worked in the 1940–1980 era. An assessment of these data indicates that the brake wear debris has no potency for lung cancer or mesothelioma (Garabrant and Pastula (2018; Garabrant et al. (2016; Goodman et al. (2004; Wong (2001).	analyses based on these studies) are not appropriate to be included in Part 1 of the Risk Evaluation for Asbestos. EPA acknowledges that there are epidemiologic studies of brake workers, cement cohorts, gas mask workers, and other groups exposed to chrysotile asbestos and many of those have supported the basis for the hazard determination that chrysotile asbestos causes cancers – which EPA accepted as settled science. However, in EPA's review of these studies suggested by public comment, none of those provided the necessary quantitative data required for the IUR derivation for commercial chrysotile asbestos.

	• The commenter provided a formula that can be used to predict lung cancer and mesothelioma mortality based on specific workplace cohort data. They noted that the total expected mortality was used as a reasonable surrogate for the age-standardized cohort size, as it was done by Hodgson and Darnton (2000) for mesothelioma. They also accounted for a shorter than lifetime exposure duration by applying the coefficient Duration/75. It can be demonstrated that this coefficient yields estimates closely comparable with the (U.S. EPA (2008) exponential correction factor for shorter-than-life duration. • Use epidemiology studies in weight-of-evidence evaluation of predicted risks and characterization of associated uncertainties. Epidemiologic findings (of no risk in auto mechanics) are consistent with and supported by current knowledge about the composition of brake wear debris (Anderson et al. (1973), the levels of exposure during motor vehicle repair (Blake et al. (2003), and the roles of fiber type, length and width, durability, and biopersistence, in determining biological hazards (Bernstein et al. (2005). This knowledge explains why the compact particles of heat-modified chrysotile in brake dust in the air of motor vehicle repair facilities are non-potent carcinogens. • EPA has eliminated studies that reported no risk by limiting the evaluations to studies for which the risk of lung cancer per unit cumulative chrysotile exposure, or data to calculate that, was available (Draft RE for Asbestos ln. 4973-4975, 4990-4992). “Epidemiologic observations of forty years (1980–2020) consistently show that there is no discernable increased risk of mesothelioma for motor vehicle mechanics. When adjusted for cigarette smoking, studies of lung cancer in vehicle mechanics fail to discern an increased risk.” For example, the commenter cited several studies showed	

	no association of mesothelioma and the COU. One study did link mesothelioma to vehicle mechanics. Several studies that examined lung cancer among vehicle mechanics found no association. • EPA should consider all the available studies in their risk assessment, basing their IUR on a meta-analysis of all studies that include data on person-years at risk and cases of mesothelioma. • An alternative approach would be to use estimates of risk from various available meta-analyses (*e.g*, Hodgson and Darnton (2000); Berman and Crump (2008a, 2008b); Berman (2003)). Whichever dataset is used, the exposures received by each case of mesothelioma/pleural cancer should be reported. If this is not possible for confidentiality and/or other reasons, the range of exposures and the mean and median exposures should be reported for the entire dataset, and for the individuals with mesothelioma/pleural cancer. This information will allow the reader of the document to evaluate the range of exposures over which the risks are extrapolated. • EPA used only those studies where only commercial chrysotile was used or where workers were exposed only to commercial chrysotile; situations where chrysotile was used in combination with amphibole asbestos, but available information did not allow separation of the two were excluded from further consideration. This decision seems to be somewhat duplicitous. • EPA ignored the epidemiological studies of gas mask workers which have not demonstrated an increased risk of developing mesothelioma from exposure to chrysotile asbestos. • It is unclear why EPA did not include many of the relevant toxicological and epidemiological studies regarding asbestos fibers in gaskets, brakes, and	

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	packing. Given this significant deficiency, there is virtually no support for the conclusions in this Draft RE for Asbestos that relies almost exclusively on a new CPF.	
4.15 **Consider available inhalation toxicology studies concerning brake dust**		
39, 42, 60, 74, 103	**PUBLIC COMMENTS:** • Toxicological studies also need to be examined and provide strong support for the conclusions from epidemiologic studies that exposure to AABL does not increase the risk of mesothelioma. • Peer reviewed and published inhalation toxicological studies concerning brake dust are available, including a 5-day exposure biopersistence study, a 28-day exposure range-finding study, and a subchronic 90-day exposure study. Combined with the epidemiology studies of brake workers, these studies provide substantial evidence that that working with automotive brakes manufactured with chrysotile does not increase the risk of disease and that exposure to brake dust does not cause disease. • The chrysotile IUR derived by EPA resulted in it concluding that certain activities, such as DIY consumer brake mechanic work, resulted in unreasonable risk. This conclusion is wildly inconsistent with numerous experimental and epidemiological studies that have addressed the same question over the past several decades. For example, well conducted toxicology studies have reported no significant inflammatory or pathological effects in the lung or pleura in animals exposed to levels of brake dust orders of magnitude greater than those measured in occupational settings (Bernstein et al. (2020a, b; Bernstein et al. (2018; Bernstein et al. (2015; Bernstein et al. (2014).	Regarding studies of auto mechanics, please see response 4.14. In terms of animal studies, SACC agreed with EPA focus on epidemiology data and did not find inclusion of additional toxicology studies warranted.

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4.16 **Revisit exclusion of Quebec, Canada chrysotile miner study (Liddell studies)**		
34, 39, 60, 68, 76	**PUBLIC COMMENTS:** • Several commenters provided detailed analysis defending the Canadian chrysotile miners' data and encouraging EPA to consider including it. • Commenter identified four non-occupational studies for EPA to consider because they provide the most direct measures of environmental risk available for non-occupational exposures (mining neighborhood exposure: Case and Sebastien (1987) ; Camus et al. (1998); women living near mines: Camus et al. (2002) ; Case et al. (2002)). • Excluding chrysotile mining and milling studies biased the IUR in an upward direction. The Quebec cohort studies must be included if EPA is to provide an accurate IUR for "chrysotile," especially for mesothelioma. • Camus et al. (2002); Camus et al. (1998) compared the observed number of cases of lung cancer and mesothelioma in regions of Quebec with primarily chrysotile asbestos exposure, with the numbers expected based on the original IUR (U.S. EPA (1988b, 1986). The EPA model greatly overestimated the numbers of both cancers; the discrepancy for mesothelioma was particularly striking. With an estimated chrysotile IUR close to the original, the current model used in the Draft RE for Asbestos is unlikely to fare any better. Liddell studies are supported: • Case identification is sufficient: • EPA improperly asserted that Liddell's method of mesothelioma ascertainment was insufficient because he mentioned that mesothelioma was rarely seen in Quebec until 1960. It was rarely seen in Quebec, as was true everywhere else in the world, because it had not yet	EPA revised evaluation on methods for the Quebec cohort based on consideration of comments from the public and the SACC. However, as Berman and Crump (2008) established, there is an order and half of magnitude in uncertainty about risk of mesothelioma, because of a sublinear relationship with exposure concentration. The statistical testing by Berman and Crump (2008) rejected hypothesis of linearity (in favor of sublinear relationship) in Quebec data with very low p-value. In contrast, no such violation of linearity assumption was observed for South Carolina cohort (Berman and Crump, 2008). As SACC recommended repeatedly, EPA evaluation is based on South and North Carolina cohorts. SACC agreed that quality of Quebec cohort is lower. However, Table 3-8 shows that range of textile and mine cohort potencies is similar between mining (including Quebec) and textile industries.

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	been well defined by the medical community. That criticism applies to every investigation world-wide, including the NC and SC textile plants that EPA relied on in the Draft RE for Asbestos. • EPA dismissed the Quebec miners' cohort on the grounds that diagnosis of mesothelioma could not be reliably made (Draft RE for Asbestos p. 147). The investigators went to great lengths to find every case of mesothelioma based on best available evidence (Liddell et al. (1997). Of all the studies relied upon by EPA, the Quebec chrysotile miner cohort was the least susceptible to under ascertainment because instead of relying on the National Death Index and the ICD; it actively sought cases through reviewing medical records, autopsies, pathology reports, biopsies, and mesothelioma registry records. • McDonald reported extensive investigations to verify the diagnoses of lung cancer and mesothelioma among the Quebec asbestos miner cohort (Mcdonald et al. (1971), "investigating and reviewing all certified cases and searching also for cases not described as such on the death certificate." • EPA did not criticize any other study for deficiency in case identification, even though other studies used inferior methods for case identification. EPA's rules for judging study quality were applied unevenly and with obvious bias against the study of Quebec chrysotile miners. • Other studies have not criticized the Quebec chrysotile miners study for inadequate case ascertainment: United Kingdom Health and Safety Executive (Berman and Crump (2008a, b; Berman (2003; Hodgson and Darnton (2000), the Health Effects Institute Hei et al. (1991),	

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	and Iarc (2012b). EPA's criticism is novel and incorrect. • EPA should not exclude the Quebec chrysotile asbestos miner cohort based on an incorrect claim that mesothelioma deaths are not reported in a way that allows for derivations of KM. • EPA's perceived discrepancy in the numbers of dust measurements is incorrect. EPA appears to have misread the documents. • EPA expressed concern about uncertainties in the conversion of particle counts to fiber counts in the Quebec chrysotile data. The conversion factor and correlation between particle counts and fiber counts were closely correlated (r = 0.84), and the relative risks for lung cancer were quite similar, regardless of whether the exposure was expressed in fibers or dust counts (Mcdonald and Mcdonald (1980). This is a more meaningful way to assess the validity of different exposure measurements—how well they predict the outcome of interest. • It is common practice to use conversion factors for comparing samples collected over various time periods and using disparate analytical methodologies; however, it does not appear that EPA explored the use or availability of conversion factors outside of the referenced cohort publications. • EPA claimed, "Gibbs and Lachance (1972), reported that the correlation between midget impinger and membrane filter counts (0.32) was poor and suggested that 'no single conversion factor was justified.'" Gibbs and Lachance (1974) found that after a logarithmic transformation of both variables, the correlation was 0.45. For skewed distributions (such as fiber or dust counts) logarithmic transformation can provide a better	

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	fit to the relationship with other variables: it is routinely done. EPA's failure to mention the superior correlation from the logarithmically transformed variables casts unmerited criticism on the Quebec data. Moreover, the conversions from particle counts to fiber counts in the NC plants (Dement et al. (2009) did not report the correlation coefficient (either arithmetic or log-transformed), so there is no valid way to say whether it was better or worse than the Quebec correlation. • Exclusion of the Quebec cohort from consideration is especially striking when the Canadian study remains the largest among other chrysotile cohorts. Both Hodgson and Darnton (2000) and Berman and Crump (2008a) included Quebec data in their meta-analysis. Quebec mining and milling worker data has never been considered inferior to the Carolina studies from a general data quality level, despite known limitations typical for historical asbestos studies. Full exclusion of the Quebec cohort from consideration in the Draft RE for Asbestos has negatively affected the statistical representativeness of the IUR and significantly affected the validity and applicability of the results.	
4.17 **Consider chrysotile miners studies from Balangero, Italy**		
34, 39, 42, 60, 68	**PUBLIC COMMENTS**: • The latest updates of the Balangero cohort (Ferrante et al. (2020; Silvestri et al. (2020) report information on both mesothelioma incidence and mortality. Thus, this cohort should have been a candidate for the mesothelioma component of the IUR. • EPA stated "The group of Balangero, Italy cohort studies including Pira et al. (2009) was excluded for lack of results from models using a continuous measure of exposure." EPA failed to consider the results from	The latest 2020 reports on the study of the Balangero cohort were published after the close of the literature search and were not systematically reviewed, therefore are not included in the derivation of the IUR. Previous studies on this cohort (Pira et al., 2009, 2017) were appropriately considered, as documented in the Supplemental File to Part 1 of the Risk Evaluation for Asbestos on data evaluation for epidemiologic studies on human health hazard, and were not included due to a lack of results from models using a continuous measure of exposure.

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	Pira et al. (2017) and Ferrante et al. (2020), provided results in relation to continuous measures of exposure (f/ml-years) at the Balangero, Italy chrysotile mine. • Pira et al. (2017) have updated the original Balangero cohort but are not referenced in the Draft RE for Asbestos, possibly because this reference is missing from the National Library of Medicine database (PubMed). • The Balangero chrysotile miner studies are superior to the NC and SC textile worker studies for many reasons, including (a) exposure to only chrysotile (without amphibole asbestos exposure), (b) original exposure measurements made by PCM of fiber counts (f/ml) without any need to convert midget impinger dust counts (mppcf) to fiber counts, (c) work area- and year-specific exposure estimates throughout the period of operation of the mine and mills, and (d) ascertainment of incident mesothelioma cases and deaths through an active surveillance system that included reviewing medical records as well as death certificates. • There are some little-known facts about the Balangero cohort in Italy that deserve attention (Pierce et al. (2016; Pira et al. (2009; Piolatto et al. (1990)	
4.18 **Consider California Coalinga chrysotile miners and millers**		
42	**PUBLIC COMMENTS**: • There is a real question as to whether chrysotile alone can cause mesothelioma (certainly at concentrations below that which causes asbestosis). Studies of the Calidria mines would be informative for understanding pure chrysotile as it is extremely pure. The epidemiology of the miners was uneventful (Ilgren (2010).	The cited study of Calidria mine lacks exposure information and therefore, could not be used in Part 1 of the Risk Evaluation for Asbestos.

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4.19 **Consider studies of South African chrysotile miners**		
34, 39, 59	**PUBLIC COMMENTS:** • Studies of South African chrysotile miners reporting no cases of mesothelioma were ignored by EPA. • There are a series of studies of mesothelioma in South Africa that have examined the asbestos fiber types to which cases were exposed (White et al. (2008; Rees et al. (1999; Solomons (1984; Cochrane and Webster (1978; Webster (1973). In 504 histologically proven cases of mesothelioma in South Africa, no cases were reported who were exposed to South African chrysotile. Mesothelioma has not been observed among South African chrysotile miners despite a workforce of 1,500–2,000 miners who produced roughly 100,000 tons per year of chrysotile from 1975 to 1992 (Rees et al. (2001). These studies, which provide substantial evidence that South African chrysotile poses little if any risk of mesothelioma, should be considered in the Draft RE for Asbestos.	The cited studies lack exposure information and therefore, could not be used in Part 1 of the Risk Evaluation for Asbestos.
4.20 **Considered studies of Polish asbestos product manufacturing workers**		
34	**PUBLIC COMMENTS:** • The Draft RE for Asbestos should consider the studies of Polish asbestos products manufacturing workers in its evaluation. Szeszenia-Dąbrowska et al. (2015) studied mesothelioma mortality in five categories of manufacturing of asbestos-containing products (asbestos cement, textiles, sealing products, friction products, and waterproofing products). They found no risk of mesothelioma associated with exposure to chrysotile from the Soviet Union, but found a clear association with exposure to crocidolite, even when it was present as a small proportion of the total asbestos used.	The cited study lacks sufficient exposure information (outside of total amount of asbestos per plant) and therefore, could not be used in Part 1 of the Risk Evaluation for Asbestos.

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4.21 **Chongqing China cohort**		
42	**PUBLIC COMMENTS:** • Commenter is not sure the Chongqing (China) cohort is worthy of much attention (Courtice et al. (2016; Pierce et al. (2016; Deng et al. (2012). Some have claimed that this study has too many shortcomings to be reliable.	EPA documents its consideration of each relevant study identified according to predefined criteria; the criteria and evaluation are included in the Supplemental Systematic Review Files. EPA used the North Carolina cohort for the derivation of the chrysotile asbestos IUR.
4.22 **Concerns with binning approach/estimating fiber size specific cancer potency factors**		
51, 57, 86	**PUBLIC COMMENTS:** • The IUR uses a flawed approach similar to the "binning" framework that the EPA SAB rejected in 2008. During development of the now-abandoned binning approach in the early 2000s, there was strong opposition to developing separate potency factors for chrysotile and other fibers. Commenter cited criticisms from the SAB, another expert review, and other publications. The SAB emphasized that "[t]here is no compelling scientific basis for estimating different potency factors for lung cancer by fiber type and OSWER should take bins that assume this off the table. Stayner, Dankovic and Lemen have reasoned convincingly that 'there is absolutely no epidemiologic or toxicologic evidence to support the argument that chrysotile asbestos is any less potent than other forms of asbestos for inducing lung cancer' and that 'chrysotile appears to be just as potent a lung carcinogen as the other forms of asbestos.'" • The IUR determination in the Draft RE for Asbestos bears similarities to the rejected "binning" approach and the concerns a commenter expressed in 2008 (provided as an attachment), which remain valid and relevant today. • The potency of asbestos fibers has been addressed several times by multiple agencies over the last 50 years	In Part 1 of the Risk Evaluation for Asbestos, EPA documents the rationale for basing the chrysotile-specific IUR calculations on data from epidemiologic studies with exposure estimates for chrysotile. EPA does, however, recognize that legacy uses are comprised of mixed fiber types and will take this into consideration in developing Part 2 of the Risk Evaluation for Asbestos (legacy uses and other fiber types of asbestos).

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	and with similar results. The accepted approach is to assign the same potency to all fibers based on the lack of convincing support for different potencies. There may be a differential risk between chrysotile and amphibole fiber types on a dose-by-dose basis, but legacy asbestos products were produced using a variety of fibers and today most are mixed fiber types, even though chrysotile may be the only fiber in active commercial use.	
4.23 **Relative potency of different types of asbestos**		
42, 40, 51, 76	**PUBLIC COMMENTS:** • It has been evident, as evidenced by the different TLVS for the fiber types in 1979 (American Conference of Governmental Industrial (1980), that the amphiboles had very different toxicity from chrysotile fibers (Bernstein et al. (2020a, b; Hodgson et al. (2005; Hodgson and Darnton (2000). For the sake of transparency, the calculations for risk in this document should be based upon the current CPF for asbestos with modification by a factor of 100 to reflect the near-consensus view that chrysotile is at least 100-fold less potent than amosite for mesothelioma (Hodgson et al. (2005; Hodgson and Darnton (2000). For the vast majority of cohorts that have been studied, the predominant factor when evaluating the risks was the percent of amosite in the product. • The Draft RE for Asbestos essentially equates chrysotile and Libby amphibole fibers by their potency (upper bound IUR = 0.16 for chrysotile and 0.17 for Libby amphiboles). If the Draft RE for Asbestos chrysotile IUR, along with the generic asbestos IUR of 0.23, are not adequately distinguished in table notations, users may ignore the fact that crocidolite, amosite, and tremolite have universally been accepted as more	EPA clarified that Libby Amphibole Asbestos IUR and 1986 IUR are not directly comparable to each other or with IUR for commercial chrysotile derived in this Risk Evaluation. Footnote 4 states "It is important to mention that the methodology involved in risk characterization has evolved over time and the existing EPA IURs for other asbestos types (U.S. EPA (2014a, 1986) estimated risks of cancer mortality and did not account for the risk of other cancers, and the 1986 IUR did not adjust for mesothelioma under-ascertainment." EPA evaluated quality of cohorts and used only cohorts that are exposed to commercial chrysotile asbestos. It should be noted that SACC supported use of these cohorts and did not suggest use of amphibole-exposed cohorts in this assessment.

	carcinogenic, particularly for mesothelioma, than chrysotile. This false sense of equivalent potency might result in under-protection of workers and populations exposed to asbestiform amphiboles and zeolites (*e.g*, erionite), in different settings such as mining, forestry, road construction, asbestos abatement, etc. • EPA's prior 1988 asbestos IUR value of 0.23 f/cc is based on 14 epidemiologic studies that include occupational exposure to chrysotile, amosite, and/or mixed fibers (*e.g*, chrysotile, amosite, crocidolite) (p. 132). EPA's current chrysotile asbestos IUR value of 0.16 f/cc, which is purportedly based on occupational exposures to commercial chrysotile, is only 1.4 times lower than this prior estimate (p. 132). Given the well-documented differences in cancer potency between chrysotile and amphibole asbestos, particularly with respect to mesothelioma, the lack of a more pronounced difference in unit risk values does not seem reasonable and is inconsistent with prior risk evaluations. For example, Hodgson and Darnton (2000) estimated that the risk differential between chrysotile and two amphibole fibers was between 1:10 (amosite) and 1:50 (crocidolite) for lung cancer and between 1:100 (amosite) and 1:500 (crocidolite) for mesothelioma. The authors noted that if the observed "gross differences are even approximately correct" then "quite small variations in the fiber mix in the cohorts exposed to several fiber types could have important effects on the mesothelioma risk in the cohort" (p. 571). • Berman (2003); Berman and Crump (2001) found that the best estimate of the potency for chrysotile was 0.27 times that for amphiboles for lung cancer and 0.0013 times that for amphiboles for mesothelioma. These authors noted that "the possibility that pure chrysotile is non-potent for causing mesothelioma cannot be ruled out by the epidemiology data" (p. 1.4). In a peer	

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	consultation of this latter work (U.S (2003), all 11 panelists unanimously agreed that the available epidemiology studies provided compelling evidence that the carcinogenic potency of amphibole fibers was two orders of magnitude greater than that for chrysotile fibers with respect to mesothelioma. In an updated assessment, Berman and Crump (2008a) found that the best estimate of the relative potency of chrysotile ranged from zero to 1/200th that of amphibole asbestos for mesothelioma, and the hypothesis that chrysotile and amphibole asbestos were equally potent for mesothelioma risk was strongly rejected by every metric. The authors concluded: "The analyses presented herein provide consistently strong evidence that chrysotile is considerably less potent than amphibole asbestos in causing mesothelioma" (p. 63-64). More recently, Garabrant and Pastula (2018) found that the relative potency for chrysotile: amosite: crocidolite was 1:83:376. A thorough discussion of these prior analyses and findings and why they differ from the current assessment should be included in EPA's risk evaluation for asbestos. • There is some evidence suggesting that the different types of asbestos fibers vary in carcinogenic potency. It appears that the risk of mesothelioma is greater with exposure to crocidolite than to amosite or chrysotile alone. Other data indicate that differences in fiber size distribution may contribute to observed variation in outcomes.	
4.24 **Clarify derivation of mesothelioma potency factor**		
SACC	**SACC COMMENTS:** • The SACC questioned the analysis upon which EPA's preferred mesothelioma potency factor is based. EPA prefers the estimate of KM from Loomis et al. (2019),	Following this and other SACC recommendations (Recommendation 56) EPA now uses the variable exposures Peto model results as reported in Loomis et al. (2019). The tables in Risk Evaluation were clarified in terms of source of

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	which reports a KM of 0.88E-9 (UCL = 1.49E-9) but which also reports a KM of 2.96E-9 (UCL = 5.87E- 9) using an alternative analysis that includes only cohort members alive in 1999. The KM value listed in Draft RE for Asbestos Table 3-9 as KM = 2.44 E-9 (UCL = 5.04 E-9) has the notation "EPA modeling of Loomis et al." Earlier in the Draft RE for Asbestos it was stated that "Because Loomis et al. (2019) reported only pleural cancers before ICD-10, EPA modeled the exposure-response for mesothelioma using data from 1999 onward when ICD-10 was in use (Table 3-4 suggests these data are in supplemental table S1b to the original publication)." SACC did not find a description of this analysis in the Draft RE for Asbestos or associated supplements. The analysis by EPA that was used to provide its preferred KM needs to be better documented and because the data used are not easily accessed, these data are provided in a supplement to the Draft RE for Asbestos. Recommendation 55: Better describe the derivation of the KM estimate used in the evaluation.	the data. As requested by SACC, the addition of these results improved the documentation of relevant mesothelioma results and allowed EPA to better describe the derivation of the KM estimate used in the evaluation.
4.25 **Cancer potency factor range**		
42	**PUBLIC COMMENTS:** • The Draft RE for Asbestos indicates that different modeling choices and combinations of cancer-specific unit risks yielded candidate IUR values ranging from 0.08 to 0.33 per f/cc. It seems implausible that EPA would believe that the plausible range of CPFs would be that narrow. The span of CPF for a chemical like this begins at zero and increases with the type of model that is applied with the data. Most of these models will all yield reasonable or plausible CPFs, especially for a generally non-genotoxic carcinogen like chrysotile.	Table 3-12 now shows that the range of candidate IURs is three-fold and EPA noted that this is a narrow range. However, this range is based on multiple analyses of two cohorts that are similar in industry, country, historical time and were both evaluated as having high quality exposure assessment. In consideration of this comment, EPA did not find any revisions or clarifications warranted in Part1 of the Risk Evaluation for Asbestos.

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	Usually, the range of plausible CPFs will often span two orders of magnitude.	
4.26 **Short chrysotile fibers might pose no risk of cancer**		
42, 64, 60, 61, 95	**PUBLIC COMMENTS:** • There is abundant literature (some supported by the EPA itself) that shows that cancer risk from asbestos minerals, including chrysotile, is related to fiber length and other physical/chemical properties. • The nature of friction materials and brake wear debris limits any potential exposure that is assumed to occur for vehicle mechanics. Brake wear debris contains very little chrysotile asbestos. The fibers present are the type most rapidly cleared from the body, are the least potent type for induction of mesothelioma or lung cancer and are shorter than the minimum length believed to be required for induction of mesothelioma or lung cancer. • Short fiber chrysotile does not cause cancer (including lung cancer or mesothelioma) at low levels of exposure, especially to fibers less than 10 microns in length, and these comprise the majority in fibers encapsulated in brakes, gaskets and packing. There is no reason to derive an IUR or CPF for it, particularly using the LMS model. • A 2002 ATSDR expert panel addressed the influence of fiber length on asbestos-related health effects. Overall, the panelists agreed that "there is a strong weight of evidence that asbestos and short vitreous fibers shorter than 5 μm are unlikely to cause cancer in humans" based on epidemiologic studies, laboratory animal studies, and in vitro genotoxicity studies, combined with the lung's ability to clear short fibers. A second expert panel convened by EPA agreed that the risk	EPA clarifies that the newer Bayesian analysis by Hamra et al. 2017, which did evaluate the independent effects of short and long fibers, shows that shorter fibers also have cancer risk.

