December 31, 2012

Nanomaterial Case Study Workshop Process: Identifying and Prioritizing Research for Multiwalled Carbon Nanotubes

Summary Report-Final

Prepared for:

U.S. Environmental Protection Agency National Center for Environmental Assessment

Prepared by:

RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709-2194



Table of Contents

Ex	ecutiv	e Summary	1	
1.	Com	prehensive Environmental Assessment (CEA) Approach	1	
	1.1	CEA Objectives	1	
	1.2	CEA Components		
		1.2.1 CEA Framework	2	
		1.2.2 CEA Process	2	
	1.3	Rationale for Applying CEA to Engineered Nanomaterials (ENMs)	3	
		1.3.1 CEA Applied to MWCNT	4	
		1.3.2 Collective Judgment of CEA Applied to MWCNT: Research Gap		
		Identification and Prioritization	5	
		1.3.3 Synopsis of Prioritized Research Areas for MWCNT in This Case Study	7	
2.	CEA	MWCNT Prioritization Process	12	
	2.1	CEA MWCNT Prioritization Tool Rating Process	13	
	2.2	CEA Prioritization Round 1		
	2.3	CEA Prioritization Round 2	15	
	2.4	Generation of Starter Research Questions	15	
	2.5	Final Workshop	16	
		2.5.1 CEA Prioritization Round 3	17	
		2.5.2 Generation of Final Research Questions	17	
3.	CEA	MWCNT Prioritization Tool Outputs and Analytical Results		
	3.1	CEA Prioritization Matrix	20	
	3.2	Group Bar Charts	20	
	3.3	Individual and Group Exhaustive Tables	21	
	3.4	Round 1 Prioritization Results	21	
	3.5	Round 2 Prioritization Results	24	
	3.6	Research Questions Submitted After Round 2	26	
	3.7	Workshop Outcomes and Round 3 Prioritization Results	26	
		3.7.1 NGT Process at Workshop	27	
		3.7.2 Round 3 Participant Ratings	28	
	3.8	Round 3 Final Research Questions		
4.	Cond	clusions and Future Directions	34	
5.	. References			

List of Appendices

Appendix A	Other CEA MWCNT Prioritization Process Documents	A1
Appendix B	Participants in the CEA MWCNT Prioritization Process	B1
Appendix C	Methods for Analysis and Reporting	C1
Appendix D	Results from Round 1	D1
Appendix E	Results from Round 2	E1
Appendix F	Workshop Outcomes and Results from Round 3	F1
Appendix G	Analyses of Changes between Prioritization Rounds	G1
Appendix H	Pre-Prioritization Process Charge to Participants	H1
Appendix I	Research Questions Submitted as Part of Charge Questions	I1
Appendix J	Breakout Groups	J1
Appendix K	CEA MWCNT Prioritization Tool Rating Process and Materials	K1
Appendix L	Workshop Presentation Slides	L1

List of Figures

Figure 1.	High-level CEA Framework.	2
-	CEA process diagram	
	Overview of the CEA prioritization process used in this case study.	
Figure 4.	Detailed CEA Framework.	7
Figure 5.	Final research priorities mapped to the detailed CEA Framework based on results from	
	the final prioritization round (Round 3).	8
Figure 6.	Distribution of participants within stakeholder groups and areas of expertise in	
	prioritization rounds	.12
Figure 7.	Overview of rating process used in CEA MWCNT Prioritization Tool	.14
Figure 8.	Prioritization Matrix	.14
Figure 9.	Relationships between research, risk assessment, and risk management.	. 19
Figure 10.	Overview of E-RRFs proposed for prioritization by participants in NGT process	

List of Tables

Table 1.	Synopsis of prioritized E-RRFs from Round 3 (shown in descending order of	
	agreement among participants) and associated research questions developed by	
	breakout groups	9
Table 2.	Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC) on	
	Prioritization Matrix for Round 1	22
Table 3.	Overview of participants' rating of E-RRFs in the "Important" (I) and "Not	
	Confident" (NC) bin for Round 1	23
Table 4.	Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC) on	
	Prioritization Matrix for Round 2	24
Table 5.	Overview of participants' rating of E-RRFs in the "Important" (I) and "Not	
	Confident" (NC) bin for Round 2	25
Table 6.	Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC) on	
	Prioritization Matrix for Round 3	29
Table 7.	Overview of participants' rating of E-RRFs in the "Important" (I) and "Not	
	Confident" (NC) bin for Round 3	30
Table 8.	Synopsis of participant rationales for prioritization of E-RRF ("Why?") from Round 3	31

Executive Summary

This report details the process of engaging diverse, expert stakeholders in an application of Comprehensive Environmental Assessment (CEA) to identify research priorities that, if carried out, could inform the assessment and management of the potential risks of multiwalled carbon nanotubes (MWCNT) in flame-retardant coatings applied to upholstery textiles. The prioritization process described herein aimed to connect calls for research with the implications that the resulting knowledge could have for supporting assessments (e.g., risk assessments, life cycle assessments) and ultimately for supporting risk management decisions. For this reason, one of the primary goals of this process was to produce a list of prioritized, actionable research questions that will enable future assessments and subsequent risk management decisions for MWCNT.

The process built upon previous applications of CEA for other engineered nanomaterials (ENMs), although it also had unique aspects, such as using a comparative material (decabromodiphenyl ether, or decaBDE, a traditional flame-retardant coating) to help identify key research gaps and other relevant considerations, as well as making greater use of remote, online exercises to gather iterative input from diverse stakeholders in the collective judgment step. In addition, this application of CEA particularly focused on, first, iteratively incorporating the collective knowledge of a diverse and balanced group of expert stakeholders that represented a variety of sectors and knowledge areas and, second, the movement from a holistic perspective toward more detailed perspectives as information areas rose to the top of the prioritization process.

Through three separate rounds of prioritization, this process collectively

identified and elevated high priority research areas based on two factors:

- **Importance:** the degree of importance for risk assessment efforts
- **Confidence:** the availability or lack of adequate information for risk management decisions.

Priority research areas identified as being most important to risk assessment efforts and which had the least confidence in the availability of adequate information for risk management decisions were then considered high research priorities.

Rather than aiming for a group consensus, the participants rated priority research areas via individual exercises. Between prioritization rounds, they reviewed and considered the collective responses of their co-participants, incorporated those views into their own as they saw fit, and carried out the subsequent round of prioritization with this potentially new view.

Following the identification of the most commonly agreed upon prioritized research areas from the final prioritization round (Round 3), in the form of Element-Risk Relevant Factor pairs (E-RRFs), detailed, actionable research questions were then developed for these research areas by experts during breakout group sessions at a face-to-face workshop. In addition to these detailed research questions, the breakout groups also developed additional information for the select E-RRFs relevant for risk management and decision making, including, among other aspects, the information needed to inform an assessment to support risk management decisions, the types of assessments needed to provide this information, and the estimated costs and

time frame for completion of the research questions.

For each prioritization round, an overview of participant responses was presented on an Importance/Confidence matrix (termed "Prioritization Matrix"). The Matrix allowed participants to identify how each E-RRF pair was most frequently rated by all participants, based on the combination of Importance and Confidence for a given E-RRF.

Round 1 of the prioritization process was carried out remotely by 31 participants. A large majority (34 out of 43, 79%) of the E-RRF pairs on the Prioritization Matrix from Round 1 were grouped in the "Important," "Not Confident" bin. These E-RRFs in the "Important," "Not Confident" bin were relevant for all five CEA Levels (i.e., major domains of the CEA framework. including Product Life Cycle; Environmental Transport, Transformation & Fate; Exposure Route; Dose (Kinetics); Impacts). In addition, all E-RRFs for the CEA Levels of Environmental Transport and Transformation & Fate and Dose (Kinetics) that were on the Prioritization Matrix were placed in this highest priority bin (100% for both of these CEA Levels, compared with 71% for Impacts, 60% for Product Life Cycle, and 33% for Exposure Route). Participants were then requested to review and consider the full set of Round 1 results (i.e., responses of other stakeholders participating in the process) prior to starting Round 2 of the prioritization process.

In total, 28 participants successfully completed Round 2 of the prioritization process remotely (with three participants dropping out after Round 1). Similar to the first prioritization round, a large majority (35 out of 42, 83%) of E-RRFs from Round 2 on the Prioritization Matrix were placed in the "Important," "Not Confident" bin . Also similar to Round 1, these E-RRFs in the

highest priority bin represented all five CEA Levels. Moreover, all E-RRFs (100%) on the Matrix within the Environmental Transport and Transformation & Fate CEA Level were in this highest priority bin (compared with 90% for the Product Life Cycle CEA Level, 88% for Dose (Kinetics), 71% for Impacts, and 33% for Exposure Route). Compared with Round 1, there was overall a 21% increase in the prioritized E-RRFs (i.e., placed in the "Important" and "Not Confident" bin) within the Product Life Cycle CEA Level. Another notable change between Rounds 1 and 2 is that the percentage of participants rating prioritized E-RRF pairs as "Important" and "Not Confident" decreased overall (i.e., the percentage of total E-RRFs in the Important/Not Confident bin). After Round 2 results were available to participants, they were then requested to review and consider the full set of Round 2 results prior to attending the face-to-face workshop and completing the final round (Round 3) of the prioritization process.

A total of 13 participants attended the faceto-face workshop. At the workshop, participants

- 1. reviewed the results of the previous prioritization rounds,
- 2. discussed in a structured Nominal Group Technique (NGT) session (i.e., Round Robin) which E-RRFs should be prioritized and the rationales for each prioritization (a process in which the participants themselves found very worthwhile, as noted in the workshop evaluation),
- completed the final prioritization round (Round 3) in a similar format to Rounds 1 and 2, and then
- 4. developed detailed research questions in breakout groups for a subset of prioritized E-RRFs that resulted from Round 3.

Similar to the previous prioritization rounds, a large majority (26 out of 39, 67%) of the E-RRF pairs from Round 3 were placed in the "Important" and "Not Confident" bin of the Prioritization Matrix. Also similar to the previous prioritization rounds, all five CEA Levels were represented in this highest priority bin; although CEA Levels of Product Life Cycle, Environmental Transport, Transformation & Fate, Dose (Kinetics), and Impacts each had a majority of their on-Matrix E-RRF pairs in the "Important" and "Not Confident" bin (70%, 89%, 75%, and 60%, respectively). One noticeable change between Rounds 2 and 3 was that there was a 31% decrease in the E-RRFs placed in the highest priority bin within the Dose (Kinetics) CEA Level and 21% decrease for Environmental Transport, Transformation & Fate CEA Level (also a decrease of 14% for Product Life Cycle). This is related to the fact that the overall percentage of participants rating prioritized E-RRF pairs as "Important" and "Not Confident" generally decreased between Rounds 2 and 3-a trend also observed between Rounds 1 and 2-which may have been an effect of participants reviewing the results from Round 2 and incorporating the opinions of others into their thought processes prior to CEA Prioritization Round 3.

From the results of Round 3, the 15 most agreed upon prioritized E-RRFs were identified. Overall, these 15 prioritized E-RRFs fell within the areas of human health and generally focused on aspects related to

- 1. release rate of MWCNT (in product manufacturing, use, disposal/recycling, and material processing),
- 2. persistence (in air, wastewater, sediments),
- 3. mobility (in wastewater, air), and

4. behavior in the human body (inhalation, absorption, metabolism, excretion).

The rationales behind the prioritization of each of the 15 E-RRFs by participants largely related to a lack of data or insufficient analytical methods for quantifying MWCNT; the importance of the prioritized E-RRFs for assessing various exposures to MWCNTs for workers, consumers, and the environment; or the importance for determining other risk parameters related to various aspects of exposures and impacts (e.g., degradation, persistency, release, distribution).

