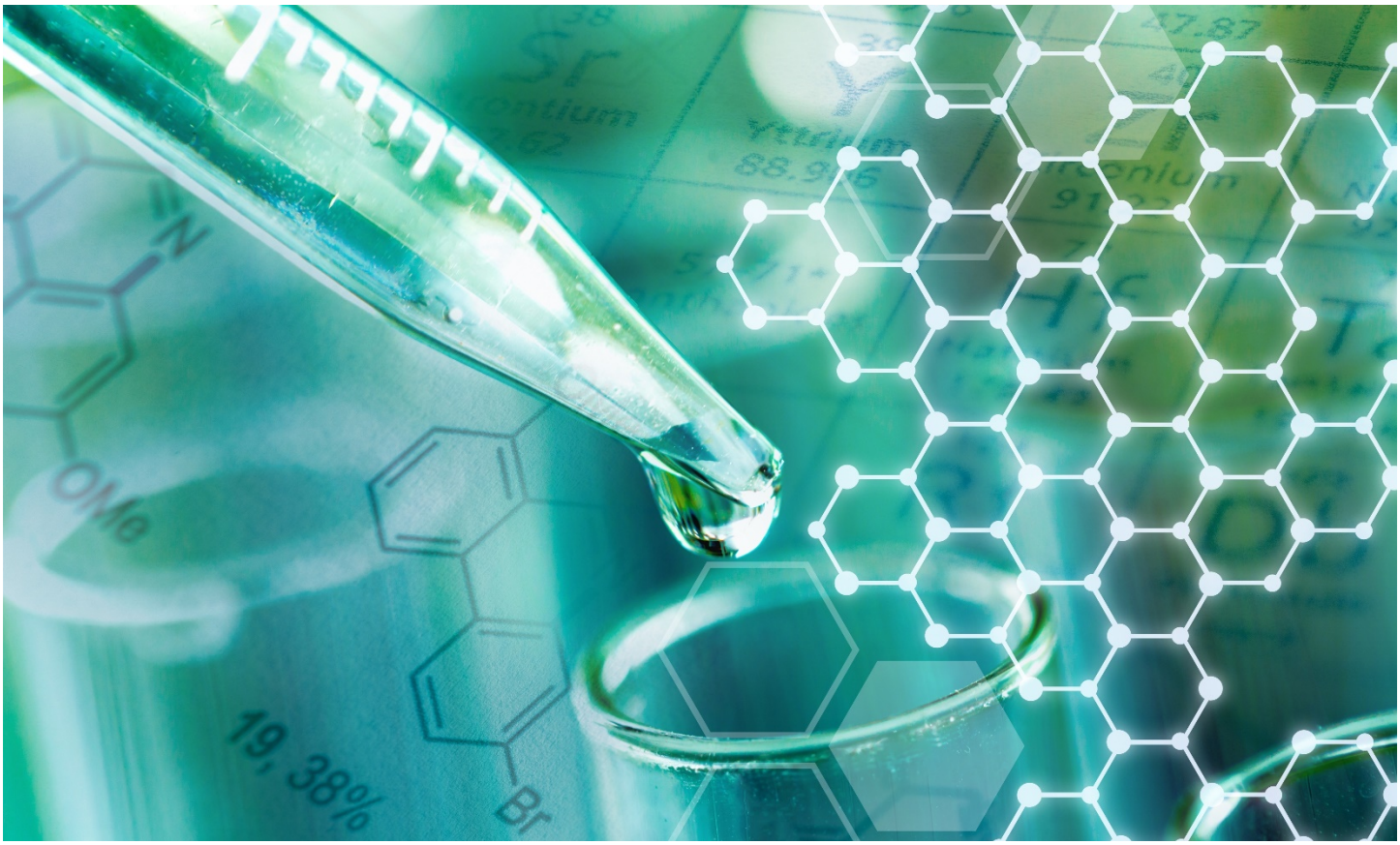
Division on Earth & Life Studies
Board on Environmental Studies and Toxicology

COMMITTEE TO REVIEW EPA'S TSCA SYSTEMATIC REVIEW GUIDANCE DOCUMENT

Virtual Meeting 2.3: August 24, 2020 (2:30 pm - 4:55 pm EDT)