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	associated with fibers less than 5 µm in length is "very low and could be zero." • Brake dust, which is characterized by a short and altered fiber, has less biological potential than the longer fibers in the textile industry. • Lung cancer mortality is not a straightforward outcome. Other potential confounders such as fiber length should be considered. • Longer asbestos fibers are more potent than shorter asbestos fibers in causing disease, including lung cancer and mesothelioma. By using textile cohort data in its Draft RE for Asbestos, EPA likely overstated the potency associated with chrysotile in other non-occupational (and occupational) settings. • Since emphases in the EPA document are COU in exposures to brake dusts, the chemical and physical properties of brake dusts containing chrysotile should be discussed. This information should describe the percentages of chrysotile included in brake pads, etc., and characteristics (including dimensions and amounts of free fibers) of chrysotile released from brake pads. Discussion on the impact of sheer stress that reduces fiber lengths as well as heat modification of fibers that affects both structural and surface properties of chrysotile, is necessary.	
4.27 **Evidence of no safe exposure levels**		
51, 57, 73, 85, 86, 104	**PUBLIC COMMENTS:** • Leading health authorities have agreed for years that asbestos is a human carcinogen and there is overwhelming consensus in the scientific community that there is no safe level of exposure. • Epidemiological studies of low levels of asbestos exposure have concluded that there are no "safe" doses of exposure. Since the early 1970s, studies have been	Under TSCA section 6(b)(4)(D), EPA is required to determine whether a chemical substance presents unreasonable risks for the conditions of use without consideration of costs or other non-risk factors. As such, TSCA does not require EPA to make a finding of whether there is "no safe level" of asbestos. As stated in Section 5.1 of Part 1 of the Asbestos Risk Evaluation, for the purposes of making risk determinations for the conditions of use, EPA

	identifying lower and lower asbestos exposure levels associated with cancer (*e.g*, Mcdonald et al. (1973); Mcdonald et al. (1980); Rödelsperger et al. (2001); Iwatsubo et al. (1998)). Thus, it is unlikely future studies will find a threshold level of exposure below which individuals are not at risk of asbestos disease. • The IARC Monograph on Asbestos Volume 14 was first released in 1977 (IARC (1977). Conclusions in the monograph have not changed fundamentally since then (*i.e.*, all forms of asbestos including chrysotile, amosite, anthophyllite crocidolite and mixed exposures of these fiber types caused lung cancer as well as mesothelioma and other cancers). IARC has conducted several update evaluations since then, the latest in 2009; all reached similar conclusions. • In 1976, NIOSH concluded that no evidence was found for a threshold or a safe level of asbestos exposure and that". (only a ban can assure protection against carcinogenic effects of asbestos)" (NIOSH, 1996). • In 1998, the WHO International Programme for Chemical Safety concluded "exposures to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks" (WHO (1998). • Other regulatory agencies have concluded that risk goes beyond the worker and recognize there is no safe risk from exposure to asbestos (*e.g*, 1977)). • The bottom line is that there is no safe way to use asbestos, all fibers cause both non-malignant disease and cancer, and there is no known safe exposure below which there is no risk for all (Lemen and Landrigan (2017). • One commenter previously submitted the same comment (no safe exposure level) to EPA in 2017 on for the Agency's Scoping Document for asbestos and in	uses 1x10-6 as the benchmark for consumers (*e.g*, do-it-yourself mechanics) and bystanders. In addition, consistent with the 2017 NIOSH guidance, EPA uses 1x10-4 as the benchmark for individuals in industrial and commercial work environments subject to Occupational Safety and Health Act (OSHA) requirements. It is important to note that 1x10-4 is not a bright line, and EPA used discretion to make risk determinations based on other considerations including other risk factors, such as severity of endpoint, reversibility of effect, or exposure-related considerations.

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	2018 for its Problem Formulation document for the Draft RE for Asbestos. • Fifty-five countries ban all asbestos uses; the United States is one of the very few countries that does not.	
4.28 **Recalculate the potency factors considering Berman and Crump (2008) who used individual [exposure] data**		
SACC	**SACC COMMENT:** • The Draft RE for Asbestos "expresses a general preference for modelling based on the data from each individual person in a study, rather than modelling based on published grouped data." The SACC agreed with the preference. The distinction between basing an analysis on individual level data versus grouped data, however, is somewhat artificial because practically all analyses of individual data involve some grouping. For example, all the analyses of the NC and SC textile cohorts for lung cancer and mesothelioma utilized Poisson regression, which involved grouping the data into bins defined by various characteristics including exposure. Having access to the individual data allows the average exposure in a group to be estimated accurately. If only a range originally is reported, the EPA uses the highest exposure reported to represent the group in the highest exposure bin (Draft RE for Asbestos ln. 5079). EPA used this approach in modeling grouped lung cancer data from both the SC and NC studies. However, this approach typically will overestimate exposure. • Berman and Crump (2008a) report an analysis of the lung cancer data from the SC textile cohort based on individual level data which uses the same exposure groupings as EPA's analysis (Draft RE for Asbestos p. 294 and Table 3-3). Berman and Crump (2008a) used the individual exposure data to calculate an exact	Following this and other SACC recommendation, EPA changed the modeling of the lung cancer data, by allowing alpha to be estimated (as well as equal to one). EPA also changed (where it was able to obtain data) the midpoint of the exposure groups to the mean. EPA also note that published simulation results (Richardson and Loomis (2004) show that midpoint and mean are, in general, both reasonable.

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	average exposure in each group (185.1 f/ml for the highest exposure group compared with the 410 f/ml assumed in the EPA analysis). Moreover, the EPA analysis assumed the relative risk model (ln. 5025) where the background parameter *a* is equal to 1, which implies that the background lung cancer rate in the SC textile mill was equal to that in the general population. Berman and Crump (2008a), however, found that the hypothesis $a = 1$ could be rejected ($p = 0.008$), with the best estimate being $a = 1.35$, which implies that the SC cohort had a higher rate of background lung cancer than the general population. • The Draft RE for Asbestos similarly overestimates exposure in the highest exposure group in the Loomis et al. (2009) analysis of the NC textile cohort lung cancer data, which probably accounts for the Draft RE for Asbestos estimate of KL based on grouped data being the smallest of the four KL estimates reported in Table 3-4. The EPA analyses of the grouped data reported in both Table 3-3 and Table 3-4 should be redone to take these problems into account. • Recommendation 57: Recalculate the potency factors considering previous analyses performed using individual [exposure] data, estimates of the background parameter *a*, and methods that do not overestimate exposures in the highest exposure group.	
4.29 **Justify choice of or replace AIC model-selection criterion**		
SACC, 63	**SACC COMMENTS:** • Recommendation 52: Replace the AIC model-selection criterion with a criterion that puts more weight on the low-exposure range of the data. Such as detailed in Atkinson and Riani (2000). Akaike Information Criteria (AIC) do not address how well the linear and exponential models fit the parts of the dose response	In other SACC recommendations (Recommendation 50), SACC recommended using linear model for lung cancer to better assess dose response at the low end of the exposure range and EPA followed that recommendation. EPA provided all modeling results (linear and exponential fit for lung cancer data) for comparison in Table 3-12 of Part 1 of

	relationship, especially at the low end of the exposure range. (SACC-115) Recommendation 102: Provide more details and further justify use of the AIC to choose among potential dose response models, and how different models change the estimated point of departure. • The Draft RE for Asbestos justifies use of the exponential model over the linear model because the exponential model provides a better fit to both the SC and NC lung cancer data, as determined by model AIC values, which measures fit over the entire exposure range. However, when computing an IUR, the primary interest is in the risk at low exposures. A better approach might be to emphasize how well the models fit the lower dose data. This could possibly be accomplished by comparing AICs using only data from lower exposures. **PUBLIC COMMENTS:** • Commenter provided detailed analysis of the Elliott et al. (2012) assessment of model fit using AIC that EPA used as justification for an exponential model. Commenter also argued that it did not appear that EPA has chosen the best model using all available data for lung cancer potency estimates using the SC cohort. • EPA's choice of a non-linear model is based solely on statistical "curve fitting;" the Draft RE for Asbestos does not cite any mechanistic or other biological basis (*e.g*, MOA) for preferring an exponential model, which is a prerequisite for overcoming the presumption of linearity under (U.S. EPA (2005) Cancer Guidelines. Others who have examined the SC and NC data have concluded that "the best model for lung cancer was linear on a multiplicative scale with the best data fit obtained when the threshold was set at zero" (Markowitz (2015). Equally important, EPA only performs its "curve fitting" analysis on two	the Risk Evaluation for Asbestos, illustrating changes in PODs and risks.

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	epidemiology studies. Without considering the much larger body of available data, EPA "makes a large leap of faith" in concluding that the exponential model is broadly applicable to asbestos carcinogenicity. • Simply the "best statistical fit" or the lowest AIC is an inadequate reason to select an exponential model over the low-dose linear model to estimate the IUR. (57, 51) Given the large uncertainties in individual exposure measurement and disease tracking, the 'good fit' of the exponential model for the SC and NC cohorts could happen by chance. The commenter quoted Silverstein et al. (2009) as saying that "[t]rying to turn fundamentally unreliable data into valid and reliable output is statistical alchemy, no matter how sophisticated and complex the mathematical models." The imprecision in the exposure levels "does not provide a strong basis for this type of 'curve fitting' modeling" (Commenter #57 as cited in comment 51-9).	
4.30 **Fit and compare linear and exponential model**		
SACC, 32, 34, 39, 40, 41, 42, 47, 51, 57, 60, 62, 63, 65, 86, 90, 95	**SACC COMMENTS:** • Recommendation 50: Compare the estimated IUR derived from the linear model fit to the IUR estimated from the exponential model fit. Fit the two competing models, the linear model and exponential model, to a low dose subset of the data and comparing results. See Elliott et al. (2012) pooled analysis for lung cancer. Berman and Crump (2008a) and Loomis et al. (2019) could be combined to evaluate the risk of mesothelioma. • The EPA Cancer Guidelines (U.S. EPA (2005) specify that the choice of the approach for extrapolation of risk to low doses be based on an understanding of the MOA by which a substance causes cancer. The Draft RE for Asbestos should link the section describing what is	Following SACC recommendation, EPA used linear model fit from North Carolina cohort in its chrysotile asbestos IUR derivation based on NC cohort. EPA provided all modeling results (linear and exponential fit for lung cancer data) for comparison in Table 3-12 illustrating changes in PODs and risks. EPA was not able to obtain data for pooled analysis of mesothelioma data. EPA does not agree with commenters proposing relative risk model for mesothelioma, because the SACC recommended that EPA use absolute risk model and EPA followed EPA cancer guidelines in its low-dose extrapolation, as indicated by expanded MOA discussion (SACC recommendation 94), which indicated appropriateness of linear extrapolation.

	known about the MOA of asbestos in causing cancer with the selection of a linear extrapolation procedure as required in the Cancer Guidelines. At least one SACC member believed that there was sufficient information to justify assessing risk from chrysotile asbestos using a threshold procedure, incorporating the results of numerous worker studies that have reported no increased risk for lung cancer and mesothelioma. **PUBLIC COMMENTS:** • Compare the linear and exponential model IURs to demonstrate the importance of model selection for the textile worker studies. • It would be useful to further understand why EPA used an absolute risk model for mesothelioma and a relative risk model for lung cancer. These are likely rational choices, but a deeper look into this statistical aspect would be useful. • The Draft RE for Asbestos states that "Limiting the results in Table 3-6 to lung cancer results based on the better fitting exponential models yielded four combinations that were essentially equivalent in terms of statistical fit and study quality (Table 3-7)" (p. 154, ln. 5661–5663). It is not clear why these models are "essentially equivalent." This needs to be better explained to be more apparent to the reader. • EPA should base its risk calculations for mesothelioma on a relative risk model. EPA uses a relative risk model for lung cancer (*e.g*, Draft RE for Asbestos p. 150 ln. 5569–5570), wherein it implicitly agrees that there is no methodological argument in favor of an absolute risk model over a relative risk model for asbestos-related malignancies. EPA provided no justification for its reliance on an absolute risk model for mesothelioma when a relative risk model was deemed appropriate for lung cancer.	

	• By using an absolute risk model for mesothelioma, EPA was unable to benchmark their findings against the body of epidemiological literature for chrysotile-exposed populations, including users of end-products, such as brakes and gaskets. • Accumulating science indicates that the LNT model is inappropriate for evaluating cancer risk at low levels of exposure. This is particularly true in scenarios such as workers using AABL, where a large body of epidemiologic evidence provides direct information related to risk. • EPA's use of an LNT model is not supported by toxicology or mechanistic evidence, which indicate a threshold for carcinogenic effects of chrysotile. The linear-no-threshold model likely considerably overestimates the cancer potency of chrysotile asbestos. Regarding DNA-reactive substances, recent scientific evidence indicates that the small increase in DNA damage that might occur from very low exposures, in addition to the already high levels of endogenous DNA damage, should not overwhelm DNA repair capacities (Cardarelli and Ulsh (2018). This indicates a threshold even for DNA-reactive substances. Evidence is generally supportive of a MOA involving chronic inflammation and cellular toxicity and repair that leads to the generation of reactive oxygen species and DNA damage, rather than direct interaction with DNA (Huang et al. (2011). This threshold mechanism can only occur at exposure concentrations high enough to overwhelm cellular defense mechanisms. • Bogen (2019) and Cox (2019) make a persuasive biological case for the existence of a threshold in inflammation-mediated carcinogenesis, which is widely believed to be the mechanism by which asbestos causes cancer (*e.g*, Iarc (2012b)).	

	• Given chrysotile's lack of genotoxicity and robust epidemiological data, the LMS model is almost certainly not appropriate. Many toxicologists have argued that safe levels of exposure can be derived by the classic safety factor approach applied to a genuine or apparent human NOEL (f/cc-year). • EPA should be cautious in applying any variation of the LMS model to short-fiber chrysotile. There is strong evidence that short-fiber chrysotile is a threshold carcinogen. • The LNT model has previously been shown to substantially overestimate the number of cases of mesothelioma expected within a population (Camus et al. (2002), especially at low cumulative exposure levels. Commenter cited additional reasons for the limited utility of the LNT approach, including consideration of asbestos pathology and weight of the epidemiological evidence. • Chrysotile is almost certainly a threshold carcinogen so the benchmark dose method should probably have been used to identify an acceptable dose. • Pierce et al. (2016) recently derived "best estimate" chrysotile NOAELs of 208–415 f/cc-years for mesothelioma and 89–168 f/cc-years for lung cancer that can be applied as thresholds in chrysotile cancer risk evaluations. EPA did not discuss Pierce et al. (2016) or acknowledge a possible threshold mode of action for chrysotile. The assumption of absolute risk for mesothelioma does not consider reports of no-observed-effects threshold for exposure to chrysotile asbestos (Pierce et al. (2016). • By using an LNT model to extrapolate risk to doses below the available exposure-response data for the two textile industry studies, the estimated chrysotile IUR will overestimate risk (Barlow et al. (2017). The risk	

	estimates are not supported by mechanistic, toxicologic, or epidemiologic evidence. • The approach taken by EPA in the Draft RE for Asbestos is more akin to the approach taken by plaintiffs' counsel in asbestos personal injury cases in that it uses an absolute risk model that is contrary to the current best available science. • In selecting an exponential risk model for asbestos and lung cancer, the EPA deviates from the linear model that it has used up to the present time, and which has been long relied upon by scientists, government agencies, and other organizations. Analyses of the data from the two textile cohort studies (used for the new IUR) have shown good fit with a linear model. Given the other uncertainties inherent in the Draft RE for Asbestos, the difference in fit does not warrant abandonment of the linear model by EPA. These uncertainties include a difference in the strength of the association between cumulative asbestos dose and lung cancer risk between the two textile cohorts, with the association being stronger for the SC cohort. • The use of an "exponential" rather than a "linear model" to determine cancer potency is not protective. Commenter cited U.S. EPA (2005) Cancer Guidelines as emphasizing the high level of evidence necessary to depart from the presumption of linearity for carcinogens. • The selection of an upper-bound IUR (combined for lung cancer and malignant mesothelioma) does not compensate for the underestimation of risk introduced by omission of amphibole fibers, cancers of the larynx and ovary, and nonmalignant asbestos-related disease from the Draft RE for Asbestos. Continued use of the more protective linear model to evaluate risk for asbestos is necessary.	

	• The Draft RE for Asbestos applies an exponential model that agencies have never used before and has been disfavored by the consensus groups of asbestos scientists. • The linear lung cancer relative risk model from the Hein et al. (2007) study is a better choice as this model: (1) includes the entire SC study cohort, (2) is based a model whose parameters were specifically chosen using the full study data, (3) is supported by a body of literature concerning quantitative risk assessment using longitudinal epidemiological data, and (4) is consistent with prior EPA risk assessment practice. • A specific numerical threshold value does not exist, or if it does exist, cannot be reliably determined. The asbestos exposure threshold concept for mesothelioma is scientifically ambiguous. First, selecting a numerical threshold necessarily involves a value judgement concerning an acceptable level of risk. Second, even if an acceptable risk level has been determined, estimation of the corresponding exposure typically requires extrapolation of a statistical risk model far-below observable data. • In the Draft RE for Asbestos discussion of the time relationship of lung cancer risk and asbestos exposure, the data can be interpreted in terms of a multistage model of cancer in which asbestos appears to act at a single late stage. The continued high risk following cessation of exposure results from the continued presence of asbestos in the lungs. This model is compatible with a linear dose-response relationship. • EPA's use of a default linear approach should be explicitly acknowledged in the risk evaluation, including a description of the uncertainties and conservatism associated with this approach. • The high end of the range for the linear model runs is an IUR 0.33 per f/cc (SC cohort) while the lower end of	

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	the range for the exponential runs is an IUR of 0.08 per f/cc (NC cohort). This four-fold difference illustrates the implications of model choice for the protectiveness of the IUR and the risk levels EPA uses for its determinations of unreasonable risk. EPA should revise its IUR derivation to use the protective linear low-dose model consistent with EPA's cancer risk assessment guidelines.	
4.31 **Consideration of background mesothelioma rates and basis of IUR concept of excess risk**		
SACC, 29, 34, 39, 40, 42, 56, 59, 60, 62, 71, 79, 102, 103	**SACC COMMENTS:** • Even if all mesotheliomas cases with no known asbestos exposure were caused by environmental asbestos exposure [American Cancer Society, Mark and Yokoi (1991), Strauchen (2011)], this would still imply a background of mesothelioma that possibly should be accounted for in EPA's assessment of risk of mesothelioma. • Therapeutic radiation for lymphoma has been reported to cause mesothelioma (Chang et al. (2017; Teta et al. (2007), and several studies have discussed mesothelioma cases with no known exposure to asbestos (*e.g*, Spirtas et al. (1994); McDonald and McDonald (1994); Mcdonald and Mcdonald (1980); Mcdonald (1985); Moolgavkar et al. (2009); Price and Ware (2009, 2004); Roggli (2007); Walker et al. (1983)). • The Peto mesothelioma model used in the calculation of the IUR does not accommodate the possibility of a non-zero background for mesothelioma. (SACC-119) Berman and Crump (2008a) applied an expanded Peto mesothelioma model to the SC mesothelioma data that accounted for variable exposures and reverted to the original Peto model when exposure was determined to	EPA followed SACC recommendation by accounting for variable exposure for North Carolina cohort. The new results are presented in Table 3-4. Use of Peto model (without background exposure term) for mesothelioma modeling is a longstanding Agency framework (U.S. EPA 1986; 2014). In addition, use of variable exposure obviates EPA modeling of NC mesothelioma data as variable exposure modeling are presented in Loomis et al. (2019). SACC agreed with EPA use of extra risk models and extra risk models are recommended by various Agency guidances (*e.g* BMDS Technical Guidance).

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	be constant. The SACC recommends that EPA reanalyze the mesothelioma data for NC textile mills using the expanded Peto model in order to more accurately account for the variable asbestos exposure patterns in the NC cohort. • Recommendation 56: Reanalyze the NC mill data on mesothelioma using a modified Peto model that incorporates a non-zero background and accurately accounts for variable exposures. **PUBLIC COMMENTS:** • EPA should acknowledge the existence of a background rate for mesothelioma for the development of the IUR for both lung cancer and mesothelioma. • Numbers of future mesothelioma cases were projected through 2055 based on analysis and modeling of SEER data through 2005 by Price and Ware (2009) and by Moolgavkar et al. (2009). Commenter updated the analysis reported in Price and Ware (2009) using SEER data through 2016. The results in Figure 2 indicate that by the year 2040 virtually all mesotheliomas in the US will be background cases. Therefore, there is little, if any, justification for conducting additional research, interventions, or regulations to further limit exposure to asbestos for controlling the occurrence of new mesotheliomas. • Incidence curves of non-asbestos related mesotheliomas in Moolgavkar et al. (2009) could be a starting point for an analysis that recognizes that mesothelioma occurs without asbestos exposure. In the United Kingdom, the Tan and Warren (2011) has developed models, one purely statistical Tan and Warren (2009) and the other based on the two-stage clonal expansion (TSCE) model, for mesothelioma rates in the population that allow for a background rate. Similarly, Banaei et al. (2000)	

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	proposed a method based on the Armitage-Doll multistage model for analyses of mesothelioma mortality in France. Another option is to extend the Peto-Nicholson model, as described in Berman and Crump (2008a, 2008b), to include a term for non-asbestos-related mesothelioma. • EPA assumed the background risk of malignant mesothelioma is zero. Numerous studies have estimated the background risk of mesothelioma to be nonzero and risk assessments must acknowledge this evidence (Moolgavkar et al. (2009; Price and Ware (2009; Teta et al. (2008; Roggli (2007; Price and Ware (2004; McDonald and McDonald (1994; Ilgren and Browne (1991; Mcdonald (1985; Walker et al. (1983; Mcdonald and Mcdonald (1980). Various epidemiology-type studies report fractions of mesothelioma cases without having been exposed to asbestos or having experienced only low-level exposure (Glynn et al. (2018; Spirtas et al. (1994; Peterson et al. (1984; Peto et al. (1981; Vianna and Polan (1978) • Tomasetti et al. (2017); Tomasetti and Vogelstein (2015) estimated that the majority of all cancer risk, about 67%, is due to biological processes with outcomes of background cases. In Tomasetti and Vogelstein (2015), Wu et al. (2016), and Tomasetti et al. (2017), there is reliable evidence that there are other causes of malignant mesothelioma besides asbestos, and that malignant mesothelioma occurs in the absence known causes (*i.e.*, there is a non-zero background rate). Other known causes of mesothelioma besides asbestos include ionizing radiation, erionite, fluoroedenite, and age. Recent literature suggests that inherited/germline BRCA associated protein 1 (BAP1) mutations are associated with very high risk of mesothelioma, as well as Carbone	

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	et al. (2019; Carbone et al. (2016; Cheung et al. (2013). Also in the literature are various articles addressing the involvement of hereditary cancer syndromes in the development of mesothelioma (Shih and Kradin (2019). EPA's calculations must be revised to include estimates of the background mesothelioma rates in different age and sex categories that are supported by scientific literature. • The data in Figure 1 [Consumption of asbestos in the US obtained from the United States Geological Service; male age-adjusted incidence of mesothelioma from the SEER database; and female age-adjusted incidence of mesothelioma from the SEER database] support the existence of background mesotheliomas. Male workers historically experienced increasing and high-level occupational exposures to asbestos starting in the 1930s and relatively high rates of mesothelioma starting in the 1970s. The trend in mesothelioma incidence among males continued to increase up to the 1990s. Following the peak in male mesothelioma in the 1990s, male incidence began to fall in response to substantially lower exposure levels in the workplace, which to a great extent were due to OSHA limits imposed on occupational exposure (37 FR 11318; 51 FR 22612; 59 FR 40964). The historical trend in mesothelioma incidence for males associated with high workplace exposures to asbestos conceals the existence of any trend for background mesotheliomas among males. However, during the same time-period, the female mesothelioma rate remained relatively constant despite the increase in domestic, product use, and environmental exposures. Female environmental exposures to asbestos released from mining, manufacturing, and product use (*e.g*, construction	

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	materials found in the home and other asbestos-containing products possibly including cosmetic talc) also would have increased during the 1930-1970 period and beyond for as long as the asbestos-containing products were in use. Notwithstanding the increases in exposure, the mesothelioma rate for women in the U.S. did not increase. The mesothelioma rate for women in the US is a reasonable approximation of the background rate for the disease (Moolgavkar et al. (2009; Price and Ware (2009, 2004; Weill et al. (2004; Ilgren and Wagner (1991; Gibbs (1990; Mcdonald (1985). • The pleural mesothelioma rate is higher in those who have had chest radiation treatments for cancer at mid-life during the 1950–1970/1980s (and who were never exposed to asbestos). Additionally, peritoneal mesothelioma often occurs in persons in their 30s to 50s when their exposure history indicates that they were always office workers (not to mention that the latency would not be consistent with the disease if it was solely due to asbestos exposure). Mesothelioma clearly occurs without exposure to asbestos in probably 20–25% of cases, if not more. As the typical American enjoys greater longevity, there is increased incidence of mesothelioma that is independent of asbestos exposure. • There is a background rate of mutation and hence of cancer development. Exposure to environmental agents simply accelerates this background process. In the original 1986 document (U.S. EPA (1986), the IUR is based on the concept of excess risk. The current DRE should do the same in their estimate of KL. • By basing risk assessments for both lung cancer and mesothelioma on excess risk and on models that explicitly consider both 1) concentration of asbestos and 2) temporal factors such as duration of exposure, EPA	

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	would take a unified and scientifically rigorous approach to the risk assessments. All the elements required for such a unified approach are already available. • Base IUR for both lung cancer and mesothelioma on excess risk model, not extra risk model.	
4.32 **Risks are underestimated due to lack of an unexposed group for internal analyses**		
63, 92	**PUBLIC COMMENTS:** • Internal exposure-response analyses within the cohorts, reduces bias and confounding. However, none of the included studies had an unexposed internal reference group. While analyses by cumulative exposure allowed meaningful exposure-response determinations, risks are likely underestimated due to this lack of an unexposed group for internal analyses. For example, the SC study (Hein et al. (2007), Table 3) shows an excess risk of lung cancer (SMR=1.54, 95% CI 1.07–2.15) among workers in the lowest category of cumulative exposure (<1.5 f/cc-year) when compared to the US population.	Hein et al. (2007) Table 1 shows that the range of cumulative exposure in this cohort was 0.1 – 699.8 f/cc-years and the analyses of this cohort that EPA considered did not rely on categorical exposure analyses, rather the exposure was modeled as a continuous variable across the whole range of cumulative exposure values. Therefore, EPA does not believe that the cancer potency values derived from this cohort underestimate risks in the manner the commenter suggests.
4.33 **Use a more appropriate "midpoint" for the highest exposed category**		
SACC	**SACC COMMENTS:** • High exposures may have an undue influence on the overall model fit. • Recommendation 51: In the fit of the linear model to grouped data, set the "midpoint" for the highest exposed category to be the median or average exposure for individuals belonging to the group. The IURs estimated from the linear model were generally higher and thus using them would be more health protective. Furthermore, if EPA is going to continue to report the grouped linear model results, the analysis should be redone to use a more appropriate "midpoint" for the highest exposed category that better reflects the typical	Following this and other SACC recommendation, EPA changed (where it was able to obtain data) the midpoint of the exposure groups to the mean. EPA also notes that published simulation results (Richardson and Loomis (2004) show that midpoint and mean are, in general, both reasonable. EPA also provided more details of modeling in Appendix J.