Four breakout groups then developed specific, detailed research questions for these 15 most agreed upon prioritized E-RRFs and illuminated the connections between the priority research, the types of assessments this research would support (e.g., human health risk assessment, ecological risk assessment, life cycle assessment), and ultimately, the risk management decisions those assessments would inform. These four breakout groups generated a total of 45 specific, detailed research questions that were framed within a given risk scenario for each of these E-RRFs. Across all 15 prioritized E-RRFs, the generated research questions largely focused on

- 1. understanding impacts to human health from inhalation of MWCNT;
- 2. understanding the release of MWCNT;
- 3. understanding the material properties of MWCNT that related to exposure;
- 4. analytical methods of detection, characterization, and quantification of MWCNT in the environment and within the body; and
- 5. understanding the fate and behavior of MWCNT in various environmental matrices.

Additional information pertaining to the research-to-risk management continuum was developed for each of the detailed research questions generated by the breakout groups.

Apart from the results generated through the prioritization rounds described above and as exemplified in this report, this process of applying CEA in this application has also resulted in the

- 1. strategic linkage between research planning, risk assessment, and risk management;
- 2. systematic integration and structuring of complex information;
- engagement of diverse perspectives to inform near- or long-term risk management efforts; and
- 4. support of holistic, sustainable risk assessment and subsequent risk management efforts.

In addition to the positive outcomes of this prioritization process, there have also been a number of challenges to this application of the CEA approach. One of these has been obtaining active participants in the prioritization process, despite a number of offered incentives to participate. This is most likely due to the time- and energyintensive nature of this CEA application. An additional challenge in the process has been the "user friendliness" of the developed CEA MWCNT Prioritization Tool. In these regards, future applications of this process may benefit significantly through the development of online, web-enabled collective judgment tools. This would also allow a large number of diverse stakeholders to participate in the prioritization process. The use of online, web-enabled collective judgment tools may also potentially eliminate many costs and impacts of travel, and would be able to more easily incorporate a range of international participants if desired.

Finally, as emerging technologies and materials continue to develop at an everincreasing pace, including the use of ENMs in a wide range of products and applications, it is becoming increasingly important to develop meaningful ways to engage a wide range of stakeholders to help identify priority research areas that, if funded, would help inform risk management decisions in both the near and long terms. This application of CEA, which focused on the use of MWCNT in flame-retardant coatings applied to upholstery textiles, is one such application of a collective judgment approach that applied a structured prioritization process in order to elicit specific, detailed research questions from a diverse group of experts. Future applications of CEA applied to other emerging materials, including ENMs, may benefit from a reflection on some of the successful results generated from this application as well as other "lessons learned" from some of the main challenges described herein.

1. Comprehensive Environmental Assessment (CEA) Approach

Managing environmental and human health risks is supported by iterative communication between research planning, risk assessment, and risk management efforts. More specifically, strategically planned and prioritized research efforts can allow for more efficient and better informed decision making, especially in areas with large knowledge gaps. The CEA approach is one method to achieve this type of decision making for environmental and human health risks (Powers et al., 2012). In brief, CEA structures information and draws insight from diverse perspectives on priority areas for consideration in risk assessments and the associated state of the science for these areas. Moreover, the CEA approach utilizes both a *framework* for systematically organizing complex information and a *process* that uses collective judgment to engage diverse stakeholders in evaluating such information.

This report details the methods and outcomes of engaging diverse, expert stakeholders in CEA to identify research priorities that, if carried out, could inform assessing and managing potential risks of multiwalled carbon nanotubes (MWCNT) in flame-retardant coatings applied to upholstery textiles. Applying CEA to MWCNT in this application follows previous efforts on nano-titanium dioxide in drinking water disinfectant and sunscreen applications (U.S. Environmental Protection Agency [U.S. EPA], 2010b) and nano-silver in a disinfectant spray (U.S. EPA, 2012c). For more information regarding the CEA approach applied to research planning in other case studies, refer to U.S. EPA (2010a, b; 2011; and 2012c).

1.1 CEA Objectives

The CEA approach can be used to identify and prioritize research to support future assessment efforts and/or to provide input to risk managers to enable decision-making for environmental and human health. In either application, the main objectives of the CEA approach include:

- Strategically linking research planning, risk assessment, and risk management;
- Integrating and systematically structuring complex information from multiple analytical techniques and approaches (e.g., life cycle assessment, risk assessment);
- Engaging diverse perspectives to inform near-term (e.g., risk trade-offs) or long-term (i.e., research gaps) risk management efforts; and
- Supporting holistic, sustainable risk assessment and subsequent risk management through prioritization

1.2 CEA Components

As noted above, the CEA approach consists of two components: a framework and a process. Details of these aspects are elaborated in the sections below. Overall, the CEA approach attempts to consider the potential health and ecological impacts of, for example, a substance or engineered nanomaterial over its life cycle, building upon other commonly used assessment types, such as life cycle analysis and aspects of traditional risk assessment (e.g., exposure assessment, hazard analysis). It uses these methods to help organize and evaluate different types of information used in research planning, risk assessment, and risk management efforts (Powers et al., 2012).

1.2.1 CEA Framework

The high-level CEA Framework is shown in Figure 1. Within this framework, the potential impacts of a given substance (e.g., MWCNT) are considered over the product life cycle (i.e., Research & Development, Manufacturing, Transport and Storage, Use, Disposal and/or Recycling). To do so, the CEA Framework encompasses downstream events from each stage of the product life cycle, including environmental fate and transformation of the product or substance, including its transport in the environment (taking into account various physical, chemical, biological, and social environmental conditions) and through various environmental media (air, water, sediment, soil). The CEA Framework also covers exposure-dose relationships in various receptors, including humans, other biota, and abiotic resources (e.g., natural features, structures, painted surfaces). Finally, the impacts of the product or substance are included, such as its impact on health, the environment, or other areas (e.g., aesthetic, energy, ethical-legalsocial dimensions). This detailed consideration of downstream events that can take place over a product's life cycle is one of the features of CEA that distinguishes it from many other life cycle-based assessment approaches. For example, CEA focuses not only on material and energy flows associated with life cycle stages, but also on subsequent events or conditions in the environment that may be important in determining how materials come in contact with organisms and other entities (U.S. EPA, 2012a).

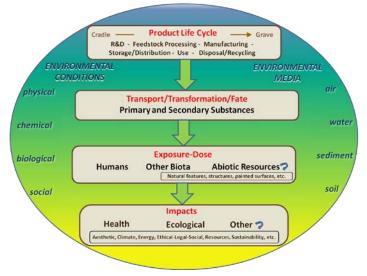


Figure 1. High-level CEA Framework.

1.2.2 CEA Process

In the CEA process, information on the substance of interest is compiled and organized according to the CEA Framework. Collective judgment techniques are then used to evaluate the information (**Figure 2**) (see U.S. EPA, 2012b for compiled and organized background information on MWCNT in flame-retardant coatings applied to upholstery textiles). Because funding and time are limited resources, prioritizing critical research needs inherently requires addressing some research gaps and holding back on others; a collective judgment *prioritization process* facilitates drawing insight from diverse perspectives to inform decisions about important research foci. Collective judgment techniques used in the CEA process rely on a structured

process to allow the interaction of a wide variety of technical and stakeholder perspectives in order to discuss and learn from each other. Importantly, the structured format allows stakeholders to arrive at their own independent judgments when prioritizing information gaps or risk trade-offs; these judgments are then reflected in the final outcome of the collective judgment step. The outcome of the collective judgment process is a list of prioritized information gaps (i.e., research priorities) or risk trade-offs. The prioritized information gaps or risk trade-offs can then be used in planning research or developing adaptive risk management plans, respectively. The knowledge gained from these research and risk management activities feeds back in an iterative process of periodic CEA updates. Note that the process summarized in this report pertains to the left side of Figure 2 (research decisions), with a focus on the collective judgment step; however, it is part of the overall process of eventually informing risk management decisions (shown on the right side of Figure 2).

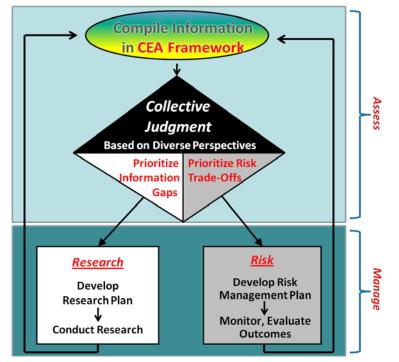


Figure 2. CEA process diagram.

1.3 Rationale for Applying CEA to Engineered Nanomaterials (ENMs)

The emerging nature of the nanotechnology field, combined with the ability to control and manipulate specific properties of ENMs, presents an opportunity to apply lessons learned from discovering unintended consequences of "revolutionary" technologies (e.g., asbestos, MTBE) (Hansen et al., 2008; Davis, 2007). Such lessons include identifying and reducing knowledge gaps, researching early indicators of potential risk, and thinking broadly about potential impacts (Hansen et al., 2008). Applying such lessons may help avoid unintended consequences of ENMs and support their sustainable development while accounting for long-term environmental, economic, and social impacts. CEA is well suited for application to the uncertain and still-developing area of ENMs based on the following points:

- CEA identifies research gaps that would inform future assessment and risk management efforts. While there is a wealth of research that could enhance knowledge and use of ENMs, only a subset of that research will ultimately support decisions about environmental health and safety (EHS) aspects. The ENM-related EHS research that has emerged over the past decade, along with lessons learned from the advent of previous "revolutionary" technologies, indicates the potential for some negative impacts. These types of issues are key to future risk management decisions but are often overlooked for various reasons (Grieger et al., 2010), including, for instance, "silos" of information between technical or sector areas (e.g., government, academia, industry) that often experience minimal communication between themselves (Hansen et al., 2008). The CEA process organizes existing information using the CEA Framework and provides a starting point for consideration of what is missing and what may be important.
- **CEA engages diverse participants in a structured format.** The interdisciplinary and trans-sector nature of nanotechnology suggests that efforts to identify key research areas to support future risk management decisions will require balanced input from across the multitude of perspectives involved in the field. Moreover, evidence indicates that, particularly in instances of high uncertainty, the inclusion of diverse perspectives may result in more accurate conclusions (Page, 2007). Notably, engaging diverse perspectives requires a dedicated effort from participants to approach the process as a collaborative one in which the input of others is thoughtfully considered and taken into account throughout the process.
- **CEA focuses on prioritization.** Numerous EHS knowledge gaps exist with respect to ENMs due to the paucity of available data (Grieger et al., 2009). Prioritization of these knowledge gaps is required as researchers and risk managers have limited resources to devote to new research projects.
- **CEA supports broad thinking about trade-offs.** Future risk management decisions for ENMs will likely require the evaluation of trade-offs associated with using a particular ENM (e.g., MWCNT) compared with an alternative material (e.g., a conventional flame-retardant coating such as decabromodiphenyl ether, decaBDE). Such trade-offs may involve impacts that span across different human populations, ecosystems, or environmental endpoints; thus, their identification will require holistic thinking. Research planning efforts that utilize a broad approach to identify information needed to evaluate such trade-offs can lay the foundation for making future risk-related decisions at a detailed level while still maintaining the perspective offered by a holistic, systems-thinking approach.

1.3.1 CEA Applied to MWCNT

Similar to previous applications of the CEA approach to other ENMs (i.e., U.S. EPA, 2010a,b; and 2012c), CEA applied to MWCNT was based on a draft case study that was organized by the CEA Framework and focused on MWCNT in a specific application, namely, flame-retardant coatings applied to upholstery textiles (U.S. EPA, 2012b). The approach used in this case study built on previous iterations of CEA but also involved the addition of a comparative element to the draft case study document by including information on a conventional flame-retardant coating, decaBDE. It was important to frame the use of MWCNT in this case study against the traditional flame-retardant material in order to identify research priorities to inform future risk

trade-off evaluations and other relevant considerations. Another addition in this application of CEA that was specific to the process was the greater use of remote, online exercises to gather iterative input from diverse stakeholders in the collective judgment step. For this part of the CEA process, participants ranked research priorities through remote online exercises during two out of three prioritization rounds (Rounds 1 and 2). These online exercises involved the participants accessing and downloading various documents through a website prior to their prioritization rounds, as well as viewing the results of these rounds via the website prior to completing the next prioritization round (Rounds 2 and 3). After the first two rounds of prioritization were completed, an in-person workshop was conducted for participants to discuss research priorities in a face-to-face setting. That workshop included a third and final round of prioritization).