Public Handout



Project Website

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Board on Environmental Studies and Toxicology

COMMITTEE TO REVIEW EPA'S TOXIC SUBSTANCES CONTROL ACT (TSCA) SYSTEMATIC REVIEW GUIDANCE DOCUMENT
VIRTUAL MEETING 2.3

PUBLIC AGENDA

MEETING OBJECTIVES

- To hear details about EPA's innovations in the TSCA data evaluation and evidence integration process

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MONDAY, August 24, 2020

2:30 PM — PURPOSE OF OPEN SESSION AND INTRODUCTION OF COMMITTEE MEMBERS
Jonathan Samet
Chair, Committee to Review EPA'S TSCA Systematic Review Guidance Document
Dean, Colorado School of Public Health

2:35 — DISCUSSION OF QUESTIONS ABOUT THE TSCA PROCESS
Stan Barone, Deputy Director, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention

2:50 — Discussion and clarifications on approach from EPA (Discussion time 35 minutes)

3:25 — **BREAK** (10 MINUTES)

3:35 — INTERACTIVE BREAKOUT SESSIONS

- These breakout sessions will discuss videos which are prerecorded and posted on the TSCA Systematic Review study website. Viewing of these videos prior to participating in the session is necessary to fully participate. Discussion moderators will pose questions from the committee and the public during the breakout session to the poster presenters.

BREAKOUT SESSION 1: EVALUATION AND SCORING
Moderated By – Bryan Brooks

Videos Discussed:

- Data Evaluation for Physical-Chemical and Fate Properties Under TSCA
  - *Tameka Taylor, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*
- Data Evaluation for Exposure and Engineering Studies Under TSCA
  - *Nerija Orentas, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*

- Data Evaluation for Environmental Hazard Studies Under TSCA
  - *Amelia Nguyen, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*
- Data Evaluation for Animal Toxicity and In Vitro Studies to Support Human Health Hazard Under TSCA
  - *Amy Benson, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*
- Data Evaluation for Epidemiological Studies Under TSCA
  - *Francesca Branch, EPA Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics*

BREAKOUT SESSION 2: EVIDENCE INTEGRATION
Moderated By – Jessica Myers

Videos discussed:

- Evidence Integration of Physical-Chemical and Fate Property Data Under TSCA
  - *Marcy Card, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*
- Evidence Integration of Exposure Data Under TSCA
  - *Eva Wong and Ariel Hou, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*
- Evidence Integration of Environmental and Human Health Hazard Data Under TSCA
  - *Kara Koehrn, Risk Assessment Division, EPA Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention*

4:20 DISCUSSION FOLLOWING BREAKOUTS GROUPS, RECAP OF BREAKOUTS

4:55 ADJOURN PUBLIC SESSION

Committee to Review EPA's TSCA Systematic Review Guidance Document

In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act updated the Toxic Substances and Control Act (TSCA) of 1976. The Act required that the US Environmental Protection Agency (EPA) conduct risk evaluations for chemicals designated as "high-priority substances" to determine whether they present an unreasonable risk to health or the environment under the chemical's conditions of use. The preamble of the TSCA Risk Evaluation Rule identifies systematic review as an evaluation method to ensure that literature reviews are complete, unbiased, reproducible, and transparent. The method is defined as ". . . a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize findings of similar but separate studies."

In May 2018, EPA released a document *Application of Systematic Review in TSCA Risk Evaluations*. This document has been used and refined as EPA has been conducting risk evaluations under TSCA. This committee will evaluate EPA's guidance document and will consider public comments on the document, EPA's responses to public comments, and enhancements to the systematic review process reflected in documentation of the first 10 chemical risk evaluations. The committee will use the strategy to make a determination about whether EPA's process is comprehensive, workable, objective, and transparent. Recommendations for enhancements to EPA's 2018 guidance document will be made.

