UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Memorandum

SUBJECT: Transmittal of Meeting Minutes and Final Report for the TSCA Science Advisory Committee on Chemicals Meeting via Phone and Webcast held June 8-11, 2020

TO: Yvette Reyes Collazo, MS
Director
Office of Pollution, Prevention and Toxics

FROM: Diana Wong, PhD
Designated Federal Official
TSCA Science Advisory Committee on Chemicals
Office of Science Coordination and Policy

Diana Wong

THRU: Steven M. Knott, MS
Executive Secretary
TSCA Science Advisory Committee on Chemicals
Office of Science Coordination and Policy

Hayley Hughes For Steve Knott
27August2020

Hayley Hughes, DrPH, MPH, CSP
Director
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HAYLEY HUGHES

Digitally signed by HAYLEY HUGHES
Date: 2020.08.27 11:05:57 -04'00'

Please find attached the meeting minutes and final report for the TSCA Science Advisory Committee on Chemicals open meeting held via phone and webcast on June 8-11, 2020. This report addresses a set of scientific issues being considered by the Environmental Protection Agency regarding the Peer Review for the Draft Risk Evaluation for Asbestos

Attachment

cc:
Alexandra Dunn
David Fischer
Yvette Reyes Collazo
Tala Henry
Mark Hartman
Sheila Canavan
Stanley Barone
Louis Scarano, PhD
OPPT Docket

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Charles Barton, PhD
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TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2020-6

Peer Review of EPA Draft Risk Evaluation of Asbestos

June 8 -11, 2020

TSCA Science Advisory Committee on Chemicals Meeting,

Held via Phone and Webcast (Virtual Meeting)

NOTICE

The Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC) is an advisory Committee operating in accordance with the Federal Advisory Committee Act and established under the provisions of TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016. The TSCA SACC provides independent advice and recommendations to the U.S. Environmental Protection Agency (EPA or Agency) on the scientific basis for risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC serves as a primary scientific peer review mechanism of the EPA, Office of Pollution Prevention and Toxics (OPPT), and is structured to provide balanced expert assessment of chemicals and chemical-related matters facing the Agency. Additional peer reviewers are considered and from time-to-time added on an *ad hoc* basis to assist in reviews conducted by the TSCA SACC. This document constitutes the meeting minutes and final report and is provided as part of the activities of the TSCA SACC.

The TSCA SACC carefully considered all information provided and presented by the Agency, as well as information presented by the public. The minutes represent the views and recommendations of the TSCA SACC and do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the federal government. Mention of trade names or commercial products does not constitute an endorsement or recommendation for use.

The meeting minutes and final report do not create or confer legal rights or impose any legally binding requirements on the Agency or any party. The meeting minutes and final report of the June 8 – 11, 2020, TSCA SACC meeting represent the SACC's consideration and review of scientific issues associated with Peer Review of EPA Draft Risk Evaluation of Asbestos. Steven Knott, MS, TSCA SACC Executive Secretary, reviewed the minutes and final report. Kenneth Portier, PhD, TSCA SACC Chair, and Diana Wong, PhD, TSCA SACC Designated Federal Official, certified the minutes and final report. The report is publicly available on the SACC website (https://www.epa.gov/tsca-peer-review) under the heading of "Meetings" and in the public e-docket, Docket No. EPA-HQ-OPPT-2019-0501 accessible through the docket portal: https://www.regulations.gov. Further information about TSCA SACC reports and activities can be obtained from its website at: https://www.epa.gov/tsca-peer-review. Interested persons are invited to contact Diana Wong, PhD, SACC Designated Federal Official, via e-mail at wong.diana-m@epa.gov.

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Peer Review of EPA Draft Risk Evaluation of Asbestos

June 8-11, 2020

TSCA Science Advisory Committee on Chemicals Meeting,

Held via Phone and Webcast
(Virtual Meeting)

Kenneth Portier, PhD
TSCA SACC, Chair
TSCA Science Advisory
Committee on Chemicals

_____/s/_____

Date: _____

Diana Wong, PhD
Designated Federal Official
TSCA Science Advisory
Committee on Chemicals

_____/s/_____

Date: _____

Toxic Substance Control Act
Science Advisory Committee on Chemicals Meeting
June 8 - 11, 2020

Peer Review of EPA Draft Risk Evaluation of Asbestos

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LIST OF ACRONYMS AND ABBREVIATIONS

ACC	American Chemistry Council
ACI	American Cleaning Institute
ADC	Average Daily Concentration
ACM	Asbestos-Containing Materials
AF	Adjustment Factors
AHERA	Asbestos Hazard Emergency Response Act
AIAN	American Indian and Alaska Native
AIC	Akaike Information Criteria
AIHA	American Industrial Hygiene Association
APF	Assigned Protection Factor
ATSDR	Agency for Toxic Substances and Disease Registry
BCF	Bioconcentration Factors
BLS	Bureau of Labor Statistics
BMR	Benchmark Response
BZ	Breathing Zone
C&D	Construction and Demolition
CAA	Clean Air Act
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEC	Constituents of Emerging Concern
CI	Confidence Intervals
COC	Concentrations of Concern
COU	Conditions of Use
CT	Central Tendency
CV	Coefficient of variation
CWA	Clean Water Act
DF	Degrees of Freedom
DHHS	Department of Health and Human Services
DIY	Do It Yourself
DMR	Discharge Monitoring Report
DQE	Data Quality Evaluation
DRE	Draft Risk Evaluation
EC_{01}	Exposure Concentration associated with 1% extra risk
ECHA	European Chemicals Agency
ELCR	Excess Lifetime Cancer Risk
EPA	Environmental Protection Agency
ER	Extra Risk
ESD	Emissions Scenario Documents
EU	European Union
FDA	U.S. Food and Drug Administration
f/cc	Fibers per cubic centimeter
GLP	Good Laboratory Practice
GS	Generic Scenarios
HAP	Hazardous Air Pollutant
HEPA	High Efficiency Particulate Air
HTS	Harmonized Tariff Schedule
IARC	International Agency for Research on Cancer
ICD	International Classification of Disease
IRIS	Integrated Risk Information System

IUR	Inhalation Unit Risk
K_L	Lung cancer potency factor
K_M	Mesothelioma potency factor
LADC	Lifetime Average Daily Concentration
MCL	Maximum Contaminant Level
MRL	Minimum Reporting Level
MSDS	Material Safety Data Sheet
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
ND	Non-detect
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NGO	Non-Government Organization
NMRD	Non-malignant Respiratory Disease
NPDES	National Pollutant Discharge Elimination System
NPL	National Priority List
NRC	National Research Council
NTTC	National Tribal Toxics Council
OEM	Original Equipment Manufacturer
ONU	Occupational Non-Users
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBZ	Personal Breathing Zone
PCM	Phase Contrast Microscopy
PEL	Permissible Exposure Limit
PESS	Potentially Exposed and Susceptible Subpopulations
PF	Protection Factors
POD	Point of Departure
PPE	Personal Protective Equipment
POTW	Publicly Owned Treatment Works
RE	Risk Evaluation
RF	Reduction Factor
RfC	Reference Concentration
SAB	Science Advisory Board
SACC	Science Advisory Committee on Chemicals
SD	Standard Deviation
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
TSFE	Time Since First Exposure
TWA	Time-Weighted Average
TWF	Time Weighting Factor
USGS	United States Geological Survey
UTV	Utility Vehicles
WPF	Workplace Protection Factor
WQX	Water Quality Exchange

INTRODUCTION

The Toxic Substances Control Act (TSCA) of 1976, as amended by The Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016, Science Advisory Committee on Chemicals (SACC or Committee) completed its review of the set of scientific issues being considered by the Environmental Protection Agency (EPA) regarding the "Draft Risk Evaluation for Asbestos." The Draft Risk Evaluation, supplemental files, and related documents in support of the SACC peer review meeting are posted in the public e-docket at https://www.regulations.gov (ID: EPA-HQ-OPPT-2019-0501). The initial notice of availability of the Draft Risk Evaluations, opening the docket for comments, was published in the *Federal Register* on April 3, 2020 (85 FR 18954-18957) and notice of the rescheduled meeting was published in the *Federal Register* on May 15, 2020 (85 FR 29446). The review was conducted in a virtual meeting on June 8 - 11, 2020. Dr. Kenneth Portier chaired the meeting. Dr. Diana Wong served as the Designated Federal Official.

In preparing these meeting minutes and final report, the Committee carefully considered all information provided and presented by the Agency presenters, as well as information presented by public commenters. These meeting minutes and final report address the information provided and presented at the meeting, especially the Committee response to the Agency charge.

TSCA SACC Peer Review – EPA Draft Risk Evaluation of Asbestos

June 8 – 11, 2020:

Opening of Meeting – Diana Wong, PhD, Designated Federal Official, EPA/Office of Chemical Safety and Pollution Prevention (OCSPP)/Office of Science Coordination and Policy (OSCP)

Introduction and Identification of SACC Members – Kenneth Portier, PhD, Chair, TSCA Science Advisory Committee on Chemicals (SACC),

Welcome and Introductory Comments - Alexandra Dapolito Dunn, Esq, Assistant Administrator, EPA/OCSPP

OPPT Technical Presentation – Overview of Asbestos Risk Evaluation – Louis Scarano, PhD, EPA/OCSPP/Office of Pollution Prevention and Toxics (OPPT)/Risk Assessment Division (RAD)

Public Comments

Oral statements were presented as follows in the order received:

Linda Reinstein
Asbestos Disease Awareness Organization

David Garabrant, MD
University of Michigan

Christine Oliver, MD
Self

Celeste Monforton
American Public Health Association

Nicholas Chartres, PhD
University of California San Francisco
Program on Reproductive Health and the Environment

Robyn Brooks
The Chlorine Institute

Chacko Mathew
United Industries Unlimited LLC

Dennis Paustenbach, PhD
Paustenbach and Associates

Greg Brorby
ToxStrategies

Adele Abrams, JD
Law Office of Adele L. Abrams PC

J. Brent Kynoch
Environmental Information Association

Steve Risotto
American Chemistry Council

Penelope Fenner-Crisp, PhD
Environmental Protection Network

Arthur Frank, MD, PhD
Drexel University

Victor Roggli, MD
Duke University

Robert Sussman, JD
Sussman & Associates

Suresh Moolgavakar, MD
Exponent

Jacqueline Moline, MD
Northwell Health

Jessica Ryman-Rasmussen, PhD
American Petroleum Institute

Gabor Mezei, MD
Exponent

Barry Castlemen, SD
Environmental Consultant

Steven Compton, PhD
MVA Scientific Consultants

Richard Lemen, PhD
Self

Liz Hitchcock
Safer Chemicals

Written statements were provided to docket as follows in the order received:

Anonymous (multiple submissions)

Richard Haffey, President and Training Director, Mystic Air Quality Consultants, Inc.

C. Maahs, Self

Brent Kynoch, Managing Director, Environmental Information Association (EIA)

Mark G. Ellis, President, Industrial Minerals Association - North America (IMA-NA)[RR]

S. E. Strauss, State of Connecticut Asbestos Inspector/Management Planner

Kevin Bogue, Platform Environmental LLC

Michelle Roos, Environmental Protection Network (EPN)

Julie E. Goodman, PhD, DABT, FACE, ATS, et al., Gradient

David Garabrant, Emeritus Professor of Epidemiology and Occupational Medicine, University of Michigan

Judith Nordgren, Managing Director, Chlorine Chemistry Division, American Chemistry Council (ACC)

John W. Spencer, President, Environmental Profiles, Inc.

G. Mezei, MD, PhD; S. Moolgavkar, MBBS, PhD; and F. Mowat, PhD, Exponent, Inc.

P.R. Williams, Principal Environmental Health Scientist, E Risk Sciences, LLP

V.L. Roggli, Professor of Pathology**,** and **T.A. Sporn,** Associate Professor of Pathology, Duke University Medical Center

Dennis J. Paustenbach, PhD, President**,** and **David Brew,** Toxicologist, Paustenbach and Associates

M.C. Sharp, Director of Training for Hazard Management Services, Forensic Analytical Consulting Service

R.A. Lemen, PhD, Retired U.S. Assistant Surgeon General, United States Public Health Services

J. Brent Kynoch, Managing Director, Environmental Information Association (EIA)

A.L. Frank, MD, PhD, Professor of Public Health and Professor of Medicine, Drexel University

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Jacqueline Moline, MD, Chair, Occupational Medicine, Epidemiology, Prevention, The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

B. Castleman, ScD, Environmental Consultant

Raja Flores, MD, System Chairman, Department of Thoracic Surgery, Mount Sinai Health System

Linda Reinstein, President, and **Robert Sussman**, Counsel, Asbestos Disease Awareness Organization

Rebecca L. Reindel, Safety and Health Director, AFL-CIO

C. Blake and R. Harbison, Apex

Michele Carbone, MD, William and Ellen Melohn Chair in Cancer Biology, Director, Thoracic Oncology, Professor of Pathology, University of Hawaii Cancer Center

P. Gottesfeld, Self

Christy A. Barlow, PhD et al., GZA GeoEnvironmental, Inc

A.M. Langer, PhD, Science Professor Emeritus, PhD Program in Earth and Environmental Science, Graduate School and University Center of the City University of New York

Bertram Price, PhD, Price Associates, Inc.

J M Dement, PhD, CIH, Professor Emeritus, Division of Occupational and Environmental Medicine, Department of Family Medicine and Community Health, Duke University School of Medicine

Bryan D. Hardin, Vice President, Principal Toxicologist, J.S. Held, LLC

Jessica Ryman Rasmussan, PhD, DABT, Senior Scientific Advisor, American Petroleum Institute

Allan Feingold, Medical Director, Occupational and Environmental Medicine, South Miami Hospital

Steve Mlynarek, PhD, CIH, QEP, President, Applied Science Inc.

B.W. Case, MD, Dipl. Occupational Hygiene, Associate Professor (post-retirement), Department of Pathology, McGill University

Thomas G. Laubenthal, Technical Chief and Training Supervisor, The Environmental Institute

Judith Nordgren, Manager Director, Chlorine Chemistry, American Chemistry Council

Kirk T. Hartley, LSP Group, LLC

Robyn Brooks, Vice President, Health, Environment, Safety, Security, Chlorine Institute

Georges C. Benjamin, Executive Director, American Public Health Association

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Kelsey Johnson, President, Iron Mining Association of Minnesota (IMA)

Andrey A. Korchevskiy, PhD, DABT, CIH, Director, Research and Development, Chemistry and Industrial Hygiene, Inc.

The Attorneys General of Massachusetts, California, Hawai'i, Illinois, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Rhode Island, Vermont, Washington, and the District of Columbia

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C. Robins, PhD, Principal Industrial Hygienist, J.S. Held, LLC

Kevin T. Wyles, Dentons US LLC, on behalf of Morse TEC, LLC

Harold A. Schaitberger, General President, International Association of Fire Fighters (IAFF)

B.T. Mossman, PhD, University Distinguished Professor, University of Vermont, Larner College of Medicine

Michael P. Walls, Vice President, Regulatory and Technical Affairs, American Chemistry Council

U.S. Chamber of Commerce et al.

Randy Rabinowitz, Executive Director, Occupational Safety and Health Law Project; and **Jonathan Kalmuss- Katz,** Staff Attorney, Earth Justice

Bob Sussman, Counsel, Safer Chemicals Healthy Families (SCHF)

Nicholas Chartres, Associate Director, Science and Policy, University of California, San Francisco

Dianne C. Barton, PhD, Chair, National Tribal Toxics Council (NTTC)

Linda Reinstein, Cofounder, Asbestos Disease Awareness Organization (ADAO)

Evan M. Beckett, MPH et al**.**, Cardno ChemRisk

Richard P. Krock, Senior Vice President, Regulatory and Technical Affairs, Vinyl Institute

Bruce Stern, President, American Association for Justice

Tony Tweedale, R.I.S.K. Consultancy

EXECUTIVE SUMMARY OF SACC REVIEW

Overall, EPA's environmental and human health risk evaluations for asbestos was not considered adequate and resulted in low confidence in the conclusions. This is due to missing data for environmental exposures, coupled with the fact that current estimates for human health risk are created for a narrow group of workers and consumer users based on limited exposure to chrysotile asbestos fibers leading to numerous uncertainties. The relatively meager concentration and exposure data available allows the risk evaluation to use the prudent approach of a reasonable worst-case analysis.

The draft risk evaluation (DRE) is focused on current commercial uses of chrysotile asbestos. The Committee encourages EPA to incorporate into the assessment other asbestos and asbestos-like fibers in addition to chrysotile exposure beyond the six conditions of use (COUs) evaluated. Because certain exposure sources (drinking water, talc, asbestos-containing building materials, vermiculite, etc.) are not included in this evaluation, the estimate for total exposure to asbestos is deficient. The impact of future chrysotile exposures for limited COUs are modeled with accounting for dominating past and ongoing exposure from "legacy" chrysotile and amphiboles. This does not fit the reality of total exposure to asbestos. This DRE includes only a limited slice of the exposure, the results of which compound uncertainties. Pathways of asbestos exposure include occupational, para-occupational, consumer, bystander, and family household to both amphibole and serpentine asbestos fibers (of a range of sizes, all potentially toxic). Most of the Committee recommended deriving one inhalation unit risk (IUR) for all types of asbestos instead of just for chrysotile asbestos.

The TSCA Science Advisory Committee on Chemicals (the Committee) responded to a series of issues posed as questions on the EPA Draft Risk Evaluation (the Evaluation) for Asbestos as follows:

Question 1 – Environmental Exposure and Release

The Committee recommended that the Agency require monitoring data either from National Pollutant Discharge Elimination System (NPDES) mandates or specific requests to COUs where chrysotile asbestos can be released into wastewater. If COU monitoring data are not available, the Committee recommended the Agency either make a statement that risk cannot be evaluated or use non-COU surface water measurements for comparison data to be compared to Concentrations of Concern (COC) values. Overall, the Committee thought stronger statements of uncertainty are needed regarding potential exposure to surface water.

The Committee recommended that the Agency provide visual figures of all asbestos fiber types and that text should be modified to reduce jargon. Regarding other asbestos-materials, the Committee recommended that the potential for co-existing fibrous amphiboles and impurities should be mentioned in the document. The Committee recommended that metrics of size include variance (Standard Deviation or Standard Error) and metrics of aerodynamics for each fiber type be provided. The Agency should remove text stating chrysotile fibers are biologically inert, and include text providing the pros/cons of methods of microscopy used to measure fibers. Given the uncertainties of occurrence, measurement and identification of chrysotile fibers, transmission electron microscopy (TEM) should be recommended for future monitoring especially in surface waters.

Question 2 – Occupational Exposure

The Committee initially engaged in a wide-ranging discussion of occupational exposures to asbestos and noted the large amount of public comment materials that accompanied this DRE. Members also noted that the DRE title refers to "asbestos" generically but focuses on present commercial chrysotile asbestos (i.e., chrysotile asbestos containing smaller amounts of other asbestos forms). Furthermore, the DRE considers only exposure via inhalation and is limited to selected COUs that exclude legacy impacts (e.g., the huge existing reservoir of asbestos-containing building materials) and contaminated articles or products (e.g., talc). The Committee was informed that EPA would be addressing legacy issues (that include ongoing occupational exposures and a well-established and sizeable abatement industry) in a future review, which EPA reported could take three to four years to prepare. The Committee also noted that "take-home" exposures (which are well documented for asbestos) are not currently addressed in the DRE and that default assumptions are used regarding personal protective equipment (PPE) and assigned protection factor (APF).

Discussion then turned to process descriptions, and data availability and adequacy. Members were appreciative of pictures/graphics and site visit descriptions where provided. EPA's hierarchy of data>modeling>occupational exposure limits or release limits were generally supported, but some members suggested that data collected in workplaces under normal operations should have priority over data collected during work simulations for litigation support. Duplicate data were identified in the chlor-alkali industry data set, and members agreed that duplicate data should be removed from the analyses (a process apparently already in progress) and that standardized approaches to addressing values less than detection limits should be adopted. While acknowledging data sparsity [especially for occupational non-users (ONUs)], members expressed a desire to see descriptions of sampling plans and methods for available data and a more structured approach to estimation of exposure point concentrations in the absence of data. Concerns were raised over completeness and representativeness of industry data and for inadequate characterization of "off-normal" events.

Some members found the discussion of uncertainties in the DRE to be adequate, but others did not. The latter were especially concerned about assumptions regarding ONUs due to absence of data and what appeared to be ad hoc remedies.

Committee members noted that in prior DREs, EPA defaulted to central tendency worker exposure point air concentrations as a surrogate for ONU exposure point air concentrations. The reason for deviating from this approach in this DRE is not adequately explained. Members questioned whether EPA has adequately tapped international experience with asbestos risk assessment given that the European Union (EU) is in the process of phasing out asbestos diaphragms in chlor-alkali production, and that in some countries marketing of asbestos brake and clutch pads is not yet restricted. Committee members reported multiple published studies that are relevant to occupational exposure but are not included in the DRE; many public commenters have suggested additional studies as well. Finally, several members searched online and found information that at least suggests that asbestos-bearing products are in circulation, including chats, how-to videos, junkyard parts listings, online advertisements of wholesale quantities, etc.

Question 3 – Consumer Exposure

The Committee found the model assumptions for do-it-yourself (DIY) consumers and bystanders reasonable for both outside and inside scenarios. The number of consumers utilizing aftermarket brake shoes and utility vehicle (UTV) gaskets containing asbestos is unknown, and it is unclear what efforts were undertaken to better ascertain these values.