Overall, the main goal of the CEA process applied to MWCNT was to produce a list of prioritized, actionable research questions that will enable future assessments and subsequent risk management decisions for MWCNT. To do so, the collective judgment mechanism employed here was based on two key principles: (1) iterative incorporation of the collective knowledge of a diverse and balanced group of expert stakeholders representing a variety of sectors (e.g., industry, academia, government) and knowledge areas (e.g., analytical chemistry, ecology), similar to other applications of CEA; and (2) movement from a holistic perspective toward more detailed perspectives as information areas rose to the top of the prioritization process. Areas that moved to the top were those collectively identified as high priority for risk assessment efforts but that lacked adequate information for risk management decisions. Detailed, actionable research questions were then developed a subset of these areas.

This case study also provided a specific focus on clearly tying the identified and prioritized research gaps to standard risk assessment approaches and risk management efforts. For instance, one part of the workshop involved the participants working in breakout groups to focus on developing research questions. During this exercise, participants were specifically requested to provide information that tied the generation of these research questions to assessment efforts, including risk assessment and risk management needs and practices. For more information on these aspects, refer to **Sections 2.4** and **2.5.2**.

1.3.2 Collective Judgment of CEA Applied to MWCNT: Research Gap Identification and Prioritization

In line with the objectives of the CEA approach (see **Section 1.1**), the research priorities for MWCNT in flame-retardant textile coatings were developed through a collective judgment process involving a diverse and balanced group of expert stakeholders representing various sectors (e.g., industry, academia, government) and knowledge areas (e.g., analytical chemistry, ecology) (see **Figure 6** in **Section 2**). Notably, experts were not asked to act as risk assessors or risk managers, but rather to apply their expertise in addressing a particular decision problem. The following was used as the decision problem for MWCNT in flame-retardant textile coatings:

What are the detailed, specific research questions that can be actively pursued in the research community to inform research planning that supports future risk assessments and risk management efforts for MWCNT in flame-retardant coatings applied to upholstery textiles? The CEA Framework was used to structure the decision problem to elicit expert judgments regarding:

- What is the most important information relevant to understanding, and therefore managing, the most significant risks associated with MWCNT in this case study?
- What is the current state of knowledge about that information?

The research gap prioritization process for MWCNT consisted of three rounds: (1) participants entered their individual opinions in a spreadsheet and submitted it to a secure online platform (https://ceananocarbon.rti.org/Welcome.aspx), (2) participants viewed the opinions of the wider group through a series of bar charts and tables¹ available via the website and were given the opportunity to re-enter their opinions in a subsequent prioritization round, and (3) a subset of participants met face-to-face in a structured workshop setting to finalize research priorities and develop detailed research questions for a subset of priorities. The iterative nature of the process was designed to progress from holistic thinking into more detailed thinking as the process moved through these rounds of prioritization (see **Figure 3**).

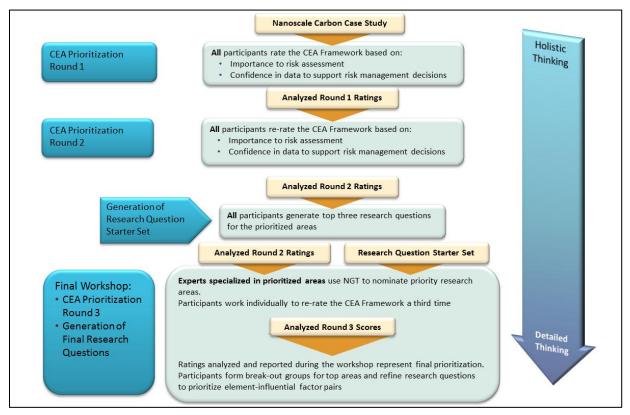


Figure 3. Overview of the CEA prioritization process used in this case study.

The CEA Framework (**Figure 1**) provided the overall structure that guided participants through each round of prioritization. **Figure 4** below shows a more detailed view of the Framework that links the high, systems-level thinking of the CEA Framework with a more granular level necessary to facilitate research prioritization for risk assessment and risk management. In

¹ Please see **Appendices D, E,** and **F** for results from Rounds 1, 2, and 3, respectively.

Figure 4, the beige bars represent the **Levels** of the CEA Framework, which correspond to the main domains depicted in **Figure 1**. As explained in more detail in subsequent sections (see **Section 2.1**), each CEA Level has a number of **Elements** (blue boxes; abbreviated as "E" in subsequent sections) that describe major areas within the Level. For each Element, there are a number of sub-levels termed **Risk Relevance Factors** (green boxes; abbreviated as "RRFs" in subsequent sections), intended to represent the different types of information that could be pertinent to understanding potential risks within the Element. Importantly, this Framework is intended to be applicable to a wide array of materials and could be used in subsequent applications of the CEA approach.

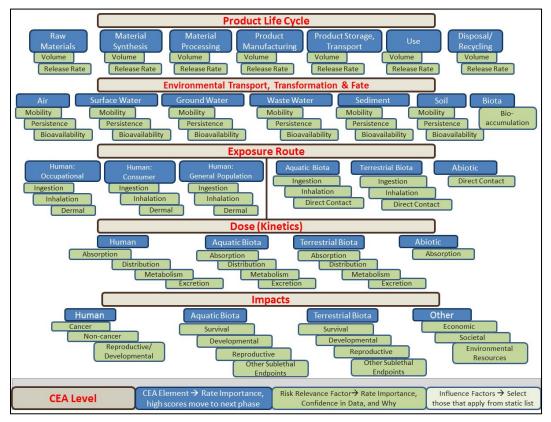


Figure 4. Detailed CEA Framework.

1.3.3 Synopsis of Prioritized Research Areas for MWCNT in This Case Study

The following is intended to serve as a synopsis of the main outcomes of the prioritization process used in this case study. Please refer to subsequent sections and appendices of this report for more information regarding the prioritization process, participating experts, methodology, and results.

For this application of CEA, the identified research priorities that resulted from the final prioritization round are represented at a high level in **Figure 5** below. In other words, **Figure 5** shows the prioritization of research areas that resulted from Round 3, based on the detailed CEA

Framework (**Figure 4**). As shown in the highlighted boxes² of **Figure 5**, these are the resulting priority research areas based on participants' ratings of Element-Risk Relevant Factor (E-RRF) pairs according to their level of "Importance" to risk assessment efforts and the current availability and utility of data to support risk management decisions ("Confidence"), whereby the most important and least confident E-RRFs were prioritized in this process. For detailed information on the distribution of participants' ratings in each area of the CEA Framework for Round 3, please refer to **Appendix F**.

As shown in **Figure 5** below, prioritized research areas fell within all CEA Levels but particularly within the Levels of Product Life Cycle, Environmental Transport, Transformation & Fate, and Impacts.

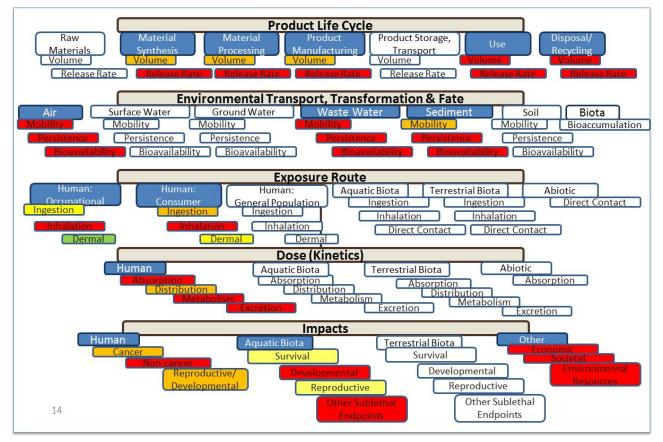


Figure 5. Final research priorities mapped to the detailed CEA Framework based on results from the final prioritization round (Round 3).

In addition, the 15 most commonly agreed upon prioritized research areas (i.e., E-RRFs that had the greatest percentage of participants rating them "Important" for risk assessment and "Not

² As described in more detail in subsequent sections (see Section 2.1), the red boxes are research areas deemed 'Important' for risk assessment and 'Not Confident' that current data can support risk management decisions based on the methodology used in the Prioritization Matrix (see Figure 8). Following a similar logic, orange boxes are research areas deemed either 'Important' and 'Somewhat Confident' or 'Possibly Important' and 'Not Confident', and a similar logic follows for the other colored boxes in the Framework (see Section 2 for more detail on this methodology).

Confident" that current data can support risk management decisions) identified from the final prioritization round (Round 3) are shown in **Table 1** below in the left column in order of agreement among participants. (See **Appendix F** for all results from Round 3, including the final distribution of E-RRF pairs over the Prioritization Matrix). The 15-most agreed upon prioritized E-RRFs were then assigned to breakout groups during the face-to-face workshop in order to develop specific, detailed research questions,³ shown in the right column of **Table 1**. In this prioritization process, the "most chosen" Importance or Confidence rating for any Element or E-RRF pair is the rating option that the participant group chose more frequently than any other rating option; thus, it is considered the group rating associated with the Element or E-RRF. The research questions developed by the breakout groups for each of these 15 E-RRFs ultimately formed the basis of the final results from the prioritization process described in this report. **Table 1** provides a synopsis of these prioritized E-RRFs and associated research questions developed by the breakout groups.

Overall, the 15 most agreed upon prioritized E-RRFs fell within the research areas of human health (as opposed to ecosystem health, for instance), and following the first E-RRF pair in **Table 1** which related to impacts of MWCNT on human health, the prioritized E-RRFs mainly focused on aspects related to 1) release rate of MWCNT (in product manufacturing, use, disposal/recycling, and material processing), 2) persistence (in air, wastewater, sediments), 3) mobility (in wastewater, air), and 4) behavior in the human body (inhalation, absorption, metabolism, excretion).

In addition, the generated research questions that were developed by the breakout groups for these 15 E-RRFs largely focused on 1) understanding impacts to human health from inhalation of MWCNT; 2) understanding the release of MWCNT; 3) understanding the material properties of MWCNT that related to exposure; 4) analytical methods of detection, characterization, and quantification of MWCNT in the environment and within the body; and 5) understanding the fate and behavior of MWCNT in various environmental matrices.

Prioritized E-RRFs	Detailed, Actionable Research Questions	Breakout Group No.
1. Human–Non-cancer	 Conduct acute and chronic rodent bioassay studies after inhalation exposure at relevant doses using well-characterized material Perform experiments to test impacts of exposure on immune- compromised individuals 	1
2. Human: Occupational– Inhalation	 Acute and chronic rodent bioassay studies after inhalation exposure at relevant doses of well-characterized material Analytical and rodent studies to examine effect of co-factors on particle size, deposition, translocation, and removal 	1
		(continued)

Table 1. Synopsis of prioritized E-RRFs from Round 3 (shown in descending order of agreement among participants) and associated research questions developed by breakout groups⁴

(continued)

³ Research questions were developed by the breakout groups in reference to specific risk scenarios. See **Appendix J** for full reports from the breakout groups, including the development of these scenarios.

⁴ The breakout groups listed these developed research questions for their assigned E-RRFs in descending order of prioritization except for Group 2, who stated that their research questions were not listed in any particular order of prioritization. The original text written by the breakout groups has been modified only in terms of correcting grammatical and spelling errors.