Committee Membership

Jonathan M. Samet, MD, MS (Chair), Dean and Professor Colorado School of Public Health

Deborah H. Bennett, PhD Professor, Department of Public Health Sciences, University of California, Davis

Bryan W. Brooks, PhD Distinguished Professor, Department of Environmental Science, Baylor University

Jessica L. Myers, PhD Toxicologist, Texas Commission on Environmental Quality

Kristi Pullen Fedinick, PhD, Director, Science and Data & Senior Scientist, Natural Resources Defense Council

Karen A. Robinson, PhD, Professor of Medicine, Director, Evidence-based Practice Center, Johns Hopkins University

Joseph V. Rodricks, PhD Principal, Ramboll

Katya Tsaioun, PhD Director, Evidence-based Toxicology Collaboration Johns Hopkins Bloomberg School of Public Health

Yiliang Zhu, PhD Professor University of New Mexico Department of Epidemiology and Biostatistics

NASEM Staff

Elizabeth Boyle, MPH, CIH Project Director

Clifford Duke, PhD BEST Board Director

Andrea Hodgson, PhD Program Officer

Tamara Dawson Program Coordinator

Committee to Review EPA's TSCA Systematic Review Guidance Document

Biosketches

Jonathan M. Samet (NAM) is a pulmonary physician and epidemiologist. He is the Dean of the Colorado School of Public Health. Dr. Samet's research has focused on the health risks posed by inhaled pollutants. He has served on numerous committees concerned with public health: the US Environmental Protection Agency's Clean Air Scientific Advisory Committee; committees of the National Academies, including chairing the Biological Effects of Ionizing Radiation (BEIR) VI Committee, the Committee on Research Priorities for Airborne Particulate Matter, the Committee to Review EPA's Draft IRIS Assessment of Formaldehyde, the Committee to Review the IRIS Process, and the Board on Environmental Studies and Toxicology, among others; and the National Cancer Advisory Board. He is a member of the National Academy of Medicine. Dr. Samet received his MD from the University of Rochester, School of Medicine and Dentistry and master's degree in epidemiology from the Harvard T.H. Chan School of Public Health.

Deborah H. Bennett is a Professor in the Division of Environmental and Occupational Health at the University of California, Davis School of Medicine. Her research focuses on the measurement and modeling of organic compounds in the indoor environment. She has served on various U.S. Environmental Protection Agency Science Advisory boards, panels, and advisory committees related to the Exposure Factors Handbook, and Exposure Metrics for the National Children's Study. She has served as Estimation Associate Editor for the Journal of Exposure Science and Environmental Epidemiology. She has served as an Elected Councilor, Treasurer, and Chair of the Awards Committee for the International Society of Exposure assessment. She has an MS and PhD from the University of California, Berkeley.

Bryan W. Brooks is a Distinguished Professor, Environmental Science and Biomedical Studies at Baylor University. His scholarship incorporates laboratory and field studies in environmental toxicology and chemistry, environmental health, hazard & risk assessment, and water resources. He leads harmful algal blooms research for the Center for Oceans and Human Health and Climate Change Interactions (OHHC2I), a NIEHS Center based at the University of South Carolina. Prof. Brooks serves as Editor-in-Chief of Environmental Science and Technology Letters. Dr. Brooks has an MS from the University of Mississippi and a PhD from the University of North Texas.

Jessica L. Myers is a toxicologist and risk assessor. She is currently working at the Texas Commission on Environmental Quality where she has drafted guidance on the development of systematic reviews for toxicity factors. She has a bachelor's and PhD in cell and molecular biology from the University of Texas at Austin.

Kristi Pullen Fedinick is a Senior Scientist and the Director of Science and Data in the Healthy People & Thriving Communities (HPTC) Program at the Natural Resources Defense Council. She also serves as part-time faculty in the Department of Environmental and Occupational Health of the Milken Institute School of Public Health at The George Washington University. Dr. Pullen Fedinick's research career includes experience in environmental health and policy; molecular, structural, and computational biology; biochemistry; and population health. Prior to joining NRDC, she worked as a scientist for a Chicago-based environmental non-profit, where she focused on air and drinking water quality, science communications, and environmental justice. Her current work focuses on the use of high-throughput technologies, predictive toxicology, and

computational approaches to chemical risk assessments. Additional work includes the geospatial and statistical analysis of chemicals in the environment, with a particular emphasis on drinking water and on the disproportionate impact of chemical exposures in vulnerable populations. She holds a bachelor's degree in biochemistry and molecular biology from the University of Maryland Baltimore County and a Ph.D. in molecular and cell biology with a focus on structural biology and biochemistry from the University of California, Berkeley. She was a Robert Wood Johnson Foundation Health and Society Scholar at the Harvard T. H. Chan School of Public Health.