Overall, the Committee members thought the methods and explanations for estimating consumer/DIY exposures in aftermarket auto brakes/linings were straightforward and understandable. The assumptions EPA made about the age at start of exposure and duration of exposure seemed reasonable, as was the approach to estimating bystander exposures. But the Committee was not in complete agreement on the exposure frequency estimates proposed. Some Committee members believed EPA's estimates were reasonable, others believed that exposure might be underestimated in younger ages and in lower income groups and overestimated at older ages. There was, however, general agreement that most consumers are "low-frequency" users of potentially asbestos-containing consumer products, including UTV gaskets, and brake shoes.

It was suggested that data from studies, which were done in real-world settings, e.g., for purposes such as establishing compliance with regulatory limits, should be prioritized over findings from simulations that were conducted in support of litigation; i.e., the hierarchy of prioritizing data over modeling over occupational or release limits remained valid, but that data generated in pursuit of a potential agenda should be prioritized below other data.

Overall, the Committee believed the methods used and explanations for estimating bystander exposures in aftermarket auto brakes/linings and UTV gaskets were straightforward and understandable. There remains concern that estimates of outdoor bystander exposure were overestimated. As with consumer/DIY exposures, there was not complete agreement on exposure frequency for bystanders; some members believed EPA's estimates were reasonable, others believed that exposure was underestimated at younger ages and in lower-income groups, and overestimated at older ages and higher-income groups. There was also some confusion regarding how the reduction factors (RF)s were derived.

The Committee concluded that the assumptions used by the Agency for consumer exposure appropriately traded conservatism for data and are essentially sound. That is, despite the arguments by some public commenters that asbestos has disappeared from consumer products in the last few decades, some compelling evidence suggests otherwise. However, absence of evidence of the non-existence of asbestos-containing products is insufficient for EPA to ignore the potential exposure and risk to what could be thousands of exposures to workers and consumers. In this regard the current DRE does a credible job.

The current sensitivity analysis within the DRE was described by Committee 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.

Data identified by several speakers during the oral public comments session should be considered by the Agency as data submitted from industry, subject to quality and documentation review. Better

data are clearly needed to refine this evaluation.

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

The Committee concluded that the focus of the assessment should be on all health endpoints, both cancer and non-cancer in nature, and not just on mesothelioma and lung cancer. Most of the Committee found the EPA approach broadly acceptable but recommended that one IUR should be derived for all types of asbestos instead of just for chrysotile asbestos. One Committee member strongly objected to this recommendation post meeting, suggesting instead that IURs should be derived for each type of asbestos separately.

There were concerns about confounding factors, including smoking. The Committee suggested that life table methods be used to estimate lung cancer risks separately for smokers and nonsmokers to partially address this. There were concerns about using textile data to address risk from non-textile uses of chrysotile. The Committee 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 Committee thought the fit of linear risk model used for lung cancer should have been carried through and compared to the exponential model. The Committee recommended some improvements to the presentation to make it easier to understand.

The DRE presents arguments for four uncertainties that address exposure and endpoints. The Committee 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: focusing only on mesothelioma and lung cancer and omitting other cancers; the IUR only characterizes cancer risk; using mortality instead of incidence; the form of the risk model; use of the linear risk model for mesothelioma; under-ascertainment of mesothelioma; and exposure measurement error in the cohort studies. The factors that may result in upward bias (overestimation) include fiber potency as a function of length and width, and 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: exposure measurement; amphibole and non-amphibole asbestos contamination (or using chrysotile to represent all types of asbestos); not considering dermal exposures; mesothelioma potency adjustment; and the assumption of no mesothelioma background.

The DRE compensates for two sources of bias by selecting the largest IUR from among four candidates. The Committee recommended EPA not use one source of bias to compensate for another. Rather, 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.

The EPA cancer guidelines (U.S.EPA, 2005) specifies that the choice of risk estimation methodology be based on the mode of action by which a substance causes cancer. The discussion in the DRE of the mode of action for asbestos should be expanded and this discussion used to support the choice of the risk estimation method.

Question 5 – Human Health and Environmental Risk Characterization

The Committee raised several issues related to the assumptions on which the health risk

characterization in the DRE 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.

The Committee 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.

Committee members noted that the statement "risk could be underestimated" referring to estimated worker, occupational non-user, and consumer risks evaluated for conditions of use is an understatement, primarily because legacy exposures are not included. Almost all the existing sources of exposure come from legacy exposure; bystander exposure is limited in scope and much focused, and as such it is not generalizable. The Committee recommended the Agency include legacy and aggregate asbestos exposures in the calculation of cancer risk for asbestos exposure.

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. Additional explicit consideration is needed on the impact of uncertainties in fiber lengths of exposures and their differential potency, and how potential contamination by tremolite in the North Carolina and South Carolina textile mill data could alter the potency of chrysotile for causing mesothelioma. The Committee provided references to several additional studies addressing exposures during repair and/or replacement of brakes and gaskets. It recommended these studies be considered and also noted other studies that were identified in the literature review but excluded should be reconsidered as providing further support to the estimated IURs.

With regard to environmental risk characterization, the Committee noted uncertainties with respect to environmental exposures 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.

Question 6 – Additional Questions

Addressing the health risk of asbestos requires that EPA consider the following PESS groups: smokers, people with chronic lung disease, children, and tribal populations.

In general, although members of the Committee 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 Committee recommended that it be done in other areas where there is uncertainty due to data

limitations. It was recommended that direct workplace visits to understand the conditions of asbestos use be conducted in support of future risk evaluations.

Estimates for chrysotile asbestos exposures for the COUs evaluated are highly uncertain. Given this situation, the Agency 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 Committee, the Agency has acted appropriately in the face of this uncertainty. Specifically, the EPA appropriately traded conservatism for high quality data. However, the 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.

The Committee recommended that the DRE include a more detailed examination of the actual levels of protection provided by respirators, given that the level of protection of the PPE is not exactly the APF (assigned protection factor) of the respirator. In addition, the Committee notes that protection provided by PPE in the workplace critically depends on the quality and actual use of the workplace respiratory protection program, which is a frequent source of violations cited by OSHA in recent years. The assumptions on PPE use have a large effect on the risk determinations.

Question 7 – Overall Content and Organization

Generally, the Committee thought that the organization and presentation of the material in the DRE was clear and well organized. However, there are several areas of improvement that could be made. Firstly, 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. The Committee recognized that to keep the DRE exclusive to chrysotile asbestos may not be feasible, as much of the available toxicity data for human health concerns involve data from mixed fiber types, and to exclude those studies would not be practical. Therefore, the Committee recommended that the EPA make the title specific to chrysotile asbestos and be specific in the DRE when data from other fiber types are used. It also recommended that the EPA clarify its regulatory charge and purpose of this document in the beginning.

The Committee advised EPA to provide levels of confidence to its TSCA risk determinations. There were concerns from several Committee members that the DRE offers risk determinations for many scenarios where risk estimates are based on little or no data and conclusions seem overly optimistic. For example, release data for environmental receptors is often lacking as is good characterization of release sources. The Committee recommended that the EPA decide *a priori* on the level and quality of information that is required to make a supportable risk characterization for different types of scenarios. In those scenarios where available data do not meet the level and quality standard, EPA should conclude that "available information is insufficient to characterize risks" rather than force a decision of "unreasonable risk" or "no unreasonable risk." The Committee also recommended that the EPA be more careful in the language/wording it uses to discuss risk (or more specifically "no risk"). The Committee expressed preference for a more appropriate determination, which would conclude that "environmental risk could not be ascertained."

COMMITTEE DISCUSSION AND RECOMMENDATIONS – EPA DRAFT RISK EVALUATION OF ASBESTOS

As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, the Toxic Substances Control Act (TSCA) requires the U.S. Environmental Protection Agency (EPA or Agency) to conduct risk evaluations on existing chemicals. Asbestos is one of the first ten chemical substances to be evaluated under the amended TSCA and the last of ten to undergo a peer review by the Science Advisory Committee on Chemicals (SACC). In response to this requirement, EPA has prepared and published a Draft Risk Evaluation (DRE) for Asbestos. The Risk Evaluation process is the second step, following Prioritization and before Risk Management, in EPA's existing chemical process under TSCA. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The TSCA Science Advisory Committee on Chemicals (the SACC or the Committee) responded to a series of issues posed as questions on the EPA Draft Risk Evaluation for Asbestos. The following are the SACC's responses to the Agency's charge questions. Page and line numbers without specific reference always refer to the *Draft Risk Evaluation for Asbestos* (U. S. EPA, 2020 EPA-740-R1-8012), which is referred to as the "DRE." In its review, the SACC makes "recommendations" to EPA on actions that the Committee suggests will improve the risk evaluation. Unanimous approval by the SACC is not required for recommendations to be included in this report. This report captures the recommendations discussed during the SACC's June 8-11, 2020, public meeting.

Question 1: **Environmental Exposure and Release:**

Based on the reasonably available information in the published literature, provided by industries using asbestos, and reported in EPA databases, there is minimal or no releases of asbestos associated with the conditions of use (COUs) that EPA is evaluating in this risk evaluation.

Q 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).**

Response to Q1.1: Analysis and Conclusion for Draft Environmental Exposure

Overall, the Agency concludes that there is little, if any, discharge of chrysotile fibers to surface water in facilities associated with COUs.

The Committee appreciated the efforts that the Agency provided to assess COU-associated surface water discharges using available data. The Agency based its conclusion on evaluation of several data

sources. The evaluation of Toxic Release Inventory (TRI) data estimated that most of the asbestos including chrysotile asbestos released from processing facilities is disposed of in a landfill and, thus, review of these discharges falls under different (non-TSCA) regulatory oversight. Evaluations of TRI data indicated zero discharge to Publicly Owned Treatment Works (POTW) and non-POTW facilities from COUs targeted in the DRE. Statements from the *Problem Formulation of the Risk Evaluation of Asbestos* report (U.S.EPA, 2018) indicated that the chloro-alkali industry in years prior to 2017 did discharge chrysotile-asbestos to wastewater. The DRE indicates that following visits to these facilities in late 2017, follow-up evaluations were conducted. The DRE noted that chlor-alkali facilities are not required to monitor asbestos through NPDES. The DRE concludes that water discharges were zero in 2018. It was unclear to Committee members how a conclusion of zero discharge was made without measurements. It was also unclear why the Agency did not request these facilities to provide discharge monitoring data after its initial scoping exercise in 2016 (U.S.EPA, 2017).

Several Committee members pointed out that while the DRE describes the filter press process used to treat waters used in the chlor-alkali process prior to it being discharged to a wastewater treatment plant, the efficiency of separation is not presented. One Committee member indicated that filter presses normally operate with an efficiency greater than 90%, but any residual asbestos in the effluent would depend on the initial concentration, the pH of the mixture, and other factors[1]. The DRE concludes that the efficiency of removal/filtration is unknown, as are the concentrations of asbestos in wastewaters after this treatment. This appears to be contrary to the DRE conclusion of low to medium uncertainty in the estimates of asbestos releases in wastewaters from processing facilities communicated to the Committee during the oral presentation.

The DRE also reports that the Agency evaluated Discharge Monitoring Report (DMR) databases, which include NPDES monitoring data, and conducted a more thorough assessment of NPDES monitoring data. After these evaluations, only one surface water sample from one historical mining site was found to have reported concentrations of chrysotile fibers. Since mining operations are no longer present in the U.S., and this activity is covered under other (non-TSCA) regulatory processes, the Agency concluded that chrysotile fibers resulting from this activity did not warrant a risk quotient evaluation for environmental receptors.

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 DRE does provide data in Table 2-1 (*Six Year Review Cycle Data for Asbestos in Drinking Water, 1998-2011*), which shows systems with reported asbestos levels in drinking water. The DRE concludes that this most likely represents measures of finished (i.e., tap water), which led several Committee members to comment that surface water concentrations are thus likely to be higher. One Committee member wondered why these data were even considered, since surface waters were the intended target for the assessment. While the Committee realizes that it is difficult to attribute the asbestos in these waters to specific COUs. Therefore, the Agency could consider doing a system-wide assessment of asbestos in surface or

1 Anonymous. (2020). Twin Filter. COMPARISON OF FILTER PRESS AND VPL/DE FILTERS. https://www.twinfilter.com/App_Files/FileInstances/Download/439/en-GB/Published/ComparisonOfFilterPressAndVPLDEFilters.pdf

drinking waters as a way of assessing total asbestos releases. Another option would be to estimate surface water concentrations based on removal of fibers during the process of converting raw to finished water during treatment. This would still not allow differentiation to COUs but could provide an overall assessment of the environmental risk for asbestos in waterways. This might also account for air releases that may be transported into waterways (see Appendix D, Table APX D-2). Drinking water values from Staten Island were provided (Meresca et al. 1984) in the DRE. Based in part on these data and other evaluations (i.e., Water Quality Exchange-WQX), the DRE concludes minimal to no discharge from the COUs.

The Committee noted several concerns with this approach. Since chrysotile asbestos is a natural component of many freshwater streams where the mineral serpentine is found, one Committee member thought that it would likely require high concentrations to elicit sufficient adverse effects that would result in unreasonable risks. While the conclusions were reasonable to this member, precise information, and logic to support them was lacking.

Overall, the Committee is concerned that the conclusion in the DRE of "minimal to no exposure" of environmental receptors to chrysotile asbestos is based not on monitoring data demonstrating low to no chrysotile in wastewaters or surface waters, but on an inability to find any relevant monitoring data and an assumption that processing facilities are not allowing chrysotile to be released to these waters. Given this, the Committee suggests that the DRE include a stronger statement of the uncertainty in this conclusion and that this finding be reflected in the report's Executive Summary.

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.

Discrepancies between the Problem Formulation document and the DRE need to be highlighted in any further documentation. In the Problem Formulation document, it is stated repetitively that surface water concentrations were within the same order of magnitude as concentrations that cause adverse effects to aquatic biota. However, that conclusion is not continued in the DRE, primarily because monitoring data could not be found to support this statement.

Relatively high concentrations of asbestos have been found in biosolids (10% of dry ash weight) and surface waters in general (Agency for Toxic Substances and Disease Registry (ATSDR), 2011). Chrysotile fibers in biosolids and surface waters may be derived from sources other than COUs, in which case processors truly have minimal discharges. Only monitoring data can provide the evidence needed to establish this and are typically found in robust risk evaluations and assessments. In lieu of monitoring data estimates from surface water should represent a worst-case scenario.

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.

Section 2.2.2.5 states: "EPA determined that water releases for aftermarket asbestos-containing automotive parts (brakes, clutches, gaskets, utility vehicle (UTV) gaskets) do not involve the use of water during the removal and clean up. EPA has not identified peer-reviewed publications that measure water releases of asbestos associated with processing, using, or disposing of aftermarket

automotive products." The Committee wondered why it was assumed that water was not used in the clean-up. At a minimum, consumer clothing used in the processes would be laundered, and people would shower following these tasks. The document does not address take-home exposures associated with the transport of asbestos-contaminated clothing (and other items) from the workplace to residence. This has been a well-documented source of exposure to asbestos, with several articles in the literature (see for example, Abelmann et al., 2017). One Committee member raised this here because 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. Similarly, brake dust or other materials derived from wetting (deliberately or via rainfall) those areas where chrysotile asbestos products were used would likely be transported to wastewaters or stormwaters. Even though it may be a small overall contribution, several Committee members suggested this be addressed as a potential source of asbestos release to surface water.

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.

Several Committee members did not agree with the logic the Agency uses to exclude COU-linked exposures in terrestrial pathways. During its presentation to the Committee, the EPA indicated that other regulations adequately assess and effectively manage exposures from asbestos releases to terrestrial pathways, including biosolids, that could impact terrestrial organisms. A similar statement was made for drinking water exposure pathways where it is assumed that these exposures are currently addressed by the Safe Drinking Water Act (SDWA) regulatory analytical process for public water systems. Several Committee members stated that excluding terrestrial pathways based strictly on statutory considerations will result in an incomplete DRE for asbestos, and recommended the Agency consider the inclusion of terrestrial and drinking water pathways in this evaluation.

Recommendation 4: Address exposures to environmental receptors by terrestrial and drinking water pathways.

The Committee concluded that the DRE does not adequately evaluate the risk to aquatic species from exposure to surface water. It was unclear how the Agency could come to this conclusion without measured or predicted concentrations that could be compared to hazard values.

Additional Suggestions:

Since asbestos is a naturally occurring mineral, the DRE should include a map showing the locations of naturally occurring asbestos deposits such as provided by USGS on its website[2].

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 (i.e., Is asbestos found more often and

2 See https://mrdata.usgs.gov/asbestos/ and https://www.sciencebase.gov/catalog/item/5c5db003e4b0fe48cb32e41e

at higher concentrations in areas located near natural deposits?).

Several Committee members questioned whether regulations that cover fugitive emissions associated with disturbing naturally occurring asbestos deposits through activities such as construction adequately cover TSCA-related concerns. The Committee noted that construction that disturbs natural asbestos should be a COU that is examined in this DRE.

Table 2-1 could use a footnote describing the abbreviations for the benefit of readers not familiar with the environmental quality shorthand.

Q 1.2	**Please comment on whether EPA adequately, clearly and appropriately presented the physical-chemical properties/characteristics of chrysotile asbestos.**

Response to Q1.2: Physical-Chemical Properties and Characteristics of Chrysotile

The Committee thought the physical-chemical properties of chrysotile asbestos are generally well cataloged in Table 1-1. Better characterization of fiber size is needed (further discussed below). A photograph or two of examples[3] would be quite useful to clarify many properties to the reader.

For readers not familiar with asbestos characteristics, the written description is rather dry, non-visual, and uninformative. One Committee member offered the paragraph as an example of writing that is too technical:

> "As with all silicate minerals, the basic building blocks of asbestos fibers are silicate tetrahedra $[SiO_4]^{4-}$ where four oxygen atoms are covalently bound to the central silicon. These tetrahedra occur as sheets $[Si_4O_{10}]$ in chrysotile. In the case of chrysotile, an octahedral brucite layer having the formula $[Mg_6O_4(OH)_8]$ is intercalated between each silicate tetrahedral sheet." [Section 1.1, lines 1290-1294]

The Committee member thought that only a mineralogist would care to read this paragraph. For everyone else, they would be lost and find it uninformative. Even though this description is accurate and does appear to set apart chrysotile from the great number of other silicates, most readers will have no idea what this description of chrysotile asbestos meant. As an example of a more visual descriptive text, the Committee member offered the following (abstracted from Van Gosen and Clinkenbeard, 2011).

> "Asbestos" is not a mineralogical term, but rather a commercial and industrial term used to describe a group of specific silicate minerals that form bundles of long, very thin mineral fibers (often described as "asbestiform"). When crushed or handled, asbestos bundles readily disaggregate and release microscopic mineral fibers. Asbestos fibers are typically less than a micrometer (one-thousandth of a millimeter) in diameter and range

3 See images at https://www.usgs.gov/media/images/secondary-electron-images-elongate-amphibole-bundles.

from several micrometers to hundreds of micrometers in length.

Commercial-grade asbestos is composed of long, thin, durable mineral fibers and fiber bundles that exhibit high tensile strength, flexibility, and resistance to heat, chemicals, and electricity. These properties, especially its exceptional insulation and fire-resistance abilities, have made asbestos widely used in numerous products and industrial applications.

Asbestos is most commonly defined as the asbestiform variety of several specific, naturally occurring, hydrated silicate minerals. Asbestos typically includes chrysotile, the asbestiform member of the serpentine mineral group, and several members of the amphibole mineral group, including, but not limited to, the asbestiform varieties of (1) riebeckite (commercially called crocidolite), (2) cummingtonite-grunerite (commercially called amosite), (3) anthophyllite (anthophyllite asbestos), (4) actinolite (actinolite asbestos), and (5) tremolite (tremolite asbestos) (see Table 1-1, page 32).

Another point that was highlighted by several Committee members was the issue of the "purity" of the chrysotile used in the products that are being evaluated by this review. Some of the largest and most productive chrysotile mines (in Vermont, Quebec, and Russia) have claimed pure deposits of chrysotile, which means that they lack amphiboles (Williams-Jones et al. 2001; Page et al. 2008; McDonald et al. 1999; McDonald and McDonald, 1997). In most chrysotile deposits, the fibrous (or asbestiform) amphiboles that can co-exist within a chrysotile ore body are anthophyllite, tremolite and/or actinolite. One Committee member indicated that there is no reason to question the purity of the Russian chrysotile (Tossavainin et al., 2000; Kashansky et al., 2001) that is being used in the chlor-alkali industry. Another Committee member disagreed, suggesting that there is no evidence that any chrysotile asbestos products have ever been amphibole asbestos free. The Committee again expressed concern that all aftermarket brake pads and linings may not be amphibole free.

Recommendation 5: Reduce technically intense text.

Several Committee members supported the conclusion that 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. If they exist, their impact on exposures would be difficult to model without additional measurement data.

Recommendation 6: The potential for co-existing fibrous amphiboles should be mentioned in the document.

Another Committee member thought 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.

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.