Table 1. Synopsis of prioritized E-RRFs from Round 3 (shown in descending order of agreement
among participants) and associated research questions developed by breakout groups
(continued)

Prioritized E-RRFs	Detailed, Actionable Research Questions	Breakout Group No.
 Product Manufacturing– Release Rate 	 What is the step in manufacturing that presents most risk of release to the environment? What is the step in manufacturing that presents most risk of occupational 	4
	 exposure? How does MWNT functionalization affect the filtration efficiency and size distribution? 	
	 How does the dispersion technique affect the filtration efficiency and size distribution? 	
4. Air–Persistence	 Develop model to predict atmospheric residence time as a function of carbon nanotube (CNT) particle characteristics quantitative structure– activity relationship (QSAR) 	2
	 Determine CNT properties and meteorological properties that increase aggregation rate and decrease residence time 	
	 Develop new methods or instruments to improve CNT quantification in air (determine number or mass of CNT/m³) 	
	Apply conventional benefit/cost analysis procedures	
5. Wastewater– Persistence	How do the degree of functionalization and changes in wastewater treatment processes affect the rate of transformation?	3
	 How to extract and characterize MWCNT from suspended and fixed biomass or treated effluent with minimal modifications to surface group, functionalization, impregnated metals, and coatings? 	
	 What are the transformation byproducts from MWCNT and flame resistant fibers? 	
6. Wastewater–Mobility	 To what extent do MWCNT surface properties and incorporation into fibers affect distribution of MWCNT between treated effluent and biosolids for different wastewater treatment plant configurations? 	3
	 Develop extraction and/or analytical techniques to quantify MWCNT of diverse origin at environmentally relevant levels in raw sewage, treated effluent, and biosolids. 	
7. Human–Absorption	 Determine particle properties that influence extent and rate of absorption across mammalian lung epithelial tissue, gastrointestinal tract luminal epithelia, and dermal layers. 	2
	 Quantify extent and rate of absorption across mammalian lung epithelial tissue, GI luminal epithelia, and dermal layers. If answer is yes then: 	
	 Maximize particle properties that decrease absorption while maintaining beneficial uses. 	
	 Rationale for this is that a group examining all three absorption processes is that you increase the potential for discovery of unique interactions among systems. While little evidence is available demonstrating dermal absorption (via abraded skin), further work should be considered because of the potential for high exposure, especially in children. 	
8. Use–Release Rate	 How do particle functionalization and matrix affect aging and release to air (use accelerated weathering test), measure quantify (number and concentration) and characterize (size distribution)? 	4
	 How do particle functionalization and matrix affect release in washing product (use mini washing machines, measure quantify (number and concentration) and characterize (size distribution)? 	

(continued)

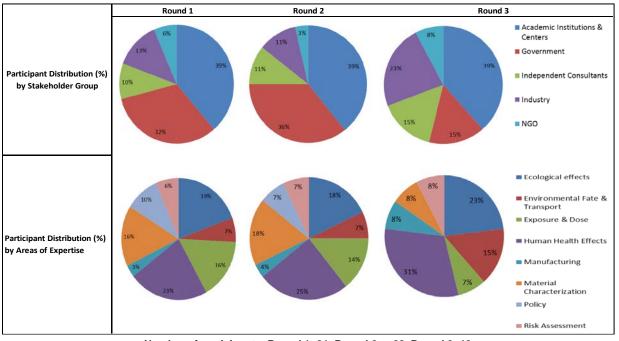
Table 1. Synopsis of prioritized E-RRFs from Round 3 (shown in descending order of agreement
among participants) and associated research questions developed by breakout groups
(continued)

Prioritized E-RRFs	Detailed, Actionable Research Questions	Breakout Group No.		
9. Disposal/ Recycling– Release Rate	 What is the airborne release rate of the MWCNT study during shredding (e.g., form, size distribution, number and mass concentration)? Survey of nano industry and municipal sewage treatment plant (STP) to gather mass of sludge/year applied to land 	4		
10. Air–Mobility	 Develop model to predict extent of mobility as a function of CNT particle characteristics (QSAR) for near-field and long-distance transport Alter CNT properties or meteorological properties to increase aggregation and decrease mobility Develop new methods or instruments to improve CNT quantification in air (determine number or mass of CNT/m³) Apply conventional benefit/cost analysis procedures 			
11. Material Processing– Release Rate	 What is occupational exposure at current MWCNT processing facilities? What is release rate in wastewater from current MWCNT processing facilities? Develop a method (instrument) to characterize and quantify MWCNT in waste liquid for monitoring What is the best method to capture/destroy CNT in waste liquid? Can CNT synthesis techniques reduce potential releases through control of initial raw CNT form? What air handling technologies can be used to reduce occupational exposure? 			
12. Human-Metabolism	 Develop analytical techniques for measuring the original MWCNT or metabolites in cells Measure the original MWCNT or metabolites in tissues after whole-body inhalation exposures 	1		
13. Human–Excretion	 Perform experiments in rodents after exposure to determine fate and clearance of MWCNT Develop tracer methodology to detect excretion by-products of the relevant MWCNT material 	1		
14.Disposal/ Recycling– Volume	 How much volume of CNTs is used in upholstery? How much volume of CNTs is lost from upholstery during life span? How much volume of CNTs is lost via destruction (e.g., burning), recycling, reuse, litter, or disposal in landfill? 	2		
15. Sediment– Persistence	 How does the degree of functionalization/changes in sediment affect the rate of transformation? How to extract and characterize MWCNT from sediment with minimal modifications to surface group, functionalization, impregnated metals, and coatings? What are the transformation by-products from MWCNT and flame-resistant fibers? 	3		

2. CEA MWCNT Prioritization Process

This CEA collective judgment prioritization process for MWCNT was designed for participants to rate components of the CEA Framework in a way that allows independent input from a theoretically unlimited number of stakeholders representing expertise in a wide range of technical and sector areas relevant for the case study. Participants completed Rounds 1 and 2 of prioritization remotely, which allowed input to be gathered from relatively large groups of stakeholders. Group consensus was not the goal of the process; rather the participants rated priority areas via individual exercises. Between prioritization rounds, they reviewed and considered the collective responses of the group, incorporated those views into their own as they saw fit, and carried out the subsequent round of prioritization with this potentially new view. Between the first two rounds of prioritization, this sharing of collective views took place by viewing reports of rating scores remotely (i.e., via online, remote access), and between the second and third rounds, this review took place remotely as well as during a face-to-face workshop. Thus, outcomes of the collective judgment step of the CEA process (**Figure 2**) represent the judgment of all stakeholders participating in a given round, with each participant having equal, independent input.

Participants in this process represented a wide range of stakeholder groups and areas of expertise (**Figure 6**). Although many of these areas of expertise pertain to multiple parts of the CEA Framework, some of them represented targeted subject-matter expertise that aligned particularly well with specific research areas within the CEA detailed Framework. See **Appendix B** for more information regarding the participants and their selection in the prioritization rounds.



Number of participants: Round 1: 31, Round 2: = 28, Round 3: 13

Figure 6. Distribution of participants within stakeholder groups and areas of expertise in prioritization rounds.

As mentioned in the previous section, this application of CEA was largely based on a prioritization process in which participants started with holistic thinking and then moved through the process into more detailed thinking (see **Figure 3**). The entire process was built on the concept of individual input from participants, iteratively informed by sharing of information. Rather than aiming for a group consensus, the participants rated priority areas via individual exercises. Between prioritization rounds, they reviewed and considered the collective responses of their co-participants, incorporated those views into their own as they see fit, and carried out the subsequent round of prioritization with this potentially new view.

2.1 CEA MWCNT Prioritization Tool Rating Process

In each round of prioritization, participants used a spreadsheet tool (entitled "CEA MWCNT Prioritization Tool") to rate components of the detailed CEA Framework (Figure 4) (see Appendix K for more details on the Prioritization Tool and other materials developed for participants in the prioritization process). For each CEA Level, the participants rated the importance of each Element⁵ (shown in blue in **Figure 4**; e.g., Raw Materials, Air) as "Important," "Possibly Important," or "Least Important" to consider in assessing the risk of MWCNT as used in flame-retardant coatings applied to upholstery textiles. For the Elements rated as "Important," the participants then rated the corresponding E-RRFs,⁶ shown in green in Figure 4 (e.g., Raw Materials – Volume, Raw Materials – Release Rate, Air – Mobility, Air – Persistence) according to how important the pair is to consider in assessing risks, and they rated their confidence ("Confident," "Somewhat Confident," or "Not Confident") in the availability and utility of current data to support risk management decisions. For each E-RRF pair rated "Important" and "Not Confident," "Important" and "Somewhat Confident," or "Possibly Important" and "Not Confident" (i.e., areas in the top right of the Prioritization Matrix, see Figure 8 below), the participants were then asked to select which Influential Factors⁷ (listed in Appendix A) might influence the potential risk of the E-RRF pair and to explain their selection ("why"?). See **Figure 7** for a schematic representation of the rating process used in the Prioritization Tool. Each rating supported the transition from a holistic evaluation of broad areas of the CEA Framework toward areas that are highly prioritized and require the gathering of more details (i.e., Element to E-RRF to Influential Factors and "why" associated with an E-RRF).

⁵ CEA Levels are divided into discrete Elements. Each Element describes a separate and distinct pathway within that Level for a material through its life cycle ("from cradle to grave").

⁶ The Elements of the CEA Levels may be important to understand the risks posed by a material for a variety of reasons. The RRFs associated with an Element are intended to capture more specific reasoning behind a participant's designation of a given Element as important to understanding risk.

⁷ For a given case study, some of the CEA Levels, Elements, and Risk Relevance Factors will be of elevated importance to understanding risk; identifying these is part of the goal of the process. Another goal is to determine the rationale behind their stated importance. The Influential Factors help identify the aspects of a particular portion of the CEA Framework that need to be understood. Influential Factors include characteristics of (1) the material itself, (2) the methods and techniques related to the material, (3) its surrounding environment, and (4) associated behaviors and relationships. Participants selected from a list of Influential Factors unique to MWCNT to indicate what aspects of the material may influence the potential risk associated with an Element-Risk Relevance Factor (E-RRF) pair.

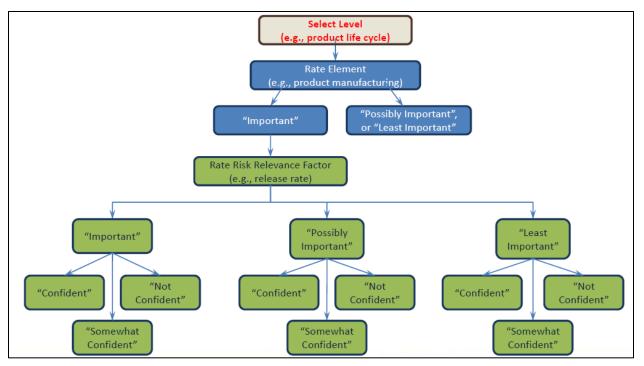


Figure 7. Overview of rating process used in CEA MWCNT Prioritization Tool.

The E-RRF pairs were then grouped into categories of similar importance and confidence in existing data in the Prioritization Matrix (**Figure 8**). The red box in the matrix represents the highest importance and lowest confidence. The orange boxes represent either a high level of importance paired with a medium level of confidence or a medium level of importance paired with a low level of confidence. Green boxes represent lower levels of importance and greater confidence. Within the matrix, the E-RRF pairs associated with the red box were the most highly prioritized for future research on MWCNT in flame-retardant coatings applied to upholstery textiles. More information on the Prioritization Matrix is provided in **Section 3.1**.