Karen A. Robinson is a Professor of Medicine at the Johns Hopkins University School of Medicine. She is also director of the Johns Hopkins University Evidence-based Practice Center and is a member of the core faculty in the Center for Clinical Trials and Evidence Synthesis at the university's Bloomberg School of Public Health. Dr. Robinson's research focuses on evidence-based health care and evidence-based research. She conducts systematic reviews that are used to develop clinical practice guidelines and to inform other health decisions. She served on the National Academies Committee on Endocrine-Related Low-Dose Toxicity, the Committee to Review Advances Made to the IRIS Process, the Committee to Review DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene and the Committee to Review EPA's IRIS Assessment Plan for Inorganic Arsenic. Dr. Robinson received an MSc in health sciences from the University of Waterloo, Ontario, and a PhD in epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Joseph V. Rodricks is a founding Principal of ENVIRON (now Ramboll), and an internationally recognized expert in toxicology and risk analysis. He has consulted for hundreds of manufacturers, new product developers, and government agencies in the evaluation of health risks associated with human exposure to chemical substances of all types. Joseph came to consulting after a 15-year career as a scientist at the US Food and Drug Administration (USFDA). In his last four years at the USFDA, he served as Associate Commissioner for Health Affairs. His experience extends from pharmaceuticals, medical devices, consumer products and foods, to occupational chemicals and environmental contaminants. He has served on the National Research Council's Board on Environmental Studies and Toxicology, and on more than 40 boards and committees of the National Academy of Sciences and the Institute of Medicine, including the committees that produced the seminal works Risk Assessment in the Federal Government: Managing the Process (1983), and Science and Decisions–Advancing Risk Assessment (2009). Most recently he served on the National Academies committee that issued Guiding Principles for Developing Dietary Reference Intakes Based on Chronic Disease. He has more than 150 scientific publications and has received 11 honorary awards from professional societies and other academic and non-academic institutions. He is author of the widely-used text, Calculated Risks, now in its second edition, published by Cambridge University Press, and has presented more than 300 lectures in countries around the world. Dr. Rodricks earned his PhD in Biochemistry from the University of Maryland, College Park.

Katya Tsaioun is Director of the Evidence-based Toxicology Collaboration at the Johns Hopkins Bloomberg School of Public Health. The collaboration's mission is to bring together the international toxicology community to facilitate use of evidence-based toxicology to inform regulatory, environmental, and public health decisions. She received her PhD in human nutrition science from Tufts University Friedman School of Nutrition Science and Policy.

Yiliang Zhu is a Professor in the Division of Epidemiology, Biostatistics, and Preventive Medicine, School of Medicine at the University of New Mexico (UNM). He directs the biostatistics, epidemiology, and research design cores for the Clinical and Translational Research Center of UNM and for the Mountain West Clinical and Translational Research Infrastructure Network, a consortium of 13 universities in seven states. His research focuses on quantitative methods in

health risk assessment, including integrative modeling of biological systems, dose-response modeling, benchmark-dose methods, and uncertainty quantification. He also conducts research in biostatistics methods, clinical- and health-outcome evaluation, and impact assessment of healthcare systems and policies in northwestern rural China. Before joining UNM Dr. Zhu was a professor at University of South Florida College of Public Health where he directed the Biostatistics PhD program and the Center for Collaborative Research. Dr. Zhu has served on several National Academies committees, including the Committee on EPA's Exposure and Human Health Assessment of Dioxin and Related Compounds, the Committee on Tetrachloroethylene, the Committee to Review EPA's Draft IRIS Assessment of Formaldehyde, and the Committee to Review the IRIS Process. He received a PhD in statistics from the University of Toronto.