Single values for size and length were provided in Table 1-1 without variance. However, during the

presentation, the Agency did address size but only regarding its impact on human health. The Committee noted disparity between animal studies and epidemiology on the effects of fiber size on adverse endpoints. Animal studies have not found short fiber chrysotile, which is not contaminated by amphibole, to be very toxic. However, human studies have shown otherwise. In the environment, fiber lengths less than 5 µm (termed micro-fibers in the plastics literature) have been shown to be readily absorbed by aquatic biota (Li et al., 2016). Aggregation is also an important endpoint with micro-fibers and there does not appear to be a metric characterizing this feature for asbestos. Size and aggregation are becoming significant issues in the characterization of micro-fibers derived from plastics. Although chrysotile is inorganic, several methods of characterization with plastic micro-fibers in the environment may allow a better estimate of exposure (Xu et al., 2018). The benefits and disadvantages of the current methods (Phase Contrast Microscopy (PCM) vs. Transmission Electron microscopy (TEM)) need to be discussed.

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 9: Given the adverse effects of micro-fibers (of any constitution) on aquatic biota, transmission electron microscopy (TEM) should be recommended for future monitoring, especially in surface waters.

Several Committee members suggested the Agency be careful when using the term biologically "inert" as many micro- and nano-sized materials have been shown to have significant biological effects following absorption even though they may be "chemically inert." This again highlights the importance of size/length characterization.

Recommendation 10: Remove text describing chrysotile asbestos as "biologically inert."

Two Committee members thought consideration of the changes to Table 1-1 suggested in the public comments by the representative of the Industrial Minerals Association North America (IMA-NA) may be warranted. Another Committee member agrees with other public commenters' recommendations to include specific CAS numbers when discussing asbestiform fiber types to reduce confusion with non-asbestiform minerals (for example in Table 1-1). These commenters also suggested other changes to optical properties in Table 1-1 (see public comments from IMA-NA[4]).

The Committee thought the DRE did not have enough discussion concerning how chrysotile structure differs from other forms of amphibole asbestos with respect to the issues important in biological outcomes. The members indicated that discussion was warranted concerning how chrysotile differs from amphiboles in its chemical composition, durability, and morphology, and how these parameters relate to dissolution and clearance of chrysotile fibers in the lung and pleura.

The Committee suggested that the entire DRE could use additional discussion in sections covering what has been learned about asbestos from animal studies. The Committee recognized that the DRE is not intended to be a detailed summary of toxicological effects but suggested that a complete risk assessment should incorporate some of the knowledge from translational experimental models. In the same light, more discussion of the physical-chemical properties of friction products is warranted with

4 Comment by Mark Ellis is at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0028

respect to fiber dimension and surface changes as these are known from animal studies to be important to outcomes. As discussed above, the Committee suggested a discussion on properties related to the suspension of fibers (i.e., agglomeration and settling rates).

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.

Recommendation 12: Include a discussion of properties related to the suspension of fibers.

Additional Suggestions:

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.

Recommendation 14: Note that National Institute for Occupational Safety and Health (NIOSH) (2011) provides helpful background information for readers of this DRE.

Question 2: Occupational Exposure:

EPA evaluated what is known about chronic exposures to workers and occupational nonusers (ONUs) for the COUs listed above via the inhalation pathway only. The principle approach EPA used to estimate occupational exposures – for both workers and ONUs - was reviewing and interpreting monitoring data, whether provided by industry or documented in the peer-reviewed literature. EPA assumed that workers and occupational non-users would be adolescents and adults of both sexes (≥16 and older).

Q2.1	**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.**

Response to Q2.1: Estimation Methods and Assumptions for Occupational Exposure Assessment

The Committee noted that many of the issues related to occupational exposures raised for the Asbestos DRE are the same or similar to those identified and discussed repeatedly in the previous nine reviews conducted by the SACC. The Committed noted that public comments on this DRE were voluminous and generally expressed dissatisfaction with one or more aspect of the DRE, finding it either insufficiently or excessively conservative. The Committee concluded that the approach used in this DRE to assess occupational exposures is adequately explained and the arguments presented could be followed. Topics of discussion that mirror prior DRE review comments include: the adequacy of the systematic review, data availability and quality, assumptions regarding the efficacy of PPE, and failure to aggregate exposures—either across routes or by adding occupational and consumer or background exposures. Unlike prior reviews, substantial discussion was devoted to the scope of the DRE.

Scope. The scope of the DRE was discussed at some length. First, the content of the DRE did not match the title of the document. Risks were evaluated for exposure to selected uses of commercial chrysotile asbestos, not "asbestos" generally. EPA reported that future efforts will expand the scope and, per court order, include legacy uses that were excluded from this DRE. The Committee expressed concern that these issues do not go unaddressed. Substantial numbers of workers in jobs involving maintenance and repair of legacy products or in the newer abatement industry are subjected to ongoing and potentially significant occupational exposures that are excluded in this DRE. The Committee acknowledged EPA's time constraints and reduced budgets but expressed mixed views regarding EPA's asbestos assessment strategy and whether EPA should go forward with the current DRE or fold it into a more comprehensive future review.

Recommendation 15: Either retitle the evaluation to reflect its limited scope or postpone completion pending future efforts to assess asbestos more broadly.

Recommendation 16: Explain how legacy uses of asbestos will be addressed in the proposed larger asbestos evaluation.

As indicated in the DRE, 95% of "asbestos" in past and current commerce is commercial chrysotile asbestos. The DRE 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 Committee members objected to a chrysotile-specific risk evaluation, pointing out that a prior review panel by the EPA Science Advisory Board (SAB) (U.S. EPA, 2008) rejected this approach. This issue is discussed further under Charge Question 4.

Recommendation 17: How this limited scope DRE for chrysotile asbestos fits into the larger asbestos evaluation process should be explained early in the document.

Overall Approach. The DRE addresses a limited number of COUs and utilizes limited data sources to evaluate them. Exposure calculations are straightforward and adequately explained. Per Figure 1-5 (page 47) and the accompanying text, the Agency expresses preference for using information in accordance with a hierarchy of data>modeling>occupational exposure limits or release limits. Committee members agreed that this is a reasonable approach. At least one member suggested that within the category of "data," studies done in real-world settings for multiple purposes, e.g., establishing compliance with regulatory limits, should be prioritized over data from surrogate populations or simulations that were conducted for support of litigation.

Systematic Review. Members reported finding relevant literature sources that were apparently overlooked or deemed inadequate for some reason (see response to Charge Question 2.3), and also noted that public commenters suggested many additional data sources. EPA's approach to Systematic Review has been the subject of extensive discussion in the Committee's prior reviews, and it is acknowledged that the TSCA systematic review process is now being reviewed by the National Academy of Sciences (NAS).

Data. (See also short-term data and COU-specific discussions below.) For several of the COUs, and especially for ONUs, data are limited. Using a single study to serve as a representative exposure for COU tasks versus having and combining multiple studies can greatly affect the final risk estimate calculated for a COU. Therefore, it is important to ensure that the exposure estimates are accurate, representative of the work tasks, and that the data were collected and analyzed using approved and validated methods. This requires knowledge of the sampling strategy and monitoring plan for collecting data and, for instance, whether the samples were drawn from a single individual, multiple times, or from certain activities more often than others.

In the "components of occupational health exposure assessment" (page 57) 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 DRE, and it was unclear whether companies having workers engaged in asbestos COUs were specifically requested to submit such descriptive data. If not, EPA may need to change their data request protocols to include capturing data about the programs generating exposure measurements, not just data that are published or in government/industry archives. Because data used to assess COU exposures are sparse in nearly all the initial nine chemical reviews, the DRE utilizes all the data provided and weighs each sample equally. Without a description of the sampling strategy, and how employee duties were monitored, it is difficult to determine the completeness and representativeness of facility worker exposure data. The

Committee found it difficult and problematic to review the data inclusion/exclusion decisions that are inherent in the DRE exposure assessment.

In the descriptions of many of the COUs, the DRE 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 Committee members suggested that international data (from countries that have not yet banned or restricted asbestos) appeared to be underutilized.

The chlor-alkali industry is the only COU under evaluation that had considerable monitoring exposure data, having data for both full shift and short-term exposures. Public comments confirmed what the DRE reports, that the ACC-submitted data might have duplicated the individual company submissions (see page 66, lines 2347-2349). During the presentation, EPA indicated they did not initially receive adequate information to determine which samples were duplicates. In the DRE, the data sets are simply combined as reported in most tables in Section 2 except Table 2-7. Despite the duplication concern, the DRE rates the data set as excellent and the exposure determination is given a high level of confidence. The Committee recommended that duplicates be identified and removed in the utilized data and the analyses be redone. EPA indicated that this reanalysis is underway, and numerical results in the final risk evaluation will report correct values[5].

The Committee found that there were chlor-alkali industry asbestos exposure studies conducted historically that are not described or referenced in the DRE. The paper by Strokova (1998) referenced in Section 2.1.1.4.4. (sheet gasket stamping inhalation) actually 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.

Non-detects. Questions were raised by members and public commenters about the treatment of non-detects (NDs) in monitoring data. EPA should describe a standard policy for assignment of values to non-detects and use it consistently. A sensitivity analysis using alternate non-zero values for ND could allay concerns. Statistical methods for better handling of non-detects are available (Helsel, 2005).

Recommendation 19: Create and consistently utilize an SOP for processing data with high levels of non-detect.

PPE. Committee members were of mixed opinions on the assignment of APFs in Section 2.3.1.2. One member suggested that the Riala and Riipinen (1998) data mentioned in the DRE (page 58) might be out of date. Others were concerned that the variable efficacy reported for these data was not

5 EPA reassessed these data, removed duplicates, and provided the Committee the reanalysis-after the SACC meeting ended.

adequately or obviously incorporated given the use of default point-estimate APFs (Table 2-3, page 58). Concerns over the use of point-estimate APFs given the complex factors that affect PPE efficacy (including training, PPE selection and availability, familiarity/fatigue, etc.) mirrored comments by the Committee in prior reviews of chemical DREs.

Recommendation 20: Reconsider or defend the default assumptions regarding PPE and APF use after considering the Riala et al. (1998) results and practical limitations in PPE programs (See Committee response to Q6.2).

Short-term monitoring. The Committee appreciated the segregation of full shift and short-term estimates presented in Table 2-24 (page 106). Description and tabular presentations of the short-term data where they were available in prior TSCA chemical DREs have been informative and useful in understanding circumstances where exposures are masked in full shift monitoring of workers where it is unknown whether the worker was performing or not performing one or more of the high exposure activities on the day they were being monitored. 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 DRE 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.

In Section 2.3.1.3.6. EPA indicated that it is uncertain whether high exposure activities are included in the data set.

Recommendation 21: Identify the frequency of high exposure activities (e.g., cleaning asbestos from damaged bags).

ONU exposures. The estimates and associated confidence levels are clearly presented in Table 2-24 (page 106). However, Committee members noted that the various methods used to estimate ONU exposures were not consistent across COUs. The results are unlikely to accurately represent actual ONU exposures because most rely upon surrogate data from unrelated studies or are so limited as to be of questionable representativeness and reliability. The Committee noted that in prior chemical DRE reviewed, when data concerning specific COU ONU exposures are not available, the default is to use the worker central tendency as the estimate for ONU exposure. This approach is not used in this DRE for estimating any of the asbestos ONU exposure levels. The various approaches taken in this DRE appear more ad hoc. Multiple Committee members suggested the need for an SOP for ONU exposure assessment, and 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 extremely limited or unavailable.

Chlor-alkali. The chlor-alkali exposure point air concentrations 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.

Sheet Gasket Stamping and use. For the sheet gasket COU the DRE uses data from a simulation (Mangold, 2006) that was not conducted in a factory setting and involved automobile gasket removal rather than a sheet gasket making process. One Committee member concluded that the DRE underutilizes available data by selecting only this particular study on which to establish exposure levels to this COU.

Recommendation 23: Collect and provide sampling plans and handling methods for data utilized to establish COU exposures when possible.

Oilfield brake blocks. For the oil field brake blocks COU, worker exposure data are also very sparse but were at least collected on an oil rig during brake block replacement. A better 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 mechanism when it is operating might also be exposed as a consequence of brake block wear. Members questioned why the DRE uses the lower of two reported worker air values rather than using a central tendency (mean, median) estimate.

Aftermarket automotive brakes. In the automotive brake repair COU, the studies used for estimating ONU exposure are simulated surrogate 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, 2008). Whether the exposures seen in that study mimic those in actual car repair facilities is unclear. The Committee suggested other studies that might be superior (see response to Charge Question 2.3).

Other gaskets/UTVs. Surrogate data are also used to estimate ONU exposure within the UTV COU. The study used 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 DRE estimate of the large number of UTV sales and service facilities, the Committee recommended using unannounced site visits to observe the processes.

<u>Miscellaneous comments:</u>

One Committee member suggested, based on submitted public comments, that the DRE discuss and include in the uncertainties assessment what is known about fiber behavior in air – e.g., settling, agglomeration, and impacts to potential exposure. Another member pointed out that rapid settling implies increased floor load, which is then available for resuspension and that air measurements reflect countervailing processes (compensating effects). Another member recommended papers investigating fiber dispersion in indoor and outdoor environments (see response to Charge Question 2.3).

One Committee member felt that a starting age of 16 years is too young for tasks typically assigned to experienced workers.

On page 56 (line 1951) the term "friable" is used without definition. One member suggests defining the term where first used.

On page 60 (line 2109), the DRE describes asbestos filters as being "vital" to the continued success of the chlor-alkali industry. One Committee member cited a 2017 USGS mineral report (USGS, 2017) that states: "The quantity of asbestos used by the chlor-alkali industry will likely continue to decline, however, as companies make greater use of non-asbestos diaphragms and membrane cells." The report also includes a subsection on alternatives to asbestos. It describes a few other minerals as "vital" for certain functions, but not asbestos. The DRE should attribute the position that asbestos is "vital" to industry statements and not to the USGS.

Committee members noted that exposure for the occupational bystander, family and friends who are exposed to asbestos brought home on the clothes and body of the worker are not discussed in the DRE. The document does not address take-home exposures associated with the transport of asbestos-contaminated clothing (and other items) from the workplace to residence. This has been a well-documented source of exposure to asbestos, with several articles in the literature (see for example, Abelmann et al., 2017). One Committee member raised this because 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.

Q 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).**

Response to Q2.2: Confidence in Occupational Exposure Estimates

Issues attached to Charge Question 2.2 were covered in the discussion of parameter estimates and uncertainties in the discussion of Charge Question 2.1. Committee members stated that Table 2.24 (page 106) is well presented, but that confidence ratings are not necessarily adequately justified in the DRE discussions. The Committee remarked on the fact that those scenarios where the exposure estimates are primarily derived from simulations that may not have been representative of real-world conditions uniformly receive medium confidence ratings that are poorly justified. COU estimates assigned low confidence ratings were not controversial since they represent scenarios with very little available information or where the quality of the data is questionable.

The discussion on key assumptions and uncertainties in the occupational exposure assessment (Section 4.3.3, page 194-195) generated mixed reviews. Some Committee members found the discussion too brief and inadequate.

In 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."

Recommendation 26: Use statutory authority granted under TSCA to request additional data on occupational exposures to fill knowledge gaps.

Q 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.**

Response to Q2.3: Alternative Approaches, Estimation Methods, or Information Sources for Occupational Exposure Assessment

Per discussion of Charge Question 2.1, the Committee noted that lack of data describing ONU exposures in the DRE was particularly problematic. Various (alternative) approaches have been used to fill those gaps which are different from the default approach used in prior chemical DREs of assuming the central tendency from worker exposures. The Committee recommended development of an SOP to guide decision making on estimation approaches for ONU exposures.

Most of the discussion on Charge Question 2.3 centered on the aftermarket brake replacement scenario. Several Committee members commented on a set of papers based on work in brake shops in Columbia, where asbestos brake pads are currently legally marketed (Cely-Garcia et al., 2012, 2016, 2017; Salazar et al., 2015). It was unclear to the Committee why the DRE does not utilize the occupational hygiene measurements reported in those studies. Committee members noted other domestic literature was identified that did not appear to have been cited in the DRE (Paustenbach et al., 2004; Williams et al., 2007). The Committee 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[6].

Recommendation 27: Utilize occupational hygiene measurements reported in a set of papers based on work in brake shops in Columbia where asbestos brake pads are legally marketed.

Arc grinding of brake shoes: Casual searches of YouTube®, eBay® and other online resources by Committee members found a variety of materials indicating current availability of or activity involving asbestos containing brake pads. YouTube® hosts multiple videos with many thousands of

6 Attachment 3, part 2, A. Frank Affidavit, Page 168 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0046

views showing occupational arc grinding of brake shoes[7]. Commercial arc grinders are available for sale online. This suggests brake grinding and related worker exposures have not ceased. Brief searches on eBay produced multiple listings for new asbestos brake pads for both automobiles and motorcycles. Some sellers list wholesale quantities. Listings for "new old stock" can also be found for some selected products. Many junkyards are now linked by inventory services with online search engines. Drum brake assemblies are a common checkable category. If rotors are being salvaged, someone is separating the old pads from them (either someone at the junkyard or the customer). It is also possible that some sellers are mislabeling brake pads as asbestos-containing to appeal to a certain type of buyer. Given ongoing commerce in asbestos pads in many foreign countries, it is unlikely that all asbestos pads are counterfeits.

Brake pads on other types of vehicles. 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 Committee member reported that one of the public commenters had provided data that included some asbestos content analysis and air fiber concentration data for non-passenger car products[8].

Near-field and far-field exposure zones and bystander reduction factors. One Committee member recommended two papers, one dealing with indoor dispersion (Donovan et al., 2011) and the other outdoor dispersion (Shade and Jayjock, 1997). The former study, which was conducted for litigation support, is listed in the DRE references but was perhaps not utilized. The latter study uses historical US meteorological data on wind speed to estimate the dispersion and concentration gradients of outdoor sources within meters of the source.

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7 https://www.youtube.com/watch?v=0n02-GU_VYs : accessed 6/2/2020

8 See Steve Compton's comments: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0098

Question 3: Consumer Exposure:

Consumers (Do-it-Yourselfers, or DIY, or DIY mechanics) and bystanders may be exposed to commercial chrysotile asbestos when consumers perform activities associated with several COUs:

- *Aftermarket automotive brakes and linings*
- *Other Gaskets (Utility vehicles - UTVs)*

Q 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).**

Response to Q3.1: Estimation Methods and Assumptions used for Consumer Exposure/DIY Exposure Assessment

The Committee found model assumptions for DIY consumers and bystanders reasonable for both outside and inside scenarios.

Age and Sex: 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. The 2017 Economic Census cited includes this information. The model used in the DRE tends to underestimate exposure at earlier ages and overestimate at older ages. There were concerns raised that DIY activity tends to occur at younger ages and varies greatly due to socioeconomic factors. There were also concerns raised that an older population would be more likely to own antique or vintage cars. This would also more accurately describe those 16 to 36 years of age that are assumed to be more likely to engage in DIY activities and further support the assumptions used in the Sensitivity Analysis described in Appendix L.

The DRE reports that EPA does not know the number of consumers utilizing aftermarket brake shoes or new or aftermarket UTV gaskets containing asbestos. It was unclear to the Committee what efforts were undertaken to better ascertain these numbers.

The DRE asserts that consumers can purchase brake shoes with asbestos from internet sites and some public commenters reiterated this point. One public commenter[9] detailed extensive and unsuccessful efforts over the past twenty years to obtain replacement brake shoes containing asbestos. Given that it has been 25 to 30 years since automotive brake shoes with asbestos have been phased out of use in passenger automobiles, the market for these products should be shrinking, but online searching reveals vendors that claim to sell asbestos brake parts for cars and motorcycles. There also appears to be sellers that claim to have old (unsold) stock as well as consortiums of junk dealers who have

9 Comments by Dennis Paustenbach, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0042.

search engines online who may have automotive brake shoes with asbestos. On the other hand, state-based activity associated with restrictions or California Proposition 65[10] labeling requirements show very few, if any, asbestos-containing products remain in the marketplace. It is unclear to the Committee to what extent searches were attempted of these secondary markets in preparing the DRE. There are also automotive clubs and on-line forums that specialize in vintage or antique cars that may provide additional insight. Many on the Committee wondered why a retailer would take the risk of placing an asbestos-containing product in the marketplace. While legal liability may be an issue for U.S. based sales, the growing international internet-based sources for automobile repair parts would not be so constrained.

The Committee concluded that because of the paucity of data, the conservative approach taken in the DRE was acceptable but recommended expanding the discussion in the DRE to describe the efforts undertaken to better ascertain these estimates.

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.

There was a suggestion that there should be a Condition of Use developed to describe those individuals who engage in auto mechanics as a hobby or part time job, i.e. "the shade tree mechanic."

Page 100, line 3662, references a "specific type" of utility vehicle that uses an asbestos-containing exhaust system gasket. The specific types of vehicles that utilize asbestos-containing gaskets needs to be better described and potential exposures quantified.

Recommendation 29: Clarify the types of vehicles potentially utilizing asbestos-containing gaskets and better discuss associated exposures.

The Committee noted several issues with the Data Quality Evaluation and questioned why certain references were not included in the DRE while others were. For example, Cely-Garcia et al. (2016), estimated personal exposure to asbestos of brake repair workers, was rated as 'High' in the Data Quality Evaluation (DQE), but did not appear to have been used in the DRE. There were 29 studies in the DQE with data extracted. Twenty-seven (27) of those studies were in the data extraction file. Studies listed in the DQE were not classified as brake or gasket studies. The data extraction file provides more description. Most studies were on brakes with just three studies involving gaskets. Table 2-25 lists five studies for brakes. There are many more studies in the DQE with decent ratings and with data extracted. It was not clear why or how the list was narrowed from 27 studies down to just the five studies cited in the DRE, with data from only two of those studies actually used to estimate exposures. Table 2-29 lists three studies on gaskets and these are in the consumer exposure calculation file. The consumer calculation file only reports results for gaskets and does not include calculations for brakes.