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	exposure for individuals belonging to that group. The median of exposures in the category, rather than the midpoint of the range, is a more appropriate estimate. The write-up of this analysis in Appendix J also needs to be better documented.	
4.34 **Method for correcting for underascertainment of mesothelioma**		
SACC, 34, 39, 40, 65, 90, 92	**SACC COMMENTS:** • The DRE acknowledges the challenge of under-ascertainment of mesothelioma and EPA's approach to adjust the mesothelioma unit risk by 1.39 (0.80–2.17). This adjustment for mesothelioma ascertainment is likely too low. The sensitivity of death certificates for identification of malignant mesothelioma is approximately 40–50% for deaths prior to ICD-10 and 80% in the initial years that followed the advent of ICD-10 in 1999. Importantly, most of the deaths in both textile cohorts occurred before the application of ICD-10, so that the earlier time period under-ascertainment estimates would apply to most of the mortality experience of the cohorts. Hence, the adjustment for mesothelioma under-ascertainment should be closer to 2.0 for the time periods covered by the relevant mortality studies. **PUBLIC COMMENTS:** • EPA's correction for under-ascertainment of mesothelioma was inappropriate and would be obviated if EPA had used a relative risk model for mesothelioma. If EPA's concern is correct, it provides a compelling argument against using its absolute risk model for mesothelioma and justifies using a relative risk model for mesothelioma. (34-29) • The method for deriving the correction factor of 1.39 was highly dependent on assumptions about the number	According to other SACC recommendations, EPA changed its approach to use North Carolina data in chrysotile IUR calculations and used post-1999 data in the analysis. For reasons articulated by this SACC recommendation, mean under-ascertainment factor (1.39) is more appropriate for this situation, and EPA continued to use this factor. As to suggestion by a public commenter of a relative risk model, EPA have used absolute risk model for mesothelioma since 1986, and SACC found this model appropriate to use (see comment 4.31). EPA clarifies that the perception of lack of significance is a misunderstanding that this is an adjustment factor and testing of a statistical hypothesis is thus, not appropriate.

	of missed mesothelioma cases, particularly peritoneal mesotheliomas. Insofar as peritoneal mesotheliomas are rarely, if ever, seen among chrysotile-exposed cohorts, this correction factor is inappropriate for use in chrysotile asbestos risk assessment. EPA provided no justification for using it in the DRE. Kopylev and colleagues provided another, smaller correction factor based solely on underestimation of mesothelioma cases on death certificates, and not on the number of missed peritoneal mesothelioma cases. EPA chose not to use that smaller correction factor, even though, according to its own reliance materials (Kopylev et al. (2011), it would have been more appropriate. • Kopylev et al. cautioned "The mean ratio of 1.39 implies that the estimated risk of exposure to the Libby amphibole asbestos would be approximately 1.4 times larger if all decedents for whom medical information and pathology samples would have supported a diagnosis of mesothelioma had been identified." (Kopylev et al. (2011). EPA erroneously invoked an implausible correction factor to deal with possible mesothelioma under-ascertainment in the North Carolina and South Carolina textile cohorts, while it ignored the studies of the Quebec chrysotile asbestos miners (Liddell et al. (1997) and Balangero chrysotile asbestos miners (Ferrante et al. (2020; Pira et al. (2017) in which all decedents for whom medical information and pathology samples supported a diagnosis of mesothelioma were identified, and in which under-ascertainment of mesothelioma cases was not an issue. • EPA should provide an appropriate justification for the need for an artificial inflation factor to compensate for under-ascertainment of mesothelioma incidence. In the analyses, all mesothelioma risk is assigned to exposure from the studied workplace regardless of time spent at that workplace, thereby inflating the risk associated	

	with site-specific exposure. There is no way to adjust for this over-estimation of risk, but EPA should not compound the problem by artificially inflating mesothelioma incidence. • It is unclear why EPA includes a risk multiplier derived from historical datasets to account for potential undercounting of mesothelioma cases in the current risk assessment, given that only the 4 mesothelioma deaths from the NC cohort that were coded according to the ICD-10 were used to derive the chrysotile asbestos IUR value (p. 144). The Draft RE for Asbestos states: "EPA modeled the exposure-response for mesothelioma using data from 1999 onward when ICD- 10 was in use" (p. 144). Exposure-response data prior to 1999 (which includes the 4 pleural cancers observed in this cohort) were excluded from EPA's analysis. • The risk multiplier value of 1.39 does not appear to be statistically significant (CI: 0.8–2.17). Further review and discussion of this issue is warranted. • While the mean ratio of the posterior distribution is 1.39, it was not statistically significantly different than 1. In fact, it was estimated with 90% probability that the true ratio is between 0.80 and 2.17. Thus, the possibility of over-counting mesothelioma cases also exists. Furthermore, Loomis et al. (2019) attempted to reduce undercounting of mesothelioma by examining death certificate data for any mention of mesothelioma and for codes often used before there was a specific ICD code for mesothelioma. Therefore, without specific evidence of undercounting of mesothelioma among the textile's studies, EPA has no basis to assume this occurred. • It would be beneficial to further understand the specifics behind EPA's multiplier of risk for mesothelioma deaths before and after the introduction of ICD-10. This multiplier is based on the Libby Worker cohort and is said to be agnostic to fiber type, but this should be	

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	confirmed given the potential implications of EPA's multiplier of risk of 1.39 (CI = 0.8–2.17). Interestingly, if the confidence limit (precision of which is not specified) has a lower limit of 0.8, does that mean EPA would 'remove' cases as a false positive if the lower bound were used? (p. 151, lines 5587–5592). • EPA's risk evaluation likely underestimates mesothelioma mortality, even with the current adjustment in the model. The 1.39 multiplier appears more appropriate for studies using death certificates coded using ICD-10 codes but seems too low for studies prior to ICD-10.	
4.35 **Male and female lifetables are different**		
39	**PUBLIC COMMENTS:** • The original IUR developed in 1986 was based on separate lifetable analyses in males and females, as shown in Table 1 in comment letter #39. Since male and female lifetables are distinctly different, this approach is reasonable, but does not appear to have been adopted in the current Draft RE for Asbestos. If not, why not?	Since 1986, the EPA has changed its approach and lifetable analysis for combined males and females is routinely used, so EPA followed recent EPA precedent. Also, the difference between male and female lung cancer rates in recent lifetables is less pronounced than in 1986.
4.36 **Consider effect modification by age**		
39, 42	**PUBLIC COMMENTS:** • Effect modification by age refers to the phenomenon that the RR of exposure often depends upon age. For many exposures, RR at older ages is significantly lower than RR at younger ages. This phenomenon occurs, not because the absolute risk associated with an exposure decreases, but because the background risk increases rapidly. Analyses of the same data used by EPA in the current Draft RE for Asbestos shows that the RR associated with a given cumulative exposure to asbestos is highly dependent on age. This dependence of RR on age has a huge impact on the estimation of IUR based	EPA has identified the best available data to describe the cancer potency factors for lung cancer and mesothelioma and applied those potency factors in the lifetable analyses across all age groups after accounting for a 10-year lag in exposure for lung cancer. EPA did not have reasonably available data on age-specific cancer potency factors, but EPA did use the best available data on age-specific cancer incidence rates and age-specific mortality data to derive the IUR. The IUR, and the partial lifetime estimates of the IUR, reflect the combination of the relative risk of lung cancer and the absolute risk of mesothelioma. As the risk function for

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	on life-table analyses. Thus, even if the SC textile workers' cohort is considered to be appropriate (which it is not) for the lung cancer IUR, the analysis used by EPA in the Draft RE for Asbestos leads to unreliable results and to a large over-estimation of the true IUR developed with proper adjustment of effect modification by age. • The incidence of pleural mesothelioma increases with age (even in unexposed cohorts), just like every other cancer.	mesothelioma directly depends on age at first exposure, the partial lifetime IUR decreases with increasing age at first exposure as would be expected since the fibers have less time to initiate and promote cancers.
4.37 **Considering detailed temporal aspects of exposure for lung cancer exposure-response model**		
39	**PUBLIC COMMENTS:** • EPA's lung cancer risk analyses are based on an exposure-response model in which exposure is measured as cumulative exposure in f/ml-yr. It is now generally recognized that cumulative exposure, which is a product of intensity and duration of exposure, is a poor measure for the understanding of exposure-response relationships and that, whenever possible, intensity of exposure should be considered separately from time-related factors in exposure, such as duration of exposure and time since exposure ceased. This is the approach taken by EPA for the derivation of the IUR for mesothelioma. When individual-level exposure estimates are available, such analyses are always possible, although perhaps more difficult than traditional analyses using cumulative exposure. Individual-level exposure estimates are available in EPA's chosen cohort for lung cancer, the South Carolina cohort. Following Richardson (2009), why does EPA not consider detailed temporal aspects of	EPA did not have access to the temporal or intensity data necessary for the suggested approach to modeling.

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	exposure for lung cancer, as it has done for mesothelioma in the NC cohort? • Base both lung cancer and mesothelioma analyses on detailed exposure histories and on models that explicitly incorporate both intensity of exposure (concentration) and temporal factors, such as duration of exposure and time since exposure ceased. For mesothelioma, EPA already does this with the Peto-Nicholson model (except that an extra term will have to be introduced into the model to incorporate a non-zero background rate). For lung cancer, Richardson (2009) has already applied this approach using the two-stage clonal expansion (TSCE) model to the South Carolina textile workers' cohort, the very cohort on which the current IUR for lung cancer is based. • In parallel with the use of the Peto-Nicholson model for mesothelioma, use a model for lung cancer that takes individual-level exposure into account and recognizes that temporal pattern of exposure is important in determining risk.	
4.38 **Clarify how lag period is incorporated**		
SACC, 65	**SACC COMMENTS:** • Recommendation 103: Clarify how the exposure lag of 10 years is incorporated into the dose response modeling and discuss the influence of this assumption on final estimates. **PUBLIC COMMENTS:** • EPA used a lag in their analysis for lung cancer "to exclude recent exposures since lung cancer effects usually take at least 10 years to become apparent" (p. 137, ln. 5030-5032). However, it isn't clear that such a lag was done for mesothelioma, where the latency period is even longer. There is a factor in the model for	The risk evaluation was updated to clarify that cumulative exposure lagged by 10 years was used in lung cancer results reported for all the cohorts (Tables 3-3 to 3-8). For mesothelioma, the Peto model (Section 3.2.4.4.1) shows that there is no lag, as there is no cumulative exposure metric to be lagged.

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	time since first exposure (p. 137, ln. 5062-5065) but it is unclear if this is a lag (does not appear to be).	
4.39 **Latency of mesothelioma**		
42	**PUBLIC COMMENTS:** • Some have postulated that the latency of mesothelioma maybe 30–35 years or even as high as 45 years. It is highly unlikely that the latency is longer than 40 years, except for perhaps radiation, but that has also been questioned in recent years. Without a lung biopsy, spontaneous mesotheliomas are indistinguishable from mesotheliomas due to asbestos exposure. Given the few workers with appreciable exposure after about 1975–1980, it is much more likely that any mesotheliomas after 40 years of the date of last exposure are spontaneous instead of the suggestion that the latency continues to get longer than once thought.	EPA agrees that the latency period for mesothelioma may be very long and notes that the detection of the maximum latency period necessarily depends upon the length of follow-up for disease-specific mortality.
4.40 **Smoking as a confounding variable**		
SACC, 39, 42, 65, 71, 76, 82	**SACC COMMENTS:** • While the text states that smoking is not an important confounder because it is not correlated with exposure, it would be better to have this statement further supported. The SACC wondered if there are any data, even on a sample, that could be used as support for this assumption. There is literature on the prevalence of smoking in certain workers, and this should be used at least as a possible estimate (Olsson et al. (2020). Similarly, age at which a worker started (and stopped) smoking may be more relevant for lung cancer than the age at which that individual started (and ended) working in an asbestos facility, and this aspect should be at least discussed (Girardi et al. (2020). Recommendation 69: Further discuss and justify the assumption that smoking	Regarding the potential for smoking to confound lung cancer risks in occupational cohorts, EPA acknowledges that confounding of the asbestos-lung cancer relationship is certainly a theoretical possibility and such comments are reasonable. However, decades of occupational epidemiology studies have shown few examples of any meaningful confounding of occupational exposures by smoking. The following long citation from Blair et al. Blair et al. (2007) summarizes a lesson in understanding potential confounding: "Confounding occurs when a factor is associated with the outcome in the absence of the exposure of interest and also with the exposure of interest. For confounding to occur, the factor must be a risk factor for the outcome and also correlated with the exposure of interest (Checkoway et al. (2004). What may not be as well appreciated is that for confounders to have much of an impact, both associations

	is not correlated with occupational exposures to chrysotile asbestos. **PUBLIC COMMENTS:** • In studies of lung cancer in which smoking was considered and controlled for among these workers, 12 case-control studies (Corbin et al. (2011; Guida et al. (2011; Consonni et al. (2010; Macarthur et al. (2009; Richiardi et al. (2004; Matos et al. (2000; Swanson et al. (1993; Morabia et al. (1992; Benhamou et al. (1988; Vineis et al. (1988; Lerchen et al. (1987; Williams et al. (1977) and two cohort studies (Veglia et al. (2007; Hrubec et al. (1995; Hrubec et al. (1992) reported no increased risk for lung cancer when compared with the general population. • During the lung cancer epidemiology for the era in question (the 1940s to 2000s), a substantial portion of the male worker population smoked. Without a comprehensive smoking history for each person or a comprehensive knowledge of the exposure to various forms of asbestos (and other airborne carcinogens), these studies cannot be used to identify a "chrysotile only" potency factor for lung cancer. As discussed in Goodman et al. (1999), there can be considerable heterogeneity in smoking habits between occupational groups and the controls. Other potential confounders such as a person's smoking history (pack-years, the age they started and the age they stopped) should be considered. • The confounding role of smoking in lung cancer is downplayed. This is incorrect when considering both epidemiological and mechanistic studies which point to critical roles of cigarette smoke in impairing clearance of asbestos fibers from the lung and initiation of these tumors (Mossman and Gee (1989). • Unlike for mesothelioma, differences in lung cancer mortality levels are highly sensitive to cigarette	(*i.e.*, risk factor for the disease and correlation with the exposure of interest) must be strong (Breslow and Day (1980). If this is not the case, the impact of confounding cannot be large. Situations fulfilling these requirements are not common. Despite these rather stringent requirements, we find that many scientific discussions about potential confounding seem to assume that it is common, and its impact is sizable. Typically, the potential for confounding is hypothesized because some putative risk factor for the outcome of interest, or because some factor thought to be correlated with the exposure of interest has not been addressed in the study design or in the analyses. For example, in evaluating a study of a specific pesticide and lung cancer risk, suspected or established lung carcinogens (with no evidence of a linkage with the pesticide of interest), or other exposures that may coincide with the pesticide of interest (with no indication that they cause lung cancer) may be suggested as possible confounders. In such discussions, it is unusual for both associations to be considered and even rarer for the magnitude of these associations to be evaluated and for supportive data to be provided. In occupational epidemiology, tobacco or other occupational exposures are commonly raised as potential confounders, particularly with retrospective cohort studies, since these studies often lack information on these factors. However, even without direct information on their occurrence or magnitude in the population under study, the possible impact of such confounding can be estimated. For example, consider tobacco use as a confounder. Axelson (1978) made an extremely important contribution to this issue when he demonstrated that confounding from tobacco use in occupational studies of lung cancer was unlikely to entirely explain relative risks greater than 1.6. So, even without information on tobacco use, the Axelson approach

	smoking rates of cohort members, and this may explain some of the differences between predicted and apparent excess numbers of lung cancer rates. • There is no mention of the multiplicative effect modification of smoking on risk for mesothelioma and lung cancer. EPA infers effect modification by smoking via noting that smokers are a potentially susceptible population (*e.g*, p. 23, ln. 978-983), but they do not account for the potential multiplicative effect of smoking on risk estimates. • EPA should acknowledge and analyze a relationship between cigarette smoking and mesothelioma. Commenter cites detailed analysis by Moolgavkar and colleagues of the mixed evidence of an association between smoking and mesothelioma.	Axelson (1978) could be used to set boundaries regarding the likely impact of smoking confounding. This approach was further evaluated and extended to additive models by Gail et al. (1988). Using these approaches, the occurrence and likely magnitude of confounding by tobacco can be reasonably estimated because we have a considerable amount of information on relative risks from tobacco use for many diseases, as well as information on tobacco use by various occupations or exposures (Brackbill et al. (1988); Stellman et al. (1988). With this information, it is relatively easy to estimate the potential impact of confounding by smoking, as suggested by Axelson (1978), thus, negating the need for pure speculation. Kriebel et al. (2004) extended this technique of indirect adjustment in a quantitative evaluation of the possible effects of confounding by tobacco and alcohol use in occupational studies. They concluded that changes of greater than 20% were unlikely. The potential for confounding by tobacco can also be evaluated by assessing the correlation between smoking and specific occupational exposures. This may not always be possible because the necessary information is often not available. However, Siemiatycki et al. (1988) evaluated the relationship between level of exposure to 10 common occupational exposures (sulfur dioxide, welding fumes, engine emissions, gasoline, lubricating oil, solvents, paints/varnishes, adhesives, excavation dust, and wood dust) and tobacco use using data from a case-control study in Montreal. They found no correlation between occupational exposure indices for any of these substances and smoking history. Of course, tobacco use could be associated with other occupational exposures, but these data suggest that a strong association between smoking and specific exposures is unlikely." EPA notes that in the IRIS Toxicological Review of Libby Amphibole Asbestos, EPA conducted specific analyses

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		designed to detect potential confounding and found no statistical support for such confounding in another cohort study of asbestos effects on lung cancer. The weight of the evidence is that the potential for meaningful confounding by smoking is small. EPA is confident that confounding by smoking is not an issue of concern in the analyses that support the derivation of the IUR. Regarding potential confounding of the relationship between asbestos exposure and mesothelioma, the commenter's citation of a few selected studies from the 1970's does not provide evidence of potential confounding. EPA is not aware of evidence of smoking confounding mesothelioma effects. EPA notes that IARC Monograph 100C (2012) on asbestos states "Malignant tumours arising in the pleural or peritoneal linings (diffuse malignant mesothelioma) have no association with tobacco smoking" and Cogliano et al. (2012) do not mention smoking as a risk factor for mesothelioma (Blair et al. (2007; Siemiatycki et al. (1988)
4.41 **Level of asbestos mortality in population**		
76, 47, 48, 51, 73, 92, 31, 58, 99, 86, 97, 57, 104	**PUBLIC COMMENTS:** • To evaluate the Draft RE for Asbestos IUR, one commenter applied it to previously studied cohorts for which exposure data have been collected and cancer incidence rates are known. They concluded that it is necessary to establish an IUR that will correlate better with known risks and existing epidemiology. • Based on the "high end" exposure estimates for the NC cohort, that the IUR predicted levels of excess cancer approximately 80 times higher than observed for	EPA derived the IUR using multiple Agency guidances as an upper bound of what happens at lifetime exposure starting from birth. Because IURs are upper bound estimates of risk, they are not suited to such post-hoc estimations of case counts provided by the commenters who appeared to use them as central estimates of risk. In assessing risks of less-than-lifetime exposures to chrysotile, such as for miners, the commenters should use the appropriate partial lifetime IUR values specific to the exposure scenarios. Applying a lifetime IUR to populations exposed in adulthood would likely explain the overestimation of risk observed by one commenter.

	mesothelioma and 3 times higher than observed for lung cancer. • For the Quebec miners epidemiological study, the overestimation of risks using the Draft RE for Asbestos IUR is considerable. And the Draft RE for Asbestos IURs predict a ratio between the upper bound estimations of lung cancer and mesothelioma risk to be 1 to 2.3, while the ratio observed in the epidemiological data for the cohort was 4.7 to 1, reversing the proportion. • The Draft RE for Asbestos chrysolite IUR applied to the new Italian cohort study (Ferrante et al. (2020) for 974 male workers from the Balangero mine resulted in a large overestimation of mesothelioma and lung cancer cases compared with those observed for the cohort. Whereas, the average IUR from the Berman and Crump (2008a) and Hodgson and Darnton (2000) central tendency estimate closely agreed with the observed Balangero cases. • The proposed IURs predict the relationship between excess mesothelioma and lung cancer cases to be "reversed" from what was observed for the NC cohort used to derive the IURs. The ratio between lung cancer and mesothelioma was observed as 13.2 to 1, while the proposed IURs (considering the underlying EPA IURs separately for lung cancer and mesothelioma) would predict a ratio of 1 to 2.3. The ratio predicted using the Berman and Crump and Hodgson and Darnton IURs was 10 to 1, matching the published data with reasonable accuracy. • Draft RE for Asbestos understates the risk to public health. • Although EPA has determined that asbestos presents unreasonable risks under the limited COUs it addresses, several commenters are concerned that these risks are greatly understated.	EPA has revised the derivation of the IUR to include the linear model for lung cancer and has developed adjustment factors to account for other cancers. In response to public comments on ratio of lung cancer and mesothelioma, EPA notes that both in 1988 EPA risk evaluation for general asbestos (U.S. EPA (1988a), and in recent IRIS risk assessment of Libby Amphibole asbestos (U.S. EPA (2014c), lifetime risk of mesothelioma exceeded lung cancer risk, so this risk evaluation of commercial chrysotile asbestos is consistent with prior EPA assessments. EPA prioritized Asbestos as one of the first 10 chemicals to undergo risk evaluation under TSCA, recognizing the importance of evaluating risks from asbestos to human health and the environment from asbestos. EPA considered all reasonably available information and considered all public comments and SACC input on the draft risk evaluation in reaching final conclusions on risk for current conditions of use of chrysotile asbestos in Part 1 of the risk evaluation for asbestos. EPA noted uncertainties throughout and accounted for those uncertainties where possible. EPA will further consider risks in Part 2 that are related to legacy uses and associated disposal for all 6 fiber types included in AHERA II definition.