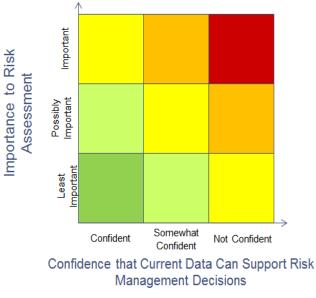


Figure 8. Prioritization Matrix.

As described at the beginning of **Section 2**, the overall process entailed three rounds of prioritization (see **Figure 3**). Each round of prioritization is discussed in more detail below.

2.2 CEA Prioritization Round 1

The first round was carried out remotely by 31 participants, who reviewed a draft case study document with extensive, up-to-date scientific literature on MWCNT and decaBDE flame-retardant coatings applied to upholstery textiles (U.S. EPA, 2012b). Participants then completed the rating process as described above using the CEA MWCNT Prioritization Tool.

The Round 1 ratings were analyzed with the objective of providing participants with input from perspectives other than their own. The methodology to analyze Round 1 results is further described in **Appendix C**. Round 1 results along with instructions for interpreting the results were made available for participants to download from a secure, password-protected website developed to support this process. Individual results were also sent to each participant via email so they could compare their own responses with those of the group and view the results according to participants' sectors and areas of expertise. See **Section 3.4** for a summary of the ratings results of CEA Prioritization Round 1. Participants were asked to review and consider the outputs from the Round 1 analysis prior to starting CEA Prioritization Round 2.

2.3 CEA Prioritization Round 2

After reviewing and considering the results of the group as a whole from CEA Prioritization Round 1, all participants repeated the prioritization exercise based on the CEA Framework similar to Round 1. The purpose of the second round of prioritization was to capture any changes in participants' ratings after they had reviewed the ratings of their peers with perspectives that might differ from their own. Participants again used the CEA MWCNT Prioritization Tool to perform the rating process. In total, 28 participants⁸ successfully completed Round 2 by returning a completed version of the CEA MWCNT Prioritization Tool. Results from Round 2 were analyzed using the same method used for Round 1 (see **Appendix C**). Refer to **Section 3.5** for a summary of the results of CEA Prioritization Round 2.

2.4 Generation of Starter Research Questions

After Round 2, all participants received the collective results of the CEA Prioritization Round 2, along with their own individual responses. As part of completing a set of Charge Questions⁹ issued by EPA to elicit feedback on the draft case study document and the prioritization process described in this report (see **Appendix H** for all details related to the Charge Questions), participants were asked to develop three research questions that they thought were most important to pursue for one or more of the priority E-RRF pairs identified in Round 2. Out of the 28 participants who completed Round 2, only 24 participants completed and submitted the Charge Questions. For a full listing of these research questions submitted by participants, see **Appendix I**. The participants were given specific guidance on the development of research questions (see **Appendix J**).

⁸ Three participants from Round 1 chose not to participate in Round 2; thus, Round 2 had only 28 participants.

⁹ See Appendix H for more information on the Charge Questions issued by EPA.

The three research questions submitted by each participant were then aggregated to identify questions that were essentially duplicates. Accounting for duplicates, the 24 participants submitted a total of 72 separate research questions (see **Appendix I**). This aggregated list of research questions formed what is hereafter referred to as the "Starter Research Question Set," intended for utilization during the next step of the collective judgment process, a face-to-face workshop. For this, each Starter Research Question submitted by participants was then assigned to the most appropriate corresponding E-RRF pair for utilization in breakout group activities at the workshop. Soliciting research questions after CEA Prioritization Round 2 allowed all participants, including those who did not ultimately attend the face-to-face workshop, to have input in detailed research question development. In addition, beginning the breakout group sessions during the workshop with a Starter Research Question Set provided a starting point for the breakout groups, which helped avoid issues with "starting from scratch" in order to ultimately develop these research questions.

2.5 Final Workshop

The original target workshop size was 25 participants based on optimal NGT group size (e.g., Cooke and Probst 2006; Aspinall 2010) and budget considerations. Invited participants were chosen according to their areas of expertise and sectors to ensure a wide distribution of participant sector affiliation and to align technical expertise with the prioritized research areas identified after Round 2. Specifically, in order to ensure that the development of detailed, actionable research questions was undertaken by those with the appropriate expertise, the E-RRFs assigned to red and orange boxes of the Prioritization Matrix based on the results of Round 2 determined who among the participants in Round 2 were invited to attend the face-to-face workshop. Some areas of expertise align clearly with an E-RRF or group of E-RRFs (e.g., ecological effects with the CEA Levels "dose" and "impacts"; manufacturing with the CEA Level "product life cycle"), while others (e.g., policy, risk assessment, material characterization) were considered pertinent to all areas of the CEA Framework. For further detail on the selection of the subset of participants to attend the face-to-face workshop, see **Appendix B**.

The number of participants included in the final workshop was informed by previous experiences with the most favorable group size for the particular collective judgment process being employed. Based on the literature, there is general agreement that the number of experts needed lies somewhere between 6 and 15. Specifically,

- A fairly recent informal survey (Walker, 2004; U.S. EPA, 2009) that was based on 38 studies found that almost 90% of the studies employed 11 or fewer experts. Nearly 60% of the studies relied on 6–8 experts and the largest number of experts used in any of the studies was 24 (U.S.EPA, 2009).
- Aspinall's experience with more than 20 panels suggests that 8–15 experts is a viable number and that bringing more experts together will not change the findings significantly but will incur greater expense and time (Aspinall, 2010).

Because only 28 participants successfully completed CEA Prioritization Round 2, all of these participants were invited to participate in the face-to-face workshop in order to obtain a target of approximately 25 participants. In practice, however, a total of 13 participants attended the face-

to-face workshop in order to complete Round 3 of the prioritization process. For a discussion of retention limitations to the workshop, see **Section 4**.

The workshop was held October 29–31, 2012, at EPA's campus in Research Triangle Park, NC. At the workshop, the participants first reviewed the results from CEA Prioritization Round 2. Then, a collective judgment process known as NGT was employed to facilitate each participant having equal input in influencing the final set of research priorities. A portion of the NGT is a Round Robin method (Van de Ven and Delbecq, 1972), where each expert is allowed a set time limit (e.g., 3 minutes) to share their nominated high priority E-RRF (or alternatively, nominate a high priority E-RRF for exclusion) and support the nomination with reasons, including associated Influential Factors where appropriate. The 13 participants presented their reasons to one another, one at a time, in 3-minute time slots with three rounds of nominations proceeding in the same order each time, resulting in a final set of 38 nominated E-RRFs to be promoted and 1 E-RRF nominated to be excluded (see **Figure 10** below). After this process of hearing each other's verbal, in-person cases for the nominated E-RRFs, participants worked individually to complete CEA Prioritization Round 3 on laptops during the workshop.

2.5.1 CEA Prioritization Round 3

To make the process of re-rating the detailed CEA Framework time efficient and to ensure that all Round 3 prioritization spreadsheets were completed, participants were encouraged to rate all areas as in previous rounds but to enter reasons "why" and select the Influential Factors only when they felt that these factors were especially pertinent to their reasoning.

Round 3 ratings were then analyzed by the same method as previous rounds (see **Appendix C**) and were shared with participants at the workshop on Day 2. A subset of prioritized E-RRF pairs (15 most agreed upon prioritized pairs) from this final round formed the basis for the detailed breakout group work during the workshop. Refer to **Appendix F** for all details related to Round 3 results.

2.5.2 Generation of Final Research Questions

Breakout groups addressed in detail the 15 most agreed upon prioritized E-RRF pairs (i.e., the largest percentages of participants rated the area as belonging in the upper right of **Figure 8**).¹⁰ The purpose of addressing these areas in breakout groups was to generate actionable research questions and to illuminate the connections between priority research, the types of assessments this research would support (e.g., human health risk assessment, ecological risk assessment, life-cycle assessment), and ultimately, the risk management decisions those assessments would inform. The cut-off number of 15 E-RRF pairs was based on the choice to limit the number of participants per breakout group so that each participant would have the chance to offer their insight, as well as the choice to assign no more than three or four E-RRF pairs to a group. Since there were a total of 13 participants at the workshop, four breakout groups were formed (i.e.,

¹⁰ To rank the E-RRF pairs in order of most prioritized to least prioritized, boxes of the same color were considered together. Within one color group of the boxes, the percent of participants who selected that Importance rating was added to the percent of participants who selected that Confidence rating in Round 3 of prioritization. See **Appendix C** for more details on this methodology.

three groups with three participants and one group with four participants, see **Table J-4** in **Appendix J**).

Participants were assigned to breakout groups after the final E-RRFs were determined via CEA Prioritization Round 3 on Day 1 of the workshop. The participants were grouped according to their area of expertise whereby, for example, experts in human health effects were grouped together and assigned E-RRFs within the fields of human health effects (i.e., Human – Non-cancer) in order to generate detailed, specific research questions during the breakout group sessions.¹¹ In other words, workshop participants and highly prioritized E-RRF pairs were divided into breakout groups based on grouping participants' areas of expertise to the most agreed upon highly prioritized 15 E-RRF pairs (**Table J-4** in **Appendix J**).

For each E-RRF pair, the participants were provided guidance in order to help them create detailed, actionable research questions that could answer the following question: "What are the detailed, specific research questions that can be actively pursued in the research community to inform research planning that supports future risk assessments and risk management efforts for MWCNT flame-retardant coatings applied to upholstery textiles?" Participants were guided towards the development of research questions that should support the CEA process (i.e., developing a research plan, conducting research, compiling new information in the CEA Framework, and informing future risk management efforts) for MWCNT as used in flame-retardant coatings applied to upholstery textiles research areas that may help answer the question, or clearly translates into directly testable research hypotheses. In addition to these concepts, participants were provided the following list of guidelines for drafting research questions that would help search out and address blind spots and gaps in scientific knowledge. More specifically, research questions should¹²:

- Be answerable through a realistic research design;
- Have a factual answer that does not depend on value judgments;
- Address a highly prioritized research area for future risk assessment and risk management of MWCNT (i.e., an E-RRF, associated Influential Factors, and reasoning);
- Be of a spatial and temporal scope that reasonably could be addressed by a research team;
- Not be answerable with "it depends";
- Not be answerable by "yes" or "no"; and
- If related to impact(s) and intervention(s), contains a subject, an intervention, and a measurable outcome.

One of the most important goals of the workshop was to move beyond a simple listing of research questions in order to connect calls for research with the implications that the resulting knowledge could have for supporting assessments (e.g., risk, life cycle) and ultimately for

¹¹ To ensure the opportunity to be flexible and efficient in optimizing the grouping of E-RRF pairs as well as the assignment of participants to address these groups, decisions were made on-site, as opposed to being prescribed ahead of time.

 ¹² Adapted from W.J. Sutherland et al.'s 2011 paper in *Methods in Ecology and Evolution*, "Methods for collaboratively identifying research priorities and emerging issues in science and policy."

supporting subsequent risk management decisions. With this linkage in mind, the breakout groups were provided with a template to lead them through the research-to-risk management continuum (**Figure 9**). See **Appendix J** for the template used during the breakout group sessions.

The template suggested that participants begin by identifying potential risk scenarios associated with their assigned E-RRFs, followed by potential risk management decisions that might mitigate or address these scenarios, then potential assessments that could be carried out to inform the risk management decisions, and finally research questions that could be asked to generate the necessary data to inform those assessments. On the final day of the workshop, breakout groups reported their work in a presentation format, including the detailed, actionable research questions and the completed research-to-risk management continuum template (see **Appendix J** for results from breakout groups and **Appendix L** for breakout group presentations, along with all workshop presentation slides).



Figure 9. Relationships between research, risk assessment, and risk management.¹³

¹³ Note that this was used specifically during breakout group sessions in order to build out scenarios in which potential risks related to MWCNT might need to be managed; thus, the overall goal, to manage such a potential risk, was the starting point. Next, group members worked collaboratively to develop possible risk management decisions and assessments that could be carried out for the scenario. For each risk management and assessment pair, group members then focused on developing detailed, specific research questions that could later be fed into (standard) assessments such as risk assessment and later used by risk managers, etc.