Recommendation 30: Explain the inclusion/exclusion criteria for brake and gasket exposure studies.

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10 There has only been one 60-day notice in the Proposition 65 Notice of Violation database (https://oag.ca.gov/prop65/60-Day-Notice-2001-03703).

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.

Q 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).**

Response to Q3.2: Approach to Developing Consumer/DIY Exposure Estimates for Aftermarket Automotive Brakes/Linings

The Committee found the assumptions made in the DRE about the age at starting and the duration of exposures reasonable, as was the approach for estimating bystander exposures.

The Committee did not have complete agreement on the reasonableness of the frequency of exposure estimates. Some Committee members commented that EPA's estimates were reasonable. Other Committee members noted that since drum brake shoes, the most likely source of consumer exposure, are becoming increasingly rare, the values used might underestimate exposure at younger ages and in lower-income groups, and overestimate exposures at older ages. Lower-income groups are more likely to own older/less-expensive cars where original equipment manufacturer (OEM) use of drum brakes is more likely, and these groups are also more likely to engage in DIY auto repair. The opinion was expressed that as these individuals age and/or have higher incomes, they are less likely to engage in DIY repair work.

There was, however, general agreement that for most consumers, engagement is "low-intensity," as is the case for users of other potentially asbestos-containing consumer products (other than users of talc-containing cosmetics, a COU outside the scope of this DRE). If a person is replacing brake shoes on a regular basis, it is likely in an occupational setting such as an auto repair shop (i.e., how often does a consumer need to replace his/her brakes, and how likely are they to do this work themselves?). One public commenter indicated that "shade-tree mechanics" who do work for relatives or as a side business have higher exposures. The number of "shade-tree mechanics" is unknown but is assumed to be a small proportion of the consumer population. Similarly, auto-salvage yard employees were mentioned, but this would be an occupational, not a consumer exposure.

One Committee member opined on the fact that Table 2-26, which identifies studies used to estimate the exposure concentrations for DIY activity, is 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. Additionally, this Committee member pointed out that Blake et al. (2003) was a study on a professional auto mechanic, not a DIY consumer, and involved simulations of various scenarios in an auto repair facility. Sheehy et al. (1989) was a compilation of NIOSH work to figure out how best to control exposures in the brake repair setting, but it was unclear to what extent those control measures are actually used by DIY mechanics. Concern was expressed

that the reduction factors applied might not closely estimate outdoor bystander exposures, with the result that estimates of outdoor bystander exposure given in the DRE are likely overestimates (Shade and Jayjock, 1997).

While there seem to be little good data on the availability of asbestos-containing brake shoes, there are good reasons to assume that asbestos-containing replacement brake shoes are, at most, a quite small proportion of the replacement market. Requirements at the state level for disclosure and health warnings for asbestos in consumer products in California and Washington were discussed, as well as the ban on these parts in Washington state. Considerable liability for sellers/distributors of these parts would accrue from these state statutes. While most of the Committee agreed with this conclusion, one member strongly disagreed, asserting that asbestos-containing brake shoes could likely be found on the internet. The bottom line for the Committee was that, while the Committee was comfortable with the conservative approach taken in the DRE, EPA should continue and expand efforts to better ascertain how prevalent these items are in the marketplace (see Recommendation 28).

Q3.3	**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).**

Response to Q3.3: Approach to Developing Bystander Exposure Estimates

The Committee concluded that the assumptions made about the age at starting and the duration of bystander exposures in the DRE seem reasonable, as is the general approach to estimating bystander exposures in the absence of data.

As was found for consumer/DIY exposures, the Committee did not have complete agreement on the reasonableness of the frequency of exposure estimates for bystanders. Some Committee members found the estimates provided in the DRE were reasonable, while others argued that exposures are underestimated for younger ages and lower income groups and overestimated for older age groups. The rationale for this finding was the same as that provided for consumers/DIY in the response to Question 3.2.

The reduction factors used for indoor bystander exposure are data-based and appear to be reasonable. Indoor bystander exposures are, in fact, highly variable, with values dependent on such factors as the strength and directionality of the indoor air movement and the ventilation rate. Given this variability, the reduction factors used in the DRE for indoor use would appear to be reasonable estimates. Some Committee members noted that 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 Committee 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).

Some on the Committee were confused on how reduction factors (RFs) for bystanders, especially for the outdoor scenario, were derived. 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 on page 114 the DRE mentions using a bystander RF of 5.75 for a gasket installation scenario using a value derived from an occupational study. Another statement on page 120 states that the DRE 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. Clarification of this discussion was recommended.

Recommendation 32: Clarify the reduction factor (RF) discussion for bystanders.

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

Response to Q3.4: Approach to Develop Consumer/DIY Exposure Estimates for Other Gaskets

For Consumer/DIY exposure estimates for other (primarily UTV) gaskets, the Committee repeated its findings on the reasonableness of age at starting and duration of exposures, concerns of potential under- and over-estimation across age and income groups due to differences in frequency of engagement, and confusion over how RFs are chosen. While the approach used in the DRE to develop these exposure estimates for UTV gaskets is detailed and well-explained, the writeup could use clarifying edits. One Committee member reiterated that the workforce engaged in UTV gasket replacement is different from the workforce engaged in automotive brake repair/replacement and, therefore, a separate COU for UTV gasket replacement is justified.

Q 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).**

Response to Q3.5: Assumptions, Uncertainties and Confidence in Consumer Exposure Estimates

Overall, the Committee found the assumptions used in deriving the consumer exposure estimates were sound. The methods rely on results reported in the peer-reviewed literature for occupational exposure as a surrogate to the extent it existed for the COUs. The strategy depicted in Figure 1-5 (page 47) and the accompanying text states that EPA prefers using information in accordance with a hierarchy of data>modeling>occupational exposure limits or release limits. The Committee found this a reasonable approach but suggested that within the category of "data," studies that were done in real-world settings for purposes such as establishing compliance with regulatory limits be prioritized over simulations that were conducted in support of litigation.

The Committee judged the assignment of medium or medium-to-low confidence ratings to the exposure estimates to be appropriate given that the consumer exposure estimates are derived from occupational exposure data, which are generally assigned in the quality ratings (QR) to a medium confidence rating.

To the Committee it appeared that the critical consumer exposure scenario involved DIY or hobbyist mechanics working with asbestos-containing materials, especially brake shoes. Some public commenters argued intensely that, for various reasons, mostly legal liability, asbestos has disappeared from these products in the last few decades. This may indeed be true; however, the Committee members in general could find no direct or compelling evidence that asbestos is no longer used or found in imported after-market products. It is difficult to prove a negative; in this case to prove that there is no asbestos in available consumer products. But one counter example only is needed to reject the null hypothesis of "none" in favor of the alternative hypothesis of "some." USGS (2020) suggests that this counter example exists somewhere in the import records but that the level of "some" may be quite low, which would tend to lower global exposure expectations.

One Committee member reportedly was able to locate brake shoes from China available for sale on the Internet that are purported to, but not confirmed to, contain asbestos[11.]

Some evidence was found indicating that DIY arc grinding of asbestos-containing brake shoes is still being done today. A 2017 YouTube®[6] video is available demonstrating arc grinding of drum brake shoes with a belt sander. During the video, the narrator advises not grinding them too much "…especially if you are working with asbestos shoes." Furthermore, this video has had almost 3000 views in the three years since it was posted, which indicates a substantial number of "internet savvy" individuals with an interest in the DIY arc grinding of brake shoes. It is difficult to estimate how many additional DIY mechanics in the U.S. might also engage in arc grinding but are not interested or capable of accessing this fairly obscure video.

A 2017 web page from a market research group[12] was located on the Internet that asserted that:

> "Most auto manufacturers haven't installed asbestos-containing brake components since the 1990s due to health concerns for those that perform brake-related automotive repair or maintenance.
>
> And yet, asbestos-containing products continue to present a health risk in the automotive aftermarket industry in North America, primarily due to high sales of low-cost, asbestos-containing brake parts from countries such as China and India. In fact, it has been reported that, between 1996 and 2006, the number of asbestos-containing imported brakes has increased 83%[13]. The low-cost advantages of such imports have continued to promote their sales through the current day, putting automotive mechanics at an increased risk of asbestos-related disease."

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11 See for example: https://www.made-in-china.com/products-search/hot-china-products/Asbestos_Brake_Pad.html
12 Freedonia: Asbestos in Brake Pads: What the Average Consumer Might Not Realize, https://www.freedoniagroup.com/Content/Blog/2017/05/22/Asbestos-in-Brake-Pads-What-the-Average-Consumer-Might-Not-Realize (accessed June 2, 2020).
13 The Baltimore Sun: Brakes using asbestos raise fresh concerns, https://www.baltimoresun.com/news/bs-xpm-2006-05-04-0605040031-story.html (accessed June 2, 2020). This reference "Bob Virta of the U.S. Geological Survey, who tallies data on imported minerals, said there has been an 83 percent increase in imports of asbestos brakes and brake material over the past 10 years [i.e., 1996-2006]."

The incentives of lower cost and perceived superior performance combined with a lack of specific regulations may be driving this critical potential exposure to asbestos.

The 2019 USGS (USGS, 2019) summary referenced in the DRE noted: "In addition to asbestos minerals, an unknown quantity of asbestos was imported within manufactured products, including asbestos-containing brake materials, rubber sheets for gaskets, tile, wallpaper, and potentially asbestos-cement pipe and knitted fabrics." However, the most recent USGS Asbestos Data Sheet (USGS, 2020) notes: "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."

Recommendation 33: Confirm and incorporate the latest information from the USGS on manufactured products including auto parts containing asbestos that are imported into the U.S.

The consensus among Committee members responding to this issue was that, at best, the availability of asbestos-containing automotive parts is unclear and a default to reasonable worst case taken by the Agency would appear to be warranted. Indeed, these could represent exposure for potentially many thousands of consumers that should not be ignored or written off without definitive evidence.

There remains a lack of clarity about how often consumers use compressed air to clean drum brakes.

Recommendation 34: Better document current uses by consumers of compressed air to clean drum brakes.

Overall, the other assumptions and uncertainties within this document related to consumer exposure estimates also appeared to be quite reasonable.

Some public commenters[14, 15] advised that, even if it is in the brake shoes, the asbestos fibers that were released during braking or from machining (grinding, drilling or sanding) during brake installation would be different and less or even non-biologically active compared to asbestos that had not been manufactured into brake material. One public commenter[15] stated that "several NIOSH studies have demonstrated that only a fraction (approx. 30-55%) of the asbestos concentrations measured during brake repair work using phase contrast optical microscopy (PCM) methods were subsequently identified as unaltered chrysotile fibers when selected area electron diffraction (SAED) or energy dispersive X-ray analysis (EDXA) methods were used (*i.e.*, these methods can differentiate between different types of fibers on the basis of morphological and structural characterization)."

If we accept that "30-55%" of airborne asbestos concentrations measured during brake repair work is "unaltered chrysotile fibers," then the brake repair scenario does not appear to suggest low

14 A. Langer comment: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0061
15 PR Williams comment: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0040

exposure. The exposure conclusions in this DRE are not changed when exposure estimates are lowered by a factor of 2 or 3. There remains a significant amount of unaltered fibers at these levels. Furthermore, even "altered" airborne chrysotile could still be biologically active. If there are unaltered airborne asbestos fibers (as identified by standard methods) from machining, then they could be an important source of inhalation exposure. The public comment does not mention sanding for "arcing" brake shoes discussed previously. That YouTube® clip[6] shows a considerable amount of dust visible in the back of the vertically-mounted belt sander and, as mentioned above, the sander is wearing what appears to be an N95 respirator. All of this points to the possibility that significant amounts of chrysotile asbestos could be in the breathing zone of people sanding drum brakes.

In summary, it may be entirely possible that asbestos may occur quite infrequently in U.S. aftermarket brakes purchased and replaced by DIY and small automotive shops working on antique (older than 30-50 years old) cars. It may be that even if aftermarket brake shoes contain asbestos, the asbestos fibers emitted from these operations may be biologically inert in which case they might pose lower risk relative to other chrysotile asbestos. However, as noted by several Committee members, the absence of proof that these asbestos fibers are biologically inert suggests that the potential exposure and risk to what could be thousands of exposed U.S. consumers and occupationally engaged workers cannot be ignored. In that regard the current DRE seemed to do a credible job.

One Committee member noted that drum brakes in motorcycles may be much more prevalent than drum brakes in cars operating in 2020. In addition, motorcyclists might be more inclined to do their own brake maintenance. Other vehicles (farm equipment, snow mobiles) that may have drum brakes may currently have asbestos-containing brake shoes because of their age and create higher exposures due to the higher propensity of owners to do their own repair work.

One Committee member mentioned that in an uncertainty analysis of exposure, the frequency of exposure is likely to be highly variable by miles driven and by age and socioeconomic status of consumers.

The Committee realizes that most risk assessments would benefit greatly from more data. The toxicity potency of asbestos and its airborne exposure during handling has been found to cause unacceptable levels of human disease and suffering. The proper assessment and management of this substance under TSCA requires definitive information regarding its exposure potential to conclude relative safety. As such, this DRE should not and does not seem to use assumptions that dismiss the possibility of exposure or base exposure estimates on presumptive, undocumented, or incomplete information. 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. Absent conclusive state-of-the-science data on the absence of biologically active chrysotile asbestos in aftermarket brake drums, the Committee believed the Agency's general approach and evaluation was valid.

One Committee member noted that the DRE discounts the dermal exposure pathway citing it will not absorb into the body through the protective outer skin layers (page 108, lines 3890-3891). However, is this not the route of exposure used in assessments of dermal exposures to 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 (2012); page 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.

Q 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).**

Response to Q3.6: Approaches for the Sensitivity Analysis for the Consumer (DIY and Bystander) Risk Estimates for Automotive Brakes and UTV Gaskets

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.

The effect of changing the duration of exposure for the users and the age at first exposure for the bystanders was a useful addition to the risk estimates.

During the meeting one Committee member offered that the above analysis done by the Agency was not actually a sensitivity analysis but more of a "what if" investigation involving some variables. To further evaluate true sensitivity, the Committee recommended that the Agency use a Monte Carlo methodology in which known or assumed distributions 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 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. For example, a triangular distribution could be used for the age at start and age at end using reasonable values for the minimum, maximum and most likely value. The airborne breathing zone concentration could be assigned a log (normal) distribution parameterized using estimates of the median and geometric standard deviation. Uniform or triangular distributions could be used for the hours of exposure per incidence and the number of incidences per year.

A real advantage of such a methodology is the built-in sensitivity analysis provided by such add-ins to Microsoft® Excel as the Oracle® Crystal Ball[16] tools that have analyses that can identify which variables are contributing the most to model response variability or that can compute probabilistic estimates of risk. That is, it can provide valuable insight into whether any specific determinant(s) is(are) driving the variability (or width of the output distribution) from either the determinant's natural variation or from the uncertainty born of a lack of knowledge about it. If the latter factor dominates, then additional research into or data informing that variable can refine (narrow) its input distribution and thus, significantly lower its contribution to the width of the final distribution of risk. That is, it can substantially raise confidence and lower the uncertainty in the final analysis.

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.

Q 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.**

Response to Q3.7: Alternative Approaches for Improving the Consumer Exposure Assessment

Several public comments[7,14] indicated that a significant amount of unpublished exposure monitoring data was available that demonstrated a relatively high level of inhalation exposure potential. These data should be obtained and discussed in this DRE. If the methodology generating these newly identified data appear valid, these data should be considered as of equal quality as the unpublished industry-supplied data. The Committee recognized that each data source presents its own built-in biases, with work done in support of plaintiffs, by NGOs, by academic researchers, or by industry all having different biases.

As mentioned in the response to Question 3.5, this assessment requires better data than is currently available in order to conclude with confidence a lack of significant risk from asbestos especially in the aftermarket brake replacement scenario for DIY consumers and small automotive repair shops working on antique cars. In this regard, definitive data could come from market research and sample analysis. This would require comprehensive, representative, and statistically significant sample acquisition from the universe of aftermarket brakes sold to US consumers and workers, followed by analysis of these samples for the presence and type of asbestos. Samples of brake shoes in which asbestos are found could then undergo machining via belt sander with emissions from this machining sampled and the distribution of asbestos fiber lengths estimated. At each stage of new data acquisition, the focus should be on providing not just central tendency estimates but actual distributions that support the sensitivity analyses recommended previously (see **Recommendation 35**)

16 Oracle. (2020). https://www.oracle.com/applications/crystalball/ (accessed June 29, 2020)

Recommendation 36: Include data from all credible but unpublished sources in the set of monitored data discussed and utilized.

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 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.

See also **Recommendation 24** and **Recommendation 25** relating to exposures from contaminated work clothing.

Overall, this risk evaluation is a classic case of having to provide an analysis given relatively meager and imperfect information. Research has not occurred that renders source rates for the airborne emission of asbestos from articles during exposure scenarios; thus, physical modeling of these scenarios is not possible. The relatively meager concentration and exposure data available allows the DRE to use only a reasonable worst-case analysis.

In conclusion, suppositions of a lack of exposure potential, even with some suggestive data that are not conclusive, and without definitive data, the DRE has chosen the prudent approach of attempting to produce a reasonable worst-case estimate. The Committee concluded that the Agency has achieved this relative to the exposure assessment of U.S. consumers to asbestos.

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

EPA derived the chrysotile-based inhalation unit risk (IUR) based on a review of the epidemiology literature describing occupational cohorts exposed to commercial chrysotile that provided adequate data for assessment of lung cancer and mesothelioma risks. Cancer potency values were either extracted from published epidemiology studies or derived from the data within those studies. Once the cancer potency values were obtained, they were adjusted for differences in air volumes between workers and other populations so that those values can be applied to the U.S. population as a whole in the standard EPA life-table analyses. The life-table methodology allows the estimation of an exposure concentration association associated with a specific extra risk of cancer mortality caused by commercial chrysotile asbestos. According to standard practice, the lifetime unit risks for lung cancer and mesothelioma were estimated separately and then statistically combined to yield the cancer inhalation unit risk.

Less-than-lifetime or partial lifetime unit risks were also derived for a range of exposure scenarios based on different ages of first exposure and durations of exposure.

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

Response to Q4.1: Choice of focusing on only lung cancer and mesothelioma

Asbestos legacy: Some Committee members remarked that there is a constant shifting, in the DRE and especially in Section 3.2.4, in use of the words "asbestos" and "chrysotile." The Committee found this not only confusing but also misrepresentative of the actual data. The DRE is restricted in scope to chrysotile asbestos only and is not about asbestos. The 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.

Several commenters noted that 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.

One commenter also noted that the CAS Registry Numbers referring to the non-asbestiform varieties of these amphiboles are used in the CAS Registry. These errors should be corrected, both in the DRE and the scope document, insofar as the current version of the DRE contains them.

Recommendation 41: Append CAS Registry Numbers when referring to asbestiform varieties.

Focus on lung cancer and mesothelioma: The Committee, as well as several public commenters, remarked that the DRE's focus on only lung cancer and mesothelioma as the key and only significant cancer endpoints is too limited. It was noticed that the DRE only includes data quality evaluations for lung cancer and mesothelioma studies and does not include any studies on other cancer endpoints. The Committee recommended that other cancer endpoints mentioned in the DRE, such as cancers of the larynx, ovary, pharynx, stomach, and colorectum (Section 3.2.3), be discussed in greater detail (available data, quality of data, etc.). The Committee recommended adding more justification as to why only lung cancer and mesothelioma are considered in this occupational risk assessment.

Committee members believed that there should be discussion of other cancer endpoints, both in the respiratory system and in other organs. As shown with other inhaled carcinogens, there is the possibility that asbestos inhalation may create a systemic inflammatory immune response that could elicit tumor progression in distant organs. In addition, inhalation can still affect other parts of the respiratory system. One member noted that there is a large component related to ingestion during the respiratory process, which has not been touched at all or considered in the decision process to limit to lung cancer and mesothelioma (Christofidou-Solomidou, 2019; Grieshober, 2018; Wong, 2016; Kodavanti, 2014; Würtz et al., 2020). The relatively narrow literature that was used to calculate the IUR focusing on the textile studies was not sufficient to actually do a similar analysis of exposure response for ovarian and larynx cancer. A broader literature inclusion would not only show that laryngeal and ovarian cancer are caused by asbestos but might also provide some information about exposure-response relationships for these cancers.

Recommendation 42: Include other cancer sites beyond lung cancer and mesothelioma as the key cancer endpoints.

Non-cancer endpoints: The DRE acknowledges that non-cancer effects are not considered and as a result the health risks of chrysotile asbestos are likely underestimated.

Some Committee members remarked that existing data permit the addition of asbestosis mortality to the risk evaluation. One Committee member concluded that the primary reason for not considering this and other non-cancer endpoints was a lack of reference concentrations for chrysotile asbestos for these diseases. However, no robust argument for this exclusion is made. More discussion should be devoted to justifying excluding asbestosis and other well-known asbestos-related diseases. At a minimum, the DRE should discuss and incorporate asbestosis mortality in the overall mortality risk associated with chrysotile asbestos exposure.

The same epidemiologic studies that EPA reviewed for lung cancer and mesothelioma mortality have data that can be used to address asbestosis mortality (Hein et al.,2007; Deng et al., 2012; Wang et al., 2013a; Loomis et al., 2009). These studies showed that asbestosis was a substantial contributor to mortality among chrysotile-exposed workers and should be evaluated by EPA as part of the review process.