	• The Draft RE for Asbestos sets aside the linear dose-response risk model without evidence that the exponential risk model is better. The Draft RE for Asbestos also considers a single fiber type among the six asbestos types in commercial use; two of the four cancers recognized by IARC as asbestos-related are ignored; nonmalignant disease is ignored; and legacy asbestos, a particular risk in public schools, is set aside for another and uncertain day. • Some of the outdoor exposure scenarios for consumers and bystanders might shift from a "no unreasonable" finding to an "unreasonable" finding if the recommended modifications to the exposure scenarios were implemented. • EPA is obligated to determine if underestimation is the case and to what degree. The non-cancer toxicity of chrysotile may be greater than that of Libby amphibole asbestos, and there is uncertainty that the IUR for chrysotile asbestos may not fully encompass the health risks associated with chrysotile exposure. • The death toll from asbestos exposure in the US remains alarmingly high. Furuya et al. (2018) reported that asbestos-related diseases are causing on average 39,275 deaths in the US annually, more than double the previous estimates of 15,000 per year. • Asbestos is likely the most hazardous substance in widespread use since the industrial revolution and is responsible for millions of deaths worldwide (51-183, 86-2, 97-1). Asbestos has taken the lives of over a million Americans and continues to kill nearly 40,000 people in the US each year. • Asbestos use has declined but the Draft RE for Asbestos indicates that the remaining active uses result in asbestos exposure by over 1.5 million workers and up to 32 million "do-it-yourself" consumers who replace asbestos brake pads and clutches. This is without	

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	counting the millions of Americans who are exposed to legacy asbestos but are outside the scope of the EPA evaluation. • From 1991 to 2017, more than one million Americans died from preventable asbestos-caused diseases (Ghdx (2017). These deaths are only a snapshot in time; the total number of deaths during the 100+ years of asbestos use is much larger. • Despite the elimination of many asbestos products due to corporate liability, asbestos deaths—calculated to be nearly 40,000 per year as noted above—remain high, demonstrating that millions of Americans have been significantly exposed to asbestos in the past and many others are exposed now. • Based on OSHA's risk estimates for worker deaths from exposure to asbestos in the US, workers will continue to die at rates higher than 1 in 10,000. There are countless others not covered by OSHA who work with or use products containing asbestos. Consider legacy asbestos found in buildings and products still in use such as lamp sockets, floor covering, cat box fill, braking mechanism in washing machines and cars, furnaces, dishwasher, asbestos cement water pipes, and many, many more products. Because many of these products have been brought into the US while others of these products were manufactured by workers in the US, they are also used, maintained, and repaired by workers in the US causing additional exposure from such consumer products and/or to environmental levels of asbestos which are not accounted for in the current EPA risk estimates.	
4.42 **Consider conducting meta-analyses**		
76	• In its Cancer Risk Guidelines, U.S. EPA (2005) emphasized the importance of meta-analysis: "This	EPA developed data quality evaluation criteria and selected studies of best quality for deriving the chrysotile IUR (see

	technique is particularly useful when various studies yield varying degrees of risk or even conflicting associations (negative and positive). It is intended to introduce consistency and comprehensiveness into what otherwise might be a more subjective review of the literature." Although EPA has stressed the limitations of the meta-analysis approach, it has been repeatedly applied to asbestos epidemiology and risk assessment. • In particular, Berman and Crump (2008a, 2008b) and Hodgson and Darnton (2000) performed two of the most widely cited meta-analyses on asbestos exposure risk, not only considering duration and age of exposure, but also including fiber types, and in some cases, fiber dimensionality. • The commenter developed an Excel spreadsheet risk calculator, using the methods of Berman and Crump (2008b) and Hodgson and Darnton (2000) (linear approach), which performs specific risk calculations based on intensity, duration, and age of first exposure. The calculator was independently validated. The commenter found good agreement between the IURs that they calculated using their spreadsheet and observed cohort data, including the Quebec cohort (see comment letter for details) (76-16), and the Connecticut chrysotile asbestos friction products plant. • The Berman and Crump (2008a) method includes a maximum likelihood estimation (MLE) approach that allows consideration of the amphibole asbestos fraction in various mixed fiber cohorts, significantly expanding the number of studies for the meta-analysis and increasing the reliability of the potency estimations. The Hodgson and Darnton meta-analysis allowed inclusion of cohorts without individuals' detailed exposure information, relying on a cumulative exposure metric for the entire cohort. Both approaches yielded similar IUR levels (effectively validating both approaches) and	Supplemental Systematic Review File for human health hazard). SACC approved of this strategy by recommending use of NC and SC cohorts (see responses to Comments 4.10 and 4.13). EPA does not believe that a meta-analysis using more studies of lesser quality would yield better results.

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	averaging the IURs derived from Berman and Crump and Hodgson and Darnton would yield the central tendency estimation of the IUR for chrysotile at the level of 0.0225, approximately 70 times lower than the average value for crocidolite asbestos. • The commenter recommended that meta-analysis be included in the determination of the IUR for chrysotile asbestos, with due consideration of the statistical data quality for each of the included and excluded studies.	
4.43 **Include confidence statements for IUR values**		
SACC, 40	**SACC COMMENTS:** • As was done for previous TSCA chemicals DREs, EPA should provide confidence statements (High, Medium, or Low) for IUR values and risk estimates for each COU. Recommendation 77: Provide confidence statements for IUR values and risk estimates for each COU. The SACC seemed to express low-to-medium confidence in most hazard conclusions and risk conclusions for COUs in this DRE. Recommendation 78: Key elements of the conclusions presented in Section 4.5.2 and 4.5.3 should be included in Section 4 for clarity. • The SACC identified additional uncertainties and recommended that all uncertainties be classified with respect to the direction of bias. The factors likely to result in downward bias (underestimation) include: (1) focusing only on mesothelioma and lung cancer and omitting other cancers; (2) the IUR only characterizes cancer risk; (3) using mortality instead of incidence; (4) the form of the risk model (linear vs. exponential); (5) use of the linear risk model for mesothelioma; (6) under-ascertainment of mesothelioma; and (7) exposure measurement error in the cohort studies. The factors that	EPA believes it is important to use a consistent approach for risk characterization and risk determination. Categorical descriptors for risk estimates have not been used in risk evaluations under TSCA, and it would take substantial effort to develop criteria for categorical descriptors and the benefit is unclear to EPA. Asbestos particle sizes and analytical methodology have been described where necessary. Study quality criteria is described in Supplemental Files for Part 1 of the Risk Evaluation, which also include evaluations for each of the relevant studies. Regarding the Uncertainties enumerated by SACC: 1) EPA developed an adjustment factor to address other cancers (more details in Section 4.1 above) 2) The IUR only address cancer risk – by definition. Non-cancer hazards are now recognized in the document (more details in Section 4.1 above) 3) The IUR was revised and now addresses cancer incidence (more details in Comment 4.4. and EPA response above)

	may result in upward bias (overestimation) include (8) fiber potency as a function of length and width, and (9) fiber lengths in current COU exposures being potentially shorter than fiber lengths from exposures in the textile mills. Uncertainties where the direction of bias have not been classified include: (10) exposure measurement; (11) amphibole and non-amphibole asbestos contamination (or using chrysotile to represent all types of asbestos); (12) not considering dermal exposures; (13) mesothelioma potency adjustment; and (14) the assumption of no mesothelioma background. More explicit consideration and presentation of sources of bias and uncertainty is needed, including estimating the magnitudes of the two sources of bias identified and discussed in the DRE, and then using this information to adjust the IUR. **PUBLIC COMMENTS:** • Additional variables that impact the magnitude of the IUR were not well described (*e.g* multiplicative effect modification of smoking, absolute/relative risk, lag period, statistical analysis, and the magnitude of the risk multiplier pre-/post-ICD 10). • It is not obvious whether or to what extent the estimated IUR value for chrysotile, which is based solely on asbestos textile manufacturing settings, is applicable to imported chrysotile-containing brake repair and replacement scenarios. This is a major source of uncertainty in EPA's risk evaluation that should be acknowledged and discussed in more detail with respect to these COUs. • The possibility that the North and South Carolina cohorts may also have been exposed to amphibole asbestos represents a major source of uncertainty that should be acknowledged and transparently described. The cumulative exposure of the four mesothelioma	4) The IUR is now based on the linear model for lung cancer (more details in Comment 4.29 and EPA response above) 5) The IUR uses the Peto model for mesothelioma (more details in Comment 4.24 and EPA response above) 6) Underestimation of mesothelioma ascertainment is addressed using the adjustment factor in Kopylev et al. (2011) (see more details in Comment 4.34 and EPA response above) 7) Exposure measurement error and the potential for bias towards the null is acknowledged in the uncertainties section (see more details in 4.3.6 of the risk evaluation) 8) Fiber length issues related to toxicity are addressed by comparing the cancer potency values across industries (see more details in Comment 4.26 and EPA response above) 9) Fiber length issues related to COUs remain an uncertainty as the fiber concentration data on COU exposures are limited to PCM measurements which do not provided fiber length data (see more details in Comment 4.26 and response above) 10) See #7 above 11) The chrysotile IUR addresses chrysotile exposures. Comments suggesting amphibole contamination were considered, but not found to be credible (see more details in Comment 4.10 and EPA response above) 12) Dermal exposures were considered, but inhalation exposures were the focus of this evaluation (see more details in Comment 1.19 and EPA response above) 13) see #6 above

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	cases should also be reported for sake of fully transparency.	14) The assumption of no mesothelioma background rate is implicit in the Peto model that EPA has relied on since the 1986/88 IRIS assessment of general asbestos. Note that comments submitted regarding people who had never been exposed having asbestos fibers in their lungs strongly suggest that recollection of no asbestos exposure is not reliable and undermines the contention that there might be a background rate of mesothelioma. (See more details in Comment 4.31 and EPA response above).
4.44 **Adjust IUR based on potential bias for each individual uncertainty**		
SACC	**SACC COMMENTS:** • Recommendation 53: Avoid using one bias term to compensate for others. Recommendation 54: Include the additional sources of bias identified by the SACC in the discussion of uncertainties and discuss how these biases will change the direction and magnitude of estimated IURs. Data should be used to inform the amount and direction of potential bias for each individual uncertainty, and then the IUR estimate adjusted based on this more detailed assessment. There should be a section explaining how this "compensation of bias" was statistically performed and where the suggestion came from (Draft RE for Asbestos p. 196). There is no direct relationship between the two sources of bias and the largest IUR. Data related specifically to the magnitudes of the two sources of bias addressed in the risk evaluation should be used to adjust for them. Data on the time between when lung cancer was identified and subsequent death from lung cancer could be used to adjust the risk estimates based on mortality data to pertain to incidence. Data from studies of human populations on cancers other than lung and	Following this and other SACC recommendations, EPA avoided using one bias term to compensate for other terms and developed separate approaches for different biases (see response to SACC recommendations in comment 4.1)

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	mesothelioma possibly caused by asbestos could be used to adjust risk estimates to account for these cancers.	
4.45 **Other suggested changes to content**		
42, 71, 82, 103	**PUBLIC COMMENTS:** • EPA should apply genomic risk analysis tools for all asbestos-associated cancers. Mesothelioma is often the focus of asbestos-related risk assessment. However, other asbestos-associated cancers exist. All should be part of risk assessment. Comments below should be read in that context. EPA's risk assessment analyses also should include recent work by Kenneth T. Bogen, Dr. P.H., regarding the role of genomic regulatory mechanisms (*i.e.* epigenetics) in the development of cancers. As explained in his work, and the work of others, expression of genes and transcription can be amplified or silenced by regulatory genomic mechanisms that do not directly mutate DNA. • On p. 133 (ln. 4923–4924), the statement "making the observance of mesothelioma in a population a very specific indicator for asbestos exposure (Tossavainen (1997)" is included. Likewise, on p. 134 (ln. 4940–4941), it is incorrectly stated that radiotherapy is "the only other known risk factor for mesothelioma, and this rare exposure there are unlikely to be a confounder" (note grammatical errors). These statements/paragraph should be modified to include more recent observations showing the importance of other environmental minerals such as erionite and fluoroedenite, spontaneous mutations, and germline mutations in causation of mesotheliomas (Carbone et al. (2019; Mossman et al. (2013). Peritoneal mesothelioma is less frequently	EPA stated in the Problem Formulation document that genomic data was out of scope and the chrysotile evaluation would rely on epidemiologic data. SACC agreed with this approach. EPA has corrected the grammatical error. EPA has edited the text on other causes of mesothelioma to acknowledge that erionite and fluoroedenite are also causes of mesothelioma. EPA considers health effects of asbestos, such as cancer, as severe and irreversible. This is not in conflict with peer-reviewed literature.

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	associated with asbestos exposure (Carbone et al. (2019). • On p. 156 (ln. 5729–5730) EPA stated "There is some evidence of a predisposition for mesothelioma related to having a germline mutation in BAP1 (Testa et al. (2011)." This sentence should be expanded to include additional germline mutations in genes regulating DNA repair such as MLH1, MLH3, TP53 and BRCA2, that have been discovered in the last decade (Carbone et al. (2019; Mossman et al. (2013). • The Draft RE for Asbestos contains several statements inconsistent with the peer-reviewed scientific literature. "The Agency also considered that the health effects associated with asbestos inhalation exposures are severe and irreversible" (Draft RE for Asbestos ln. 731–733) conflicts with the effect of dose-response observations in human cohorts and animal inhalation experiments (Bernstein et al. (2020a, b; Mossman et al. (2013). These studies indicate thresholds for exposure to asbestos at low concentrations. • Gradient of association with asbestos by anatomic site of mesothelioma: The fraction of mesothelioma cases attributable to asbestos exposure differs by time period and geographic area due to differences in the prevalence of asbestos exposure(s) and the magnitude of detected association(s) – Pleura – Strongest association with asbestos exposure (~80% among men and 20% among women in the U.S. attributable to asbestos exposure) – Peritoneum – Weaker association with asbestos exposure (<10% among men and <1% among women in the US attributable to asbestos exposure).	

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4.46 **IUR – general comments**		
SACC, 42	**PUBLIC COMMENTS:** • "[T]his document is among the most thoroughly transparent analyses that I have read in my 40-year career as a risk assessor…." • "It is refreshing to see the Agency be thorough concerning wanting to make the uncertainties in the assessment of the IUR transparent. For the topics discussed, in my view, the agency has done a reasonable job of identifying many of them."	EPA thanks the commenter for these acknowledgements.
4.47 **Clearer documentation of IUR is needed**		
SACC, 65, 82	**SACC COMMENTS:** • Add a graph and discussion of the potency factors, exposure concentrations (ECs), and lifetime unit risks across the five cohorts because it is challenging to digest these differences as currently presented. Finally, reporting the estimates relative to the target level would make it easier to digest the reported results. • Recommendation 92: Present the findings of Table 3-8 in a graph, reporting risk estimates relative to the target level. • Recommendation 93: Provide clearer documentation for IUR calculations, such as those presented in Appendix J. **PUBLIC COMMENTS:** • Table 3-13 (p. 155) shows the lifetime IUR for chrysotile asbestos. There is no discussion of how this IUR relates to other environmental or societal risks. This is necessary for interpretation of data.	Following SACC suggestions, EPA changed Table 3-8 to present lung cancer and mesothelioma potency factors from 5 considered cohorts instead of cancer risks. Because goal of Table 3-8 is to present comparisons between textile and mining industries, the potency factors are sufficient for the goal. EPA also updated Appendix J providing more details on the modeling. EPA provided missing details on lag and clarified presentations throughout modeling sections. The IUR is a statistic that reflects risk of mesothelioma, lung cancer, and other cancers relative to exposure to chrysotile asbestos. It is not clear how environmental or societal risks could be accounted for in the IUR and no specific recommendation was made in the public comment.

5. Human Health Risk Characterization

Charge Question 5:

5.1 Please comment on whether the analysis presented supports the conclusions outlined in the draft risk characterization section concerning asbestos. If not, please explain the limitations of these conclusions, and whether there are alternative approaches or information that could be used to further develop the risk estimates within the context of the requirements stated in EPA's Final Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726) (Section 4).

5.2 EPA presented overall human health risk conclusions (Section 4.6.2) based on risk estimates for cancer. Please comment on EPA's approach including any alternative considerations for determining and presenting risk conclusions including the risk summary tables (Table 4-57 and 4-58).

5.3 Please comment on the clarity and validity of specific confidence summaries presented in Section 4.3.

5.4. Throughout this charge we have asked reviewers to comment on the uncertainties and data limitations associated with the methodologies used to assess the environmental and human health risks. Please comment on whether that information has been carried forward to the characterization of the risk evaluation such that the strength of the brake conclusions is characterized in a clear and transparent manner (Section 4.3).

5.5 Please comment on any other aspect of the environmental or human health risk characterization that has not been mentioned above (Section 4).

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5.1	**Provide more information on assumptions**	
SACC	**SACC COMMENTS:** • The health risk estimates calculated were only for chrysotile asbestos and did not include the likelihood of exposure to amphibole asbestos and exposures to mixed fibers from other uses (industrial talc, drinking water pipes, etc.). Specifically, SACC members recommended that more information should be provided on the assumptions embedded in the health risk derivations. Recommendation 59: Provide more information on the assumptions embedded in the health risk derivations. • The assumptions on PPE use have a large effect on the risk determinations. Table 4-38 clearly shows the effect of assuming PPE use on risk determination. Recommendation 87: Include a more detailed	For evaluation of the COUs included in Part 1 of the Risk Evaluation for Asbestos (focused on chrysotile asbestos), EPA applied an IUR specific to chrysotile asbestos. EPA believes Part 1 of the Risk Evaluation has been revised throughout to make the focus on chrysotile asbestos more explicit. As a result of the court decision in Safer Chemicals Healthy Families v. EPA, 943 F.3d 397 (9th Cir. 2019), the Agency will evaluate legacy asbestos uses and associated disposals of those uses in Part 2 of the Risk Evaluation for Asbestos. As a part of that effort, EPA will apply an IUR that addresses asbestos fibers that continue to be present in legacy COUs.

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	examination of the actual levels of protection provided by respirators and take actual levels into account to the extent possible in calculating risks to workers wearing respirators. • The SACC considered the assumptions underlying PPE use scenarios to be unrealistic, therefore associated risk estimates should not be considered in the risk characterization. More realistic and likely scenarios should be included for evaluation of consumer and by-stander use of asbestos-containing brakes and gaskets.	While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a COU presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each COU, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1.
5.2 **Analysis supports conclusions**		
51, 73, 92, 101	**PUBLIC COMMENTS**: • Commenters applauded EPA's finding that for almost every COU evaluated, asbestos has been deemed to present an "unreasonable risk." • Decades of unbiased scientific research from around the world has repeatedly demonstrated that all asbestos exposure poses unreasonable risks (92-1). Industrial producers and users of chrysotile have tried to argue that the serpentine fibers are harmless and that only amphibole fibers pose cancer risks; EPA's analysis rejects that conclusion. • Commenters agreed with the Draft RE for Asbestos finding that nearly all ongoing commercial and consumer uses of asbestos reviewed by EPA present an unreasonable risk of mesothelioma and lung cancer,	EPA appreciates the comment.

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	particularly under the occupational COUs evaluated in the Draft RE for Asbestos and also for consumers.	
5.3	**Draft RE for Asbestos overestimates cancer risk**	
42, 60, 65, 68, 72, 95, 144	**PUBLIC COMMENTS:** • The chlor-alkali industry has a proven record of the safe use of asbestos within the chlorine production process. With the effective engineering and administrative controls currently in place, including respiratory protection, a scientifically-based risk assessment of the chlor-alkali industry's use of asbestos in chlorine production will demonstrate that this use does not pose an unreasonable health risk to workers. • One commenter does not believe that hundreds of thousands of persons each year in the future may be exposed to dangerous levels of asbestos. EPA discarded the OSHA PEL, generated inaccurate exposure scenarios, and derived a "new" cancer potency factor for chrysotile alone to conclude that occupational conditions for the six categories of workers evaluated by EPA (see Draft RE for Asbestos p. 26) are at "an unreasonable risk to health." • Even considering the short-term personal breathing zone (PBZ) exposures for chlor-alkali industry, the commenter considered the data to present "an incredibly narrow range of sample results for short-term, allegedly high exposure, sampling," well below the OSHA PEL of 0.1 fibers/cc. That means statistically, a high level of certainty for the results. Thus, the commenter did not find that the data supported a finding of "unreasonable risk." • EPA found an unreasonable risk to workers in several COUs (Table 4-54). However, the workers in these facilities are nearly all exposed to TWA concentrations well below the current OSHA PEL. As shown in Table	EPA based the risk calculations and the risk determinations made in Part 1 of the Risk Evaluation for Asbestos based on reasonably availably information including information provided by industry. As such, the Agency stands by its risk determination conclusions. EPA has also adjusted its estimates of exposed individuals in Part 1 of the Risk Evaluation for Asbestos based on public comment and reasonably available information. EPA derived the IUR using multiple Agency guidances as an upper bound of what happens at lifetime exposure starting from birth. Appendix K presents IURs for partial lifetime exposures starting at various ages. In regard to the OSHA PEL for asbestos, TSCA compels EPA to evaluate chemicals without consideration of non-risk factors (such as feasibility of meeting a standard) to determine whether they present unreasonable risk under the COUs. EPA's "no unreasonable risk" standard has not necessarily been met at the OSHA PEL.

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
	2-5, there were 650 PBZ samples collected between 1996 and 2017, for which the 50th percentile concentration was 0.006 fibers/cc, and the upper 95th percentile concentration was 0.05 fibers/cc (8-hour TWA full-shift samples). Therefore, those data do not support a finding of "unreasonable risk" considering the OSHA PEL (42-144). Exposure data presented by EPA does not identify any cohorts routinely exposed above about 1/10 to 1/2 the current OSHA PEL for asbestos (and the number of plausible workers is very low). • Draft RE for Asbestos Table 4-11 presents the ELCRs for workers stamping gaskets from sheets, using exposure data from two sampling durations (8-hour full shift; 30-minute short-term). This scenario is not important given the low airborne concentrations, the low potency of short, encapsulated chrysotile fibers, and the exposures of only one or two employees for a handful of hours per year. It genuinely should not be of interest to EPA. • Table 4-56 provides a summary of risk estimates for consumers and bystanders. Cancer risks were exceeded for all consumer and bystander UTV gasket replacement exposure scenarios (Draft RE for Asbestos p. 7437–7442). If the person conducting the work is not at risk, it is implausible that there would be bystanders at risk. Also, the number of bystanders multiplied by the risk estimate should equal at least one person getting cancer for a national regulation. • API "provided petroleum industry specific information which indicates that EPA has over-estimated risk both to workers and ONUs." • There are so many flaws in the derivation of IURs for chrysotile (presented in this document) that it is not	

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
	appropriate for anyone to categorize any of these exposures as "presenting an unreasonable injury to health." (42-141) In the Draft RE for Asbestos, the exposure estimates and new IUR for chrysolite asbestos overestimate risk to occupational workers and ONUs in general. EPA concluded that exposure to brakes and gaskets poses a "significant health hazard to workers," but the epidemiology and toxicology for that COU information do not support that claim. • The lifetime doses for any exposed persons will almost certainly be 1,000 to 10,000-fold less than those that might cause an asbestos-related disease. • One commenter noted that it is clear from the data in the EPA's document, that few, if any, persons in the US should ever again be exposed to chrysotile above trivial concentrations. Lifetime doses will almost certainly be 100 to 1,000-fold less than those that should cause an asbestos-related disease. Fewer than 100 persons in the US annually could have measurable exposure to asbestos today from brakes, gaskets, and packing (for various reasons). EPA found that the present an unreasonable risk to workers in several COUs in Table 4-54. However, the commenter concluded that the workers in these facilities are nearly all exposed to TWA concentrations that are well below the current OSHA PEL of 0.1 fibers/cc. • Based upon Table 4-15, it seems that EPA would conclude that the few employees working in sheet gasket stamping are not at any significant risk of harm. In light of the background risk of cancer being approximately 40%, historically, a risk to two workers of 10-4 is trivial. • Relying on the 1988 EPA risk assessment as a starting point may be perilous. The 1988 EPA risk assessment	

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	for "asbestos" mixed studies of different fiber types, and in so doing overestimated chrysotile risk by more than an order of magnitude for both lung cancer (Camus et al. (1998) and mesothelioma (Camus et al. (2002; Case et al. (2002). • The risk involved in the continued use of chrysotile, in limited products in which the fiber is encapsulated, involving exposure to small numbers of people, is small. The characterization as "unreasonably risky" is hyperbole. The use of the TSCA machinery may be clever, but the end results may bring consequences that are unintended. Do substitutes exist that offer the same level of safety to the worker and others as the proposed reduction of risk following chrysotile exposure? EPA's position and rationale for exposure reduction is not supportable.	
5.4 **Use of inhalation volumetric adjustment factor**		
16, 34	**PUBLIC COMMENTS:** • One commenter asked if it is appropriate to include an inhalation volumetric adjustment factor in the equation used to estimate cancer risk for workers; they had not seen the use of a volumetric adjustment factor in that kind of context. • In the current Draft RE for Asbestos, the adjustment factor for the different volumes of air inhaled by workers and those environmentally exposed (step 3 of the IUR process) is somewhat larger (3.04) in the current Draft RE for Asbestos than in U.S. EPA (1986), where an adjustment facto/r of 2.8 was used. This small discrepancy arises from the fact that the original adjustment assumed a 52-week work-year, whereas the current Draft RE for Asbestos assumes a 50-week work-year.	EPA routinely adjusts effects using a volumetric adjustment factor that account for faster breathing in occupational settings compared to non-occupational settings. The IUR is for continuous, lifetime, exposure based on a standard assumption of breathing 20 cubic meters of air per day (equivalent to 6.67 cubic meters per 8 hours). In applying the IUR to occupational scenarios, EPA adjusts the risks to account for an assumption of an occupational breathing rate of 10 cubic meters per 8 hours.