3. CEA MWCNT Prioritization Tool Outputs and Analytical Results

After Rounds 1 and 2 of the CEA Prioritization Process, several types of analytical reports were distributed to the participants for review and consideration. The ability of individuals to understand and consider the expert judgments of their peers is critical to implementing the collective judgment aspect of CEA. Because participation was remote for Rounds 1 and 2 of prioritization, this information was conveyed via a series of reports capturing the ratings and opinions of each participant, organized in a variety of formats to answer a variety of anticipated questions regarding the judgments of participants within different areas of expertise and various sectors. These included individualized reports for each participant and several group-wide and sub-group reports. Each type of report is described briefly below, followed by results from CEA Prioritization Round 1, Round 2, and Round 3, in **Sections 3.4, 3.5**, and **3.7**, respectively.

3.1 CEA Prioritization Matrix

The Group-wide Importance/Confidence Matrix allowed participants to identify how each E-RRF pair was most frequently rated by all participants by displaying a matrix with nine cells into which E-RRF pairs were binned (see Figure 8). Only E-RRF pairs whose parent Element's most chosen Importance rating was "Important" were included on the Matrix.¹⁴ The horizontal axis of the matrix defines an E-RRF's most chosen Confidence rating, and the vertical axis defines an E-RRF pair's most chosen Importance rating. Both axes have three values ("Important," "Possibly Important," and "Least Important" for Importance; "Confident," "Somewhat Confident," and "Not Confident" for Confidence). It should be noted that while this prioritization process aimed at identifying the E-RRFs that were most chosen by expert participants through the prioritization rounds (i.e., the red cell, with the most "Important" and least "Confident" E-RRF pairs), E-RRFs in other cells of the Prioritization Matrix may also be important for other stakeholder groups. For instance, other stakeholder groups such as organizations or risk managers may also be interested in reviewing the E-RRFs in other cells of the Prioritization Matrix, particularly including those that fall within the "Important" and "Confident" cell (i.e., upper left-hand corner of the Prioritization Matrix), indicating that some E-RRFs are important and experts are confident (as opposed to not confident) that the current data can support risk management decisions.

3.2 Group Bar Charts

Three types of bar charts were produced to analyze the results of a round of prioritization. First, the *Group-wide Element Importance Stacked Bar Chart* allowed participants to see the distribution of Importance ratings within each Element. For each Element, a vertical bar

¹⁴ The "most chosen" Importance or Confidence rating for any Element or E-RRF pair is the rating option that the participant group chose more frequently than any other rating option. In case of a tie, the highest priority rating (i.e., closest to the upper-right corner of the Prioritization Matrix; Figure 8 in Section 2.1) involved in the tie is "most chosen." For example, if at least 10 of 20 participants rated an Element as "Important," its "most chosen" Importance rating is "Important." Only the 10 participants who rated the Element as "Important" continue to rate the Element's E-RRF pairs. If at least 4 of those 10 participants rated one of the Element's E-RRF pairs as "Important" while 3 chose "Possibly Important" and 3 chose "Not Important," that E-RRF pair's "most chosen" Importance is "Important" (even though it is not a majority). The same logic applies to the "most chosen" Confidence rating for E-RRF pairs. The "most chosen" Importance and Confidence ratings for an E-RRF pair defined in this manner are used to locate the pair on the Prioritization Matrix.

consisting of up to three smaller bars represents the percentage of total participants choosing each Importance rating option ("Important," "Possibly Important," and "Least Important"). Participants could find Elements for which "Important" was the most chosen response and examine the relative size of the stacked bars within each Element in order to assess general consensus and dissent for rating Element Importance.

Second, the *Group-wide CEA Level-Specific Bar Charts* allowed participants to more closely evaluate the differences between their personal responses in their *Participant Specific Table* and the *Group-wide Prioritization Matrix*. These charts display a bar for each Element from a specific CEA Level and two bars for each E-RRF pair within those Elements—one for Importance and one for Confidence. Participants could compare the small bars within each bar in order to identify how much general consensus or dissent existed in the ratings.

Finally, the *Expertise-specific, CEA Level-specific Bar Charts* and *Sector-specific, CEA Level-specific Bar Charts* provided additional detail by further dividing the CEA Level-specific Bar Charts by an Expertise (e.g., manufacturing, material characterization) or Sector group (e.g., industry, academia). These charts allowed participants to look for areas of agreement/disagreement across Expertise and Sector groups, to examine how people with different expertise or who work in different sectors responded during a round of prioritization, and to develop interest in understanding why key differences and similarities might exist based on the perspectives of others.

3.3 Individual and Group Exhaustive Tables

Results pertaining to individual participants' results were displayed in a Participant-specific Table, which allowed participants to privately review their individual responses for each Element and E-RRF pair as a way to recall their thought processes from a round of prioritization. The layout of this table mimics the design of the CEA MWCNT Prioritization Tool in order to help participants recall the reasons why they rated Elements and E-RRF pairs the way they did and which Influential Factors they chose. Participants were instructed to focus on the "Why" field of the table and compare their responses with the Group-wide Prioritization Matrix (see Section 3.1). The Group-wide Table (without Influential Factors) allowed participants to inspect the anonymous "Why" responses of other participants to identify the underlying rationales responsible for the group's responses, responses for specific expertise or sector groups, and similarities and differences among them. Participants could also inspect the "Why" field to identify differences between their personal rationales from the Participant-specific Table with other reasons from the group. This table exposes participants to the ideas of others so that they may consider them in their own thought process. Finally, the Group-wide Table (with Influential Factors) allowed participants to examine which Influential Factors were selected for E-RRF pairs of interest.

3.4 Round 1 Prioritization Results

This section summarizes the group-wide results of CEA Prioritization Round 1, for which 31 participants completed and submitted the CEA MWCNT Prioritization Tool (described in **Section 2.2**). Refer to **Appendix D** for all other results from Round 1 as reviewed by participants.

As shown in **Table 2**, a large majority (34 out of 43, 79%) of the E-RRF pairs on the CEA Prioritization Matrix from Round 1 were placed in the "Important," "Not Confident" bin (refer to **Appendix D** for an overview of all the E-RRFs across the Prioritization Matrix for Round 1). In addition, both the Environmental Transport, Transformation & Fate CEA Level and Dose (Kinetics) CEA Level had a majority of their total E-RRF pairs (including those not on the Matrix¹⁵) grouped into this bin of the CEA Prioritization Matrix.

CEA Level	No. E-RRF Pairs on Matrix/Total No. E-RRFs	No. E-RRFs in I-NC Bin	Total E-RRFs (%) in I-NC Bin	% on Matrix E- RRFs in I-NC Bin
Product Life Cycle	10 / 14	6	43%	60%
Environmental Transport, Transformation & Fate	13 / 19	13	68%	100%
Exposure Route	6 / 16	2	13%	33%
Dose (Kinetics)	8 / 13	8	62%	100%
Impacts	7 / 14	5	36%	71%

Table 2. Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC)on Prioritization Matrix for Round 1

Table 3 presents the percentage of participants that rated each E-RRF pair as "Important," "Not Confident." This percentage varies widely among the E-RRF pairs, indicating that the E-RRFs in the "Important" and "Not Confident" bin may not be considered equal research priorities by the participant group as a whole and that some will stand out as relatively higher research priorities compared with others. For example, within the Impacts CEA Level for the E-RRF pair Human-Cancer, 82% of participants rated this pair "Important" and 57% of participants rated this pair "Not Confident." However, within the same Level but for the E-RRF pair Aquatic Biota-Reproductive, only 32% and 36% of participants rated the pair "Important" and "Not Confident," respectively. Even though both of these E-RRF pairs resulted in the "Important," "Not Confident" (i.e., red) bin, significantly more participants rated the first pair as "Important," "Not Confident" than the second pair. Overall, many of the E-RRF pairs were categorized into the "Important," "Not Confident bin even though for some E-RRF pairs only a relatively small percentage of the total number of participants rated the pair this way. The summations of the percentage of participants who ranked the E-RRF pair as "Important" and "Not Confident" are shown in the right column of Table 3 (Note: this information was not used in Round 1 but used later in Round 2 and Round 3 results in order to identify the most prioritized E-RRFs). See Appendix C for further details.

Participants reviewed the results of Round 1 (see **Appendix D**) prior to completing the CEA Prioritization Round 2 in order to incorporate the responses of other participants into their thought process during Round 2.

¹⁵ Only E-RRF pairs whose parent Element's most chosen Importance rating was "Important" were included on the Matrix. See Section 3.1 for more information regarding this aspect of the prioritization process.

"Not Confident" (NC) bin for Round 1								
Element (E)	Risk Relevance Factor (RRF)	"Important" Rating (% of participants)	"Not Confident" Rating (% of participants)	Total (∑ Importance% + Confidence%)				
Product Life Cycle	Product Life Cycle							
Material Synthesis	Release Rate	61%	36%	97				
Product	Volume	71%	36%	107				
Manufacturing	Release Rate	75%	39%	114				
Use	Volume	61%	32%	93				
	Release Rate	64%	46%	110				
Disposal/Recycling	Release Rate	61%	39%	100				
Environmental Tran	sport, Transformat	ion & Fate						
Air	Mobility	86%	61%	147				
	Persistence	61%	54%	115				
	Bioavailability	64%	68%	132				
Surface Water	Mobility	43%	21%	64				
	Persistence	36%	21%	57				
	Bioavailability	36%	29%	65				
Wastewater	Mobility	61%	36%	97				
	Persistence	54%	36%	90				
	Bioavailability	39%	43%	82				
Soil	Mobility	25%	29%	54				
	Persistence	43%	25%	68				
	Bioavailability	43%	32%	75				
Biota	Bioaccumulation	46%	29%	75				
Exposure Route								
Human: Consumer	Ingestion	39%	43%	82				
	Inhalation	57%	39%	96				
Dose (Kinetics)			1					
Human	Absorption	86%	68%	154				
	Distribution	79%	68%	147				
	Metabolism	54%	75%	129				
	Excretion	71%	71%	142				
Aquatic Biota	Absorption	43%	25%	68				
	Distribution	43%	36%	79				
	Metabolism	25%	39%	64				
Impacts		L	·					
Human	Cancer	82%	57%	139				
	Non-cancer	75%	50%	125				
Aquatic Biota	Developmental	32%	36%	68				
	Reproductive	32%	36%	68				
	Other sub-lethal endpoints	18%	36%	54				

Table 3. Overview of participants' rating of E-RRFs in the "Important" (I) and "Not Confident" (NC) bin for Round 1

3.5 Round 2 Prioritization Results

Twenty-eight participants completed and submitted the CEA MWCNT Prioritization Tool for Round 2 (compared with 31 for Round 1). Refer to **Appendix E** for all other results from Round 2 as reviewed by participants. As in Round 1, a large majority (35 out of 42, 83%) of all E-RRF pairs from Round 2 were placed in the "Important" and "Not Confident" bin of the CEA Prioritization Matrix. As shown in **Table 4**, the Product Life Cycle CEA Level, Environmental Transport, Transformation & Fate CEA Level, and Dose (Kinetics) CEA Level each had a majority of their E-RRF pairs in the "Important" and "Not Confident" bin.