Hein et al. (2007) included an exposure-response analysis for asbestosis hazard death rate. Comparing Figures 1 and 2 in Hein et al. (2007), the asbestosis mortality rate per fiber-year/cc is approximately 1/3 that of lung cancer mortality rate. In counts, there were 36 excess deaths due to asbestosis versus 96 excess deaths due to lung cancer and 2 deaths ascribed to mesothelioma.

Deng et al. (2012, Figure 1 and Figure 2) described the results of several models evaluating relations for asbestos exposure and mortality risk for lung cancer and asbestosis in Chinese textile workers. Deng et al. (2012) demonstrates that data exist to include asbestosis mortality in the EPA asbestos risk evaluation. Deng et al. (2012) also showed that the estimated asbestosis mortality per fiber-year/cc may be as high as that for lung cancer mortality.

Wang et al. (2013b) also evaluated non-malignant respiratory disease (NMRD) among Chinese chrysotile miners and provides exposure response data in their Tables 5 and 7. NMRD mortality was excessive at all levels of cumulative chrysotile exposure.

Loomis et al. (2009) also provided estimates of risk of asbestosis death by categories of cumulative asbestos exposure in the North Carolina textile cohort.

Committee members stated concerns that other cohorts with substantial chrysotile asbestos exposure resulting in asbestosis have been studied, but reports were not identified in the literature review or were found but not used in the DRE. For example, the Courtice et al. (2016) and Wang et al., (2013a, 2013b) references are cited in the DRE but their findings on asbestosis are barely acknowledged. One Committee member mentioned that Tossavainen (1997) studied chrysotile asbestos exposures to workers and examined non-cancer effects.

Recommendation 43: Include asbestosis in the discussion and analysis of non-cancer endpoints.

Q 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).**

Response to Q4.2: Approach, assumptions, strengths & weaknesses of Chrysotile-based IUR

Overall approach:

The Committee understood the constraints under which EPA is developing these TSCA evaluations. Most of the Committee recommended that one IUR should be derived to cover all types of asbestos instead of just chrysotile asbestos alone. One Committee member strongly objected to this approach post meeting suggesting that an IUR should be derived for each type of asbestos. See also the discussion preceding **Recommendation 54** where the impact of other sources of bias on the estimation of the IUR are discussed.

Recommendation 44: Derive one IUR to apply to all type of asbestos not just chrysotile asbestos[17].

EPA developed evaluation criteria specific to chrysotile asbestos in this DRE. The Committee found these criteria to be broadly acceptable, specifically concurring with EPA's approach to adjusting the exposure evaluation criteria, the general outcome evaluation and study participation criteria for mesothelioma, and the analysis evaluation criteria. The Committee had concerns about the potential confounding criterion, particularly since smoking was not measured in the North Carolina and South Carolina cohorts and acknowledging not only its potentially confounding effect, but also its important synergism with lung cancer. While smoking prevalence was generally high and EPA was working under the assumption (based on evidence) that smoking did not vary by level of exposure, the discussion did note that smoking rates tended to be lower among African American workers, who tended to have the jobs exposed to the highest levels of dust. While the challenge of how to address smoking is difficult to overcome, the Committee suggested that life table methods be used to estimate lung cancer risks separately for smokers and nonsmokers as a way to partially address the concerns about the effects of smoking on lung cancer.

Recommendation 45: Use life table methods to estimate lung cancer risks separately for workers exposed to asbestos who also smoke.

<u>Assumption underlying choice of study cohorts:</u>

The DRE assumes that exposures to textile workers to chrysotile asbestos will induce lung cancer and mesothelioma effects that are comparable to exposures from current chrysotile asbestos uses, such as changing brakes. Some Committee 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, making the above assumption problematic. This assumption needs better justification in the DRE.

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.

The DRE assumes mortality is the best outcome for assessing health outcomes. Some Committee members were concerned that modeling based on a mortality outcome rather than on incidence biases the IUR estimate. Survival times for lung and mesothelioma cancers are increasing, allowing time for more deaths to be recorded to other outcomes, with the result being undercounting of deaths associated with lung and mesothelioma cancers. However, mortality and incidence of lung and mesothelioma cancers were more similar in earlier time periods, including the time-period when the occupational data were collected. The distribution of times from diagnosis until death from mesothelioma or lung cancer could be used to estimate the bias in the use of mortality statistics. 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.

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17 One Committee member strongly objected to this recommendation in post meeting communications.

Strengths and weaknesses of choice of study cohorts:

The DRE focuses on cohorts occupationally exposed to chrysotile asbestos in the manufacture of textiles. The Committee concurred that the North Carolina and South Carolina cohorts (Burdorf, 2011; Lenters, 2012) have the best exposure data and that this was a good reason to focus on these cohorts. The Committee identified other studied occupational populations that should be given more consideration and possibly used in the analysis. These included studies from Italy (Pira, 2017; Ferrante, 2020) China, (Wang et al. 2013a; 2013b) and Canada (Liddell, 1997; Liddell, 2002).

Some Committee 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 discussion revealed that mining exposures might be even less relevant for this DRE given that mining exposures are quite different than, for example, exposures from changing brakes. The Committee agreed that given the constraints necessary for IUR modeling, it was appropriate to focus on the South Carolina and North Carolina cohorts because of their higher quality exposure data.

Regardless, the Committee recommended that some discussion of the exposure assessment and epidemiology studies of mechanics be added, with the rationale for why they were not considered in the evaluation. Among the COUs considered in the DRE, 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[18]. 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 DRE docket and are summarized in two meta-analysis publications (Goodman, 2004; Garabrant, 2016). 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 (McDonald and McDonald, 1980; Teta et al., 1983; Spirtas et al., 1985; Woitowitz and Rodelsperger, 1994; Teschke et al., 1997; Agudo et al., 2000; Hanzsen and Meersohn, 2003; Hessel et al., 2004; Welch et al., 2005; Rolland, et al., 2020; Rake, et al., 2009; Aguilar-Madrid, 2010), and five cohort studies (Jarvholm, and Brisman, 1988; Hansen,1989; Gustavsson et al., 1990; Merlo et al., 2010; Van den Borre and Deboosere, 2015). For asbestos associated lung cancer, these studies include twelve case-control studies (Williams et al., 1977; Lerchen et al, 1987; Benhamou et al., 1988; Vineis et al., 1988; Morabia,et al., 1992; Swanson et al., 1993; Matos et al., 2000; Richiardi et al., 2004; MacArther et al., 2009; Consonni et al., 2010; Corbin et al., 2011; Guida et al., 2011), and two cohort studies (Hrubec et al. 1992; Veglia et al., 2007). Committee members note 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 actually performed brake replacement. Also, none of the studies were specifically designed to study brake replacement (Lemen, 2004; Egilman, 2005; Welch, 2007; Teschke, 2016; Vermuelen, 2016; Kanarek 2018). The DRE should review these studies and consider whether they can be used to

18 One Committee member noted that legacy exposures as well as current construction pipe fitters and insulation workers are likely more highly exposed.

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.

Key calculation decisions and modeling to derive the IUR:

The DRE uses potency factors from the literature. Some Committee members noted that when the data are available to reproduce these estimates, it would add value for EPA to verify calculations of them in this DRE, as they are the basis for important policy judgments. The Committee did not anticipate that substantial differences would be found.

The approach to combining the IUR estimates from the two endpoints seemed reasonable to the Committee. Nevertheless, some Committee members expressed concern with the approach used in the DRE that uses endpoint information from distinct cohorts for the two outcomes, namely combining the lung cancer endpoint from the South Carolina cohort with the mesothelioma endpoint from the North Carolina cohort.

The Committee suggested that fitting and assessing the linear risk model should have been performed and incorporated into the final IUR estimates. The DRE focuses on the linear model for historical reasons but then noted that the exponential model fit the data much better and as a result of d the IURs were based on the exponential model. Concern was expressed that the choice of model, based on overall model fit as determined by the Akaike Information Criteria (AIC), does not address how well the linear and exponential models fit the parts of the dose response relationship, especially at the low end of the exposure range. Given the large range of exposures and the relatively few individuals with extremely high exposures, high exposures may have an undue influence on the overall model fit. (Although it was noted that this should be less of a concern in the South Carolina cohort.) This may strongly affect the conclusion since the fit at lower exposures is more relevant to determining the choice between the linear and exponential risk models. One Committee member suggested that an approach to combine robust model fitting techniques and a structured search through the data combined, as detailed in Atkinson (2000), would help address this concern. Such an approach as this may appropriately replace the "drop the highest dose" recommendation in many EPA dose-response model fitting guidance documents. The Committee also noted that the 2005 Cancer Guidelines (U.S.EPA, 2005) stated that when the weight of evidence is insufficient to establish the mode of action for a tumor site, linear extrapolation should be the default and is more health protective. 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 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.

Recommendation 50: Compare the estimated IUR derived from the linear model fit to the IUR estimated from the exponential 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.

Recommendation 52: Replace the AIC model-selection criterion with a criterion that puts more weight on the low-exposure range of the data.

Q 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).**

Response to Q4.3: Characterizing the implications of the assumptions and uncertainties associated with the derivation of the IURs

The DRE presents arguments regarding exposure and three endpoint-related uncertainties, specifically exposure measurement, omitting other cancers, mortality rather than incidence, and only characterizing cancer risk in the IUR. The Committee identified additional uncertainties that it recommended be classified with respect to the direction of bias. The Committee addressed its thoughts about each risk in the list below.

The DRE compensates for two sources of bias by selecting the largest IUR from among four candidates (page 154, Table 3-12), arguing that "This largest estimate was most likely to cover the total risk of incident cancers" (page 155, line 5703). However, the Committee could identify no connection between the likely effect of the two biases identified in the DRE and the largest IUR. The Committee considered it more appropriate to use data related directly to the two biases to estimate their effect. The distribution of times from diagnosis until death from mesothelioma could be used to estimate the bias in the use of mortality statistics. Information on the risk of other cancers compared to lung cancer and mesothelioma in studied cohorts could be used to modify the IUR accordingly. The Committee recommends not using one bias to compensate for others. Instead the Committee recommends that each of these biases be compensated for using data that informs the amount of the bias, to the extent possible.

Recommendation 53: Avoid using one bias term to compensate for others.

All the uncertainties that the Committee discussed are listed below along with its judgment about the direction of biases, namely likely downward bias, possible upward bias, and additional uncertainties where we have not classified the direction of the bias.

- Uncertainties likely to bias estimates lower

- *Only focusing on mesothelioma and lung cancer and omitting other cancers*: The argument that the numbers are insufficient to add other cancers (e.g., laryngeal, ovarian) is of concern when coupled with the undercounting of mesothelioma risks and the reliance on mortality rather than incidence data. Together they are a source of undercounting that operates only in the direction of the IUR being too low.

- *IUR only characterizes cancer risk*: The argument that cancer is the risk driver ignored that the non-cancer risks such as asbestosis are also important and together, they would produce a more comprehensive and informative IUR estimate.

- *Using mortality instead of incidence*: The document makes the argument that mortality approximates incidence for these cancers and that the underestimation for mesothelioma has been directly accounted for. The Committee concluded that this will lead to underestimation of the IUR, particularly for the linear risk model.

- *Form of the risk model (linear vs. exponential)*: The choice of the exponential model over the linear risk model has major implications for the IUR estimate, but this uncertainty is not discussed sufficiently.

- *Use of the linear risk model for mesothelioma*: Berman and Crump (2008b) studied characteristics of both the Peto mesothelioma model and the linear lung cancer model and assessed agreement with data from several cohorts exposed to various types of asbestos. The assumption that mesothelioma risk varies linearly with exposure was firmly rejected by fits to both the data from Wittenoom, Australia (crocidolite exposure, 222 mesotheliomas) and data from Quebec, Canada (chrysotile exposure, 35 mesotheliomas) (P-value < 0.0001 in both cases), with the best-fitting models having exposure exponents of less than 1. If non-linearity is supported for the low-dose region, it would mean that mesothelioma risk from quite small exposures are underestimated in the DRE. The uncertainty associated with this should be discussed, and EPA should consider further exploration of this issue, as it could have a large impact on risk estimates for mesothelioma.

- *Exposure measurement error in the cohort studies*: Exposure measurement error is a huge challenge in most occupational epidemiologic cohort studies. While the bias from mis-measured exposures can be in any direction, the most typical pattern is that the uncertainty in the exposure leads to underestimates, which would result in a downwardly biased IUR estimate.

- *Under-ascertainment of mesothelioma:* The DRE acknowledges the challenge of under-ascertainment of mesothelioma and adjusts the mesothelioma unit risk by 1.39 (0.80-2.17), based on a simulation by Kopylev et al (2011). Per EPA (2014), the sensitivity of death certificates for mesothelioma "ranged from 40% for ICD-9 (Selikoff and Seidman, 1992) to about 80% for ICD-10 (Camidge et al., 2006; Pinheiro et al., 2004)." Deaths recorded in the South Carolina and the North Carolina textile studies (Hein 2007; Loomis 2009) occurred between 1940 and 2003 and used pre-ICD-10 coding versions, which under-ascertained mesothelioma deaths by 40% to 50%. This suggests that under-ascertainment of mesothelioma deaths in the textile studies was an important problem and that the 1.39

adjustment factor for mesothelioma ascertainment used by EPA in the DRE document is too low and should be closer to 2.0.

- Uncertainties likely to bias estimates higher

  - *Fiber potency as a function of length and width*: Some Committee members noted that potency of fibers depends upon their length and possibly their width, with longer fibers being the more potent. Other Committee members noted that the literature does not suggest a difference in potency by size. The DRE should discuss the likely difference in distribution of fiber lengths in the North Carolina and South Carolina textile mills compared to fibers to which workers are exposed in various jobs being evaluated, and further discuss the implications of this on the accuracy of estimates of risk presented in the DRE. If gaskets or chloro-alkali diaphragms do not require fibers as highly milled as those used in textiles, which seems likely, this may cause risks to exposure to fibers released from gaskets and those in the chloro-alkali plants to tend to be overestimated. If feasible, EPA should use information on the fiber grades and fiber lengths and available relevant airborne measurement data in the products for which the risk is being estimated and consider whether to adjust the risk estimates.

    Overview of this fiber potency literature: Differential fiber potency as a function of length was first observed in rodent studies by Stanton and colleagues (Stanton and Wrench, 1972 and Stanton et al., 1977, 1981) and has been supported in animal studies by many other investigators (for a list see Berman and Crump 2008b, Hodgson and Darnton, 2000). Longer fibers also may be more potent in causing human cancer (Case et al., 2000; Sebastien et al., 1989; Berman and Crump, 2008b; Stayner et al., 2008; Loomis et al. 2010), though more recent, highly relevant studies from the South Carolina and North Carolina textile cohorts do not support a clear hierarchy in risk according to fiber length (Hamra et al., 2014; Hamra et al., 2017), as noted by Dr. Dana Loomis at the SACC meeting on June 8, 2020. Additional studies that support potency of short fibers were found in Dodson et al., 2003; Davis and Jones, 1988; and Boulanger et al., 2014. If fiber length matters, it implies that the same fiber concentrations measured by PCM can pose different cancer risks because PCM counts all fibers longer than 5 microns the same, regardless of their length. Except for mining studies, all of the epidemiological studies involved milled asbestos. The asbestos studies from South Carolina and North Carolina from which EPA calculated the carcinogenic potency produced textiles which presumably require fiber grades that contain longer fibers though the vast majority of asbestos fibers in textile plants were, in fact, short fibers, i.e., less than 5 microns in length (Hamra et al., 2014, Hamra et al, 2017)

  - *Fiber lengths in expected exposures (changing brakes) versus those in textile mills*: The Committee 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.

- **Additional uncertainties, where the bias direction is not yet classified**

  - *Exposure measurement*: The Committee expressed varying perspectives on this issue. While the comparison of results using PCM vs. TEM appeared reassuring, suggesting that this is not an important source of uncertainty in the IUR estimation, some Committee 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 DRE. The Committee notes, as stated above, that the vast majority of asbestos fibers in textile plants were, in fact, short fibers, i.e., less than 5 microns in length.

  - *Amphibole contamination*: Chrysotile asbestos typically is contaminated with small amounts of amphibole asbestos and there is a long history of debate about whether mesothelioma cases associated with chrysotile asbestos exposures are due to chrysotile asbestos per se, or whether they are caused by contamination from amphibole asbestos. However, since EPA's goal is to calculate the IUR for commercial chrysotile, this source of contamination may not bias the IUR.

  - *Non-amphibole asbestos contamination or using chrysotile asbestos alone to represent all types of asbestos*: Commercial chrysotile asbestos is often contaminated by tremolite asbestos. Berman and Crump (1995) considered comparable animal data on several varieties of asbestos: chrysotile, amosite, crocidolite and tremolite, and tremolite was about the most potent tumor producer, although the result of the single study of tremolite fell within the range of seven chrysotile studies. The degree and direction of the bias would depend upon the relative potencies as well as the relative mixture in the different asbestos forms assumed for each exposure COU being evaluated compared to the asbestos mixture used in the Carolina mills, if possible.

  - *Not considering dermal exposures*: The DRE discounts the dermal exposure pathway, citing it would not absorb into the body through the protective outer skin layers. The Committee recommends providing a rationale for this assumption, one that discusses the reduced potential for dermal absorption through likely skin contact points of the highly keratinized palms of the hand and forearms. Furthermore, exposure through a mucous membrane, not intact skin, is the route of exposure for those who have used body powder containing asbestos, where fibers have been reported in internal tissues.

  - *Assumption of no mesothelioma background*: The DRE assumes that there is no mesothelioma background rate. However, the American Cancer Society states that "About 8 out of 10 people with mesothelioma have been exposed to asbestos"[19] suggesting that 20% of mesothelioma cases have no known asbestos exposure link. It was noted, however, that in a high percentage of mesothelioma cases that report no recalled asbestos exposure, asbestos fibers are found in the lung. The absence/rarity of background incidence of malignant

19 https://www.cancer.org/cancer/malignant-mesothelioma/causes-risks-prevention/what-causes.html

mesothelioma apart from asbestos exposure was reported in Mark and Yokoi (1991) and Strauchen (2011). However, even if all mesotheliomas cases with no known asbestos exposure were caused by environmental asbestos exposure, this would still imply a background of mesothelioma that possibly should be accounted for in EPA's assessment of risk of mesothelioma.

The discussion of uncertainties should be expanded to include the uncertainties identified above. An analysis of these potential sources of bias should be performed and, to the extent possible, the magnitude and direction of bias on the estimated IURs estimated.

Recommendation 54: Include the additional sources of bias identified by the Committee in the discussion of uncertainties, and discuss how these biases will change the direction and magnitude of estimated IURs.

Q 4.4	**Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in deriving the commercial chrysotile based IUR.**

Response to Q4.4: Alternative Approaches in deriving the Chrysotile-based IURs

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 mode of action by which a substance causes cancer. The DRE should link the section describing what is known about the mode of action of asbestos in causing cancer with the selection of a linear extrapolation procedure as required in the cancer guidelines. At least one Committee 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.

EPA's default risk assessment methodology is to use a low-dose linear model to calculate IURs when such a model is scientifically plausible or when the mode of action for a tumor site is not sufficiently established (U.S.EPA, 2005). A low-dose linear model is one in which the slope of the dose-response is positive at a dose of zero. For lung cancer, the DRE reports results from evaluating both the linear model and the exponential model. Both models are low-dose linear models. The linear model has been used in the past to assess risk from asbestos (U.S.EPA, 1986). As is also discussed in the Question 4.2 response, the DRE justifies use of the exponential model over the linear model because the exponential model provides a better fit to both the South Carolina and North Carolina lung cancer data, as determined by model AIC values. The AIC measures the fit of the model over the entire exposure range. However, when computing an IUR, the primary interest is in the risk at low exposures. Given that, it is not clear that how well models fit to all of the dose response data (including high-dose data) is particularly important. A better approach to evaluating models might be to use a method that emphasizes how well the models fit the lower dose data. This could possibly be accomplished by comparing AICs using only data from lower exposures.

The North Carolina and South Carolina data sets are of about equal quality. Therefore, it is recommended that the data for calculating an IUR for chrysotile asbestos exposures from the

Carolina textile mills be the combined data from the North Carolina and South Carolina 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 North Carolina and South Carolina for lung cancer. Berman and Crump (2008a) and Loomis et al. (2019) contain analyses of the individual level mesothelioma data from South Carolina and North Carolina, respectively and results from these analyses could be combined to evaluate the risk of mesothelioma. Thus, using these analyses, the IUR for both lung cancer and mesothelioma could be based on combined individual level data from North Carolina and South Carolina mills.

The Committee questioned the analysis upon which EPA's preferred mesothelioma potency factor is based. The DRE expresses preference for the estimate of K_M based on Loomis et al. (2019), which reports a K_M of 0.88E-9 (UCL = 1.49E-9). Loomis et al. also reports a K_M of 2.96E-9 (UCL = 5.87E-9) using an alternative analysis that includes only cohort members alive in 1999. However, the K_M value listed in Table 3-9 as K_M = 2.44 E-9 (UCL = 5.04 E-9) has the notation "EPA modeling of Loomis et al.". Earlier in the DRE 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)." The Committee did not find a description of this analysis in the DRE or associated supplements. The analysis by EPA that was used to provide its preferred K_M needs to be better documented and because the data used are not easily accessed, these data are provided in a supplement to the DRE.