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5.5	**EPA's approach for risk calculation**	
92	**PUBLIC COMMENTS:** • Evaluating exposures to legacy asbestos separate from, and on a different track than, its evaluation of chrysotile exposures means that EPA will not look at the full exposure potential workers face. For example, workers can be exposed both at their job under current COU, during repairs that involve legacy asbestos at a facility, and when performing home renovations or DIY brake repairs. Failure to consider the health effects of legacy asbestos, alone or in combination with chrysotile exposures, violates TSCA.	In Part 2 of the Risk Evaluation for Asbestos that will focus on legacy uses and other fiber types, EPA will consider the reasonably available information and use the best available science to determine whether to consider aggregate or exposures for asbestos and will include in that consideration information from Part 1 and Part 2, as appropriate.
5.6	**Clarity and validity of specific confidence summaries presented in Draft RE for Asbestos Section 4.3**	
SACC, 90, 41	**SACC COMMENTS:** • Although members of the SACC disagreed with some of the conclusions reached, the assumptions, data gaps, limitations, and other sources of uncertainty in the risk characterization for workers were clear and easy to follow. The sensitivity analysis was useful where it was provided; the SACC recommended that sensitivity analyses be done in other areas with data limitations. The SACC recommended direct workplace visits to understand the conditions of asbestos use for future risk evaluations. • The current sensitivity analysis within the Draft RE for Asbestos was described by SACC members as more of a "what-if" investigation. A true sensitivity analysis would be facilitated via the use of Monte Carlo or similar sampling simulations. • Given the uncertainty around availability, use, and effectiveness of appropriate respirator protection, some SACC members recommended deleting the APF's in the exposure estimates and risk calculations (remove	EPA appreciates the recognition from SACC that the sensitivity analyses that were presented were clear, easy to follow, and a strength in the risk evaluation. EPA tried to provide examples, where possible, to show the impact of several of the assumptions and uncertainties. However, full probabilistic uncertainty analyses were beyond the scope of this risk evaluation. Following SACC recommendations, EPA's health risk characterization is based on incidence of all cancers causally related to asbestos exposure, and not just mortality from lung cancer and mesothelioma (detailed in Appendix M). The risk determination did consider non-cancer risks, and it is important to point out that non-cancer risks are not limited to deaths as the commenter suggests. While the commercial chrysotile asbestos risk evaluation did not quantify non-cancer risks, EPA recognizes that there are such risks and has noted that the point of departure (POD) for the critical non-cancer effect in the IRIS Toxicological Review of Libby Amphibole asbestos (U.S. EPA (2014a) was 2.6E-2 fiber/cc

	from Table 4-55). Another member, however, considered it appropriate to present risk with and without PPE because there are industries and individual facilities that comply with respiratory protection protocols. Recommendation 61: Clarify in Table 4-55 that risks under PPE use are potentially unachievable lower bounds that assume a comprehensive respiratory protection program is always in place everywhere. **PUBLIC COMMENTS:** • While it would have been a seemingly straightforward task, EPA made no attempt to validate their model (or their risk characterization) based on the disease risk in the populations of interest for the other COUs evaluated. For example, despite using company-specific data for their evaluation of risk in cohorts potentially exposed to asbestos during the manufacturing and use of gaskets, EPA did not attempt to determine if their risk estimation accurately reflected the observed risks in this population of workers. • The Draft RE for Asbestos notes that the estimated risks of death are conservative because they have not considered non-neoplastic asbestos-related diseases in their analysis. However, it "is well recognized" that asbestosis requires exposure beyond a threshold (Sporn and Roggli (2014; Roggli et al. (2010; Schneider et al. (2010). There is no convincing evidence that the low levels of exposure considered in the Draft RE for Asbestos cause or contribute to any level of asbestosis, let alone the levels that result in fatal pulmonary fibrosis. With respect to benign asbestos-related pleural diseases, only diffuse visceral pleural fibrosis has been associated with mortality and then only rarely (Manni and Oury (2014). There is no evidence that the level of exposure considered in this document cause or contribute to fatal diffuse visceral pleural fibrosis.	with a RfC of 9E-5 fiber/cc indicating that there can be health risks at low concentration of fibers.
5.7	**In-depth sensitivity analyses is a strength**	

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SACC	**SACC COMMENTS:** • A strength of this section is the in-depth sensitivity analyses presented in Appendices K and L that address factors such as age at first exposure, and various bystander scenarios. Many of the uncertainties need to be better documented and judgments made about the direction and magnitude of the bias that may result.	EPA appreciates SACC comments.
5.8 **Uncertainties, limitations, and strength of the risk conclusions (Draft RE for Asbestos Section 4.3)**		
SACC, 42, 64, 64, 95, 42, 91	**SACC COMMENTS:** • SACC raised several issues related to the assumption on which the health risk characterization in the Draft RE for Asbestos are based. These include restricting health risks examined to only lung cancer and mesothelioma mortality, calculating risks only for the chrysotile form of asbestos, not considering legacy uses of asbestos, and not accounting for aggregate exposures. These assumptions and their impact on risk estimates should be explicitly discussed in the risk characterization. Several uncertainties as well as lack of data make it difficult to evaluate the validity of the assessment of exposure and the discussion on confounding presented in the risk characterization section. Uncertainties with exposure data could be addressed with sensitivity analyses and with collection of more data. • Consider the confidence in the risk estimate when it is based on limited data. One SACC member suggested using categorical descriptors of risk estimates (*e.g*, high, medium, low) when data are limited or nonexistent. Provide a short summary section on the analytical methods used to quantify the various asbestos particle types and sizes. Discuss how the analytical	Following SACC recommendations, EPA's health risk characterization is based on incidence of all cancers causally related to asbestos exposure, and not just mortality from lung cancer and mesothelioma (detailed in Appendix M). EPA will consider risks for legacy uses (and associated disposal) and other fiber types of asbestos in Part 2 of the Risk Evaluation for Asbestos. Sensitivity analyses for exposure scenarios were conducted and described in Appendix L. EPA did not believe that collection of more data was necessary because there was sufficient information reasonably available to complete Part 1 of the Risk Evaluation for Asbestos using a weight of scientific evidence approach. EPA believes it is important to use a consistent approach for risk characterization and risk determination. Categorical descriptors for risk estimates have not been used in risk evaluations under TSCA, and it would take substantial effort to develop criteria for categorical descriptors and the benefit is unclear to EPA. Asbestos particle sizes and analytical methodology have been described where necessary. Study quality criteria is described in Supplemental Files for Part 1 of, which also include evaluations for each of the relevant studies.

	methodology has evolved over time and how that might impact study quality assessment. • In the risk characterization for environmental exposures, as the SACC has seen in previous chemical Draft REs, there is limited discussion of uncertainties and typically "worst-case" scenarios that are not considered. To be conservative, the Draft RE for Asbestos should favor "worst-case" risk estimates for low/no data COUs until the necessary data are obtained. Recommendation 96: Data gaps and related uncertainties should be discussed and have greater weight in the Risk Characterization sections. • Recommendation 97: Define the minimal data/information needed to produce a reliable and confident estimate of risk. **PUBLIC COMMENTS:** • While the commenters agree that EPA should give serious consideration to the "… the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization," an enormous amount of uncertainty is not discussed. In particular, the enormous degree of uncertainty regarding lung cancer and mesothelioma cancer potency factors used for chrysotile is not adequately disclosed.	Section 4.3.6 in Part 1 of the Risk Evaluation for Asbestos details key assumptions and uncertainties related to cancer risk values. EPA believes that these uncertainties are appropriately considered in drawing conclusions but did elaborate and expand upon biases in Appendix H. EPA did not identify any data gaps that would preclude a reasoned analysis for Part 1 of the Risk Evaluation. TSCA does not contemplate development and submission of a "minimum data set" before risks can be assessed; rather EPA assessments under TSCA are fit-for-purpose. As noted by the commenter, TSCA provides EPA authority to require development of information, where necessary. However, EPA had sufficient information to complete the chrysotile asbestos risk evaluation using a weight of scientific evidence approach. EPA selected the first 10 chemicals for risk evaluation based, in part, on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. With regard to uncertainty, EPA evaluates the quality of the data cited in sources using data quality metrics and data evaluation scoring described in the *Application of Systematic Review in TSCA Risk Evaluations*. These include metrics that are designed to take the QC processes and overall quality of sources into account when assessing the quality of the data. The data quality criteria also specifically identify what flaws in particular data sources would render a data source unacceptable. If no applicable monitoring data were identified, exposure scenarios were assessed using a modeling approach that requires the input of various chemical parameters and

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
		exposure factors. When possible, default model input parameters were modified based on chemical-specific inputs available in literature databases.
5.9	**Significant digits**	
16	**PUBLIC COMMENTS:** • In characterizing risk, how many significant digits should be used to present cancer risk estimates?	EPA traditionally presents IUR with two significant digits (US EPA, 1986, 2014).
5.10	**Concerns about risk estimate benchmark for workers**	
42, 85	**PUBLIC COMMENTS:** • One commenter stated that he has never seen an occupational assessment where a cancer risk of 3.5 E-04 cancer risk for two to four employees is considered unacceptable. • EPA should consider the number of persons who are likely to be exposed when determining whether an exposure scenario "indicates unreasonable risk" rather than simply comparing risk estimates to the 10-4 or 10-6 benchmarks irrespective of the number of people who might be exposed. In several of the COU exposure scenarios, particularly involving brakes/clutches/gaskets, no more than a handful of people could be exposed in the future. • EPA's Draft RE for Asbestos "accepts far greater risks to workers than to consumers and other members of the general public" by using the benchmark of 10^{-4} for workers and 10^{-6} for the public. The commenter did not see a valid reason for EPA to accept such high risks to workers. • EPA cited NIOSH guidance; however, NIOSH is not required to set risk management limits for carcinogens at a level that avoids unreasonable risk to potentially exposed and susceptible subpopulations. Further, the commenter cites NIOSH 2017 policy that the excess	Under TSCA, EPA does not need to consider the number of exposed individuals to reach a determination of unreasonable risk to health. EPA considered a variety of factors as part of its risk determinations for the chrysotile asbestos conditions of use including exceedances of the risk benchmarks, the physical-chemical properties of asbestos and the severe and irreversible health effects associated with asbestos inhalation. EPA relied on Agency precedent and NIOSH guidance (Whittaker et al., 2016) when choosing the 10-4 cancer risk benchmark to evaluate risks to workers from chrysotile asbestos exposure. NIOSH's mandate, on pg iii of Whittaker et al. (2016), is to: "… describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p. 20, states that: "exposures should be kept below a risk level of 1 in 10,000, if practical [emphasis added]" EPA adheres to the 1 in 10,000 benchmark during the risk evaluation stage for TSCA chemicals. The standard cancer benchmarks used by EPA and other regulatory agencies range from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
	lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk and that NIOSH will continue to recommend reducing exposure to carcinogens as much as possible through the hierarchy of controls (Whittaker (2017). • EPA cited *Indus. Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607 (1980) (the "Benzene decision"). That decision interprets the Occupational Safety & Health Act, and it has no bearing on EPA's duty to identify and manage unreasonable risks under TSCA.	exposed. EPA has consistently applied a cancer risk benchmark of $1x10^{-4}$ for assessment of occupational scenarios under TSCA. This is in contrast with cancer risk assessments for consumers or the general population, for which $1x10^{-6}$ is applied as a benchmark. EPA, consistent with 2017 NIOSH guidance, used $1x10^{-4}$ as the benchmark for the purposes of unreasonable risk determinations for individuals exposed to chrysotile asbestos in industrial and commercial work environments, including workers and ONUs. $1x10^{-4}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks as appropriate. See Section 5.1.2 of the risk evaluation for additional information EPA has removed reference to Indus. Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980) (the "Benzene decision"). TSCA compels EPA to evaluate chemicals without consideration of non-risk factors (such as feasibility of meeting a standard) to determine whether they present unreasonable risk under the conditions of use. EPA's "no unreasonable risk" standard has not necessarily been met at the OSHA PEL.
5.11 **An asbestos ban is not needed under TSCA**		
42	**PUBLIC COMMENTS:** • EPA should discuss somewhere in the Draft RE for Asbestos that in 2018, EPA decided that a ban on imported asbestos was not necessary at that time. • One expert on asbestos concluded that given possible sources of asbestos exposure, number of people potentially exposed, and current U.S. regulations regarding environmental and worker protection and	EPA did not determine that a ban on imported asbestos was not necessary in 2018. As required by the Lautenberg amendments to TSCA, and following EPA's designation of asbestos as one of the first 10 chemicals to undergo risk evaluation, EPA must first evaluate the risks posed by asbestos. Following completion of the risk evaluation, the Agency must pursue risk management for any COUs determined to pose unreasonable risk to health or the environment. Therefore, upon finalization of the Asbestos Risk Evaluation (Part 1: Chrysotile Asbestos), EPA will pursue risk management for the COUs that pose

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
	imports of asbestos-containing materials are adequate; an asbestos "ban" under TSCA is not needed. • If there are a handful of applications in essential industries that require the importation of a limited number of asbestos-containing gaskets or packing to produce militarily or economically crucial goods, EPA could ban the importation of asbestos, except for these special applications.	unreasonable risk to health or the environment. Risk management options provided under TSCA 6(a) include, but are not limited to, a prohibition on commercial use. EPA will also evaluate legacy uses of asbestos in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope document. If unreasonable risk to health or the environment is found for any of the legacy asbestos COUs, EPA will pursue risk management for those COUs.
5.12 **Asbestos should be banned under TSCA**		
25, 27, 31, 45, 47, 68, 85, 86, 89, 92, 101, 111	**PUBLIC COMMENTS:** • Several commenters recommended that EPA use its authority under TSCA to completely ban asbestos uses and imports as soon as possible. • Since December 2016 when EPA announced that asbestos would be one of the first 10 chemicals for risk evaluation, EPA has received public comments in four unique dockets. They contain over 175,000 comments and petition signatures. The commonalities in all of this public input is: – Asbestos is a known carcinogen. – There is no safe level of exposure to asbestos. – The Significant New Use Rule (SNUR) would not ban existing and future imports and use. – Asbestos imports and use must end. – Legacy asbestos is a great danger in homes, schools, and workplaces. • One commenter summarized some of the reasons they consider the Draft RE for Asbestos to underestimate true risks from exposure to asbestos for those whom the EPA is obliged to protect: – It sets aside the decades-old linear dose-response risk model that is supported by sound scientific	As required by the Lautenberg amendments to TSCA, and following EPA's designation of asbestos as one of the first 10 chemicals to undergo risk evaluation, EPA must first evaluate the risks posed by asbestos. Following completion of the risk evaluation, the Agency must pursue risk management for any COUs determined to pose unreasonable risk to health or the environment. Therefore, upon finalization of the Asbestos Risk Evaluation (Part 1: Chrysotile Asbestos), EPA will pursue risk management for the COUs that pose unreasonable risk to health or the environment. Risk management options provided under TSCA 6(a) include, but are not limited to, a prohibition on commercial use. EPA will also evaluate legacy uses of asbestos in Part 2 of the Risk Evaluation for Asbestos, beginning with a draft scope document. If unreasonable risk to health or the environment is found for any of the legacy asbestos COUs, EPA will pursue risk management for those COUs. Regulatory actions to address unreasonable risks are outside the scope of the risk evaluation process. EPA did not set aside linear model. EPA considered and used linear model in derivation of IUR.

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	evidence, and protective of the public health, without evidence that the exponential risk model chosen is better. – Among the six asbestos fiber types in commercial use, the Draft RE for Asbestos considers only one. – Two of the four cancers recognized by IARC as asbestos-related are ignored – Nonmalignant disease is ignored. – Legacy asbestos, a particular risk in public schools, is set aside for another and uncertain day. • Under these circumstances, the only option for protection from unreasonable risk of injury to health from continued exposure to asbestos in the US is a federal ban on asbestos. • A blanket ban on asbestos with strict regulations about the continued use of legacy materials, much like TSCA's approach to PCBs is needed. EPA's final evaluation should reverse the conclusions of the draft and determine that all importation, distribution in commerce and disposal of asbestos presents an unreasonable risk of injury. • Rather than allow for (even with restrictions) any new uses for asbestos, EPA should seek to ban all new uses of asbestos because there are adequate alternatives to asbestos. (See original Attachment 2 for a screen shot of the website change.org with the title "Ban Asbestos in the US Now, Without Loopholes or Exemptions." • Other countries have banned asbestos. As of March 2019, 66 countries have banned the use of asbestos, including all members of the European Union, but not the US. An additional 10 nations are placing restrictions on its use. These include many developed countries that have banned import or use of asbestos. Brazil, who as recently as 2017 supplied most of the	

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
	chrysotile for use in the US chlor-alkali industry also voted for a ban in November of 2017. Others offered essentially the same observations on bans by other countries.	
5.13 **Previous TSCA legislation**		
	PUBLIC COMMENTS: • Mixed results have occurred when EPA has attempted to mitigate risk to asbestos under Toxic Substances Control Act (TSCA). EPA promulgated the Asbestos Ban and Phase Out Rule (ABPR) in 1989, but industry won; the Fifth Circuit Court of Appeals overturned the ban. Since 1989, the US has consumed nearly 400,000 metric tons of asbestos and buried one million Americans. • The 2016 TSCA amendments were enacted in part because of frustration with EPA's inability to regulate asbestos. • In April 2019, EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5, which does not represent a permanent ban. The SNUR can track but not ban the reintroduction of discontinued asbestos products. Thus, under the SNUR, the possibility exists that importing, processing or manufacturing as well as discontinued uses could be approved in the future; it therefore does not protect persons from exposure to asbestos and associated risks of injury or death. Given the significant number of asbestos sites that EPA has to clean up due to improper disposal or abandonment, opening the door to new uses of asbestos is not an economically wise or health-protective idea.	EPA acknowledges the commenters' opinions. EPA clarifies that the SNUR is a restrictive rule prohibiting the discontinued uses of asbestos from restarting without EPA's review and evaluation of each intended use (*i.e.*, significant new use) for potential risks to health and the environment and any necessary regulatory action, which may include a prohibition. The SNUR does not provide a means by which prohibited uses under the 1989 partial ban under TSCA Section 6 could return to the marketplace.

#	Summary for Comments for Specific Issues Related to Charge Question 5	EPA/OPPT Response
5.14 **Include a "mobile app" for users to calculate risk**		
SACC	**SACC COMMENTS:** • The SACC recommended that this (and other TSCA) risk evaluations would benefit from creation of a "mobile app" that would ease communication of these risk findings to risk managers. A "mobile app" might also allow a user to calculate risk from a specified exposure scenario in which he/she is interested. Such an "app" would have KL and KM hardwired in, and have options for selecting the COUs, full shift or ONU workers, level of exposure (central tendency or high-end), APF (0, 10 or 25), with the user able to select the age at which exposure begins and the duration of that exposure. Other options that allow the user to compute the risk from scenarios not considered in the risk evaluation (such as different exposure levels or time-varying exposures) could be included. The "mobile app" could serve as a useful adjunct to the risk tables currently in the RE or possibly as a partial replacement. • Recommendation 66: Consider creating an "app" to make it easier for readers to digest and use the information presented in Table 4.2 to Table 4.38.	EPA thanks the commenter for this suggestion but planning or development of a "mobile app" is outside the scope of EPA's Risk Evaluation for Asbestos.

6. Environmental Risk Characterization and Determination

EPA did not include a charge question specific to environmental risk characterization and determination, but SACC and public comments addressed these topics.

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
6.1 **Overarching comments on environmental risk characterization**		
SACC, 31	**SACC COMMENTS:** • SACC noted uncertainties with respect to environmental exposure that limit conclusions that can be drawn and that require additional explanation, including the inconsistency between lack of data regarding potential asbestos release into water, and determination of no unreasonable risk to aquatic organisms. The reliance on a macrophage mechanism of action raises concerns of asbestos exposures for longer-lived species. • Recommendation 76: Add explicit uncertainty discussion and explanation for environmental exposures. **PUBLIC COMMENTS:** • One commenter concurs, in general, with EPA's overall draft assessment of risk posed by chrysotile asbestos to the natural environment.	EPA added an acknowledgement of uncertainty in Section 2.2.2.1 regarding releases from chlor-alkali facilities. However, EPA believes uncertainty is low and that there is minimal risk posed to aquatic species. Generally, the conclusions made in Part 1of the Risk Evaluation for Asbestos for environmental exposure and aquatic species are based on reasonably available information on chrysotile asbestos releases to surface waters identified and evaluated under EPA's systematic review process which shows little to no evidence of releases of asbestos to surface water associated with the COUs that EPA is evaluating in Part 1. Additionally, no releases were identified or reported to EPA's TRI for COU's evaluated in Part 1 of the Risk Evaluation for Asbestos. Therefore, the conclusion of little to no exposure (and therefore no unreasonable risk) is based on little to no releases to the environment (surface water) which, in turn would indicate little to no exposure (and associated effects) to aquatic species resulting from chrysotile asbestos. If exposure does not occur, then there would be no unreasonable risk to aquatic species.
6.2 **Risk to aquatic species not adequately evaluated**		
SACC	**SACC COMMENTS:** • The hazard sections for environmental effects are relatively well presented with a weight of evidence section. However, the precise selection of studies is not conveyed in the Environmental Hazard section (Section 3.1) nor is an adequate justification provided for why toxicity data ranges by four orders of magnitude.	The reasonably available information for each chemical substance allowed EPA to complete the risk evaluation and determine whether the chemical substance presented an unreasonable risk under the COUs. In some cases, when information available to EPA was limited, the Agency relied on models; the use of modeled data is in line with EPA's final Risk Evaluation Rule and EPA's risk assessment

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
	Selecting one or two specific studies to be representative of effects to all aquatic organisms (*i.e.*, the critical study approach) presents the appearance of bias. • Recommendation 100: Present the available aquatic toxicity data graphically, include results from studies of low quality, and particularly results from studies that examine receptors not otherwise considered in the evaluation. • The SACC concluded that the Draft RE for Asbestos does not adequately evaluate the risk to aquatic species from exposure to surface water. It was unclear how EPA could come to this conclusion without measured or predicted concentrations that could be compared to hazard values. • Asbestos "releases from chlor-alkali facility treatment systems to surface water and POTW are not known," and while the chlor-alkali filtering treatment is expected to capture asbestos solids, its specific efficiency is unknown (Draft RE for Asbestos p. 53). In view of this, it is not clear how the Draft RE for Asbestos can make a determination "of no exposure regarding potential releases to water for the COU's in this evaluation" (page 194) and "no unreasonable risk to aquatic…organisms" (page 207). An additional concern was expressed regarding the conclusion (Section 4.5.1) of basing a risk determination of no environmental risk on a lack of "reported" exposure data. Determinations of risk should be based on measured data rather than "expectation and/or lack of identification." • Recommendation 75: Limit environmental risk determinations to scenarios/COUs that have available actual exposure data.	guidelines. EPA did not use its TSCA data collection authorities to gather additional information for this chemical because EPA believes it has sufficient information to make a reasoned analysis and in light of the limited time available under the statute for completing the risk evaluation. In the future, EPA will have additional time prior to risk evaluation to evaluate data needs and judge whether testing or chemical specific data collection is appropriate. EPA thanks SACC for the recommendations and will consider a graphical representation of aquatic toxicity data in the supplement asbestos document. As stated in the PF, EPA evaluated reasonably available information while focusing on the possible presence of asbestos in water for exposure to aquatic organisms. After the PF, it was determined that while there are releases of asbestos to surface waters, not all releases are subject to reporting (*e.g*, effluent guidelines) or are applicable (*e.g*, friability). Based on the reasonably available information, including published literature, EPA databases, and provided by industry, there is minimal or no releases of asbestos to surface water and sediments associated with the COUs in this document and therefore , EPA concludes in Part 1 of the Risk Evaluation for Asbestos there is no unreasonable risk to aquatic or sediment-dwelling organisms from the evaluated COUs. Chlor-alkali facilities are not required to monitor effluents for asbestos releases and TRI reporting is not required for other forms of asbestos (*e.g*, non-friable asbestos, asbestos in aqueous solutions) (U.S. EPA (2017b).
6.3 **Limitations of EPA's conclusions**		

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
SACC, 105	**SACC COMMENTS:** • The title for Section 3.1 is "Environmental Hazards." The SACC noted that the term "environmental hazards" has broad interpretation and could be construed as including all hazards, either directly or indirectly affecting any organism, resulting from an exposure because of an environmental release. The contents of Section 3.1 suggest a narrower definition since this section only refers to direct effects to non-human receptors (better described as "ecotoxicity" or "hazards to environmental receptors"). EPA should consider renaming these sections more specifically. • Recommendation 99: Rename Section 3.1 Environmental Hazards to be either "Hazards to Environmental Receptors" or "Ecotoxicity." **PUBLIC COMMENTS:** • EPA rated Zebedeo et al. (2014) (low-dose mouse injection study) as irrelevant to ecologic risks, unlike all other injection experiments that EPA rated relevant. EPA also classified as irrelevant to both human and ecologic risk another low dose immunotoxicity experimental finding from another lab (Pfau et al. (2008).	EPA acknowledges this comment. The title of Section 3.1 will remain "Environmental Hazards" for consistency across TSCA risk evaluations. For human health, Part 1 of the Risk Evaluation included a limited range of outcomes including lung cancer, mesothelioma. Zebedeo et al. (2014) and Pfau et al. (2014) were both identified by EPA but did not meet criteria for ultimate inclusion for hazard identification.
6.4 **Alternative approaches for surface water scenarios**		
SACC	**SACC COMMENTS:** • In lieu of monitoring data, EPA should either make a statement that risk cannot be evaluated or use surface water measurements as a "worst-case" scenario for comparison to concentrations of concern (COC). • The available information in the Problem Formulation report (**U.S. EPA (2018)**) indicated that there were surface water releases of asbestos; however, not all releases were subject to reporting (*e.g*, effluent guidelines) or were applicable (*e.g*, friability). The Draft RE for	EPA did not use surface water measurements as a "worst-case" scenario for comparison to COCs because these concentrations cannot be attributed to COUs included in Part 1 of the Risk Evaluation for Asbestos focused on chrysotile asbestos. Surface water measurements and environmental releases will be further considered in Part 2 of the Risk Evaluation for Asbestos (legacy uses and other fiber types of asbestos).