NASEM REVIEW OF EPA'S TSCA SYSTEMATIC REVIEW APPROACH:

VIRTUAL MEETING 2.3 - ABSTRACTS

MEETING INFORMATION

The National Academies of Sciences, Engineering, and Medicine (NASEM) TSCA committee has initiated a study evaluating EPA's guidance document *Application of Systematic Review in TSCA Risk Evaluations* and associated materials. Information on the meeting is available here: https://www.nationalacademies.org/our-work/review-of-epas-tsca-systematic-review-guidance-document.

BACKGROUND INFORMATION

The strategies for assessing the quality of data/information sources use a structured framework with predefined criteria for each type of data/information source. EPA developed a numerical scoring system to inform the characterization of the data/information sources during the data integration phase. The goal is to provide transparency and consistency to the evaluation process along with creating evaluation strategies that meet the TSCA science standards for various data/information streams. Examples of data/information streams can be found in Appendix B-H of EPA's guidance document *Application of Systematic Review in TSCA Risk Evaluations.*

The term data/information source is used in a broad way to capture the heterogeneity of data/information sources that are used in the TSCA risk evaluations. The data/information are intended to understand the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations as required by the amended TSCA.

The general structure of the TSCA evaluation strategies is composed of data evaluation domains, metrics and criteria. Evaluation domains represent general categories of attributes that are evaluated in each data/information source. Each domain contains a unique set of metrics, or sub-categories of attributes, intended to assess an aspect of the methodological conduct of the data/information source. Each metric specifies criteria expressing the relevant elements or conditions for assessing confidence that, along with professional judgement, will guide the identification of study strengths and limitations/deficiencies.

By design, the TSCA systematic review process uses a fit-for-purpose literature search and relevance-driven eligibility criteria to identify the most relevant data/information sources for the TSCA risk evaluation.

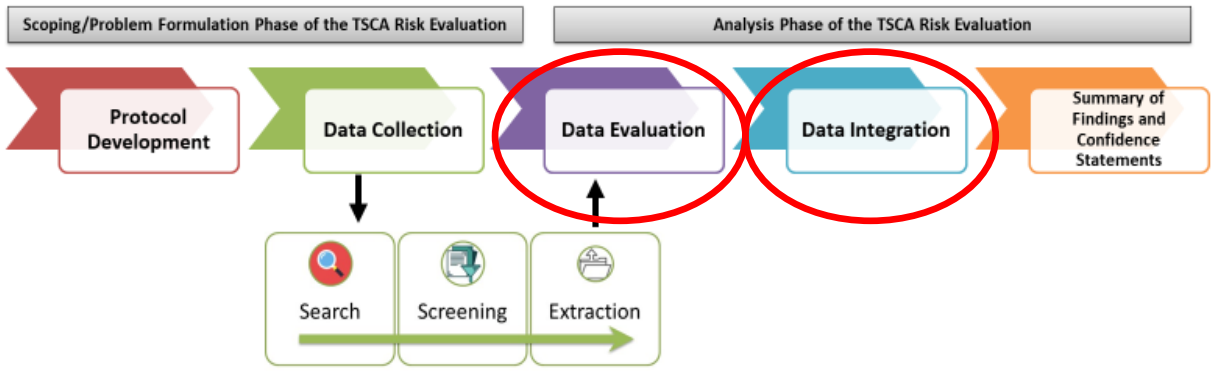
The TSCA evaluation strategies in some cases refer to study guidelines along with professional judgement as helpful guidance in determining the adequacy or appropriateness of certain study designs or analytical methods. Drawing upon the evaluation strategies, OPPT developed criteria to evaluate several important study metrics, organized within domains. EPA scored each metric numerically and then provided an overall numerical data quality score for the study that translated into acceptable (high, medium, low) or unacceptable data quality ratings.

Based on the strengths, limitations, and deficiencies of each data/information source, the reviewer assigns a confidence level score of 1 (high confidence), 2 (medium confidence), 3 (low confidence) or 4 (unacceptable) for each individual metric that is evaluating a particular aspect of the methodological conduct of the data/information source. Although many metrics have criteria for all four bins (i.e., High, Medium, Low, and Unacceptable), there are some metrics with dichotomous or trichotomous criteria to fit better the nature of the criteria. Critical metrics (as described in the posters for each data type) were given greater weight.