Recommendation 55: Better describe the derivation of the K_M estimate used in the evaluation.

The Peto mesothelioma model used in the calculation of the IUR does not accommodate the possibility of a non-zero background for mesothelioma. However, therapeutic radiation for lymphoma has been reported to cause mesothelioma (Chang et al., 2017; Teta et al., 2007). Several studies have discussed mesothelioma cases with no known exposure to asbestos (e.g., Spirtas et al., 1994; McDonald and McDonald, 1980, 1994; McDonald, 1985; Moolgavkar, 2009; Price and Ware, 2004, 2009; Roggli, 2007; Walker, 1983). The EPA should consider modifying the Peto mesothelioma model to account for background mesotheliomas not caused by documented exposures to asbestos.

The Peto mesothelioma model assumes exposure is constant during the period exposure takes place. Thus, to use the model for exposure that is not constant requires that an average exposure be applied. A worker's exposures are typically higher early in employment due both to how new hires are assigned to jobs and the fact that exposures in a mill likely are reduced over time as more effective dust control systems are employed. Summarizing such exposures by an average exposure over a worker's work history for use in the Peto model, as must have been done in the Loomis et al. (2019) mesothelioma analysis of North Carolina data, underestimates the effect of higher exposures early in employment. Berman and Crump (2008a) applied an expanded Peto mesothelioma model to the South Carolina mesothelioma data that accounted for variable exposures and reverted to the original Peto model when exposure was determined to be constant. The Committee recommends that EPA reanalyze the mesothelioma data for North Carolina mills using the expanded Peto model in order to more accurately account for the variable asbestos exposure patterns in the North Carolina cohort.

Recommendation 56: Reanalyze the North Carolina mill data on mesothelioma using a modified Peto model that incorporates a non-zero background and accurately accounts for variable exposures.

The DRE 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 Committee agreed that this seemed appropriate. However, the distinction between basing an analysis on individual level data versus grouped data is somewhat artificial because practically all analyses of individual data involve some grouping. For example, all of the analyses of the North Carolina and South Carolina for lung cancer (Hein et al., 2007; Elliott et al., 2012; Loomis et al., 2009) and mesothelioma (Loomis et al., 2019) utilized Poisson regression, which involved grouping the data into bins defined by various characteristics including exposure (e.g., Richardson, 2008). However, having access to the individual data does have the benefit of allowing the average exposure in a group to be estimated accurately rather than having to estimate average exposures from only the exposure ranges when the average exposure within each range is not provided in a published report. In these cases, to estimate the average exposure in the highest exposure category, the DRE uses the highest exposure reported in the publication as the value for the upper bound to estimate an average exposure in the highest exposure category (line 5079). EPA used this approach in modeling grouped lung cancer data from both the South Carolina (Hein et al., 2007, Table 3-3) and North Carolina (Loomis et al., 2009, Table 3-4) studies. However, this approach typically will overestimate exposure. For example, Berman and Crump (2008a, page 32), report an analysis of the lung cancer data from South Carolina based on individual level data which uses the same exposure groupings as EPA's analysis (page 294 in the draft DRE, also reported in Table 3-3). In their analysis, Berman and Crump use the individual level exposures to calculate exact average exposures in each exposure group. This analysis obtains an exact average exposure for the highest exposure group of 185.1 f/ml compared to 410 f/ml assumed in the EPA analysis. Correspondingly, the EPA estimates $K_L = 0.0173$ whereas in a comparable analysis Berman and Crump (2008a) estimate $K_L = 0.03$, a difference of a factor of 1.7. Moreover, the EPA analysis assumes the relative risk model (line 5025) where the background parameter α is equal to 1, which implies that the background lung cancer rate in the South Carolina mill was equal to that in the general population, whereas Berman and Crump (2008a) found that the hypothesis $\alpha = 1$ could be clearly rejected (P-value = 0.008), with the best estimate being $\alpha = 1.35$, which implies that the South Carolina cohort had a higher rate of background lung cancer than the general population.

The DRE similarly overestimates exposure in the highest exposure group in the Loomis et al. (2009) analysis of the North Carolina lung cancer data, which probably accounts for the DRE estimate of K_L based on grouped data being the smallest of the four K_L 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 taking into account previous analyses performed using individual data, estimates of the background parameter α, and methods that do not overestimate exposures in the highest exposure group.

A synergistic relationship between smoking and asbestos in causing lung cancer has been reported in several studies (e.g., Hammond et al., 1979; Liddell and Armstrong, 2002; Berry and Liddell, 2004). However, the only reference in the DRE to the important susceptible subgroup of smokers is the

single sentence: “Cigarette smoking is an important risk factor for lung cancer in the general population” (page 156, lines 5730-5731).TSCA requires that a risk evaluation determine whether a chemical substance presents an unreasonable risk of injury to health to a potentially exposed or susceptible subpopulation. The DRE quantified the risk for some segments of the population to satisfy this requirement. The Committee recognizes the lack of smoking information in the key cohort studies. Nevertheless, the DRE should do the same for susceptible subgroups to the extent possible.

The IUR as currently derived in the DRE is based on mortality data of the general population which contains both smokers and nonsmokers. One Committee member suggested that quantifying the extra cancer risk in smokers due to exposure to asbestos should be relatively straightforward. Such smoking-specific risks were calculated, along with a description of the methodology and the data tables used, in an EPA report (Berman and Crump, 2003). In general, the calculated K_L and K_M values are used in a life table analysis that uses background rates for lung cancer and all causes that apply to smokers. The Committee recommended that the DRE be expanded to include quantitative estimates of the carcinogenic risk from exposure to asbestos among the large susceptible subgroup of smokers. Risk tables in the IUR should be revised to include risks specific for both smokers and nonsmokers, with the risk for nonsmokers based on background rates that pertain to nonsmokers.

Recommendation 58: Revise risk estimates and tables to provide separate risk estimates for smokers and nonsmokers.

Question 5: Human Health and Environmental Risk Characterization

Q 5.1	**EPA presented overall human health risk conclusions (Sections 4.5.2 and 4.5.3) based on risk estimates for cancer. Please comment on EPA’s approach including any alternative considerations for assessing and presenting risk conclusions including the risk summary tables (Table 4-55 and 4-56).**

Response to Q5.1: EPA’s Approach for Assessing and Presenting Risk Conclusions

The Committee raised numerous issues related to risk estimates for cancer. Committee members expressed concerns that calculations that led to assessment of the risk estimates for cancer were restricted to lung cancer and mesothelioma mortality, and thus could underestimate risk. Specifically, the incidence of other cancers (ovary, larynx, digestive, etc.) that have been associated with asbestos exposures, as well as diseases such as asbestosis were not included (see **Recommendation 42** and **Recommendation 43**).

In addition, 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, Committee 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.

Risks from asbestos for disease is cumulative. Thus, the Committee suggested that calculations of the risk estimates for cancer should consider legacy asbestos exposures. In addition, this would require incorporation of aggregate exposures, as these are essential to understand how humans may be affected by multiple sources/pathways of legacy use.

Recommendation 60: Include legacy and aggregate asbestos exposures in the calculation of cancer risk estimates.

Similarly, the Committee expressed concerns about the unrealistic inclusion of respiratory protection and associated APFs for consideration in risk estimation for workers, as in Table 4-55 (page 208) for several reasons. First, respiratory protection programs, as established and operated by some employers, are inadequate. Citation by OSHA for such inadequacy, specifically for respiratory protection programs, has routinely been among the five most common OSHA violations nationally over the past several years.[20]

Even when PPE may be used, it is sometimes incorrectly used, or a lower PPE standard is used. For example, in the sheet gasket stamping operation included in the risk evaluation, EPA found that workers used N95 respirators. However, according to EPA (and OSHA), N95s are not the appropriate respirator to use when working with asbestos (page 161). The problem is further exacerbated by the fact that most of the airborne asbestos concentrations used to estimate worker exposures in the risk evaluation do not exceed the permissible exposure levels (PELs) or the action levels established by OSHA and, therefore, would not trigger the requirement for the employer to enforce a proper respiratory protection program. Additionally, in the material provided by the American Chemistry Council regarding use of asbestos at chlor-alkali plants, respiratory protection is not used in certain tasks even when the air sampling shows asbestos fiber concentrations that approach the OSHA Short-Term Exposure Limit (STEL), i.e., cell assembly, hydro-blasting. This is noted in the risk evaluation (page 64-67). 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 knowledge or resources to establish such a program. Table 2-7 (page 68) summarizes the short-term sampling results from industry.

Likewise, at the Branham sheet gasket stamping operation (described in Section 2.3.1.4.1), the stamping machine operator wore a N95 respirator, which is not in accord with OSHA requirements. The monitoring data did not exceed the OSHA PEL and STEL, so that OSHA respirator requirements did not apply.

For some uses of asbestos (e.g., replacement of brakes, clutches and UTV gaskets), small businesses are likely to be the dominant user of the asbestos product. Businesses that use asbestos-containing friction products when asbestos-free alternatives are readily available may not even know that the products they are using contain asbestos and or/may be insufficiently impressed by the hazards of asbestos to implement effective and appropriate use of respirators.

Additional confusion is imparted by the statement in the risk evaluation that "Nominal APF may not be achieved for all respirator users" (page 161, line 5904). EPA appeared to agree with the limitations of the APF approach. For example, on page 59 it was stated that APFs might lower asbestos

20 For fiscal year 2018, see https://www.osha.gov/top10citedstandards

exposure, "assuming employers institute a comprehensive respiratory protection program" (page 59). But, for the reasons cited above, that assumption was not fully supported. Given the uncertainty around availability, use, and effectiveness of appropriate respirator protection, as indicated by EPA, the EPA should delete use of APF's in their risk caculations, removing them from Table 4-55. However, one Committee member commented it is appropriate for EPA to present risk both with and without PPE since 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 and based on the assumption that a comprehensive respiratory protection program is in place, universally used, and constantly maintained.

The Committee also believed that the presentation in the risk evaluation of exposure scenarios for consumer and bystander use of asbestos-containing brakes and gaskets would be more plausible if it highlighted more likely scenarios in Table 4-56. For instance, what is the risk for a worker who started as a sheet gasket stamper at age 20 and worked for 10 years before moving to an occupation without asbestos exposure? The scenarios could be developed to describe people who would characterize individual table cells, as well as alternatives that were not captured in the table. This would make the estimates more accessible to a broader cross-section of readers.

The DRE indicates on page 204 that 2/3 of U.S. households have two or more vehicles, and one-quarter have 3 or more vehicles. People who replace the brakes of their own vehicles often also replace brakes of cars of family members, friends and neighbors. The term "shade tree mechanics" has been applied to these individuals. Replacing five or six sets of brakes per year would be a reasonable scenario for people who do this work. They and other DIY consumers are unlikely to do this work until age 78; stopping at age 50 or 60 would be more likely. Starting in the latter teenage years, as the DRE posits, is reasonable.

Recommendation 62: Develop and discuss more likely exposure scenarios on the use of asbestos-containing brakes and gaskets by consumer and bystander.

Recommendation 63: Provide qualifying statements as to the limitations of the DRE and its analyses in its restriction to current intentional uses of chrysotile asbestos fibers and only including lung cancer and mesothelioma mortality.

Table 4.2 to Table 4.38 present risks to workers and ONUs for the asbestos exposure scenarios examined in the DRE. The conditions of exposure considered involve various assumptions regarding exposures based on monitoring data and assumptions, use of PPE, etc. and were reasonably comprehensive. However, there were too many tables for a reader to digest easily. Some of the tables had only very few entries (e.g., two). Instead of upwards of eight tables displaying risks from a single use, consideration should be given to combining these into only one table for each use, with an overall summary table. This consolidation would foster easier comparisons among the different scenarios and better overall comprehension. A graphical presentation should also be considered as an adjunct to the summary table. The numbers in the table should all be presented relative to the cancer benchmark value. It is difficult to process the scientific notation and make comparison across cells when the estimates were presented in the format used in Table 4.2 to Table 4.38.

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.

The Committee 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 K_L and K_M 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.

Q 5.2	**Please comment on the clarity and validity of specific confidence summaries presented in Section 4.3.**

Response to Q5.2: Clarity and Validity of Confidence Summaries in Section 4.3

Asbestos legacy:

Committee members noted that there was no mention of existing sources of asbestos exposures for all those workers who are dealing with old structures, ships or other mechanical equipment that contain asbestos.

By relegating legacy uses of asbestos to another document, EPA is ignoring an important source of exposure. There should be at least some discussion of the prevalence of legacy uses and changes in them over time. Without that discussion, it is too easy to conclude (by not paying attention to it) that legacy uses do not contribute to population risk (see **Recommendation 16**).

The approach of "voluntary report of importing asbestos" seems like a low bar. There should be an attempt to collect more extensive data on the topic.

Recommendation 67: Actively collect more data on imported products suspected of containing asbestos instead of relying exclusively on voluntary reporting.

Occupational exposure:

EPA acknowledged "limited data" means they might not have captured some worker exposures, or that there was variation among manufacturing facilities. They also acknowledged the data they received from various companies might not be representative of all tasks and all facilities and that they were uncertain about the numbers of exposed workers. It is important to note that underestimation of the range of exposures implies that the high-end exposure risks are most likely underestimated. The direction and magnitude of some of the uncertainties were not described. The Committee was unclear why the number of potentially exposed workers was uncertain. This is something that certainly EPA in its full authority can require and request.

Recommendation 68: Require reporting of numbers of potentially exposed workers from industrial facilities that process asbestos.

Consumer exposure:

There were uncertainties in the durations of exposure activity (changing brakes), the sizes and typical ventilation of the areas where brake maintenance occurs, the full range of activities leading to exposures (vehicle types), the practice of using blown air to clean brakes, and the age at start of exposure and exposure duration for individuals. Only for the latter was there an attempt to quantify this uncertainty through a set of sensitivity analyses. 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. (See **Recommendation 54** for further comments on this topic.)

The sensitivity analysis for Consumer DIY/Bystander risk is useful and should be retained (page 199-201 and Appendix L).

The estimates of aftermarket automobile brakes/linings and clutch workers, ONU's, and DIY consumers are unrealistic given the small volume of asbestos-containing brakes that may be imported into the U.S. (see **Recommendation 37**).

Confounding:

The DRE acknowledges that the smoking history of exposed workers is missing from most, if not all, key studies but argues that this lack does not seriously impact the utility of the final analysis (Page 195, lines 7054-7064). For smoking not to be an important confounding factor, it has to be uncorrelated with either the exposure or the outcome. For this DRE, the Committee considered it important to further discuss the plausibility that smoking is not correlated with occupational exposures to chrysotile asbestos. 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 Committee wondered if there are any data, even on a sample, that could be used as support for this assumption. Are there other studies that suggest exposures in asbestos-related or related occupational settings are similar for smokers as for non-smokers? There is literature on the prevalence of smoking in certain workers, and this should be used at least as a possible estimate (Olsson 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 2020).

Recommendation 69: Further discuss and justify the assumption that smoking is not correlated with occupational exposures to chrysotile asbestos.

Exposure:

For calculation of cancer risk for workers and consumers, EPA uses less than lifetime inhalation unit risk (IUR_{LLT}). The derivation of IUR_{LLT} is not presented in the text, and the methodology was questioned by some Committee members.

Recommendation 70: Present clearly how the values for less than lifetime inhalation unit risk (IUR_{LLT}) are calculated in the text.

Key uncertainties in human risk estimates include levels and variation of exposure profiles (including age at start of exposure, exposure duration and intensity), magnitude of the underlying risk estimates and how to incorporate sensitivity of various subpopulations. The number of potentially impacted individuals is also unknown.

- 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.

- Like previous comments, many of the uncertainties need to be better documented and judgments made about the direction and magnitude of the bias that may result.

- 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.

While the argument that direct comparison of TEM vs. PCM is impossible seems reasonable (page 198, lines 7060-7066), the Committee wondered if there were another way to make this comparison? For instance, would comparison based on cancer incidence be possible in order to derive “equivalent” increments of exposure regarding their impact on incidence? Justification based on model fit is

potentially missing important information, though without more in-depth study, it is not clear how this could be approached.

Uncertainty in converting mass measurements to fiber counts (page 198, lines 7068-7077) could be evaluated by using a range of conversion factors and assessing impact. It would be informative to try this. 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 North Carolina and South Carolina cohorts is reassuring.

Additional comment:

There are cases in the draft risk assessment where the wording suggests that risk below $1x10^{-4}$ or $1x10^{-6}$ are the same as "no risk." As used in the DRE, the statement "risk still persisted," seems to imply that when exposures are below the target there is no risk. The Committee would like to avoid misinterpretation of the DRE findings by the public at large by recommending that statements using the phrases "no risk" or "risk still persisted" be revised to be clearer. An example would be to report that "risks are estimated to be below target risks" or "risks are estimated to be above the target risks."

Recommendation 72: Include a section that identifies data gaps; information that is needed to improve estimates of populations at risk.

Q 5.3	**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 unreasonable risk conclusions is characterized in a clear and transparent manner (Section 4.3).**

Response to Q5.3: Uncertainties and Data Limitations associated with Methodologies carried forward to the characterization of the Risk Evaluation

This section extends discussions in response to Questions 5.1 and 4.3, along with the recommendations provided in those sections.

Underestimates of Risk due to Exclusion of Asbestos Legacy Exposure:

Members noted that the statement "risk could be underestimated" because legacy exposures were not included is an understatement. Almost all the existing sources of exposure come from "legacy exposure"; the so called "bystander exposure" is limited in scope and much focused, and as such it is not generalizable. An important feature is that legacy exposures could impact some exposures more than others and thus differentially impact the risk estimates. Some effort to quantify this, or at least

characterize differential impacts of legacy exposures across categories should be considered. The Committee has recommended the Agency to include legacy exposure in the calculation of cancer risk from asbestos exposure (see **Recommendation 60**).

Bias: The Committee expressed concerns about the concept of "compensation of bias" and how it was applied in this DRE. On page 196, the DRE states: "The lack of sufficient numbers of workers to estimate risks of ovarian and laryngeal cancer is a downward bias leading to lower IUR estimates in an overall cancer health assessment; however, the selected IUR was chosen to compensate for this bias." There should be a section explaining how this "compensation" was statistically performed and where the suggestion came from. (See **Recommendation 53**)

Endpoints:

The Committee 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. Therefore, the Committee expects a large proportion of early stage lung cancers in these populations.

EPA should consider that other non-cancer related endpoints are relevant when discussing cancer risk, as many of them are a precursor of mesothelioma and/or lung cancer. Committee members did not agree that the uncertainty was low when leaving non-cancer endpoints out of the equation.

The DRE acknowledges the challenge of under-ascertainment of mesothelioma and adjusts 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% to 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.

Exposure:

It was unclear to the Committee why information on market share was not available for this DRE. The 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 U.S. and testing the products for their asbestos content. Even if asbestos-containing products were not found, 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.

The reliance on industry-generated data and their limited documentation for the chlor-alkali facilities and the gasket stamping operation is problematic. The lack of details provided by companies on the sampling methods undermines confidence in the sampling results (page 69). EPA noted, for example, that it is unclear if certain high-exposure activities in the chlor-alkali industry were associated with air monitoring results. EPA should have used its authority to obtain all sampling data from all chlor-

alkali facilities and the gasket stamping company. 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 (page 79).

The DRE uses very few studies in the peer-reviewed published literature to estimate asbestos exposure in some COUs. This is especially true of exposure associated with repair and/or replacement of brakes where one or two studies are referenced and used in the relevant portions of the DRE.

The DRE 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 (building materials). If these have been investigated, then they should also be listed in Appendix C.

Recommendation 73: Use a broader set of available exposure assessment studies to estimate exposures for the designated COUs.

Uncertainties and assumptions in context:

Overall, it is difficult to weigh the importance of the uncertainties and assumptions in the context of the values reported and thus one either trusts the values reported or not. It would be helpful to have a better sense of the uncertainty of the reported estimates. The Committee suggested providing a tabular summary of the uncertainties along with an assessment about the likely direction of the bias and suggested carrying some of the uncertainties through to provide risk estimates in sensitivity analyses by making alternate assumptions.

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.

Q 5.4	**Please comment on whether the analysis presented in Section 4 supports the conclusions for both the environment (Section 4.5.1) and human health (Section 4.5.2 and 4.5.3) 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).**

Response to Q5.4: Limitations of the Conclusions for Environment and Human Health in the Risk Characterization Section for Asbestos

Many of the topics that limit conclusions regarding the risk characterization were covered in previous sections. These topics are brought up again with cross-referencing to allow fuller development while limiting repetition.

Environmental exposures:

The Committee noted uncertainties with respect to environmental exposures that required explanation. On page 53, the DRE states that the treatment efficiency of the chlor-alkali treatment regimen for asbestos is unknown. How then does one know whether asbestos fibers survive the filtration process when "asbestos releases from chlor-alkali facility treatment systems to surface water and POTW are not known"? (page 53). In view of this, it is not clear how the DRE 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.

It was not clear to the Committee why derived COCs are not compared with exposure estimates. Rather, the EPA rationalized the available information by suggesting levels in freshwater sources were well below those where toxicity was described. However, the reliance on a frustrated phagocytosis of macrophages mechanism coupled with the fact that macrophage-like cells exist in many other aquatic organisms raised concerns about effects to longer-lived species (e.g., ambystomid salamanders, turtles, etc.). It is suggested that the DRE explicitly discuss this possibility in the uncertainty sections.

Recommendation 76: Add explicit uncertainty discussion and explanation for environmental exposures.