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
	Asbestos reported asbestos levels in drinking water, which led several SACC members to comment that surface water concentrations are thus likely to be higher. One SACC member wondered why these data were even considered, since surface waters were the intended target for the assessment. EPA could consider (1) doing a system-wide assessment of asbestos in surface or drinking waters as a way of assessing total asbestos releases (2) estimating surface water concentrations based on removal of fibers during the process of converting raw to finished water during treatment.	
6.5 **Discuss uncertainties about concentrations of asbestos in effluent**		
SACC	**SACC COMMENTS:** • The SACC appreciated the efforts that EPA provided to assess COU-associated surface water discharges using available data. Evaluations of TRI data indicated zero discharge to POTWs and non-POTW facilities from COUs targeted in the Draft RE for Asbestos. Statements from the Problem Formulation of the Risk Evaluation of Asbestos report (U.S. EPA (2018) indicated that the chlor-alkali industry in years prior to 2017 did discharge chrysotile-asbestos to wastewater. The Draft RE for Asbestos indicates that following visits to these facilities in late 2017, follow-up evaluations were conducted. The Draft RE for Asbestos noted that chlor-alkali facilities are not required to monitor asbestos through NPDES. The Draft RE for Asbestos concludes that water discharges were zero in 2018. It was unclear to SACC members how a conclusion of zero discharge was made without measurements. It was also unclear why EPA did not request these facilities to provide discharge monitoring data after its initial scoping exercise in 2016 (U.S. EPA (2017a). (SACC-31)	EPA clarifies that a conclusion of zero discharge is not made, but rather Part 1 of the Risk Evaluation states that "there were minimal or no releases of asbestos to surface water associated with the COUs that EPA is evaluating" (Section 2.2.3) in Part 1 of the Risk Evaluation for Asbestos. EPA did not request the development of new data from facilities because EPA believes it had sufficient information to complete the Part 1 of the Risk Evaluation for Asbestos using a weight of scientific evidence approach. EPA investigated industry sector, facility, operational, and permit information regulated by NPDES under the Clean Water Act to identify any permit limits, monitoring and reporting requirements, and any discharge provisions related to asbestos and its COU, as stated in Appendix D. EPA identified NPDES permits for facilities that may release asbestos (chlor-alkali and sheet gasket facilities), and most chlor-alkali facilities have issued NPDES permits for industrial operations and general stormwater projects; none of the NPDES limits/monitoring requirements contained asbestos or asbestos-related parameters codes or any direct effluent screening information for asbestos.

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
	• SACC noted additional uncertainties related to water discharge, specifically the lack of measurements of chrysotile fibers in surface waters associated with the targeted COUs. Monitoring data of surface waters clearly show the occurrence of fibers in surface waters (Belanger et al. (1986). Consequently, there is a disconnect between the Problem Formulation document (U.S. EPA (2008) indicating specific COUs (chlor-alkali) discharge waste to POTWs and the Draft RE for Asbestos conclusion of no discharge based on a lack of monitoring data for POTWs which are not required to monitor asbestos. Friable chrysotile asbestos is filtered during the COU for the chlor-alkali industry. The Draft RE for Asbestos does not report the mesh-size of the filter, which is critical as fiber length may have significant impact on biological responses. Additional uncertainty for water discharge is also present with other COUs, including brake dust cleanup. During brake pad replacement, compressed air is used to clean dust which typically would settle to the surface of the areas where the cleaning or replacement occurs. If these events occur within residential areas during consumer use, these surfaces are largely watered down with the resulting waste transported into POTWs or stormwater basins. This pathway was not addressed in conceptual models for the Scope nor Problem Formulation. • Recommendation 80: Discuss the uncertainty related to potential releases of asbestos in water discharged to POTWS or stormwater basins as a result of brake dust cleanup.	In Section 2.2.2.1, EPA included the following text related to uncertainty for the presence of asbestos in stormwater or POTWS from chlor-alkali facilities: "While the treatment technologies employed would be expected to capture asbestos solids, the precise treatment efficiency is not known." EPA acknowledges the uncertainty associated with the various mesh filters used by these facilities. Asbestos fibers, due to their structure, should collect in the mesh filters following the discharge from facilities to wastewater. TRI does not indicate discharges to surface water, chlor-alkali facilities do not indicate releases after treatment. While EPA acknowledges that use of compressed air to clean dust during a brake pad replacement can result in a settling of chrysotile asbestos fibers that may collect in stormwater basins, EPA believes the concentrations of fibers that could results from this scenario would be minimal.
6.6 **Action is needed to require measurement of asbestos in effluent**		

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
31	**PUBLIC COMMENTS:** • One commenter requested that EPA amend their effluent guidelines to require measurement of asbestos in effluents of relevant industries and to set specific limits for asbestos from those operations where discharges are allowed. • For certain asbestos manufacturing operations, EPA reported (Draft RE for Asbestos ln. 1815–1819) that their effluent guidelines establish limits on the allowable levels of TSS, pH, or COD). However, the regulations do not establish specific limits for asbestos from those operations where asbestos discharges are allowed. Thus, without the requirement to measure asbestos concentrations in effluent, estimating asbestos levels in effluent or receiving waters is challenging. The commenter strongly recommended that EPA amend their effluent guidelines to require that (1) concentrations of asbestos in effluent be measured, and (2) specific limits be established for asbestos from those operations where discharges are allowed.	These comments are sufficiently addressed by newly added text in Section 1.4.4. EPA appreciates the suggestion to amend effluent guidelines. The Clean Water Act (CWA) publishes recommended criteria for priority pollutants, requiring NPDES discharge permits to include stringent discharge limits. EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for asbestos, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. The CWA and NPDES permitting guidelines are the legal mechanisms to require effluent guidelines in the US.
6.7 **Environmental risk determination**		
SACC	**SACC COMMENTS:** • Several SACC members noted that the Risk Determination section for environmental risk concludes "low or no potential for environmental risk to aquatic receptors" based on the observation (assumption?) that water releases associated with the COUs are not expected and were not identified. The SACC suggested that a more appropriate determination would be to conclude that "environmental risk could not be	This statement has been added to the Risk Determination, Section 5.1.3, for clarity, "environmental risk could not be ascertained."

#	Summary of Comments for Specific Issues Related to Environmental Risk Characterization/Determination	EPA/OPPT Response
	ascertained," because water releases associated with the COUs are not expected and were not identified. • Recommendation 101: Because water releases associated with the environmental COUs while not expected are not actually assessed, the decision on environmental risk should be stated as "environmental risk could not be ascertained."	

7. Potentially Exposed or Susceptible Subpopulations

Charge Question 6:

6.1 Has a thorough and transparent review of the available information been conducted that has led to the identification and characterization of all PESS (Sections 2.3.3, 3.2.5., and 4.4.1)? Do you know of additional information about PESS that EPA needs to consider? Additionally, has the uncertainty around PESS been adequately characterized?

6.2 Please comment on whether EPA has adequately, clearly, and appropriately presented the reasoning, approach, assumptions, and uncertainties for characterizing risk to workers using PPE (exposure - Sections 2.3.1.2.; risk Section 4.2.1 and Tables 4-3 and 4-38).

6.3 Please comment on whether EPA has adequately, clearly, and appropriately presented the reasoning, approach, assumptions, and uncertainties for characterizing risk to ONUs who would not be expected to use PPE (Sections 4.2.1 and 4.3.7).

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
7.1 **Differentiate risk estimates for smokers and nonsmokers**		
SACC	**SACC COMMENTS:** • Recommendation 58: Revise risk estimates and tables to provide separate risk estimates for smokers and nonsmokers. There's evidence for a synergistic relationship between smoking and asbestos in causing lung cancer. The IUR was derived based on mortality data containing both smokers and nonsmokers, which	EPA searched the CDC Wonder and SEER databases for cancer statistics on smokers and did not find data on rates for smokers. Higher background rates of lung cancer among smokers would be expected to be associated with higher values of the IUR and thus higher risks. The data necessary for lifetables were also not available for other PESS groups. Therefore, EPA was not able to follow this SACC recommendation based on the timeframe and reasonably available information.

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	should be revised to distinguish background risks for smokers and nonsmokers. • The Draft RE for Asbestos discusses some susceptible subpopulations but does not fully discuss incorporation of these vulnerabilities into risk assessments. For example, smokers should have different and distinct risk calculations given that the combined effect of both asbestos exposure and smoking is most likely supra-additive. The Draft RE for Asbestos correctly identifies cigarette smokers as a susceptible subpopulation for the effects of asbestos exposure.	
7.2 **Address population with underlying health conditions**		
SACC, 42, 51, 92	**SACC COMMENTS:** • The SACC considered workers who smoke cigarettes a susceptible subpopulation when it comes to lung cancer. Workers, ONUs, and DIY-exposed individuals who have chronic lung disease, including chronic obstructive lung disease and pulmonary fibrosis, have an elevated risk of lung cancer and form a susceptible population. Recommendation 82: Discuss how the increment in exposure associated with the COUs may cause individuals with early-stage lung disease or pulmonary fibrosis to exceed the designated targets of unreasonable risk. • Recommendation 83: Add quantitative estimates of the added risk of cancer from exposure to asbestos for the following susceptible subgroups: smokers, individuals who have chronic lung disease, including chronic obstructive lung disease and pulmonary fibrosis, and other individuals having an elevated risk of lung cancer. Quantifying the extra cancer risk in smokers due to exposure to asbestos can be accomplished by applying the already-calculated KL and KM in a life table	EPA was not able to identify reasonably available information in the timeframe for completing Part 1 of the Risk Evaluation that would allow for quantitative consideration of some susceptible populations, including smokers and those with early-stage lung disease. Accordingly, EPA was unable to update life tables using methods to characterize smokers explicitly. However, EPA notes qualitatively that, if the underlying PESS conditions increased the condition-specific background risk of incident lung cancer, this would be expected to decrease the exposure concentration needed to increase the extra risk of lung cancer by 1% and increase the IUR for that PESS condition. In Section 3.2.4, EPA describes that there "some evidence of genetic predisposition for mesothelioma related to having a germline mutation in BAP1." EPA has not included an extensive description of the evidence because it would not be feasible to estimate the size of the potentially susceptible population for the purposes of refining risk determination. Furthermore, EPA used high-end risk estimates to account for PESS that could not be quantified.

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	analysis that uses background rates of lung cancer and death from all causes that apply to smokers. • Recommendation 45: Use life table methods to estimate lung cancer risks separately for workers exposed to asbestos who also smoke. • Recommendation 85: Discuss how the science related to asbestos risk and BAP1 or related mutations is insufficient at this time to define individuals having these mutations as a PESS. **PUBLIC COMMENTS:** • Though a synergistic relationship for lung cancer risk between asbestos exposure and smoking has been demonstrated in some studies of cohorts exposed to high cumulative asbestos exposure levels, there is no evidence that this relationship exists at low cumulative asbestos exposure levels, such as those experienced by a career automobile mechanics. • EPA's risk evaluation fails to address individuals exposed to asbestos across multiple routes and pathways and persons at increased risk such as cigarette smokers and individuals with underlying lung disease.	EPA considered the reasonably available information and used the best available science to determine whether to consider aggregate exposures for chrysotile asbestos. EPA determined that using the high-end risk estimate for inhalation risks separately as the basis for the unreasonable risk determination is a best available science approach. There is low confidence in the result of aggregating inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk.
7.3 **Consider aggregate exposures and multiple pathways when defining PESS**		
51	**PUBLIC COMMENTS:** • Aggregate exposures for asbestos were not assessed by routes of exposure, since only inhalation exposure was evaluated in the Draft RE for Asbestos. EPA chose not to employ simple additivity of exposure pathways at this time within a COU because of the uncertainties present in the current exposure estimation procedures. This lack of aggregation may lead to an underestimate	As the commenter states, EPA articulated the reasons for which aggregated exposures by routes of exposure for chrysotile asbestos were not assessed. EPA has the most confidence in evidence for cancer resulting from inhalation exposures. In Section 4.4.2, EPA does acknowledge that there is the potential for underestimating risks that may result from other routes of exposure, but the additional cancer risk is expected to be minimal. Furthermore, EPA discussed factors that could contribute to increased susceptibility, including physiological factors and potential for increased exposure, but there was not data reasonably available to

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	of exposure but based on physical chemical properties most of the exposure is believed to be from inhalation. • Risks are understated because Draft RE for Asbestos does not account for increased risks to subpopulations with greater susceptibility to asbestos or multiple pathways of exposure.	quantitively consider additional risk with sufficient confidence.
7.4 **Consider firefighters, teachers, contractors not covered by OSHA**		
15, 50, 51, 73, 81, 92	**PUBLIC COMMENTS:** • By amending TSCA in 2016, Congress also acknowledged that existing protections for workers from chemical hazards are inadequate, including exposure to asbestos. More than 8 million workers are not covered by the OSH Act, including 8 million public sector workers, such as firefighters and the professionals who work in schools and for government agencies. Others who are not covered by the OSH Act include the 15 million people who are independent contractors or otherwise self-employed, and agricultural workers on small farms. • The Draft RE for Asbestos specifically ignores legacy use exposures to firefighters. The 2013 NIOSH study found higher rate of mesothelioma in firefighters and likely linked these findings to exposure to asbestos. Since asbestos fibers are known to be released during fire, firefighters are under high exposure to these fibers when extinguishing fires. Therefore, firefighters should be considered as a susceptible population given the high risk of exposure. • Emergency response crews and volunteers (as well as building occupants) are at high risk of legacy asbestos exposure in the wake of fires and other disasters. Where the duration of exposure is prolonged and more exposure events occur, the risk of asbestos-related	EPA acknowledges the potential for these additional populations to be exposed to asbestos. However, Part 1 of the Risk Evaluation for Asbestos focused on COUs and exposures relevant to chrysotile asbestos. EPA will consider legacy uses and related exposures, both occupation and general population, in Part 2 of the Risk Evaluation for Asbestos (legacy uses and other fiber types of asbestos).

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	disease is increased (Bianchi and Bianchi (2007). A well-studied disaster resulting in widespread asbestos release was the 2001 attack on the New York World Trade Center (WTC) (Landrigan et al. (2004). • The Draft RE for Asbestos ignores exposures to workers, visitors, students, and teachers who can be present for extended periods (30–40 hours per week) in asbestos-containing buildings and schools. Asbestos can be released during building upkeep and maintenance or from damaged and poorly maintained building components. The City of Philadelphia provided an example of the hazards posed by asbestos-containing insulation in public schools and illustrates the importance of consideration of amphibole fibers for asbestos risk (Graham and Ruderman (2020).	
7.5 **Consider tribal communities**		
SACC, 88	**SACC COMMENTS:** • The health disparities in American Indians/Alaska Natives (AIAN) are relevant to currently manufactured chrysotile asbestos in this Draft RE for Asbestos. Recommendation 84: AIAN populations should be included in the PESS discussion and analysis. **PUBLIC COMMENTS:** • Tribal communities need to be given consideration as susceptible population because of dependence on potentially contaminated foods, higher prevalence of cigarette smoking, close proximity to landfill or waste disposal site, higher mortality rate of lung cancer than non-Hispanic Whites.	EPA did not identify reasonably available information to indicates that the AIAN population is a potentially exposed or susceptible population. EPA acknowledges that there are unique health statistics for the AIAN population, but EPA did not identify evidence indicating that there is greater susceptibility for this population than other populations.
7.6 **Family members and others in communities exposed through occupational take-home exposures**		
SACC, 41, 58, 73, 85	**SACC COMMENTS:** • The longer latency period for children as DIY bystanders is discussed in the Draft RE for Asbestos but	The chrysotile asbestos IUR in Part 1 of the Risk Evaluation for Asbestos incorporates mesothelioma risk, which is a function of time since first exposure, so higher risks for

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	this is not incorporated into the exposure or risk modeling. Take home routes of exposure are not discussed in the Draft RE for Asbestos, and this is a primary route of exposures to which family members of workers are exposed to asbestos; in particular, children are highly susceptible. **PUBLIC COMMENTS:** • There's evidence showing that asbestos-related disease is linked to take-home or para-occupational exposure. Therefore, workers' household is a subpopulation under risk of exposure to asbestos.	children are incorporated in risk calculations for particular COUs. Take-home exposures are possible for most of COUs including auto brake and gaskets. However, the frequency and magnitude of take-home exposure and contaminations on clothing and shoes depend on several potential factors, including personal hygiene and visibility of the chemical on skin or clothing. EPA acknowledges that take-home exposures may occur and that take-home exposures have been shown to cause health effects among non-workers exposed to take-home asbestos exposures, however, EPA does not believe there are reasonably available data to reliably predict take-home exposure and any associated risks.
7.7 **Consider workers with unique conditions**		
73	**PUBLIC COMMENTS:** • Vulnerable workers who are unauthorized immigrants, low-income persons, homeless, the ex-incarcerated, and do not speak English are unique category of "potentially susceptible or exposed subpopulations." They are often less familiar with asbestos-containing materials, are less likely to make inquiries about proper work practices, training, and equipment, are significantly less likely to complain about unsafe working conditions, therefore in need of consideration.	EPA thanks the commenter for these suggestions and acknowledges that these subpopulations may have the potential to be at a disadvantage when it comes to communications related to or protections from environmental policies and regulations. For Part 1 of the Risk Evaluation for Asbestos and the risk determinations, the process relies upon evaluation of COUs and the relevant populations that are expected or anticipated to be exposed.
7.8 **Additional populations to consider**		
SACC, 43	**SACC COMMENTS:** • Recommendation 86: Discuss the possibility that asbestos-containing construction materials still in	EPA identified and evaluated all reasonably available information to determine PESS relevant for chrysotile asbestos exposures from COUs included in Part 1 of the Risk Evaluation. EPA makes conclusions on PESS based on evidence and reasonably available information and does not rely on speculation or hypotheses for identification PESS for risk determinations. ACBM and those potentially exposed

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	commerce identify certain construction workers as a PESS. **PUBLIC COMMENTS:** • The exposed population to brake pad dust is not only those who drive, but also potentially those that live and work downwind, or nearby, the roadways.	will be further considered in Part 2 of the Risk Evaluation (legacy uses and other fiber types of asbestos).
7.9 **Subpopulations not defined appropriately**		
42	**PUBLIC COMMENTS:** • It is mere speculation that genetic predisposition for mesothelioma caused by germline mutation in BAP1 makes any specific person more genetically susceptible to mesothelioma than someone else. • The definition of "susceptible subpopulations" is not warranted because the populations included have a low probability of exposure to asbestos through working with brakes or gaskets. • Since concerns about sensitive subpopulations have focused on exposure scenarios where millions of citizens are exposed to appreciable levels of a toxicant, the sensitive subpopulations defined in this report were not appropriate because they are only composed of a handful of adults across the nation who might be exposed to the scenarios presented.	With regard to BAP1, EPA states in Section 3.2.4 that there is "some evidence of genetic predisposition for mesothelioma related to having a germline mutation in BAP1." EPA cited Testa et al. (2011) as just one example of a study reporting an association between BAP1 mutations and mesothelioma incidence, and EPA believes its inclusion is warranted. EPA continues to believe the PESS described in Part 1 of the Risk Evaluation are accurate and warrant inclusion.
7.10 **Extent to which the uncertainty around PESS been adequately characterized**		
SACC	**SACC COMMENTS:** • The SACC concluded that the uncertainty around PESS has been adequately characterized. In several sections (*i.e.*, Sections 2.3.1.3.6, 2.3.1.4.6, 2.3.1.5.6, 2.3.1.6.6, 2.3.1.7.6, 2.3.1.9.5), data assumptions, uncertainties, and level of confidence are discussed. Although the uncertainty analysis does not quantify uncertainty, a sensitivity analysis was performed (Section 4.3.7 and	EPA appreciates these comments from the SACC. EPA has not included upper and lower bounds to describe the uncertainty in the exposure estimates, as the approach that has been used in the TSCA REs has instead presented the central tendency and high end estimates with confidence ratings in addition to sections on key assumptions, uncertainties, and confidence for exposures related to each COU.

#	Summary of Comments for Specific Issues Related to Charge Question 6	EPA/OPPT Response
	Appendix L), which helps provide insights to how uncertainties impact risks for DIY users and bystanders for the brake repair/replacement scenarios. These same insights apply to PESS. • Estimates for chrysotile asbestos exposures for the COUs evaluated are highly uncertain. Given this situation, EPA has purposely chosen exposure estimates that were likely high, within the respective error bands in keeping with the precautionary principle of defaulting to reasonable worst case in the face of uncertainty. EPA has concluded, for example, that the risk of exposure to chrysotile asbestos from brake shoe repair was unacceptable. In the opinion of the SACC, EPA has acted appropriately in the face of this uncertainty. Specifically, EPA appropriately traded conservatism for high quality data. However, EPA should attempt to describe the uncertainty in the resulting estimates by providing both upper and lower bounds that are consistent with the limitations of the data available.	
7.11 **Risk to DIYs and ONUs who would not be expected to use PPE (Draft RE for Asbestos Sections 4.2.1 and 4.3.7)**		
SACC, 43, 85	**SACC COMMENTS:** • The assumptions, data gaps, limitations, and rationale for the risk characterization for ONUs were clear and easy to follow. SACC considered it appropriate for EPA to not assume PPE use for ONUs. Section 4.2.1 clearly explains the approach for estimating risk from asbestos exposure for workers and non-workers. Section 4.3.7 explains the confidence in estimates for workers and ONUs. • The estimates on the number of ONUs for most COUs are low, except for the chlor-alkali plant workers. There are few chlor-alkali plants and tasks that are clearly described and numbers of workers by tasks tabulated.	EPA agrees that there are challenges associated with use of PPE; they are described in Section 5.1. By providing risk estimates that account for use of PPE, EPA is not recommending or requiring use of PPE. Rather, these risk estimates are part of EPA's approach for developing exposure assessments for workers that relies on the reasonably available information and expert judgment. When appropriate, EPA will develop exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. EPA did assess the risk to workers and ONUs in the absence of PPE, and those risks are presented in Section 4 Risk Characterization under Table 4-55, Summary

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	Table 4-54 would be improved if a column were added for an assessment of the confidence in the estimates and a short description of how the values were obtained. • Recommendation 89: Incorporate results from the NIOSH/BLS survey of respirator use across industry groups into the discussion of respirator use by ONUs. **PUBLIC COMMENTS:** • The DIY television shows which teach homeowners about handling materials without always wearing proper protective suits can mislead the public and create more exposure for homeowners and families. • EPA lacks data measuring exposures by workers who do not regularly handle or work with asbestos but who work in or near areas where asbestos is used including the cleaning workers, skilled trade workers, supervisors, and managers who EPA misleadingly characterizes as ONUs. The range of workers that EPA defines as ONUs is too large to support a single classification. Supervisors have very different exposure patterns than skilled trade workers, yet EPA assumes both groups of workers face similar risks under EPA's overbroad ONU categorization.	of Risk Estimates for Inhalation Exposures to Workers and ONUs by COU. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a COU presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each COU, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1.

8. Overall Content and Organization

Charge Question 7:

7.1 Please comment on the overall content, organization, and presentation of the asbestos draft risk evaluation. Please provide suggestions for improving the clarity of the information presented.