After data evaluation, data integration is implemented. Data integration is the stage where the analysis, synthesis and integration of data/information takes place by considering quality, consistency, relevancy, coherence and biological plausibility. It is in this stage where the weight of the scientific evidence approach is applied to evaluate and synthetize multiple evidence streams in order to support the chemical risk evaluation. EPA is required by TSCA to use the weight of the scientific evidence in TSCA Risk Evaluations. As defined in the final rule, Procedures for Chemical Risk Evaluation Under Amended TSCA, application of weight of evidence analysis is an integrative and interpretive process that relies on a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

The last step of the systematic review process is the summary of findings in which the evidence is summarized, the approaches or methods used for the weight of the scientific evidence are discussed and used for the strength of the evidence score for hazard or exposure. The basis for the conclusions of the confidence level for risk estimation is the recommendation that considers the strength of the evidence and uncertainties in the risk estimate.

VIRTUAL MEETING 2.3: SPECIFIC APPLICATIONS OF EVALUATION CRITERIA AND EVIDENCE INTEGRATION



Key Terms in Data Evaluation

- **Domain** – categories of attributes that are evaluated in each data source.
- **Metrics** – sub-categories of attributes, intended to assess an aspect of the methodological conduct of the data source.
- **Criteria** – Specific criteria are developed for each metric, which express conditions of the confidence level assigned to the metric (high, medium, low)

Data evaluation and evidence integration are the steps of the Systematic Review for the first 10 Risk Evaluations that were discussed on July 23 through oral presentations. EPA provided presentations that addressed specific applications of scoring and evidence (available here: https://www.nationalacademies.org/our-work/review-of-epas-tsca-systematic-review-guidance-document#sectionPastEvents) and will follow up with more details through poster presentations.

EPA will discuss data evaluation and data integration as performed for the first TSCA 10 chemical risk evaluations and plans for moving forward. The presentations at this meeting will reinforce those approaches that remain the same or similar to what was used in the first 10 TSCA Risk Evaluations and highlight innovations and improvements EPA is implementing for the next set of Risk Evaluations based on EPA's experience and on feedback received from SACC peer reviewers and the public.

Virtual Poster Session for Meeting 2.3: (5-10 minutes recorded poster presentations)

POSTER: **Data Evaluation for Physical-Chemical and Fate Properties under TSCA** (Tameka Taylor *et al.*)

- Following literature searching and screening as described in the June 19, 2020 "NAS Review of EPA's TSCA Systematic Review Approach: Webinar 1," the references that were included in both title/abstract and full-text screening moved forward to data extraction and data quality evaluation. This poster describes the data quality metrics and criteria, metric weighting, and scoring used to evaluate literature relevant to physical-chemical and fate properties. While some physical-chemical and fate property study metrics are broadly applicable to studies in those disciplines (e.g., whether a property is measured or estimated), some metrics are applicable only to specific type of study (e.g., a specific measurement like biodegradation half-life). Both physical-chemical and fate study metrics include data quality criteria assessing the identity of the test substance, appropriateness of the experimental methods or model outputs for the substance given its known properties, and reliability of the reported results. The metrics specific to physical-chemical property studies also reflect study quality criteria for physical-chemical property databases and indexes including their reported review and quality control processes. The metrics specific to fate studies reflect other factors that can affect the reliability and interpretation of fate properties, such as test conditions, media, and organisms being tested. This presentation will describe lessons learned from the first 10 TSCA Risk Evaluations and refinements made for the next 20 Risk Evaluations.