CEA Level	No. E-RRFs Pairs on Matrix/Total No. E-RRFs	No. E-RRFs in I-NC Bin	Total E-RRFs (%) in I-NC Bin	% on Matrix E- RRFs in I-NC Bin
Product Life Cycle	10/14	9	64%	90%
Environmental Transport, Transformation & Fate	12/19	12	63%	100%
Exposure Route	6/16	2	13%	33%
Dose (Kinetics)	8/13	7	54%	88%
Impacts	7/14	5	36%	71%

Table 4. Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC)
on Prioritization Matrix for Round 2

Table 5 presents the percentage of participants who binned each E-RRF in the highest priority category of the Prioritization Matrix. As shown, the summations of the percentage of participants who ranked the E-RRF pair as "Important" and "Not Confident" are shown in the right column of **Table 5**. Based on the results of Round 2, particularly the identification of the E-RRFs assigned to the red and orange boxes of the Prioritization Matrix, a subset of participants was selected for invitation to the face-to-face workshop (see **Appendix B.2** for more details). See **Appendix C** for further details on the methodology used in analysis and reporting.

Participants were provided with the results of Round 2 in order to allow workshop participants to further incorporate the thoughts of other participants into their thought processes and to allow all participants an opportunity to review the results thus far in the CEA MWCNT prioritization process.

As detailed more in **Appendix G**, which analyzes and reviews the changes in results generated between prioritization rounds, one noticeable change between Rounds 1 and 2 was a 21% increase in the prioritized E-RRFs (i.e., the "Important" and "Not Confident" bin) within the Product Life Cycle CEA Level. In addition, another notable change between Rounds 1 and 2 was that the percentage of participants rating prioritized E-RRF pairs as "Important" and "Not Confident" decreased overall, which may have been an effect of participants reviewing the results from Round 1 and incorporating the opinions of others into their thought processes prior to CEA Prioritization Round 2.

It should also be noted here that while three participants from Round chose not to participate in Round 2, it is not fully clear how this affected the results of Round 2. While the main difference between Rounds 1 and 2 was related to an increase in prioritized E-RRFs in the Product Life Cycle CEA Level, it is unclear if this was due to the loss of these three participants or the effect

of viewing other co-participant responses prior to starting Round 2. It is furthermore outside the scope of this study to speculate on how the results of Round 2 would have differed if these three participants would have continued their participation in the prioritization process.

Element (E)	Risk Relevance Factor (RRF)	"Important" Rating (% of participants)	"Not Confident" Rating (% of participants)	Total (∑ Importance% + Confidence%)			
Product Life Cycle							
Material Synthesis	Volume	57%	25%	82			
	Release Rate	61%	36%	97			
Material Processing	Volume	29%	25%	54			
Product	Volume	71%	36%	107			
Manufacturing	Release Rate	68%	39%	107			
Use	Volume	61%	36%	97			
	Release Rate	64%	57%	121			
Disposal/Recycling	Volume	46%	25%	71			
	Release Rate	46%	36%	82			
Environmental Trans	port, Transformation &	Fate					
Air	Mobility	82%	61%	143			
	Persistence	54%	57%	111			
	Bioavailability	64%	64%	128			
Wastewater	Mobility	64%	36%	100			
	Persistence	61%	36%	97			
	Bioavailability	39%	50%	89			
Sediment	Mobility	18%	21%	39			
	Persistence	36%	21%	57			
	Bioavailability	39%	29%	68			
Soil	Mobility	14%	21%	35			
	Persistence	32%	18%	50			
	Bioavailability	36%	25%	61			
Exposure Route							
Human: Consumer	Ingestion	39%	43%	82			
	Inhalation	46%	36%	82			
Dose (Kinetics)							
Human	Absorption	79%	64%	143			
	Distribution	71%	64%	135			
	Metabolism	43%	68%	111			
	Excretion	57%	64%	121			

Table 5. Overview of participants' rating of E-RRFs in the "Important" (I)
and "Not Confident" (NC) bin for Round 2 ¹⁶

¹⁶ Bold E-RRF pairs in **Table 5** indicate the 16 most commonly agreed-upon high-priority E-RRFs assigned to the red box in the Prioritization Matrix of Round 2 (Note: As there was a tie between the 15th and 16th most highly prioritized E-RRF pairs, the 16 most commonly agreed-upon, as opposed to 15, E-RRFs were then selected from Round 2. However, 15 E-RRFs were selected from Round 3 to develop specific, detailed research questions by breakout groups, as described in subsequent sections). These 16 E-RRFs from Round 2 were subsequently used as a part of the methodology to identify participants to invite to the workshop for CEA Prioritization Round 3 (see Appendix B.2).

(continued)

Element (E)	Risk Relevance Factor (RRF)	"Important" Rating (% of participants)	"Not Confident" Rating (% of participants)	Total (∑ Importance% + Confidence%)
Aquatic Biota	Absorption	43%	21%	64
	Distribution	43%	32%	75
	Metabolism	32%	29%	61
Impacts				
Human	Cancer	82%	50%	132
	Non-cancer	64%	39%	103
Aquatic Biota	Developmental	36%	32%	68
	Reproductive	32%	32%	64
	Other sub-lethal endpoints	21%	36%	57

Table 5. Overview of participants' rating of E-RRFs in the "Important" (I) and "Not Confident" (NC) bin for Round 2 (continued)

3.6 Research Questions Submitted After Round 2

As described in **Section 2.4**, all participants were asked to provide their top three recommended research questions, which formed the Starter Research Question Set used at the face-to-face workshop by the breakout groups. In total, 24 participants submitted a total of 72 separate research questions (see **Appendix I** for a full listing of research questions submitted by participants). These research questions were then collated into 66 total research questions (accounting for duplicates) that were used by the breakout groups during the workshop as a part of the Starter Research Question Set (see **Appendix I**).¹⁷

As shown in more detail in **Appendix I**, Breakout group 1 was assigned 12 Starter Research Questions related to the E-RRF pairs of Human – Noncancer; Human: Occupational – Inhalation; Human – Metabolism; and Human – Excretion. Breakout group 2 was assigned 14 Starter Research Questions mainly related to the E-RRF pairs of Air – Persistence; Air – Mobility; Human – Absorption; and Disposal/Recycling – Volume. Breakout group 3 was assigned 8 Starter Research Questions related to the E-RRF pairs of Wastewater – Persistence; Wastewater – Mobility; and Sediment – Persistence. Finally, Breakout group 4 was assigned 8 Starter Research Questions related to the E-RRF pairs of Product Manufacturing – Release Rate; Use – Release Rate; Disposal/Recycling – Release Rate; and Material Processing – Release Rate.

3.7 Workshop Outcomes and Round 3 Prioritization Results

After Round 2 was completed, a subset of participants was invited to attend the face-to-face workshop (see **Appendix A** for the final workshop agenda). In total, 13 participants ultimately attended the workshop (see **Appendix B** for a list of participants as well as a list of public

¹⁷ It should be noted that only the research questions relevant to the E-RRFs assigned to the breakout groups were used during breakout group sessions (i.e., 42 of the original 66 collated questions). The other remaining research questions were not deemed useful for the breakout groups to develop research questions for their assigned E-RRFs. See **Appendix I** for a list of all submitted research questions by participants as well as research questions used by the breakout groups at the workshop.

observers).¹⁸ The workshop focused on 1) reviewing the results of the previous prioritization rounds, 2) discussing in a structured NGT session which E-RRFs should be prioritized and the rationales for these prioritizations, 3) completing the final prioritization round (Round 3) in a similar format to Rounds 1 and 2 (individually), and 4) then developing detailed research questions in the breakout groups for the prioritized E-RRFs that resulted from Round 3.

The following section provides an overview of the outcomes of the workshop, including the results of the NGT process, as well as the final prioritization round (Round 3). See **Appendix F** for all results related to the outcome of the workshop, including a summary of the information gathered during the workshop sessions, and all results from Round 3; **Appendix J** for all information relevant to the breakout groups, including breakout group reports presented on the final day of the workshop; and **Appendix L** for all workshop presentation slides.

3.7.1 NGT Process at Workshop

During the NGT session, each participant was given 3 minutes to advocate an E-RRF pair that they considered to be high priority. Each participant was asked to state the E-RRF pair along with the rationale for its prioritization. Participants were also able to agree or disagree with a previous participant's prioritized E-RRF. Participants used a star-shaped sticky note along with a poster of the detailed CEA Framework to advocate their particular E-RRF or an X-shaped sticky note on the poster to state the E-RRF pair should not be prioritized. A total of three rounds took place during this NGT session.

In total, there were 38 separate E-RRF pairs that were advocated by participants during the three rounds, and one E-RRF that was proposed to not be prioritized by one participant (**Figure 10**). As shown in **Figure 10**, the advocated E-RRFs fell mainly within the CEA Levels of Product Life Cycle (10 E-RRFs), Environmental Transport, Transformation & Fate (10 E-RRFs), and Impacts (10 E-RRFs). Refer to **Appendix F** for all details related to the NGT session.

¹⁸ An original attendance of 25 participants was planned for the workshop. However, only 13 participants were able to ultimately attend the face-to-face workshop, due to illness, scheduling conflicts, inclement weather, and other unforeseeable events. The final number of 13 participants, in fact, corresponds well with optimal group sizes for NGT style face-to-face workshops as supported by the literature (e.g., Cooke and Probst 2006; Aspinall 2010).

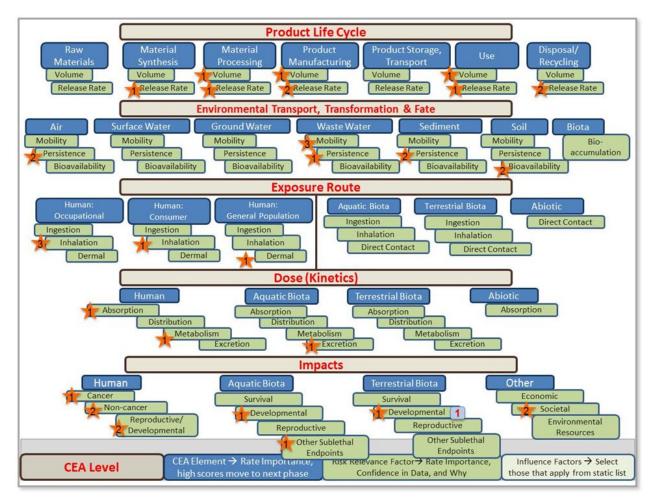


Figure 10. Overview of E-RRFs proposed for prioritization by participants in NGT process.*

Numbers within the star-shaped symbols represent the number of E-RRFs proposed for prioritization by participants during the NGT process, while the number in the square-shaped symbol represents the number of E RRFs proposed for exclusion from prioritization by one participant.

3.7.2 Round 3 Participant Ratings

All 13 workshop participants completed and submitted the CEA MWCNT Prioritization Tool for Round 3 (compared with 28 for Round 2 and 31 for Round 1). Similar to the previous prioritization rounds, a large majority (26 out of 39, 67%) of the E-RRF pairs from Round 3 were placed in the "Important" and "Not Confident" (i.e., red) bin of the CEA Prioritization Matrix (**Table 6**). See **Appendix F** for all results related to Round 3. As shown below, the CEA Levels of Product Life Cycle, Environmental Transport, Transformation & Fate, and Impacts each had a majority of their E-RRF pairs in the "Important" and "Not Confident" bin.

CEA Level	No. E-RRFs Pairs on Matrix/Total No. E-RRFs	No. E-RRFs in I-NC Bin	Total E-RRFs (%) in I-NC Bin	% on Matrix E- RRFs in I-NC Bin
Product Life Cycle	10/14	7	50%	70%
Environmental Transport, Transformation & Fate	9/19	8	42%	89%
Exposure Route	6/16	2	13%	33%
Dose (Kinetics)	4/13	3	23%	75%
Impacts	10/14	6	43%	60%

Table 6. Overview of E-RRFs binned as "Important" (I) and "Not Confident" (NC) on Prioritization Matrix for Round 3

Table 7 presents the percentage of participants that binned each E-RRF in the highest priority category of the CEA Prioritization Matrix for Round 3. As shown in the table, the summations of the percentage of participants who ranked the E-RRF pair as "Important" and "Not Confident" are shown in the right column of **Table 7**. This information was used to identify the most prioritized E-RRFs from Round 3, whereby the 15 most agreed upon prioritized E-RRFs that were in the Important/Not Confident bin were then used to develop research questions by participants in the breakout groups. See **Appendix F** for detailed Round 3 results and **Appendix J** for all results from the breakout groups. For an overview of the final research priorities mapped to the detailed CEA Framework from Round 3, refer to **Figure 5** in **Section 1** and to **Appendix F** for full details related to Round 3 results.