Human health:

With respect to human health, the Committee concluded a need for clearer consideration and presentation of potential sources of bias and uncertainty in the risk estimates as was also discussed in the text leading up to **Recommendation 53**. The risk calculations are based on mortality rather than incidence, and they do not consider risk from cancers other than lung or mesothelioma. EPA compensated for these two sources of negative bias by selecting the largest IUR from among four candidates (Table 3-12), even though there is no direct relationship between the two sources of bias and the largest IUR. Consistent with **Recommendation 47**, 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 mesothelioma possibly caused by

asbestos could be used to adjust risk estimates to account for these cancers.

As discussed in response to question 5.2, the DRE is not clear in presentation of its approach in calculation of cancer risk. The IUR derived in Section 3.2.4.9 of 0.16 per f/cc was for lifetime IUR. For calculation of cancer risk for worker and consumer exposure, IUR_{LTL} (less than lifetime inhalation unit risk) was used and a table for this is provided in Appendix K (pages 297-298). The values of IUR_{LTL} are dependent on age at first exposure and duration of exposure. The calculations for IUR_{LTL} are not shown, and more explanation should be provided in the text (see **Recommendation 70**).

In addition, time since first exposure is important in mesothelioma risk but not in lung cancer risk, according to the calculations used by EPA, though DRE states repeatedly that it is important in "estimates of cancer risk" (page 198).

It appeared to the Committee that the North Carolina and South Carolina data sets are of roughly equal quality, albeit with multiple sources of heterogeneity as noted in Elliott et al. (2012). Consistent with **Recommendation 43**, the Committee recommended fitting the two competing models, the linear model and exponential model, to a low dose subset of the data and comparing results. Elliott et al. (2012) conducted a pooled analysis of data from the North Carolina and South Carolina textile cohorts for lung cancer. Berman and Crump (2008a) and Loomis et al. (2019) conducted analyses of mesothelioma data from North Carolina and South Carolina textile cohorts, respectively, both of which were based on individual data, and these analyses could be combined to evaluate the risk of mesothelioma.

As discussed in response to question 4.3, there has been some uncertainty about whether mesothelioma cases associated with chrysotile asbestos exposure are due to chrysotile per se, or whether they are at least partially caused by contamination from amphiboles [see Berman and Crump (2008b) for references]. Thus, the potency of chrysotile for causing mesothelioma could depend largely upon the amphibole contamination and it cannot be assumed that all "commercial chrysotile" is equally contaminated by amphiboles. Both the North Carolina and South Carolina textile mills used asbestos from Quebec, which is known to be contaminated by tremolite asbestos. Also, both the South Carolina mill and some of the North Carolina mills processed some amounts of amphiboles. These uncertainties of exposures need to be recognized and discussed in the risk evaluation. There might be useful data if there are air monitoring studies in some exposure environments that have been analyzed by TEM.

As mentioned in the response to Question 4.3, the potency of fibers may depend on their lengths. It has been suggested that longer fibers are possibly more potent. This conclusion is based on an animal study (e.g., Berman et al., 1995) and studies in humans (Case et al., 2000; Sebastien et al., 1989; Berman and Crump, 2008b; Stayner et al., 2008; Loomis et al. 2010). More recent analysis of data from the South Carolina and North Carolina textile cohorts do not support a clear hierarchy in risk according to fiber length (Hamra et al., 2014; Hamra et al., 2017). The same fiber concentrations measured by PCM may pose different cancer risks because PCM counts all fibers longer than 5 microns as equally potent, regardless of their length, and does not count fibers shorter than 5 microns. Asbestos textile manufacture requires asbestos that has been milled to contain a greater percentage of longer fibers compared to asbestos used in products for which risk is assessed in the risk evaluation, which may produce a positive bias in the risk estimates in the risk evaluation. These issues could be

better understood if studies in addition to the South Carolina and North Carolina studies used TEM analysis to capture the full spectrum of asbestos exposure. EPA should encourage the development of monitoring data analyzed by TEM in the environments for which risk estimates are required, including the analysis by TEM of any achieved samples from existing studies.

As discussed in response to Question 4.2, the high friction environment in vehicle braking will cause the asbestos fibers to degrade both chemically and physically, which will shorten the length of the fibers released during brake replacement compared to their original length and likely compared to the length of those encountered in the textile mills of North Carolina and South Carolina. Concomitantly, the braking action will likely increase the proportion of fiber shorter than 5 microns, which are not counted by PCM. It is noted, however, that asbestos fibers may enter the brake repair environment from the manipulation of new brakes where the braking-related degradation described above is not a factor.

Overall, EPA's environmental and human health risk estimates have important limitations that should be addressed in a revised DRE (see **Recommendation 54**).

Comparing the discussion in Section 4.3.3 where the DRE summarizes key assumptions and uncertainties to similar discussions in DREs for previous TSCA chemicals showed that what is missing in this Chrysotile Asbestos DRE are statements expressing the confidence in the IUR values estimates used to assess risk. In previous assessments, an overall assessment of confidence using ratings of High, Medium, or Low were assigned to estimates for each COU. It was noted that confidence statements were provided to studies that provided the data for these estimates (e.g., Table 2-23 to Table 2-32). These confidence assessments were not carried forward to the hazard summaries in the DRE as has been the practice in past evaluations. In general, the Committee seemed to express low-to-medium confidence in most hazard conclusions and risk conclusions for COUs in this DRE.

Recommendation 77: Provide confidence statements for IUR values and risk estimates for each COU.

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.

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

Response to Q5.5: Other Aspects of the Environmental or Human Health Risk Characterization

The Committee recommended the risk evaluation consider the following additional studies with respect to repair and/or replacement of brakes and gaskets and to reconsider some studies included in the assessment:

1. Cowan (2015) as cited in the DRE (pages 91-92) noted results of 19 samples taken by OSHA in

the course of inspections of auto repair facilities between 2000 and 2011. One Committee member commented that this number of inspections is barely adequate to support any conclusions about asbestos exposure. In addition, related information on tasks performed during sampling is not provided making interpretation of the results difficult if not impossible. Table 2-14 showing data from Cowan (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 of new brakes. It mentioned a Weir (2001) study but rejected use of its data for lack of details.

4. EPA failed to cite other highly relevant studies (page 92). The risk evaluation did not cite a NIOSH 1982 study (NIOSH, 1982) nor the Rohl (1976) study. Unlike the Blake et al. (2003) study that EPA cited, these studies were not simulated automobile repair operations but 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 risk evaluation stated that PCM may overstate asbestos fiber concentrations (citing Blake, 2003 and Weir, 2001) but ignored Rohl (1976) and failed to cite NIOSH (1982) and Sheehy (1989), which both show that asbestos fibers counted by TEM are greater than those counted by PCM.

The Draft Risk Evaluation cited just two published studies of gasket removal and used Chemours sampling data (which lack critical documentation). The Committee suggested that the risk evaluation should consider the following additional studies with respect to gasket use (pages 78-79), including:

1. Cheng RT, McDermott HJ. (1991). Exposure to asbestos from asbestos gaskets. Appl Occup Environ Hyg; 6(7): 588-591.

2. Longo WE, Egeland WB, Hatfield RL and Newton LR. (2002). Fiber release during the removal of asbestos-containing gaskets: a work practice simulation. Appl Occup Environ Hyg; 17(1): 55-62.

3. McKinnery WN and Moore RW. (1992). Evaluation of airborne asbestos fiber levels during removal and installation of valve gaskets and packing. Am Ind Hyg Assoc Jl. 53(8):531-532.

4. Millette JR, Mount MD, and Steves MH. (1995). Releasibility of asbestos fibers from asbestos-containing gaskets. EIA Technical Journal, Fall 1995.

Recommendation 79: Discuss and incorporate findings from the additional studies on gasket use identified by the Committee.

The Committee also noted additional uncertainties related to water discharge, specifically with respect to the lack of measured data 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 (chloro-alkali) discharge waste to POTWs, and then concluding it did not occur in the risk evaluation especially when this conclusion was based on a lack of monitoring data from the POTWs due to no requirements for asbestos monitoring. Friable chrysotile asbestos is filtered during the COU for the chloro-alkali industry. The mesh-size of the filter is not provided in the DRE and 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.

The Committee expressed concerned that 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. In contrast, recent risk analyses evaluating the ecological effects of micro-fibers (< 5µM) and nanofibers (<1 µm) has indicated significant environmental effects in aquatic organisms (Li et al., 2016). If filtering during COUs is meant to remove only the fibers that are greater than 5 µm (which is the detection limit for phase contrast microscopy), all fibers having significant environmental effects in aquatic organisms would be discharged into wastewater. For future ecological assessments, the Agency should consider fate models derived from micro-fiber analyses (Carr, 2016).

Recommendation 81: Discuss the utility of fate models derived from micro-fiber analyses for future ecological assessments of asbestos.

Question 6: Additional Questions:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016) (amended TSCA) states that "potentially exposed or susceptible subpopulations" (PESS) be considered in the risk evaluation process. PESS is defined in the Lautenberg Act to include populations with greater exposure or greater response, including due to lifestyle, dietary, and biological susceptibility factors, than the general population.

Q 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?**

Response to Q6.1: Additional Information about PESS and Characterization of the Uncertainty around PESS

Identification and Characterization of all PESS:

The Committee 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. While people with advanced lung disease may not engage in activities at work or otherwise that involve exposure to asbestos, those with earlier stages of these disease remain part of the active population and may be exposed to asbestos through the six COUs addressed in the Draft Risk Evaluation, further increasing their risk of lung cancer.

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.

The DRE 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 DRE correctly identifies cigarette smokers as a susceptible subpopulation for the effects of asbestos exposure. A synergistic relationship between smoking and asbestos in causing lung cancer has been reported in many studies (e.g., Hammond et al., 1979; Liddell and Armstrong, 2002; Berry and Liddell, 2004). However, the only reference in the DRE to this important susceptible subgroup was the single sentence: "Cigarette smoking in *(is)* an important risk factor for lung cancer in the general population" (page 156, lines 5730-5731).

TSCA requires that a risk evaluation determine whether the substance under review presents an unreasonable risk of injury to health to a potentially exposed or susceptible subpopulation. The DRE partially satisfies this requirement for other segments of the population by quantifying their risk. The

DRE should do the same for susceptible subgroups to the extent possible. Quantifying the extra cancer risk in smokers due to exposure to asbestos can be accomplished, as previously suggested, by applying the already-calculated K_L and K_M in a life table analysis that uses background rates of lung cancer and death from all causes that apply to smokers. Risks to non-smokers can similarly be quantified. It is recommended that the DRE include quantitative estimates of the carcinogenic risk from exposure to asbestos separately among smokers and non-smokers.

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.

The longer latency period for children as DIY bystanders is discussed in the DRE but this is not incorporated into the exposure or risk modeling. As also mentioned previously, take home routes of exposure are not discussed in the DRE, and this is a primary route of exposures to which family members of workers are exposed to asbestos; in particular, children are highly susceptible.

Diane Barton's letter from the National Tribal Toxics Council (NTTC)[21] included points the Committee recommends be included in the discussion of PESS in the DRE. The letter states: "Tribes are a minority and low-income population whose lifeways place them at higher exposure potential …" and it includes a figure that describes the "unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population." The health disparities in American Indians/Alaska Natives (AIAN) are relevant to currently manufactured chrysotile asbestos in this DRE. The NTTC noted the following for AIAN:

- 17% higher mortality from lung cancer for AIAN compared to non-Hispanic Whites. (U.S. DHHS, NCI 2020)
- 53% higher lung cancer incidence for AIAN compared to non-Hispanic Whites. (U.S. DHHS, NCI 2020)
- Higher rate of stomach cancer and higher mortality rate for AIAN compared to non-Hispanic Whites. (NCI 2020) [see discussion in Response to Q4.1: Choice of focusing on only lung cancer and mesothelioma and the IARC Monograph 100c (IARC, 2012)].
- High rate of tobacco use among AIAN. (U.S. DHHS, 1998)

Recommendation 84: American Indian/Alaska Native (AIAN) populations should be included in the PESS discussion and analysis.

The relation between germline BAP1 mutation occurrence and asbestos in raising the risk of mesothelioma is unsettled. In addition, testing for BAP1 mutation is likely to occur only in families with an increased occurrence of a specific set of cancers, which is uncommon, so that few people would know their personal BAP1 status.

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.

21 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0501-0088.

Additional Information on the characterization of PESS for EPA to Consider:

The completeness of the characterization of PESS concerns the possibility that asbestos-containing construction materials are still in commerce and as a result potentially identify certain construction workers as a PESS. Table 2-3 in U.S.EPA (2017) provides samples of products that contains asbestos and indicates that some of these building materials may contain asbestos. Table 2-3 includes a link to the website for the Fields Coatings and Mastics Corp[22] which in turn points to the MSDS for the product C200 Roofbond, which contains 4 to 12% asbestos by weight. Another asbestos-containing product is Dissco 540 mastic from Denver Industrial Supplies and Coatings (DISSCO). Information on their website[23] reports that this product is 5 to 20% asbestos. The question then is whether EPA was able to determine that this material is still in commerce, as it is listed on the company website (see **APPENDIX A**).

Recommendation 86: Discuss the possibility that asbestos-containing construction materials still in commerce identify certain construction workers as a PESS.

Uncertainty around PESS:

The Committee 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 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.

Q 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).**

Response to Q6.2: The Reasoning, Approach, Assumptions, and Uncertainties for Characterizing Risk to Workers using PPE

Given the relatively high level of uncertainty about chrysotile asbestos exposure levels associated with the COUs, EPA has appropriately selected the high exposure estimates on which to identify risk. The Committee concluded that this is appropriate.

A worker, whose respirator does not fit well or who works for an establishment without a good PPE respiratory protection program in effect, may receive far less protection from the respirator than indicated by the assigned APF. The protection afforded to workers whose respirators achieve a good tight fit and used in accordance with OSHA guidelines will be even greater than indicated by the APF. Table 4-3 clearly explained the PPE assumptions. The DRE includes the usual statements

22 http://fieldscorp.com/
23 https://www.dissco.net/wp-content/uploads/04a-msds-540.pdf

about how the assumption of 100% correct PPE use is not supported by data. In section 2.3.1.2, the DRE cites Riala et al. (1998) on performance of respirators and HEPA units in 21 different exposure abatement scenarios, with three abatement scenarios relevant to the current DRE. In these three scenarios, actual APFs are reported as 50, 5, and 4. The DRE concludes that "even with every worker wearing *(a)* respirator, some of these workers would not be protected" (page 60, lines 2098-2099). This statement reflects the position that this Committee has taken in its prior reviews of chemical DREs where it recommends against the assumed use of PPE and the application of protection factors in determining whether the COU risk is unreasonable or not.

The question remains whether the assumed use of occupational PPE for relevant COUs in this DRE is warranted, especially given the OSHA requirements related to abatement of asbestos exposures. Riala et al. (1998) conclude that high quality management of such exposures must include proper training of workers in respirator use, and further periodic training to ensure the upkeep of good personal protection practices. Many on the Committee concluded that it is not reasonable to assume that proper respirator use has occurred even in the case of workers exposed to asbestos. OSHA data indicate that violations of the OSHA respiratory protection standard are among the most common OSHA violations.

Section 2.3.1.2 explained the hierarchy of controls. This has been recommended in previous reviews by this Committee. This section also clearly explains OSHA regulations specific to asbestos and acknowledges that nominal APFs may not be achieved in practice.

When presenting risks to workers based on their using PPE, the assumption in the DRE is that the level of protection of the PPE is exactly the APF (assigned protection factor) of the respirator. However, OSHA sets APF for a respirator based on whether 95% of the samples in the studies of the respirator where a good PPE respiratory protection program is in place have protection at least equal to the assigned APF. This approach only considers overall percent of samples and does not address personal differences in the protection afforded (e.g., Crump 2007). Thus, a worker, whose respirator does not fit well due to facial geometry or facial hair, or who works for an establishment without a good PPE respiratory protection program in effect, may receive far less protection from the respirator than indicated by the assigned APF. Consequently, it is possible that 5% or more of the workers using respirators may receive little protection from the respirator. On the other hand, the protection afforded to workers whose respirator achieves a good tight fit and is used in accordance with OSHA guidelines will be even greater than indicated by the APF.

On the use of the APFs, NIOSH stated in the NIOSH Guide to Industrial Respiratory Protection DHHS (NIOSH, 1987) Publication No. 87-116: "Many of the assigned protection factors (APF's) that appear in this decision logic are based on laboratory studies and should be regarded as approximate." (page 199) and "For the present, APF's should not be considered reliable predictors of performance levels that will be achieved during actual use, since APF's are not based on a sufficient amount of workplace testing." (page 200). The DRE acknowledges this, writing "APFs are intended to guide the selection of an appropriate class of respirators to protect workers after a substance is determined to be hazardous, after an occupational exposure limit is established, and only when the occupational exposure limit is exceeded after feasible engineering, work practice, and administrative controls have been put in place. For asbestos, the employee permissible exposure limit (PEL) is 0.1 fibers per cubic centimeter (f/cc) as an 8-hour, time-weighted average (TWA) and/or the excursion limit of 1.0 f/cc averaged over a sampling period of 30 minutes" (page 59, lines 2062-2067). The DRE further cites

the Riala et al. (1998) study, which reports that some workplace protection factors (WPFs) for respirators used for asbestos are substantially below the APF values.

In several places in the text, the DRE states that while some workers have protection above nominal APF, other workers have protection below nominal APF, or similar language to this. Despite acknowledging these limitations, the APF values are used in the risk calculations, reducing the risk estimates by factors of 5, 10, or 25. In other cases, such as for sheet gasket stamping as reported in Table 4-3, workers are reported as wearing N95 respirators (which as the DRE notes are not approved for protection against asbestos); nevertheless, a hypothetical APF of 10 to 25 is assigned (inexplicably) and used in the risk calculation. The concept of a hypothetical APF should be revisited. The National Personal Protective Technology Laboratory may be a resource on the use of realistic protection factors.

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. The DRE should discuss the issues surrounding actual levels of protection provided by PPE and take them into account to the extent possible in calculating risks to workers wearing respirators with specific APFs.

Recommendation 87: Include a more detailed 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.

Recommendation 88: Consider visiting facilities where asbestos is processed to increase EPA understanding of the worker conditions, including PPE use.

Q 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).**

Response to Q6.3: The Reasoning, Approach, Assumptions, and Uncertainties for Characterizing Risk to ONUs not using PPE

In general, the assumptions, data gaps, limitations, and rationale for the risk characterization for ONUs were clear and easy to follow. The Committee 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 exposures could be over- or underestimated.
- The length of time between exposure and mortality introduces uncertainty in exposures.
- The number of work years and age starting work were reasonable but introduced uncertainty.

The DRE does not mention in this section:

- Uncertainties in deriving the chrysotile IUR introduce uncertainty into the risk estimates.
- Exposure to different fibers than the textile cohorts used to derive the IUR may result in different risks.
- Not including other cancers and non-cancer endpoints underestimates risk.

The estimates on the number of ONUs for most COUs are low, with the exception of the chlor-alkali plant workers. There are few chlor-alkali plants and tasks that are clearly described and numbers of workers by tasks tabulated. 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.

NIOSH and the Bureau of Labor Statistics conducted a survey of respirator use across industry groups and reported results in a publication entitled Respirator Usage in Private Sector Firms 2001[24]. The Committee recommends this publication as a useful source of information. This report could also provide some insights into the question of respirator use by ONUs.

Recommendation 89: Incorporate results from the NIOSH/Bureau of Labor Statistics survey of respirator use across industry groups into the discussion of respirator use by ONUs.

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24 https://www.cdc.gov/niosh/docs/respsurv/

Question 7: Overall Content and Organization:

EPA's Final Rule, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726) stipulates the process by which EPA is to complete risk evaluations under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

As part of this draft risk evaluation for asbestos, EPA evaluated potential environmental, occupational and consumer exposures. The evaluation considered reasonably available information, including manufacture, use, and release information, and physical-chemical characteristics. It is important that the information presented in the risk evaluation and accompanying documents is clear and concise and describes the process in a scientifically credible manner.

To increase the quality and credibility of scientific information disseminated by EPA, EPA uses the peer review process specifically as a tool for determining fitness of scientific information for the intended purpose. The questions below are intended to guide the peer reviewers toward determining if EPA collected, used and disseminated information that is 'fit for purpose' based on utility (the data's utility for its intended users and for its intended purpose), integrity (the data's security), and objectivity (whether the disseminated information is accurate, reliable, and unbiased as a matter of presentation and substance). The peer reviewers' critical focus should pertain to recommendations of the technical information's usefulness for intended users and the public.

Q 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.**

Response to Q7.1: Overall Content, Organization, and Presentation of the Asbestos DRE

Generally, the Committee commends the EPA for the overall level of organization and clarity. However, there are some areas that several on the Committee noted leave readers confused. The title suggests the DRE covers "asbestos" risks when it specifically addresses risks related to the commercial use of "chrysotile asbestos." The terms "chrysotile" and "asbestos" are used interchangeably throughout the DRE, which adds additional confusion as to when does the phrase "asbestos" actually refer to "chrysotile asbestos" and when does it refer to "asbestos" any form unspecified. The DRE needs to be specific as to when data are used to address chrysotile exposures that may not be based solely on chrysotile asbestos exposures and evaluate those uncertainties. (see **Recommendation 15: Either retitle the evaluation to reflect its limited scope or postpone completion pending future efforts to assess asbestos more broadly.**)

As discussed in response to Question 2.1, the Committee found that the DRE 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 DRE include.