7.2 Please comment on the objectivity of the information used to support the risk characterization and the sensitivity of the agency's conclusions to analytic decisions made.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
8.1 **Draft RE for Asbestos is clear, thorough, and transparent**		
SACC, 40, 42, 79	**SACC COMMENTS:** • Overall organization and presentation of the material in the Draft RE for Asbestos is clear and well organized. • The approach used in the Draft RE for Asbestos to assess occupational exposures is adequately explained and the arguments presented could be followed. There is substantial discussion devoted to the scope of the Draft RE for Asbestos. • The various assumptions regarding exposures based on monitoring data and other assumptions, such as the use of PPE, were reasonably comprehensive. **PUBLIC COMMENTS:** • EPA's Draft RE for Asbestos represents an enormous effort on the part of EPA. It is a very detailed and transparent EPA analysis and focused on the objectives. EPA was very thorough in making the uncertainties of the assessment transparent. • EPA is to be commended on such a substantial effort to compile and review numerous studies and evaluate exposures and risks of chrysotile. • Commenter applauded EPA staff for the care and patience that they expended into the analysis.	EPA thanks the SACC and public commenters for these acknowledgements of effort and technical proficiency.
8.2 **Draft RE for Asbestos title is misleading**		
SACC	**SACC COMMENTS:** • The title is misleading in that the evaluation discusses the risks from commercial use of only the chrysotile form of asbestos and not asbestos in general as implied in the title. Make the title specific to chrysotile asbestos	EPA agrees with the SACC and has changed the name of to Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos. The Risk Evaluation for Asbestos Part 2 will include Legacy Uses and Other Fiber types of Asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	and be specific in the Draft RE for Asbestos when data from other fiber types are used. • Recommendation 15: Either retitle the evaluation to reflect its limited scope or postpone completion pending future efforts to assess asbestos more broadly.	
8.3 **Clarify regulatory charge, scope, and rationale of evaluation**		
SACC, 42, 64, 95	**SACC COMMENTS:** • Recommendation 5: Reduce technically intense text. • As discussed in response to Question 2.1, the SACC found that the Draft RE for Asbestos does not adequately outline its purpose, which seems to be to evaluate the risk of present commercial use of chrysotile asbestos. In addition, it is unclear what the specific regulatory objectives of the Draft RE for Asbestos include. • Recommendation 90: Provide more discussion in the introduction on the regulatory charge and scope to help establish the focus of the evaluation. • Recommendation 17: How this limited scope Draft RE for Asbestos for chrysotile asbestos fits into the larger asbestos evaluation process should be explained early in the document. • Recommendation 63: Provide qualifying statements as to the limitations of the Draft RE for Asbestos and its analyses in its restriction to current intentional uses of chrysotile asbestos fibers and only including lung cancer and mesothelioma mortality. **PUBLIC COMMENTS:** • Reviewing TSCA, commenters were unable to find a rationale justifying the preparation of the document. One commenter was not convinced that EPA is required	EPA understands the need for additional clarity on the efforts and process to complete the risk evaluation for asbestos. EPA has added a Preamble to Part 1 of the Risk Evaluation of Asbestos to clarify that the current document is focused on imported, processed, and distributed uses of chrysotile asbestos. Part 2 of the Risk Evaluation for Asbestos, as described in the Preamble, will begin with a draft scope document that is being developed to articulate EPA's plan to evaluate other uses and disposals of asbestos and other fiber types. This scope document will be available for public comment.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	to address this topic to fulfill its responsibilities under the Lautenberg Act. • It is not clear why EPA used the following approach: In the problem formulation document, it was stated that the Draft RE for Asbestos would focus on epidemiological inhalation data on lung cancer and mesothelioma for all TSCA Title II fiber types, just as stated in the 1988 EPA IRIS Assessment on Asbestos (U.S. EPA (1988b). This rationale needs to be explained in more detail. • EPA should refocus on the information needs for risk management decisions by asking whether the assessment is achieving its objective to inform decisions. For this Draft RE for Asbestos, the answer is 'no.' The risk assessment team needs to "make adjustments, revisit steps or develop additional information as needed."	
8.4 **Expand discussion of mode of action (MOA)**		
SACC	**SACC COMMENTS:** • The EPA Cancer Guidelines (U.S. EPA (2005) specifies that the choice of risk estimation methodology be based on the MOA by which a substance causes cancer. The discussion in the Draft RE for Asbestos of the MOA for asbestos should be expanded. • Recommendation 94: Revise the MOA discussion in Section 3 to incorporate effects of dimensionality, physical-chemical properties and bio-persistence, which may affect and influence adverse outcome pathways. Some discussion of the MOA should be presented in more detail, specifically describing how those processes may affect and influence the available toxicity data for long-lived aquatic receptors.	Following SACC recommendations, EPA sufficiently expanded the MOA discussion (Section 3.2.2.3) providing more details. EPA has not expanded the MOA discussion to address long-lived aquatic receptors because releases to water are not known or reported for the COUs evaluated in this Risk Evaluation for Asbestos Part 1, and therefore, water pathways are not expected to result in unreasonable risk.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
8.5	**Supplemental documents should include updated photos of asbestos-containing building materials**	
15, 17, 29, 30	**PUBLIC COMMENTS:** • EPA needs to set aside more time to study, formulate, and publish "subsequent supplemental documents" about ACBMs. These supplemental documents should be complete and easy to read, to interpret, and to put into practice. The supplemental documents should avoid old photographs but use most current digital photographs of Legacy ACBMs for building owners and residents to use to identify ACBMs in buildings.	EPA thanks the commenter for these suggestions and will take this into consideration when developing the Part 2 of the Risk Evaluation for Asbestos, beginning with a scope document that will describe COUs to be included.
8.6	**Include CAS registry numbers**	
SACC, 28	**SACC COMMENTS:** • Recommendation 41: Append CAS Registry Numbers when referring to asbestiform varieties. **PUBLIC COMMENTS:** • The EPA did a good job in acknowledging the Chemical Abstract Service Registry Numbers (CASRNs) "are available for specific fiber types," other than the general CASRN for "asbestos," but the EPA should specifically identify the applicable CASRNs for each of the regulated fiber types noted in the document to avoid confusion with the non-asbestiform analogs.	EPA provided the CASRNs for each of the fiber types included in the risk evaluation in Table 2-1 of the Scope Document. EPA adopted the TSCA Title II AHERA definition of asbestos which does not include non-asbestiform analogs. EPA has added a Preamble to clarify the focus of Part 1 and Part 2 of the Risk Evaluation for Asbestos.
8.7	**Tables should be condensed and modified for readability**	
SACC	**SACC COMMENTS:** • The tables in the document are not easy to read with only a few entries and the large quantities of them. A	EPA appreciates these suggestions to improve the readability of Part 1 of the Risk Evaluation for Asbestos. EPA will take these suggestions into account when developing subsequent risk evaluations.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	graphical presentation can be considered as an adjunct to the summary table. • Recommendation 64: Summarize Table 4.2 to Table 4.38 in one table and showing results relative to the cancer benchmark value. • Recommendation 65: Consider summarizing risks to works and ONUs across scenarios in a graph. • Readability would be improved if tables could be modified to each use; specifically, color codes could be used to highlight particularly relevant data. • Table 2-1 could use a footnote describing the abbreviations for the benefit of readers not familiar with the environmental quality shorthand.	
8.8 **Clarify derivation of IUR_{LLT}**		
SACC	**SACC COMMENTS:** • For the calculation of cancer risk for workers and consumers, EPA uses less than a lifetime inhalation unit risk (IUR_{LLT}). Its derivation and methodology used are not clear. Recommendation 70: Present clearly how the values for less than lifetime inhalation unit risk (IUR_{LLT}) are calculated in the text.	The methodology for the derivation of the values is described in Appendix K. It generally follows derivation of IUR sections, that are cited in Appendix K.
8.9 **Other recommendations to improve document clarity, particularly regarding uncertainties**		
SACC	**SACC COMMENTS:** • Recommendation 74: Provide a tabular summary of the uncertainties and carry some of the uncertainties through to provide risk estimates in sensitivity analyses by making alternate assumptions. • In prior DREs, EPA defaulted to central tendency worker exposure point air concentrations as a surrogate for ONU exposure point air concentrations. The reason	EPA will consider providing a tabular summary of uncertainties in future risk evaluations but was not able to generate such tables in the timeframe for the current document. However, EPA did note uncertainties, where appropriate, and sensitivity analyses, when conducted. In Part 1 of the Risk Evaluation, EPA did not need to default to central tendency work exposure point air concentrations as a surrogate for ONU exposures because, Section 2.3.1 states, "where available, EPA used inhalation monitoring data from industry, trade associations, or the public literature…For

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	for deviating from this approach in this Draft RE for Asbestos is not adequately explained. • Table 2.24 (p. 106) is well presented, but the confidence ratings are not necessarily adequately justified. Specifically, exposure estimates are primarily derived from simulations which might not represent real-world conditions; the uniform medium confidence ratings are poorly justified. COU estimates assigned low confidence ratings were not controversial, given they represent scenarios with very little available information or where the quality of the data is questionable.	inhalation exposure, in cases where no ONU sampling data are available, EPA typically assumes that ONU inhalation exposure is comparable to area monitoring results that may be available or assumes that ONU exposure is likely lower than workers." All but one air concentration estimate in table 2-24 are based on actual monitoring data. The only estimate based on a "simulation" is ONU exposure for gasket stamping COU. The confidence ratings relate to how closely these values represent the actual concentration of the workplaces. The factors and considerations contributed to each confidence rating are detailed in the Data Assumptions, Uncertainties, and Level of Confidence section in each COU. The factor and considerations include relevance, representativeness, and age of the data.
8.10 **Map and correlate asbestos deposits in natural environment**		
SACC	**SACC COMMENTS:** • Since asbestos is a naturally occurring mineral, the Draft RE for Asbestos should include a map showing the locations of naturally occurring asbestos deposits such as provided by USGS on its website. • To better understand the potential impact of these natural deposits, it would be appropriate to determine if there is a correlation between the location of asbestos deposits and the prevalence (and concentrations) of drinking water or air measurement detects.	EPA acknowledges that this addition to the document would have added useful context and background, however, this information was not added due to time constraints and it was not necessary for the evaluation and determination of risk for COUs evaluated in Part 1 of the Risk Evaluation for Asbestos.
8.11 **Define terms**		
SACC	**SACC COMMENTS:** • On page 56 (ln. 1951), the term "friable" is used without definition. One member suggests defining the term where first used.	EPA has added a definition for the term "friable."

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
8.12 **Correct the attribution for statements about asbestos being vital**		
SACC	**SACC COMMENTS:** • On page 60 (ln. 2109), the Draft RE for Asbestos describes that asbestos filters as being "vital" to the continued success of the chlor-alkali industry. However, such position should be attributed to industry and not to USGS.	EPA has revised this sentence to more accurately attribute physiochemical properties to USGS and not viewpoint that asbestos filters are "vital."
8.13 **Correct quotation/citation**		
42	**PUBLIC COMMENTS:** • Regarding Richter et al. (2009) cited in the Draft RE for Asbestos, the quote needs to be corrected. On page 88, lines 3169–3171, the Draft RE for Asbestos says: "Since the mid-1990s, material and design … phasing out drum brakes in passenger automobiles (Richter et al. (2009)." However, on page 459 of the paper, the full quote is, "The introduction of disc brakes in the 1960s in the United States … By the 1990s, most automobiles sold in the United States had disc brakes on all four wheels." (42-210) • On page 88, lines 3180–3182, Draft RE for Asbestos says: "Use of asbestos-containing braking systems began to decline in the 1970s … and availability of asbestos-free substitutes (Paustenbach et al. (2004a)." This is appropriately quoted but could add that litigation associated with asbestos that has occurred since 1975 ensured that no asbestos-containing auto parts would be present in cars in the post-1980 or 1985 era.	EPA has revised the text to improve accuracy. EPA did not elaborate on litigation.
8.14 **Clarification on Jiang et al. (2008) – obtaining clutches or brakes with asbestos is not likely in 2020**		
42	**PUBLIC COMMENTS:** • It is incorrect to suggest that it is plausible in 2020 to obtain clutches or brakes that contain asbestos from a warehouse. As noted in the article Jiang et al. (2008), the authors believe the bulk of exposures when handling	While the authors make this assertion, EPA must take into consideration that there is the potential to obtain asbestos-containing brakes, which was supported by the SACC.

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	boxes of old brakes or clutches was due to dust not on the inside but on the outside of the box which contained asbestos from near the production.	
8.15 **Revise how Paustenbach et al. (2006) is interpreted**		
42	**PUBLIC COMMENTS:** • Commenter suggested that EPA embrace this sentence: "Overall, based on the PCM analysis of the 23 valid samples, the study authors reported an average worker asbestos concentration of 0.024 fibers/cc and a maximum concentration of 0.066 fibers/cc (Paustenbach et al. (2006)." Commenter was involved in the testing of the samples, 17 out of 23 had no detectable concentrations of asbestos (by PCM). It is unlikely that the six samples that had detectable asbestos concentrations were overloaded with chrysotile asbestos fibers from an encapsulated gasket.	EPA states in Section 2.3.1.9.4 that 17 of 23 samples were non-detect and that 6 samples contained asbestos as detected using TEM. Furthermore, in Section 2.3.1.9.4, EPA clarifies the uncertainties in the Paustenbach study related to five of the personal breathing zone samples being overloaded by particulates, and thus, not being suitable for analysis. EPA does not assert that these samples are overloaded with chrysotile but does acknowledge that they "cannot rule out the possibility that these overloaded filters might have contained elevated levels of asbestos," in Section 2.3.1.9.
8.16 **Remove the term "inert"**		
SACC	**SACC COMMENTS:** • Recommendation 10: Remove the text describing chrysotile asbestos as "biologically inert." Many micro- and nano-sized materials have been shown to have significant biological effects following absorption even though they may be "chemically inert," especially importance of size/length characterization.	EPA has revised the risk evaluation draft document to avoid describing chrysotile as biologically inert (*e.g*, the text biologically was removed from the second sentence in Section 2.1.
8.17 **Use the term "chrysotile asbestos" in place of the single word "chrysotile"**		
SACC	**SACC COMMENTS:** • There is a constant shifting, in the Draft RE for Asbestos and especially in Section 3.2.4, in use of the words "asbestos" and "chrysotile." This is not only confusing but also misrepresentative of the actual data. The Draft RE for Asbestos is restricted in scope to chrysotile asbestos only and is not about asbestos. The	EPA agrees with the SACC that this would add clarity. In many instances, EPA followed SACC recommendation and used "chrysotile asbestos" instead of just chrysotile throughout the text of the risk evaluation (except where direct quotes are using word chrysotile). However, a footnote was also added in the Preamble to the document that chrysotile refers to chrysotile asbestos.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	correct term should be "chrysotile asbestos," and this should be clear throughout the entire document. • Recommendation 39: Use the term "chrysotile asbestos" in place of the single word "chrysotile" and in any references to "asbestos" data or estimates that specifically reference chrysotile asbestos.	
8.18 **Clarify terms for asbestiform and non-asbestiform varieties**		
SACC, 28, 75	**SACC COMMENTS:** • Several varieties of amphiboles are present in both asbestiform and non-asbestiform habits: tremolite, anthophyllite and actinolite. Whenever the asbestiform varieties of these substances are referenced, "asbestos" should be attached to their name. Recommendation 40: Append the word "asbestos" to all references to amphiboles. **PUBLIC COMMENTS:** • EPA should add the word "asbestos" following use of the words "anthophyllite," "tremolite" and "actinolite." The inclusions would avoid unintended confusion with their non-asbestiform analogs. Similarly, EPA should add the word "asbestiform" before the words "serpentine," "riebeckite" and "cummingtonite-grunerite." The word "asbestiform" is a description of mineral morphology as opposed to "asbestos."	For the purposes of the asbestos risk evaluation, EPA adopted the TSCA Title II definition of asbestos which is the "asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite." As such, EPA is only evaluating the asbestiform varieties of these mineral fibers. EPA added a preamble to the chrysotile risk evaluation document that further explains the asbestos fibers being evaluated in Part 1 and Part 2 of the asbestos risk evaluation. In Part 1 of the Risk Evaluation for Asbestos, EPA has further clarified that non-asbestiform mineral varieties are not included in the added Preamble.
8.19 **Use more complete descriptions of "risk" wording**		
SACC	**SACC COMMENTS:** • There are cases in the Draft RE for Asbestos where the wording suggests that risk below 1x10-4 or 1x10-6 are the same as "no risk." To avoid misinterpretation of the Draft RE for Asbestos findings by the public at large by recommending that statements using the phrases "no risk" or "risk still persisted" should be revised to be clearer. An example would be to report that "risks are	EPA has clarified the text in Part 1 of the Risk Evaluation for Asbestos used to describe risk.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	estimated to be below target risks" or "risks are estimated to be above the target risks."	
8.20 **Include data gaps section**		
SACC	**SACC COMMENTS:** • Recommendation 72: Include a section that identifies data gaps; information that is needed to improve estimates of populations at risk.	EPA requested information on all aspects of risk evaluations throughout the risk evaluation process, including opening public dockets for receipt of such information, conducting outreach to manufacturers, processors, users and other stakeholders, as well as conducting tailored data development efforts for some of the first 10 chemicals. Given the timeframe for conducting risk evaluations on the first 10 chemicals, use of TSCA data gathering authorities has been limited in scope. In general, EPA intends to utilize TSCA data gathering authorities more routinely for the next 20 risk evaluations. EPA has identified in several sections the key assumptions necessary to fill and uncertainties associated with data gaps to complete the risk evaluations utilizing the data identified and evaluated as part of EPA's systematic review process. In addition, EPA performed additional supplemental, targeted searches to fill data gaps where feasible.
8.21 **Be clearer on how cited epidemiology papers conducted and modeled their studies**		
SACC	**SACC COMMENTS:** • SACC made editorial comments made regarding the Draft RE for Asbestos. These comments include discrepancies noted in the document about the Berman and Crump (2008a) paper, the Loomis et al. (2009) paper, and the Elliott et al. (2012) study. Overall, the SACC suggests that EPA be clearer in how the papers used to identify exposure and risk conducted and modeled each of their epidemiological studies, and that statistical analyses that were used. The SACC listed out the references in correlation to the line number(s) of the	EPA made multiple edits according to editorial comments provided by the panel, including descriptions of Berman and Crump (2008a), Elliott et al. (2012) and Loomis et al. (2009) and a number of other responsive changes.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	Draft RE for Asbestos document being addressed and outline specific places in the document where edits are recommended.	
8.22 **Rename the section "selected optical properties"**		
28	**PUBLIC COMMENTS:** • EPA needs to be consistent with the referenced NIOSH *Current intelligence bulletin 62: Asbestos fibers and other elongate mineral particles: State of the science and roadmap for research.* In outlining the optical properties of asbestiform, EPA should rename the section "Selected optical properties" since it is not a complete listing of optical properties useful for the identification of the various asbestos minerals (*i.e.*, refractive index is not included).	EPA has revised Table 1-1 to include only the most relevant properties. Optical properties are no longer presented.
8.23 **Redefine the term "most susceptible"**		
42	**PUBLIC COMMENTS:** • The term "most susceptible" used in the following sentence is misleading: "Workers exposed to asbestos in workplace air, especially if they work directly with asbestos, are most susceptible to the health effects associated with asbestos." (p.23, ln. 972 - 973) The word susceptibly was and should be limited to those who are biologically more susceptible like children and elderly. Relatively high exposure and susceptibility should not be confused as similar terms as they are entirely different concepts.	EPA has revised this sentence to clarify that the assertion that these workers are most susceptible is due to higher exposures. While EPA acknowledges there are a wide variety of perspectives and definitions related to susceptibility, the risk evaluations consider susceptibility related to both physiologic factors and exposures.
8.24 **EPA ignored gaps identified in the Problem Formulation**		
SACC, 97	**SACC COMMENTS:** • EPA ignored the gaps identified in the Problem Formulation and did not mandate collection of monitoring data, specifically on the efficacy of asbestos removal by filtration in the chlor-alkali process. There's	With regard to the chlor-alkali process, EPA conducted site visits to 2 chlor-alkali facilities as described in the Scope and PF document and also held conference calls with industry regarding processing and disposal of asbestos diaphragms.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	a large uncertainty for environmental exposures due to a general lack of monitoring data present for surface water. Recommendation 95: Harmonize differences between issues raised in the Problem Formulation document and those evaluated in the Draft RE for Asbestos. **PUBLIC COMMENTS:** • Based on the many information gaps in the problem formulation, commenters petitioned EPA to use its authority under TSCA to require industry to report comprehensive import, use, and exposure information to inform the risk evaluation; however, EPA did not do so.	EPA did not use its TSCA data collection authorities to gather additional information regarding asbestos because EPA believes it had sufficient information to complete Part 1 of the Risk Evaluation for Asbestos using a weight of scientific evidence approach. EPA selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation.
8.25 **The Draft RE for Asbestos is not "fit for purpose"**		
64	**PUBLIC COMMENTS:** • With respect to risk management decisions pertaining to exposures to dusts generated in motor vehicle repair, the Draft RE for Asbestos is not 'fit for purpose.' This Draft RE for Asbestos estimates risks for exposures to chrysotile fibers as previously found in asbestos textile manufacturing, which no longer exist in the US. The Draft RE for Asbestos does not make a valid assessment of risks associated with compact particles of heat-modified chrysotile as were formerly found in motor vehicle repair environments. • The Draft RE for Asbestos is not fit for the purpose of informing risk management decisions pertaining to chrysotile in motor vehicle repair environments. It ignores the large body of epidemiologic studies, in vivo laboratory animal studies, in vitro studies, and mechanistic, kinetic, and mode of action (toxicity pathways) studies that contribute to hazard identification for compact particles, such as heat-	EPA has evaluated risk from exposure to chrysotile asbestos in Part 1 based on the relevant COUs that were described in the Scope document and Problem Formulation document. Part 2 of the Risk Evaluation for Asbestos will evaluate risks related to COUs for legacy uses and associated disposals for asbestos and will include other fiber types. Part 1and Part 2 will comprise EPA's Risk Evaluation for Asbestos, and EPA is confident that its evaluation is "fit for purpose" in the context of meeting the statutory requirements under TSCA. EPA considered all relevant information that was reasonably available. Part 1 of the Risk Evaluation for Asbestos includes narrative describing the process used to select studies for which data was utilized for the evaluation. Additional inclusion/exclusion criteria for all studies is included the Application of Systematic Review in TSCA Risk Evaluations document. Furthermore, EPA made available the documentation of the literature search strategy and the resulting references with the Scope document and the data quality evaluation and extraction files are provided as

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
	modified chrysotile as found in motor vehicle repair environments.	Supplemental Files to Part 1 of the Risk Evaluation for Asbestos.
8.26 **The Draft RE for Asbestos does not address TSCA requirements**		
68	**PUBLIC COMMENTS:** • The provided risk assessment exercise does not address the task as defined by TSCA. EPA does not actually address "asbestos" in this risk assessment.	Part 1 of the Risk Evaluation for Asbestos is focused on risk determinations for exposures to uses of chrysotile asbestos. EPA is developing a supplemental scope document to look at legacy uses and associated disposals for asbestos, which will inherently consider other fiber types included in the definition for asbestos adopted by EPA for the purposes of the asbestos risk evaluation under TSCA. The definition and plan for the asbestos risk evaluation is clarified in the Preamble.
8.27 **Correct error in Table 2-4**		
42	**PUBLIC COMMENTS:** • It is not clear why Table 2-4 has 11 f/cc as the maximum result when, as noted in the footnote, it should read 0.019 fibers/cc. This incongruency is perhaps just a typographical error that needs to be corrected.	EPA clarifies that 11 f/cc is the maximum value reported in the study despite it being considered an anomaly. For accuracy, this maximum value is reported with the next highest value being indicated in a footnote for appropriate interpretation/consideration.

#	Summary of Comments for Specific Issues Related to Charge Question 7	EPA/OPPT Response
8.28	**Non-cancer effects of chrysotile are not similar to Libby amphibole**	
82	**PUBLIC COMMENTS:** • In the Draft RE for Asbestos, the sentence "if the non-cancer effects (*e.g*, asbestosis and pleural thickening) of chrysotile are similar to Libby amphibole asbestos, the non-cancer effects of chrysotile are likely to contribute to the overall health risk of asbestos beyond the risk of cancer" (Draft RE for Asbestos ln. 7636–7639) should be deleted or modified as: (1) Libby amphibole is not classified as one of the six asbestos types; (2) the pleural thickening in individuals exposed to Libby amphibole is remarkable and has not been noted in chrysotile workers who exhibit asbestosis; and (3) there are no scientific data supporting this hypothesis.	EPA believes there are inaccuracies in the comment as asbestosis and pleural plaques are separate outcomes and are evaluated independently. EPA did not find the suggested revision to be warranted.

9. Systematic Review

EPA did not include a charge question specific to systematic review because, but SACC and public comments addressed these topics.

#	Summary of Comments for Specific Issues Related to Systematic Review	EPA/OPPT Response
9.1	**Systematic review supplemental file effort recognized**	
42	**PUBLIC COMMENTS:** • The supporting document to the proposal, entitled "DRAFT evaluation for Asbestos: Systematic Review Supplemental file: Data Quality Evaluation of Human Health Hazard Studies: Mesothelioma and Lung Cancer Studies" (March 2020) shows extraordinary discipline and patience of the staff.	EPA thanks the commenter for this acknowledgement.

#	Summary of Comments for Specific Issues Related to Systematic Review	EPA/OPPT Response
9.2	**Relevant literature sources were overlooked or deemed inadequate**	
SACC, 95	**SACC COMMENTS:** • Members reported finding relevant literature sources that were apparently overlooked or deemed inadequate (including occupational exposure). • Recommendation 73: Use a broader set of exposure assessment studies to estimate exposures for the designated COUs. **PUBLIC COMMENTS:** • Commenter found nearly 100 relevant papers that were not cited.	EPA clarified the literature search strategy in the Scope for the Risk Evaluation for the Asbestos and the related supplemental files. EPA appreciates the suggestions on the implementation of systematic review under TSCA and is continuing to refine its Systematic Review protocol. In addition, EPA is seeking feedback from the National Academies of Science (NAS) on its Systematic Review process, including data evaluation criteria and data quality rating methods used in TSCA Risk Evaluations. The NAS webinars took place from June through August 2020. EPA will consider all comments and feedback received in updating its protocol. EPA will consider these comments during revisions to future literature search strategy documents. The literature search for the first 10 chemicals was conducted in consistency with EPA's existing systematic review process.
9.3	**Request to improve transparency, including use of previous assessments and process for backward searching**	
SACC, 34, 39, 42, 65, 77, 83, 87, 96, 106	**SACC COMMENTS:** • Occupational and consumer exposures need further discussion on the quality and relevance of available exposure data. This is particularly an issue for the gasket replacement COU. • Recommendation 98: Clarify quality and relevance of occupational and consumer exposure data. **PUBLIC COMMENTS:** • For the systematic review, the scope of the literature search appears to go beyond chrysotile asbestos, suggesting that the IUR for chrysotile asbestos is confounded by other forms. For greater transparency, commenter asked for greater detail in how previous assessments were leveraged for the current assessment	All studies used in Part 1 of the Risk Evaluation for Asbestos, including industry submissions, are evaluated using the same data quality criteria under the process described in the Application of Systematic Review in TSCA Risk Evaluations document. Specific information on data quality evaluation are posted as Supplemental Files to Part 1 of the Risk Evaluation for Asbestos. In consideration of comments received, EPA is in the process of updating the TSCA Systematic Review protocol to improve the transparency of this review process and further reduce possible bias such that all studies are appropriately considered.