POSTER: **Data Evaluation for Exposure and Engineering Studies under TSCA** (Nerija Orentas *et al.*)

- This presentation describes the metrics and criteria used to evaluate and score peer-reviewed and gray literature relevant to occupational exposure, environmental releases, environmental exposure, general population exposure, and consumer exposure. The presentation will describe the process used for the first 10 TSCA Risk Evaluations, lessons learned, and refinements planned for evaluating studies for the next 20 TSCA Risk Evaluations. EPA developed study evaluation criteria based on EPA science standards in TSCA and as outlined in the "*Application of Systematic Review in TSCA Risk Evaluations.*" Guidance documents were developed and used to train reviewers to promote data evaluation in a consistent manner across reviewers. Exposure and engineering assessments rely on multiple data types (e.g., monitoring data and survey data) and EPA has identified and presents the seven data types for exposure studies and five data types for engineering studies. After title/abstract screening, studies tagged as on-topic undergo full-text screening using the Distiller SR tool and are categorized according to the study's data type. EPA developed metrics unique to each data type that covered these four domains: reliability, representativeness, accessibility and variability/uncertainty of the data. Each metric specifies criteria expressing the relevant elements or conditions for assessing confidence that, along with professional judgement, will guide the identification of study strengths and limitations/deficiencies. Based on the strengths, limitations, and deficiencies of each data/information source, the reviewer assigned a confidence level score to each evaluation metric and a total study evaluation score of high, medium, low or unacceptable.

POSTER: **Data Evaluation for Environmental Hazard Studies under TSCA** (Amelia Nguyen *et al.*)

- This presentation provides an overview of OPPT's evaluation of environmental hazard data to support the TSCA Risk Evaluations (REs). OPPT's refinements to the TSCA data evaluation of environmental hazard studies, based on lessons learned from the first 10 TSCA REs and leveraging new SR tools and techniques will be highlighted. In May 2018, EPA issued guidance titled "*Application of Systematic Review in TSCA Risk Evaluations.*" As discussed in the guidance, OPPT leveraged EPA's ECOTOXicology knowledgebase (ECOTOX) as a source of single chemical toxicity data for aquatic and terrestrial organisms. Using a modified ECOTOX literature search and screening protocol, OPPT performed a wide search based on chemical-specific search terms to gather environmental toxicity information. Title/abstract and full-text screening decisions were based on the modified ECOTOX minimum applicability criteria that parsed citations into "on-topic" and "off-topic" bins. The "on-topic" references were further subjected to a full-text screening step to confirm relevancy. Only citations that fulfilled the full-text screening criteria moved to the data evaluation step. OPPT considered the ECOTOX criteria and the Criteria for Reporting and Evaluating Ecotoxicity Data (CRED) along with professional judgment when developing the data evaluation criteria. Evaluations of environmental hazard data are conducted in DistillerSR, which tracks and records the evaluations for each reference. In addition, training, calibration exercises, quality checks, and multiple levels of reviews are deployed to reduce bias and improve evaluation consistency among reviewers based on pre-established data quality evaluation criteria. Reviewers used a scoring method to assess the quality of references as acceptable (i.e., high, medium, or low), not applicable, or unacceptable for RE purposes. References with acceptable quality served as the basis for hazard characterization and were extracted for integration into the TSCA REs. Updates to the environmental hazard evaluation criteria to better consider methodological design, implementation, and reporting to address public and peer review comments will be presented.

POSTER: **Data Evaluation for Animal Toxicity and *In Vitro* Studies to Support Human Health Hazard under TSCA** (Amy Benson *et al.*)

- This presentation provides an overview of OPPT's evaluation of animal toxicity and *in vitro* studies to support the human health assessments in the first ten TSCA Risk Evaluations (REs) and future updates and improvements to the data quality evaluation criteria. EPA's *Application of Systematic Review in TSCA Risk Evaluations* document describes the data evaluation process for animal and *in vitro* studies. Drawing upon existing data evaluation and risk of bias tools as well as professional judgment, OPPT developed criteria to evaluate several important study metrics, organized within domains (e.g., test organisms, outcome assessment, confounding/variable control). EPA scored each metric numerically and then provided an overall numerical data quality score for the study that translated into acceptable (high, medium, low) or unacceptable data quality ratings. Critical metrics were given greater weight. EPA relied generally on references with high and medium overall data quality ratings as the basis of studies that might be used for dose-response assessment. EPA is updating the criteria to consider dichotomous data, precision of criteria as they relate to scoring (e.g., high, medium, low, unacceptable), among other updates.