Recommendation 90: Provide more discussion in the introduction on the regulatory charge and scope to help establish the focus of the evaluation.

Several Committee members commented that the DRE does not adequately justify why a separate

IUR for chrysotile asbestos is needed and why the IUR derived in this evaluation is superior to the one proposed in the comprehensive 1988 EPA IRIS Assessment on Asbestos (U.S.EPA 1988). The Committee noted that 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 IUR proposed.

It would have been helpful to show direct comparison of the North Carolina and South Carolina textile worker study results with the other cohort risk estimates, which was done in a limited way in Table 3-8. The Committee suggests adding a graph and discussion of the potency factors, 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.

One Committee member thought the discussion of Mode of Action (MOA) in Section 3 needs revision. The concepts of the importance of dimensionality ("fiber size"), physical-chemical properties, and bio-persistence should be mentioned and put into a framework of why these factors may be important in consideration of present and future COUs. Additionally, some discussion of the MOA (i.e., macrophage phagocytic "frustration") should be presented in more detail, specifically describing how those processes may affect and influence the available toxicity data for long-lived aquatic receptors (e.g., salamanders, turtles).

Recommendation 94: Revise the MOA discussion to incorporate effects of dimensionality, physical-chemical properties and bio-persistence, which may affect and influence adverse outcome pathways.

According to the EPA risk assessment paradigm, the Problem Formulation document also identifies unresolved data gaps that need to be clearly described to reduce uncertainty. The Agency seems to have ignored these 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 chloro-alkali process. For the environmental sections, significant detail is provided showing evaluations of a number of databases, site visits and discussions with COUs showing a significant degree of uncertainty for environmental exposures due to a general lack of monitoring data present for surface water. Monitoring data are not accompanied with descriptions of the methods used to characterize how the values were generated/collected.

Recommendation 95: Harmonize differences between issues raised in the Problem Formulation document and those evaluated in the DRE.

Consider the confidence in the risk estimate when it is based on limited data. One Committee 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 methodology has evolved over time and how that might impact study quality assessment.

In the Risk Characterization for environmental exposures, as the Committee has seen in previous chemical DREs, there is limited discussion of uncertainties and typically "worst-case" scenarios that are not considered. To be conservative, the DRE 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.

The Committee has recommended in previous reviews of TSCA DREs that EPA should establish *a priori* 1) what constitutes a minimum data set adequate for quantifying exposures, and 2) the degree of uncertainty that would result in an inability to adequately estimate risk. Together this establishes the minimal information that is necessary and sufficient to establish a reliable decision on risk. The Problem Formulation document should identify those data needed to reach that minimal information threshold. The Agency should use its TSCA powers to obtain missing critical information.

The Committee also recommended that EPA identify conditions where, despite having no data, the Agency could be confident in a determination of unreasonable risk.

Recommendation 97: Define the minimal data/information needed to produce a reliable and confident estimate of risk.

Be explicit what data would improve the risk estimate or be required to produce one that could be used to support a decision.

In the DRE, the quality and relevance of epidemiology studies are described clearly, increasing confidence is their use in establishing hazard and risk. However, 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.

The title for Section 3.1 is "Environmental Hazards." The Committee 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”.

Q 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.**

Response to Q7.2: Objectivity of the Information used and the Sensitivity of the Agency’s Conclusions

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. 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.

Several Committee 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 Committee suggested that a more appropriate determination would be to conclude that “environmental risk could not be 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”.

EPA’s reliance on published sources, industry reports, and multiple publications helps to assure objectivity. However, one Committee member suggested that an independent re-analysis of some of the key findings that went into the risk estimates would provide an additional reassurance about the objectivity of the information used.

Some Committee members expressed concerns that the dose response model used did not fit the range of dose response data in the grouped linear model (Appendix J of the DRE). AIC should not be the only criterion to select the best model. Choosing the best model to describe dose responses should focus on the range of exposures available in the dataset, especially in the low end of the exposure range (see the discussion preceding **Recommendation 51** and **Recommendation 52**). Some on the

Committee suggested that the dose response modeling section discuss how model assumptions impact quantitatively the estimate of the point of departure. How different are point of departure estimates if different model forms are fit to the same data?

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.

Exposure lag of 10 years is not discussed in the DRE but is used in the dose response modeling for both lung cancer and mesothelioma. Several Committee members suggested that how this is accomplished in the model fitting needs clarifying and the impact of this assumption needs to be further discussed.

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.

Readability would be improved if tables could be modified to each use; specifically, color codes could be used to highlight particularly relevant data.

EDITORIAL COMMENTS

- Page 135: The Berman and Crump (2008a) modelling of the individual level mesothelioma data from South Carolina (Tables 3-3, 3-9, 3-10, 3-11 and 3-12) was conducted independently of Hein et al. (2007) although based on the same data as Hein et al. (2007). Thus, this analysis was not "based on Hein et al. (2007)," as stated in the DRE. Lines 4993-4995 incorrectly states that the Berman and Crump modelling of the South Carolina mesothelioma data was conducted using the grouped data. The Berman and Crump analysis of the mesothelioma data was based on the individual level data (Berman and Crump, 2008a, page 32).

- Page 135: Table 3-2 mistakenly lists Berman and Crump (2008a) as analyzing the North Carolina data.

- Page 148: The results of Berman and Crump (2008a) modelling of the individual level mesothelioma data from Quebec should be reported in Table 3-6.

- Page 148, line 5491: incorrectly states that Berman and Crump (2008a) estimated the lung cancer potency for Quebec from analyses of the original data. Berman and Crump estimated mesothelioma potency using individual level data from Quebec but estimated lung cancer potency in the Quebec data using summarized data in Liddell et al. (1997). However, Table 3-6 contradicts the statement on line 5491 by correctly stating that the Berman and Crump (2008a) analysis of lung cancer in Quebec was based on published grouped data. Table 3-6 should contain the results of the Berman and Crump (2008a) modelling of the individual level mesothelioma data for Quebec.

- Page 153: When the DRE first discusses the Elliott et al. (2012) study, it should clarify that this paper reports on a pooled analysis of both the South Carolina and North Carolina data sets, and also includes separate analyses of both data sets individually. For the DRE reader, without knowing this, it can be confusing for Elliott et al. (2012) to be associated with both South Carolina and North Carolina summaries. Consequently, the discussion of model fit as measured by AIC (Section 3.2.4.7.1) is confusing.

- Page 149: Table 3-8 compares unit risks in textile and mining environments. Details of the calculation of these unit risks (e.g., what unit risk goes with what study) are not provided. A much clearer and understandable comparison would be to compare the ranges of K_Ls and K_Ms rather than unit risks. The same is true of several of the preceding tables. If the K_Ls and K_Ms are provided it would be much easier for readers to check the ranges.

- Page 155, lines 5686-5687 state: "…. in the absolute risk model even one incident case close to the follow-up date and missed in follow-up will increase the risk estimate." This phrase is superfluous.

- Page 143, lines 5318-5319 states: "Only one worker in the [North Carolina] cohort, who did not develop lung cancer or mesothelioma, had a history of employment in the operation where

amosite had been used." That comment seems strange. Loomis et al. (2009) reports on more than one worker who worked in the amosite operation. Did all of them contract lung cancer? In scans of Loomis et al. (2009), Elliott et al. (2012) and Loomis et al. (2019), no support for this comment was found.

- Page 141, lines 5201-5202 state: "For both U.S. textile cohorts, the exposure assessment methods and results have been published in full detail." References are needed for this statement.

- Page 69: The numbers in paragraph around line 2438 do not seem to agree with those in Table 2-8.

- Page 138: Line 5106 states that the IUR represents the risk when exposed for a lifetime. The footnote on page 30 says exposure for 70 years. This assumption should be consistent throughout the document.

- Page 131: The DRE should review the evidence for ingestion of asbestos being a cause of cancer (or lack thereof) in animal studies, to support its decision to focus on inhalation risk.

- Page 140: Since EPA uses the word "benchmark" in a different and quite specific way in low dose risk assessment (e.g., in the Benchmark Response (BMR)),; to avoid confusion, it is suggested that "goal" or "target" be used instead of "benchmark" when talking about the cancer risk target (e.g., $1x10^{-4}$).

- Pages 20, 183, 208: There are places in the DRE where the wording suggests that risks below $1x10^{-4}$ or $1x10^{-6}$ are the same as no risk. For example, in rows 843, 6489, and 7418 the DRE states that risk "still persisted," implying that exposures below the target would pose be no risk. To avoid misinterpretation by the public-at-large, these statements should be revised to say something like "risk is still above the target."

- Page 137, line 5021 states: "For lung cancer, the risk for grouped data from epidemiologic studies from exposure to asbestos is …." The linear lung cancer model being referred to is applied to ungrouped data as well as grouped. All analyses of lung cancer data reported in Table 3-9 with model designated as "linear" are based upon individual level data (ungrouped) and all use this model.

- Pages 136 and 138: Clarify adjustment for differences in air volumes between cohorts (line 5009) – as this is addressed elsewhere (Section 3.3.4.4.3), this just needs cross-referencing.

- Page 138: Wording implies the grouped data model does not treat exposure as continuous, but that is probably not what is meant (line 5073).

- Page 138: On line 5077 it is not clear what is meant by the word “parameter.” The midpoint of the exposure range is the exposure used for the entire group in the modeling. What is the parameterization of the model?

- Page 150: Sort the rows of Table 3-9 by endpoint then by cohort so it is easier to focus on the range of estimates by endpoint. Also remove the scientific notation so it is easier to compare values quickly. Consider using a graphic of this information to make it easier for the reader to digest.

- Page 150: The term “missed” on line 5572 is a bit misleading. Presumably missed mesothelioma deaths are still characterized on death certificates with a related diagnosis and this information could be leveraged to better understand the sensitivity of the estimates to underreporting.

- Page 144: The document should be reformatted so that entire tables appear on a single page, or that tables break in a sensible location in the table to facilitate table review (see for example Table 3-4).

- The list of abbreviations has items missing. The abbreviations RE, APF, and PBZ have not been included.

- Page 135: Given the hyperlinks in Table 3-2, the column with the HERO IDs is not necessary. It would be more useful to devote space in this table to some basic facts about the cohorts and individual studies, such as the numbers of workers included and other key details.

- Page 130: The DRE should briefly summarize, following line 4763, the unique data quality criteria used in this review even though they are set out in detail in companion documents.

- Page 142: The text on line 5259 uses the phrases “no significant trends … and no significant differences …” These represent a poor use of statistical significance because it obscures understanding. It is hard to understand whether the point is that there is no meaningful difference when the focus (appears to be) entirely on statistical criteria.

- Page 196: Starting on line 6938 there is discussion about the volume of a former automobile repair facility and comparison to a residential garage. Clarify with details and/or a cross-reference.

- Page 200: Reformat cells in Table 4-50 to make it easier to compare across cells.

- Page 201: A clearer summary of the analysis described in Appendix L should be provided by the test in lines 7175-7179 and Table 4-52. As it stands, readers will have to read Appendix L to understand the summary.

- Page 205: In Table 4-54, the “footnotes” (c) and (d) are not provided.

- Page 208: The reference on line 7410 needs corrections since there is no Table 4-57. The correct reference is Table 4-55, which starts later on the page.

- Page 208: It would be clearer if all the cancer risk estimates in Table 4-55 were in the same units, preferably not in scientific notation, to make it is easier to compare estimated risks. The term 'N/A' is defined as 'Not Assessed.' The indication code of '—' needs definition.

- Page 217: On line 7652 indicate the tables to which this statement applies.

- Page 294: Appendix J should have some descriptive text added. Without any text it is difficult to make sense of the results. It is evident from this appendix that the approach to assigning the exposure for the highest category is highly influential on the results. This should be revisited and a more sensible "midpoint" for the highest category selected. One panelist mentioned there is literature to guide this choice.

- Page 206: Please check all Appendix references. The document incorrectly refers to Appendix J when it appears it should be referencing Appendix K, and Appendix G or I when it appears it should be referring to Appendix J. See for example page 206, line 7357.

- Page 22 and Page 197: It is not clear what the phrase "lack of sufficient numbers of workers" means (line 930). Does this refer to the estimate of current and future workers engaged in the six COUs as described in the Risk Evaluation or is this the number of workers in the North Carolina and South Carolina cohort studies?

- Page 150, lines 5579-5581 state: "For example, primary diagnosis of pleural mesothelioma is by chest exam and pleural effusion, but the latter is absent in 10-30% of pleural mesothelioma cases (e.g., Ismail-Khan et al., 2006)." This is incorrect. The diagnosis of malignant mesothelioma is nearly always based on pathology findings.

- Page 205: Add the word "Potentially" after "Exposure" in the title of Table 4-54. A footnote to this table should explain that all estimates except for the number of chlor-alkali workers have a high level of uncertainty.

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LIST OF RECOMMENDATIONS

APPENDIX A

The completeness of the characterization of PESS concerns the possibility that asbestos-containing construction materials are still in commerce. Table 2-3 in *Use and Market Profile for Asbestos* (U.S.EPA. 2017) provides samples of products that contains asbestos and indicates that some of these building materials may contain asbestos. Table 2-3 in this document includes this link to the website for the Fields Coatings http://fieldscorp.com/ and Mastics Corp.

Maximum Performance FIELDS ROOFING AND WATERPROOFING PRODUCTS

About Fields
History
Pro Affiliations

Services
RMS Services
Certification

Product Guide
Coatings/Mastics
Hot Asphalts
Organic Felts
BUR Sheets

Advertising
Ad Images
CO/OP Info

BUR Systems
Design Criteria
Installation Guide
Quality Assurance
UL/FM Classifications

Search

Fields Company LLC

Product Guide

100/300 | 400/600 | 700/SW | Hot Asphalts | Felts | BUR Sheets

The following is a listing of our cutback coatings including prior number, ASTM, and packaging information. The "Product Info" column contains product descriptions and links to individual Product Information Sheets. The "MSDS" column contains links to individual MSDS Sheets.

Printing? use this version

Coatings & Mastics 100 to 300 Series

100 Series: Asphalt Coatings & Adhesives

Product Info	MSDS	ASTM	Sizes
M100 RubrCoat SEBS Coating & Adhesive	MSDS	D4479 Type 1	1, 5, 55, Bulk
F100 PowrCoat Asphalt Coating & Adhesive	MSDS	D4479 Type 2	1, 5, 55, Bulk
A100 (1818) AtcoCoat Asphalt Coating & Adhesive	MSDS	D4479 Type 2	1, 5, Bulk
C100 RoofCoat Asphalt Coating & Adhesive	MSDS	D2823 Type 2	5, 55, Bulk
F110 PowrLap Lap Adhesive & Coating	MSDS	D3019 Type 3	1, 5, qt
A110 (1825) AtcoLap Lap Adhesive & Coating	MSDS	D3019 Type 3	1, 5, qt
M150 RubrSeal All Weather SEBS Asphalt	MSDS	D4479 Type 1	1, 5, 55, Bulk
F150 PowrSeal All Weather Coating & Adhesive	MSDS	D4479 Type 2	1, 5, 55, Bulk

200 Series: Plastic Asphalt Cements

Product Info	MSDS	ASTM	Sizes
M200 RubrBond SEBS Asphalt Cement	MSDS	D4586 Type 1	1, 3, 5
F200 PowrBond Plastic Asphalt Cement	MSDS	D4586 Type 2	1, 3, 5
A200 AtcoBond Plastic Asphalt Cement	MSDS	D4586 Type 2	1, 3, 5
C200 RoofBond Plastic Asphalt Cement	MSDS	D2822 Type 2 Class1	3, 5
C240 TileBond Plastic Tile Cement	MSDS	D2822 Type 2 Class 2	3, 5
C250 RoofFlash Plastic Flashing Cement	MSDS	D2822 Type 2 Class 1	5

300 Series: All Weather Asphalt Mastics

Product Info	MSDS	ASTM	Sizes
M300 RubrMastic All Weather SEBS Mastic	MSDS	D4586 Type 1	1, 3, 5, 11oz, 29oz
F300 PowrMastic All Weather Asphalt Mastic	MSDS	D4586 Type 1	1, 3, 5, 11oz, qt
A300 (1823) AtcoMastic All Weather Asphalt Mastic	MSDS	D4479 Type 2	1,3,5,11oz,29oz,qt
C300 RoofMastic All Weather Asphalt Mastic	MSDS	D2822 Type 1 Class 2	3, 5

The link to the MSDS for C200 RoofBond yields:

< Fields Coatings & Mastics 100 to 300 Series

Material Safety Data Sheet

C200 RoofBond

Plastic Asphalt Cement

PHYSICAL PROPERTIES:
Appearance and Odor: Black viscous liquid with solvent odor.
Boiling Point: 310 deg. F
Vapor Pressure: Less than 10mm @ 25 deg. C
Vapor Density (air = 1): 4.8
Evaporation Rate (BuOAc = 1): Less than 1
Specific Gravity (H20 = 1): .92 to 1.04
Solubility: Insoluble in water, soluble in petroleum solvents.

FIRE AND EXPLOSION HAZARD DATA:
Flash Point: 107 deg.F (42 deg.C) TCC
Flammable Limits: LEL: 0.9; UEL: 7.0
Extinguishable Media: CO2, foam, dry chemical
Unusual Fire and Explosion Hazards: Closed containers are an explosion hazard when exposed to extreme heat.
Special Fire Fighting Procedures: Use water to cool closed containers. Use self contained breathing apparatus in confined areas.

REACTIVITY DATA:
Stability: Stable
Hazardous Polymerization: Will not occur
Hazards Decomposition Products: Carbon Monoxide and Carbon Dioxide.
Conditions to Avoid: Heat and sources of ignition.
Compatibility (Materials to Avoid): None known

CONTROL MEASURES:
Respiratory Protection: Wear NIOSH approved organic vapor respirator.
Ventilation: Mechanical, local, or general exhaust is recommended.
Protective Gloves: Wear chemical resistant gloves if contact is likely.
Eye Protection: Wear safety goggles if contact is likely.
Other Protective Equipment: Coveralls may be used.

HEALTH HAZARD DATA:
Routes of Entry: Inhalation, ingestion, skin, and eyes.
Inhalation: Nasal, respiratory irritation, fatigue, dizziness, and headache.
Inhalation: Nasal, respiratory irritation, fatigue, dizziness, and headache.
Ingestion: Gastrointestinal irritation, nausea, vomiting, and diarrhea. Aspiration into lungs can cause chemical pneumonia.
Skin Contact: Possible irritation.
Eye Contact: Redness, irritation, and blurred vision.

EMERGENCY FIRST AID PROCEDURES:
Eye Contact: Flush with clean water for at least 15 minutes. If irritation persists, get medical attention.
Inhalation: If overcome by vapor, remove from exposure and administer oxygen if breathing is irregular. Get medical attention immediately.
Ingestion: DO NOT INDUCE VOMITING. Material can be aspirated into lungs and cause chemical pneumonia. Get medical attention.
Skin Contact: Remove saturated clothing. Wash skin with soap and water.
Chronic Health Effects: Not listed as a carcinogen by the NTP, IARC, or OSHA. No adverse long term affects known.
Medical Conditions Aggravated by Exposure: Preexisting lung or skin conditions could be aggravated by continued exposure.

PRECAUTIONS FOR SAFE HANDLING AND USE:
Steps to be Taken in Case Material is Released or Spilled: Eliminate ignition sources. Recover product. Spread sand, earth, or other suitable absorbent to spill area. Minimize vapor or skin contact. Keep product from sewers and water courses by constructing a dam or impounding.
Waste Disposal Method: Dispose in accordance with Federal, State, and local regulations.
Storage: Store in a ventilated area away from heat and ignition sources.
Other Precautions: Avoid breathing vapors. Keep containers closed when not in use.

SECTION 313 SUPPLIER Notification: This product contains no toxic chemicals subject to the reporting requirements of section 313 of the Emergency Planning and Community Right to Know Act of 1986 and of 40 CFR 372.

HAZARDOUS INGREDIENTS:

Chemical & Common Name	% Weight	OSHA PEL	ACGIH TLV
Mineral Spirits	20 to 30	100 ppm	500 ppm
Asbestos Fibers *	4 to 12	N/A	N/A

* Asbestos is nonhazardous when encapsulated as in this product and will not create dusting.

The same question applies to products from Denver Industrial Supplies and Coatings (DISSCO) as this information is on their website https://www.dissco.net/wp-content/uploads/04a-msds-540.pdf

DISSCO

MATERIAL SAFETY DATA SHEET
DISSCO 540 MASTIC
WATERPROOFING COMPOUND

Denver Industrial Sales & Service Company
850 South Lipan Street
Denver, CO 80223

I. PRODUCT IDENTIFICATION

			Hazard Rating
Product name:	**DISSCO 540 Mastic**		
Chemical name:	Asphalt cutback	Health	1
Chemical Family:	Petroleum hydrocarbon	Fire	3
		Reactivity	0
ASNI:	Caution! May cause eye and skin irritation		
DOT Hazard Class:	Tars Liquid, 3, UN1999, PG II		

II. HAZARDOUS CONSTITUENTS

Chemical	CAS No.	Percent	TLV	PEL
Petroleum asphalt	8052-42-4	40 – 60	5mg/m3	None established
Petroleum naphtha	8008-20-9	40 – 60	N/E	500 ppm
Asbestos Fiber	12001-29-5	5 – 12	N/E	.02 f/c
Additives	N/A	.5 – 2.0	N/E	None established