#	Summary of Comments for Specific Issues Related to Systematic Review	EPA/OPPT Response
	and what process was used to conduct the "back-ward" searching. • EPA distinguishes its systematic review of asbestos from its previous draft risk evaluation but did not explain the protocol by which it conducted the data integration step to help in clarifying the differences in approach. • No clear definition of inclusion and exclusion criteria for the identified and reviewed papers was provided • EPA generally followed the Problem Formulation, except that the systematic review does not seem thorough, and there was an insufficient examination of the quality of the critical assumptions regarding both the exposure and cancer potency.	
9.4 **Comments about criteria for data/study inclusion and exclusion**		
SACC, 31, 34, 39, 42, 60, 67, 77, 82, 83, 85, 87, 92, 95, 96, 105	**SACC COMMENTS:** • The SACC generally supported EPA's hierarchy of data>modeling> occupational exposure limits or release limits, but some members suggested that data collected in workplaces under normal operations should have priority over data collected during work simulations for litigation support. • SACC noted several issues with the data quality evaluation (DQE) and questioned why certain references were not included in the Draft RE for Asbestos while others were. For example, Cely-García et al. (2016b), estimated personal exposure to asbestos of brake repair workers, was rated as 'High' in the DQE, but did not appear to have been used in the Draft RE for Asbestos. There were 29 studies in the DQE with data extracted. Twenty-seven (27) of those studies were in the data extraction file. It was not clear why or how the list was narrowed from 27 studies down to just	EPA appreciates the comments and is currently in the process of updating its Systematic Review protocol. In addition, EPA awaiting feedback from the National Academies of Science (NAS) on its Systematic Review process, including data evaluation criteria and data quality rating methods used in TSCA Risk Evaluations. The NAS held webinars from June through August of 2020 to review the TSCA's Systematic Review protocol. EPA will consider all comments and feedback received in updating its Protocol. Regarding the scope of Part 1 of the Risk Evaluation being limited to lung cancer and mesothelioma, EPA described the rationale for this in the Scope and Problem Formulation documents. Briefly, these outcomes are those for which there is high confidence in the association between exposure and effect. However, in response to public comment and SACC input, EPA has evaluated additional studies on laryngeal and ovarian cancers to develop an adjustment factor to the IUR to account for these other cancer in the risk estimates.

	the five studies cited in the Draft RE for Asbestos, with data from only two of those studies actually used to estimate exposures. • Recommendation 30: Explain the inclusion/exclusion criteria for brake and gasket exposure studies. • Recommendation 31: Each study rated acceptable in the DQE should be described/discussed and a justification provided when results from that study are not utilized in the risk evaluation. **PUBLIC COMMENTS:** • There is a lack of consideration of all data regarding chrysotile asbestos. For the most part, only articles favoring the conclusions of EPA are included in the analyses. • Was it appropriate to narrow the scope only to certain cancers (lung and mesothelioma) in epidemiology studies? Did EPA appropriately apply systematic review principles when narrowing the scope? EPA's systematic literature review as it relates to AABL is overly narrow in scope and ignores a large body of scientifically sound epidemiologic evidence that clearly indicates no increased risk of asbestos-related disease in persons working with and around AABL. • EPA needs to re-consider these papers, Garabrant et al. (2016; Goodman et al. (2004) regarded off-topic. • EPA failed to include or exclude studies based on the protocol's pre-specified criteria. EPA failed to use two or more members of the review team to independently screen and select studies. • EPA has failed to appropriately document the disposition of each of these 10,320 references following title and abstract screening or offer an explicit justification for their exclusion at the full text screening step. • In section 2.3.1.6, the single study considered by EPA was rated "low" in the systematic review and the	EPA's quality evaluation method was developed following identification and review of various published qualitative and quantitative scoring systems to inform our own fit-for-purpose tool. The development process involved reviewing various evaluation tools/frameworks (*e.g*, OHAT Risk of Bias tool, CRED, etc.; see Appendix A of the Application of Systematic Review in TSCA Risk Evaluations document. and references therein), as well as soliciting input from scientists based on their expert knowledge about evaluating various data/information sources specifically for risk assessment purposes. EPA published the Strategy for Conducting Literature Searches for Asbestos in June 2017 along with the Scope document for Asbestos, similar to all first 10 TSCA chemical risk evaluations. This document outlined the literature search strategy and title/abstract inclusion/exclusion criteria used for screening, found in Appendix E. Part 1 of the Risk Evaluation for Asbestos includes narrative describing the process used to select studies for which data was utilized for the evaluation (Section 1.5.1) Generally, for consumer and bystander exposures, 30 studies were identified, evaluated, and extracted. However, five studies were selected for use based on the studies meeting certain factors and assumptions described in Section 2.3.2.1 and 2.3.2.1.1 and the associated, assumed representativeness of an expected DIY consumer scenario. Specifically, while they were occupational in nature, the studies selected were studies which did not involve the use of engineering controls, did not involve PPE, did not involve methodologies uncharacteristic of an expected consumer methodology. Citations for each reference are provided, along with a link to the HERO database to allow individuals to review at a minimum, the abstract for each study identified to provide some insight about each reference.

#	Summary of Comments for Specific Issues Related to Systematic Review	EPA/OPPT Response
	limitations of this study are unacceptable. Such flimsy data should not be used as "fit-for-purpose" or "best available science." • Draft RE for Asbestos fails to consider data collected by accepted methods as required by TSCA as best available science. • EPA method for including studies in the literature flow diagram for human health hazards is inconsistent with its flow diagram for Environmental hazard in Figure 1-7.	Inclusion/Exclusion criteria for all studies identified and evaluated as part of EPA's systematic review process are described in the Application of Systematic Review in TSCA Risk Evaluations document published by EPA. A full description and discussion on each study rated acceptable within Part 1 would result in prohibitively long document with little added benefit in relation to justifications when the process is described in the Application of Systematic Review in TSCA Risk Evaluations document.
9.5 **EPA should not rely on voluntary information from manufacturers/importers**		
77	**PUBLIC COMMENTS:** • EPA should not rely on manufacturers/importers voluntarily offering crucial exposure information.	All studies used in the Risk Evaluation, including industry submissions, are evaluated using the same data quality criteria under the TSCA Systematic Review process described in the Application of Systematic Review in TSCA Risk Evaluations document. In consideration of comments received, EPA is in the process of updating the TSCA Systematic Review protocol to improve the transparency of this review process and further reduce possible bias such that all studies are appropriately considered.

10. Physical/Chemical Properties

EPA did not include a charge question specific to physical and chemical properties, but SACC and public comments addressed this topic.

#	Summary of Comments for Specific Issues Related to Physical/Chemical Properties	EPA/OPPT Response
10.1 **Conduct studies on physical/chemical properties**		
SACC, 109	**SACC COMMENTS:** • Different testing methods such as surface area electron diffraction (SAED) or energy dispersive X-ray analysis (EDXA) versus phase contrast optical microscopy (PCM) methods should be used to differentiate better	As part of the consideration of reasonably available information and what is needed to conduct a risk evaluation, EPA considers data gaps and the need for additional information as appropriate. EPA considers reasonably available data on a chemical by chemical basis and would

#	Summary of Comments for Specific Issues Related to Physical/Chemical Properties	EPA/OPPT Response
	between the morphological and structural characterizations of types of fibers. **PUBLIC COMMENTS:** • Separate studies should be conducted on "the characteristics," "homogeneous nature," or "friability of each type of asbestos."	exercise information gathering in a fit-for-purpose manner. EPA did not determine a need for more data on testing methods or physical properties to conduct a risk evaluation for asbestos.
10.2 **Concerns about terminology and misclassification**		
SACC, 92	**SACC COMMENTS:** • There's issue of the "purity" of the chrysotile used in the products that are being evaluated by this review. Since there is no evidence that any chrysotile asbestos products have ever been amphibole asbestos free, the SACC has concerns that all aftermarket brake pads/linings may not be amphibole free. • Some paragraphs are too technically written for the general audience and are more appropriate for a mineralogist. **PUBLIC COMMENTS:** • EPA's definition of asbestos used in the report is outdated and does not consider the physical properties of other fibers. This is based on 1980 rule of classifying asbestiform versus non-asbestiform fibers, which thus classified talcum products as non-asbestiform. However, modern technologies do detect asbestiform contamination in talcum powder, and the industry has been linked with workers dying at higher rates of mesothelioma and other cancers (Emory et al. (2020). • EPA should revisit the notion "no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape." As said in the National Academy of Science's evaluation on NIOSH's Research Roadmap on Asbestos, the definition of these dimensions should be periodically refined as knowledge	The issue of purity and the possibilities of amphibole contamination in commercial chrysotile fibers has already been discussed in the Section 1. EPA has revised and clarified the language used in Section 1.1.

#	Summary of Comments for Specific Issues Related to Physical/Chemical Properties	EPA/OPPT Response
	of these mineral particles and their potential for health effects accumulates.	
10.3 **Improve discussion of fiber length and aerodynamic aspects**		
SACC, 82	**SACC COMMENTS:** • The length of fibers was largely ignored in the risk evaluation, given that this physical-chemical property has significant impact on the biological responses of asbestos. • Recommendation 7: If available, provide metrics of aerodynamics for each fiber type. At a minimum, discussion regarding this characteristic should be provided in the text. • Recommendation 8: Discuss variation in fiber size and length in addition to means, including the pros and cons of different microscopy methods used to measure fibers. • Recommendation 12: Include a discussion of properties related to the suspension of fibers. • Recommendation 81: Discuss the utility of fate models derived from micro-fiber analyses for future ecological assessments of asbestos. **PUBLIC COMMENTS:** • One of the most important physical properties associated with asbestos fibers is the aerodynamic aspects of the fiber that allow penetration into pulmonary areas of the lung. This is not discussed in the document.	EPA has included more information about the fiber length and diameter in Section 1.1. The advantages and disadvantages of different microscopy methods used to measure fibers has been described. EPA has added text in Section 3.2.2.3 to describe that aerodynamic diameter is a determinant of deposition and penetration of fibers into the respiratory tract.
10.4 **Include information from animal studies on the physical-chemical properties**		
SACC	**SACC COMMENTS:** • Recommendation 11: Include in the discussion of the physical-chemical properties the fiber dimension and surface changes of friction products known from animal studies to be important to health outcomes.	EPA has added a new Section 3.2.2.3 on Mode of Action Considerations for Asbestos which includes information on the physiochemical properties of chrysotile fibers.

#	Summary of Comments for Specific Issues Related to Physical/Chemical Properties	EPA/OPPT Response
10.5 **FDA's parallel effort on chrysotile**		
SACC	**SACC COMMENTS:** • Recommendation 13: Acknowledge that the U.S. Food and Drug Administration (FDA) is conducting a "parallel effort" to further explore the physical-chemical properties and characteristics of chrysotile.	EPA is aware of the Interagency Working Group on Asbestos in Consumer Products (IWGACP) effort to develop standardized testing methods for asbestos and other mineral particles of health concern in talc. EPA has several representatives on the workgroup and is working with other government scientists to develop recommendations on asbestos testing and analytical methods.
10.6 **NIOSH has background information**		
SACC	**SACC COMMENTS:** • Recommendation 14: Note that NIOSH (2011) provides helpful background information for readers of this DRE.	EPA has made revisions to present more chrysotile-specific information on physical-chemical properties. EPA will additionally consider NIOSH as a source of background information in the Part 2 of the Risk Evaluation for Asbestos where other uses of asbestos are evaluated.

11. Public Comment and Peer Review Processes

The following summarizes public comments addressing the public comment and peer review process.

#	Summary of Comments for Specific Issues Related to Public Comment and Peer Review Processes	EPA/OPPT Response
11.1 **Concerns about insufficient time**		
31, 42, 51, 66, 67, 88	**PUBLIC COMMENTS:** • Less than 3 weeks (between April 3rd and 22nd) were provided for comments to reach the SACC was largely considered insufficient. Also, the timing of release for this document during peak COVID limits the time many physicians and scientists and other subject matter experts to review this in a timely manner. • If the report had been released before April, the 2-month comment period may have been adequate, considering the large scope of this report. • Tribal environmental offices and staff being disproportionately affected by the crisis, found the 60-	The Lautenberg amendments to TSCA provide a three- and one-half-year timeframe for completion of existing chemical risk evaluations. However, in the first year following enactment, EPA's focus was on issuing the Risk Evaluation Rule outlining the framework for implementing TSCA section 6(b). Consequently, the time for completing the first 10 risk evaluations was compressed. As discussed in the Introduction, EPA believed peer reviewers were most effective in their role if they received the benefit of public comments on draft risk evaluations prior to peer review. For this reason, and consistent with standard Agency practice, the public comment period preceded peer review. The final

#	Summary of Comments for Specific Issues Related to Public Comment and Peer Review Processes	EPA/OPPT Response
	day comment period insufficient. In the future, a 90-day comment period should be considered. • The SACC would be most effective if they could receive the public comments on Draft RE for Asbestos prior to peer review. However, the time for the panelists to digest the public before the meeting is too short.	risk evaluation changed in response to public comments received on the draft risk evaluation and/or in response to peer review, which itself may be informed by public comments. EPA will consider these comments for future risk evaluations. EPA acknowledges the coronavirus pandemic and adapted accordingly, to include a virtual public meeting for the SACC review. However, statutory requirements for the timeline of the chemical risk evaluations under TSCA were unchanged.
11.2 **Balance, independence, and bias of peer review**		
42, 69, 74, 76, 80, 84, 89, 104	**PUBLIC COMMENTS:** • It may be noted by trial lawyers, who will likely be submitting comments, that all the meta-analyses were conducted by experts who have testified on behalf of defendants. That is true, but EPA should weigh the quality of the work and the fact that they survived peer review in journals with solid impact factors. • NIOSH and OSHA did not evaluate or perform third party assessments of exposure in the chlor-alkali industry, instead relying on measurements from employers. Validation should be required for the respective data. • The Draft RE for Asbestos should not be unduly influenced by experts whose scientific theories have been rejected as not representative of mainstream science and whose involvement in asbestos advocacy organizations calls into question the impartiality of their work. • Several commenters expressed that the EPA panel may not be completely unbiased and without other financial interest. One commenter stated that EPA appears to be lobbied and guided by the Asbestos Disease Awareness Organization – and affiliated individuals, some of	EPA has implemented procedures to obtain input by the public and the SACC, and considers all comments submitted. EPA has developed a rigorous process to identify all reasonably available information and to evaluate scientific data and information according to pre-defined criteria. The assumptions and uncertainties related to analyses and conclusions are noted throughout the risk evaluations.

#	Summary of Comments for Specific Issues Related to Public Comment and Peer Review Processes	EPA/OPPT Response
	whom testify routinely as plaintiff experts in asbestos cases, who are deeply committed to perpetuating the narrative that brakes manufactured with chrysotile asbestos pose a risk. EPA has placed three experts on SACC, including ad hoc members, who earn significant sums by testifying for plaintiffs in asbestos litigation and, therefore, have a clear financial stake in the risk evaluation's outcome. This participation is contrary to EPA's own rules for conflicts of interest in connection with participation on the SACC. Additionally, there are calls for increased diversity in the EPA review panel. • It may not be possible to form a committee of the top experts in the field who have never been involved in asbestos litigation in some way. However, "the participation of experts involved in the litigation must be balanced and provide EPA with a diversity of perspectives." • One comment recommended "expansion of the EPA panel to include several leading epidemiologists, toxicologists, mineralogists, biostatisticians, and pathologists working worldwide" • Although current panels contain many credible professionals, only one or two persons on the panel/ad hoc group have been seriously studying asbestos toxicology and epidemiology for the recent decades. Obtaining "an independent review of the science underlying the risk assessment" is difficult. • The Draft RE for Asbestos is the first comprehensive assessment of asbestos risks in over 30 years. The public is depending on the SACC to provide the honest and hard-hitting feedback that EPA needs in order to do its job correctly and fully examine the impact of this deadly chemical.	

#	Summary of Comments for Specific Issues Related to Public Comment and Peer Review Processes	EPA/OPPT Response
	• There are three other dockets from 2017–2020 with a lot of evidence that reiterate our concerns listed above. EPA should not ignore the concerns expressed by the public.	
11.3 **Withdraw draft and issue a revised Draft RE for Asbestos**		
77, 85, 86, 111	**PUBLIC COMMENTS:** • Commenters urged EPA to withdraw the current Draft RE for Asbestos and address its shortcomings in a revised risk evaluation for asbestos in which EPA complies with its obligations under TSCA and the Administrative Procedure Act.	EPA recognizes there are many perspectives on approaches to conducting the risk evaluation for asbestos under TSCA. EPA has described the approach it will take moving forward in the Preamble that describes the current effort as Part 1 focused on chrysotile asbestos and that Part 2 will be subsequently developed (scope document under development now) and focus on legacy uses and associated disposals of asbestos (including other fiber types).

12. Other

#	Summary of Other Comments	EPA/OPPT Response
12.1 **Agency should recognize impact of risk evaluation on tort/personal injury litigation**		
42, 74	**PUBLIC COMMENTS:** • The document could have a dramatic impact on current and future toxic tort litigation, which is important to recognize. • Agency documents are routinely used as evidence in asbestos personal injury litigation, both as exhibits and as reliance materials by expert witnesses. The document if finalized as is puts EPA in the position of supporting plaintiffs in asbestos litigation, by issuing a risk evaluation that addresses only an illusory current COU. Defendants in asbestos personal injury litigation will be significantly and directly harmed by such a result, forced to defend cases based upon the product-specific science, and also explain how and why EPA's risk evaluation process entirely disregarded that science,	In conducting risk evaluations under TSCA, EPA must meet the statutory requirements of the law. Consideration of personal injury litigation is outside the scope of these requirements.

#	Summary of Other Comments	EPA/OPPT Response
	thus reaching an erroneous conclusion. Such harm can be avoided and ameliorated only if EPA adheres to its statutorily mandated objectivity and mission and is equally careful to ensure that it permits no exceptions to its conflict of interest requirements and follows the best available science on the issue. • EPA is legally obliged to be a neutral arbiter of available relevant science in this and each of its risk assessments. The fact that the Final Risk Evaluation will have a significant impact on private litigation with many stakeholders is reason for creating a risk assessment process which provides a voice to the positions of defendants as well as plaintiffs, and which is based upon current applicable science, unimpaired by the agenda of one set of litigants or the other.	
12.2 **EPA should expand the category for required notification to "any use" of asbestos**		
43	• Allowing new asbestos containing materials to be used in construction will only increase the number of workers (miners, manufacturers, construction trade contractors, etc.) exposed to asbestos and lengthen the potential exposure period, perhaps by decades. To even consider allowing, even at times seemingly encouraging, additional AC materials and products to be used is counterproductive to the stated goals of the EPA.	EPA finalized an Asbestos Significant New Use Rule (SNUR) under TSCA Section 5 on April 25, 2019 that prohibits manufacture (including import) or processing of discontinued uses of asbestos from restarting without EPA evaluating and making a determination on whether the chemical presents unreasonable risks to health or the environment and to take regulatory action, as appropriate, under section 5.
12.3 **Concern about feasibility for timely review of risk evaluation or SNUR application**		
109, 43	**PUBLIC COMMENTS:** • The SNUR requires that all entities notify EPA days before commencing any manufacturing. Given the latency period of 10 to 30 years and the dose-response relationship of asbestos and the difficulty determining the nature and means of exposure, is it feasible to review an application in within this timeframe?	Information on the requirements and procedures for notices submitted under the SNUR for Asbestos is provided in that specific rulemaking. The Docket ID for this rulemaking is EPA-HQ-OPPT-2018-0159 and the rule was published in the FR (84 FR 17345).

#	Summary of Other Comments	EPA/OPPT Response
	• EPA requires manufacturers to submit notification at least 90 days before manufacturing an asbestos-containing product. The SNUR implies that the EPA cannot use historic data to evaluate the new product. This begs the question, "How can the EPA conduct a rigorous review of a new product in only 90 days?"	
12.4 **State interest in ensuring Draft RE for Asbestos is conducted in accordance with TSCA**		
77	**PUBLIC COMMENTS:** • State commenters expressed a significant interest in ensuring that the risk evaluation for asbestos is conducted in accordance with TSCA. They cited state regulations, new cases of mesothelioma, associated deaths, and exposure sources in their states. The commenting states included Massachusetts, California, Maryland, Minnesota, New York, Oregon, and Washington State.	EPA is confident that Risk Evaluations for the First 10 Chemicals completed under TSCA meet the statutory requirements. EPA considered and evaluated reasonably available information and considered comments from the public and the SACC on its evaluation and conclusions. EPA is aware of state regulations on asbestos, but these do not have bearing on mandates required of EPA under TSCA.
12.5 **Not prudent to burden the chlor-alkali industry while responding to COVID**		
42	**PUBLIC COMMENTS:** • During the peak of the COVID-19 crisis, it would not seem to be a prudent time to be placing further constraints on the chlor-alkali industry that produces the most widely used disinfectant (chlorine), when the data shows that the workers are not over-exposed to asbestos (based upon the OSHA PEL).	EPA has conducted Part 1 of the Risk Evaluation for Asbestos focused on chrysotile asbestos according to the statutory requirements and timelines required under TSCA. EPA will initiate risk management action to address unreasonable risks identified in Part 1 of the Risk Evaluation, and the public will have an opportunity to comment on any proposed rulemaking under TSCA section 6(a).
12.6 **EPA's narrow scope of evaluation for asbestos should not be a template for future risk evaluation**		
25, 45	**PUBLIC COMMENTS:** • EPA's narrow scope of evaluation for asbestos should not be used as a template for future risk evaluation by EPA because it has been hastily crafted and is designed to underestimate risk. Even with the narrowing of the scope of the risk evaluation and the resulting underestimating of the risk of exposure to asbestos,	Since TSCA was amended in 2016, EPA has worked expeditiously to conduct risk evaluations for the First 10 Chemicals according to the statutory deadlines while meeting all requirements of the law. As a part of these risk evaluations, EPA has received a wealth of input from the public and from the SACC that will lead to refinements and

#	Summary of Other Comments	EPA/OPPT Response
	EPA still arrives at the conclusion that asbestos poses an unreasonable risk in most COUs. Streamlining should not be used in other evaluations, just because it makes the process of risk evaluation easier for EPA. • It is concerning that what EPA does here to estimate risk will be the template for all other US assessments and perhaps international ones as well. EPA has admittedly used methods and template that might underestimate the risk of asbestos related deaths. Since EPA is looked to as an authority on risk assessments, it is important that its methodology is fair, not erring on the low side of asbestos exposure, asbestos cancer and asbestos deaths.	improvements in the processes used to develop risk evaluations under TSCA.
12.7 **EPA should continue to support asbestos regulations**		
29	**PUBLIC COMMENTS:** • EPA should ensure that it continues to support all its Asbestos Hazard Emergency Response Act (AHERA) and Asbestos School Hazard Abatement Reauthorization Act (ASHARA) regulations concerning the risks posed in the management and abatement of ACBMs including legacy ACBMs.	AHERA and ASHARA regulations are rules established before, and are independent of, the amended TSCA and are not impacted by the implementation of risk evaluation and risk management under TSCA.
12.8 **Insurance coverage for medical surveillance for asbestos-exposed people**		
15, 17, 29, 30	**PUBLIC COMMENTS:** • Commenters asked EPA to work with OSHA, NIOSH and ILO to forge ahead with affordable, insurance-covered low dose CT scanning for medical surveillance of persons with exposures, where appropriate, particularly for laborers exposed to fiber releases from ACBMs from buildings (*e.g*, schools). In 2017, the CDC released its meta-study showing an increase in mesothelioma in construction type trades from 1999 to 2015. • Commenter suggested pushing OSHA, NIOSH, and ILO to lobby Congress to provide insurance coverage	EPA's obligations and requirements under TSCA and its risk evaluation for asbestos do not pertain to insurance coverage or medical surveillance.

#	Summary of Other Comments	EPA/OPPT Response
	for low dose CT scanning and medical surveillance for asbestos-exposed workers and residents of buildings where legacy ACBMs are present.	
12.9 **Consider Canada's regulatory approach for asbestos**		
68	**PUBLIC COMMENTS:** • Commenter outlined how Canada regulated asbestos. A similar action by EPA would meet the very limited mandate of the current task and does not require a new risk assessment.	As noted in the Scope and Problem Formulation documents for Asbestos, EPA ascertained all the international laws and regulations pertaining to Asbestos (Appendix A-3 in each document). EPA reviewed these laws and regulations to inform its consideration of approaches to conducting the risk evaluation and subsequent risk management.
12.10 **Availability of information on consumer products and associated manufacturers**		
109	**PUBLIC COMMENTS:** • Will you be able to separately list the new consumer products anticipated to entering the market based on the risk evaluation and the SNUR? • Who are the anticipated manufacturers of these construction, manufacturing, wholesale trade and transportation entities and the current political affiliation and of these entities?	For more information on the SNUR, please review the specific rulemaking documents. The Docket ID for this rulemaking is EPA-HQ-OPPT-2018-0159 and the rule was published in the FR (84 FR 17345). Since finalization of the asbestos SNUR in 2019, EPA has not received any significant new use notices. EPA is not aware of manufacturers that may anticipate submitting a notice under the SNUR.
12.11 **Research for worker conditions in asbestos mines outside of U.S.**		
43	**PUBLIC COMMENTS:** • Although there are no active asbestos mines in the US at this time, someone has to mine the asbestos, package it, and ship it to us for our use. The U.S. has rules and programs that look at ensuring products sold in the U.S. are not manufactured in other countries using child labor or sweat shops, where worker safety is compromised in the name of profit. Has the EPA done any research on the conditions and exposures workers must endure when working in asbestos mines?	The questions raised in this public comment are outside the scope of TSCA risk evaluations and the associated statutory requirements that EPA must meet.

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