POSTER: **Data Evaluation for Epidemiological Studies under TSCA** (Francesca Branch *et al.*)

- This presentation will describe the evaluation criteria that EPA designed to review epidemiologic data. Epidemiologic studies can contain information both on chemical exposure and human health hazards and are assessed independently to support the exposure and hazard assessments. EPA used elements of evaluation procedures implemented in past TSCA risk assessments, and adapted and supplemented these with elements from other established evaluation tools (e.g., IRIS, OHAT, Lakind et al. 2014) in order to design epidemiologic evaluation criteria that are fit-for-purpose to fulfill the scientific standards under TSCA. The focus of the presentation will be on explaining

the various epidemiologic evaluation criteria domains, how risk of bias elements are incorporated, and the metric weighting and scoring. The presentation will also touch on updates made to epidemiological criteria since publication of the *Application of Systematic Review in TSCA Risk Evaluations*, and the chemical-specific epidemiological data evaluation criteria developed for the Asbestos Risk Evaluation.

POSTER: **Evidence Integration of Physical-Chemical and Fate Property Data under TSCA** (Marcy Card *et al.*)

- This presentation describes the evidence integration process for physical-chemical and fate property data, and how the results of physical-chemical and fate property evidence integration inform the exposure assessments and ecological and human health hazard assessments. After data extraction and evaluation are complete for all data sources (i.e., peer-reviewed literature, gray literature, TSCA submissions, and other reasonably-available information), the physical-chemical and fate information is synthesized to develop the fate and transport assessment. Values for physical-chemical and fate properties must be selected for use in models and other quantitative and qualitative assessments throughout the Risk Evaluation. When weighing the evidence for physical-chemical and fate properties, the first factors considered are data quality and whether the information was measured or estimated. Other factors considered in evidence integration include concordance with other reported values, study protocols most appropriate to the chemical or closer to standard protocols, test conditions most applicable to environmental conditions, and uncertainties in the information.

POSTER: **Evidence Integration of Exposure Data under TSCA** (Eva Wong and Ariel Hou *et al.*)

- This presentation will describe the evidence integration of data for exposure assessment. Consistent with TSCA, the exposure assessment evaluates, where relevant, the likely duration, intensity, frequency and number of exposures to human populations (e.g., general population, consumer, worker), including sentinel populations, potentially exposed or susceptible subpopulations, and environmental receptors (e.g., aquatic, terrestrial species) for the conditions of use of the chemical substance. The choice of whether to use measured data or modeled estimates or a combination of both approaches to estimate exposure may depend on the complexity of the exposure scenario and the amount or extent and quality of available information for the specific chemical and exposure scenario. Use of measured data includes a review of the reasonably available monitoring data (*e.g.*, media concentrations, emissions data, personal monitoring from grey literature, peer-reviewed literature and TSCA submissions). Estimation approaches rely on parameterization of a computational model to arrive at exposure estimates in the media of interest for the receptor of interest. Parameterization of models utilizes default and/or chemical or exposure/scenario specific inputs, which may also include measured values or distributions of values to address uncertainties. Considerations for integrating exposure information broadly include data quantity and quality, use of surrogate and chemical or scenario-specific data, use of validated or peer-reviewed modeling approaches, confidence in parameterization for computational estimation, use of qualitative data, and uncertainty and variability.

POSTER: **Evidence Integration of Environmental and Human Health Hazard Data under TSCA** (Kara Koehrn *et al.*)

- This presentation will outline how OPPT integrates human health and environmental hazard data in TSCA Risk Evaluations. Consistent with EPA guidance, EPA considers both quality and relevance in weighing the scientific evidence during data integration. Specifically, for human health hazard data integration, EPA considers quality, consistency, relevancy, coherence, and

biological plausibility (i.e., Bradford Hill considerations) when integrating evidence across human, animal, and if needed, mechanistic information as outlined in EPA's 2018 *Application of Systematic Review in TSCA Risk Evaluations*. For environmental hazard data integration, EPA also uses Bradford Hill considerations, including quality and relevance when integrating data across species, effect, and endpoint (U.S. EPA, 1998; U.S. EPA, 2016). In this presentation EPA will outline current methods and provide two examples of how EPA integrated hazard data in the TCE Risk Evaluation. The presentation will also introduce the human health hazard framework to be used for future TSCA Risk Evaluations.