In addition, the 15 most agreed upon prioritized E-RRFs that resulted from Round 3 were shown previously in **Table 1** of **Section 1** (along with the relevant research questions developed by the breakout groups). These 15 E-RRFs, along with an overview of the rationales for their prioritization according to the participants, are shown in **Table 8** below. Many of the participants' rationales behind the prioritization of these 15 E-RRFs by participants largely related to 1) a lack of data or insufficient analytical methods for quantifying MWCNT; 2) the importance of the prioritized E-RRFs for assessing various exposures to MWCNTs for workers, consumers, and the environment; or 3) the importance of determining other risk parameters related to various aspects of exposures and impacts (e.g., degradation, persistency, release, distribution) (**Table 8**). For a full list of the rationales behind participants' prioritization of E-RRFs for Round 3, see **Appendix F**.

As detailed more in **Appendix G**, a noticeable change between Round 2 and Round 3 was that three CEA Levels (Product Life Cycle; Environmental Transport, Transformation & Fate; Dose (Kinetics) had fewer E-RRF pairs rated as "Important," "Not Confident" in Round 3. Another notable change between Round 2 and Round 3 is that the percentage of participants rating prioritized E-RRF pairs as "Important" and "Not Confident" decreased overall—a trend also observed between Round 1 and Round 2—which may have been an effect of participants reviewing the results from Round 2 and incorporating the opinions of others into their thought processes prior to CEA Prioritization Round 3. It is interesting to note that the distribution of prioritized E-RRFs from Round 3 results is very similar to the distribution of nominated E-RRFs from the NGT session (**Figure 10**).

Table 7. Overview of participants' rating of E-RRFs in the "Important" (I)and "Not Confident" (NC) bin for Round 3

Element (E)	Risk Relevance Factor (RRF)	"Important" Rating (% of participants)	"Not Confident" Rating (% of participants)	Total (∑ Importance% + Confidence%)
Product Life Cycle				
Material Synthesis	Release Rate	31%	23%	54
Material Processing	Release Rate	54%	46%	100
Product Manufacturing	Release Rate	85%	62%	147
Use	Volume	38%	38%	76
	Release Rate	62%	38%	100
Disposal/Recycling	Volume	46%	38%	84
	Release Rate	62%	38%	100
Environmental Trans	oort, Transformatic	on & Fate		
Air	Mobility	62%	38%	100
	Persistence	77%	54%	131
	Bioavailability	31%	38%	69
Wastewater	Mobility	69%	46%	115
	Persistence	77%	46%	123
	Bioavailability	31%	46%	77
Sediment	Persistence	46%	38%	84
	Bioavailability	23%	38%	61
Exposure Route				
Human: Occupational	Inhalation	100%	54%	154
Human: Consumer	Inhalation	46%	31%	77
Dose (Kinetics)			·	
Human	Absorption	62%	46%	108
	Metabolism	46%	46%	92
	Excretion	46%	46%	92
Impacts			·	
Human	Non-cancer	92%	77%	169
Aquatic Biota	Developmental	38%	31%	69
	Other sub-lethal endpoints	31%	31%	62
Other	Economic	15%	23%	38
	Societal	31%	31%	62
	Environmental Resources	23%	23%	46

Prioritized E-RRFs	Synopsis of Participant Rationales for Prioritization of E-RRF ("Why?")
1. Human-Non-cancer	 Insufficient data
2. Human: Occupational– Inhalation	 Inhalation may be the first initial exposure occurrences with workers Inhalation must be controlled as inhalation exposure can cause effects
 Product Manufacturing– Release Rate 	 Better analytical methods are needed for carbon nanotube quantification Critical to determine exposure Insufficient data
4. Air-Persistence	 Known to persist Insufficient data Important for inhalation by workers
5. Wastewater-Persistence	 Unsure how structure changes Unlikely that substantial degradation will occur MWCNT appear to be persistent
6. Wastewater–Mobility	 Expect releases to wastewater from manufacturing and possible washing of textiles by consumers Extent to which nanotubes are moved or not by wastewater treatment processes determines which environmental compartment is exposed (water or soil) Insufficient data Physicochemical characteristics of CNTs in water media have been similar to some other ultrafine and nano materials
7. Human-Absorption	Insufficient dataSignificant for exposure
8. Use–Release Rate	 Better analytical methods are needed for quantification Insufficient data on releases from processing, envision fabric coating operations resulting in releases to environment Critical to determine exposure
9. Disposal/ Recycling– Release Rate	 Better analytical methods are needed for quantification Most important parameter for consumer exposure
10. Air–Mobility	 Better analytical methods are needed for quantification. It also depends upon how the recycling is performed. Critical to determine exposure If waste is incinerated releases to air, if landfilled releases to water possible Large volumes of waste may be accumulated and increase the potential for a release event
11. Material Processing– Release Rate	 Insufficient data are available in this regard Primary route of exposure
12. Human–Metabolism	 Expect releases to wastewater from manufacturing and possible washing of textiles by consumers The extent to which nanotubes are moved or not by wastewater treatment processes determines which environmental compartment is exposed (water or soil) Insufficient data Physicochemical characteristics in water media have been similar to some other ultrafine and nano materials
13. Human Excretion	Insufficient data

31

Prioritized E-RRFs	Synopsis of Participant Rationales for Prioritization of E-RRF ("Why?")
14. Disposal/ Recycling– Volume	 Better analytical methods are needed for quantification Insufficient data on releases from processing, envision fabric coating operations resulting in releases to environment Critical to determine exposure
15. Sediment–Persistence	 Better analytical methods are needed for quantification This is most important parameter for consumer exposure

Table 8. Synopsis of participant rationales for prioritization of E-RRF ("Why?") from Round 3(continued)

3.8 Round 3 Final Research Questions

The 15 most agreed upon prioritized E-RRF pairs from Round 3 were then selected in order to develop specific, detailed research questions by the breakout groups. In this prioritization process, the "most chosen" Importance or Confidence rating for any Element or E-RRF pair is the rating option that the participant group chose more frequently than any other rating option. The final research questions developed by the breakout groups are outlined in **Table 1** in **Section 1**. In addition, the entire set of results generated from the breakout group sessions is available in **Appendix J**, including the breakout group reports, which outline the developed research questions, along with other critical information related to the research-to-risk management continuum (see subsequent paragraphs for an overview for these aspects). Also see **Appendix L** for the breakout group presentation slides.

Overall, the 15 most agreed upon prioritized E-RRF pairs were assigned to four breakout groups (where E-RRF pairs were assigned to the most appropriate breakout group based on the participants' areas of expertise) (see **Appendix J**). These four breakout groups produced a total of 45 specific, detailed research questions that were framed within a given risk scenario for the relevant E-RRF. These specific detailed research questions were also developed with other pertinent information detailed in the breakout group template (i.e., What risk management actions or decisions could avoid or mitigate the potential risks posed in this scenario for this E-RRF? What information would you need from an assessment to support these risk management decisions? What type of assessment could provide this necessary information? What information would enable this assessment but is currently unavailable? What specific, detailed research question in US\$? What is the estimated time frame for completion of this research question in years?).

Overall, these 15 prioritized E-RRFs fell within the research areas of human health (as opposed to ecosystem health for instance), and following the first E-RRF pair listed which relates to impacts of MWCNT on human health, these prioritized E-RRFs mainly focused on aspects related to 1) release rate of MWCNT (in product manufacturing, use, disposal/recycling, and material processing), 2) persistence (in air, wastewater, sediments), 3) mobility (in wastewater, air), and 4) behavior in the human body (inhalation, absorption, metabolism, excretion). In addition, the generated research questions that were developed by the breakout groups for the most prioritized E-RRFs large focused on 1) understanding impacts to human health from inhalation of MWCNT; 2) understanding the release of MWCNT; 3) understanding the material properties of MWCNT that related to exposure; 4) analytical methods of detection,

characterization, and quantification of MWCNT in the environment and within the body; and 5) understanding the fate and behavior of MWCNT in various environmental matrices.

The breakout group reports also included other information related to the research-to-risk management continuum for the assigned prioritized E-RRFs. As seen in more detail in Appendix J, the risk management actions or decisions proposed by the breakout groups for their assigned E-RRFs mainly focused on 1) implementing a ban or moratorium on MWCNT, 2) implementing risk management controls in order to manage the potential risks of MWCNT in various environmental media (e.g., personal protection equipment; control technologies for wastewater, air, and disposal), or 3) altering physicochemical parameters of MWCNT to reduce potential exposures (e.g., reducing potential for absorption, atmospheric residence time, increase aggregation, pretreatment of MWCNT used by industry to limit release from products). Related to these risk management actions or decisions, the types of information needed from an assessment to support these actions/decisions generally focused on 1) understanding exposure concentrations in various environmental media and developing safe exposure limits, 2) understanding behavior of MWCNT in biological systems (e.g., half-life, absorption), 3) understanding fate and behavior of MWCNT in wastewater treatment and aspects of transformation and release, and 4) using control technologies to reduce exposures. Related to these items of information needed from an assessment, the types of (standard) assessments that could be used to provide this information include 1) No Observable Adverse Effect Level (NOAEL) and Lowest Observed Adverse Effect Level (LOAEL); 2) various aspects of standard risk assessments (human health and environmental health), including exposure assessments and laboratory experiments; 3) cost-benefit-analyses; and 4) life cycle assessments.

The breakout groups also provided additional information that would enable these assessments, specific for the developed research questions for the assigned E-RRFs. Finally, estimates of financial costs and time frames needed to complete the research questions were also provided by the breakout groups; the estimated costs ranged from \$50K to \$5M (with many research questions estimated at \$300K and \$500K for completion), and the time frames were estimated to be 1 to 5 years for completion (with most research questions requiring 3 years).

4. Conclusions and Future Directions

This report details the process of engaging diverse, expert stakeholders in an application of CEA to identify research priorities that, if carried out, could inform the assessment and management of the potential risks of MWCNT in flame-retardant coatings applied to upholstery textiles. Through three separate prioritization rounds, which involved participant ratings of research areas based on the CEA Framework, this process collectively identified and elevated high priority research areas based on their importance for risk assessment efforts (i.e., "Importance") as well as the associated lack of adequate information for risk management decisions (i.e., "Confidence").

Thirty-one participants completed Round 1 of the prioritization process, whereby a large majority of the E-RRF pairs on the CEA Prioritization Matrix were grouped in the "Important," "Not Confident" (highest research priority) bin. After reviewing the full set of Round 1 results, 28 participants completed Round 2. Similar to the first prioritization round, a large majority of E-RRFs from Round 2 were placed in the highest research priority bin on the Matrix. Participants then reviewed the full set of Round 2 results prior to attending the face-to-face workshop and completing the final prioritization round. Thirteen participants attended the face-to-face workshop; a final participant number that coincided well with optimal NGT group size as supported by the literature (e.g., Cooke and Probst, 2006; Aspinall, 2010). During the workshop, participants discussed in a structured NGT session (i.e., Round Robin) the E-RRFs proposed for prioritization and the associated rationales and then completed the final prioritization round (Round 3). Similar to Rounds 1 and 2, a large majority of the E-RRF pairs from Round 3 were placed in the highest priority bin on the Prioritization Matrix. One notable difference between prioritization rounds was that the overall percentage of participants rating prioritized E-RRF pairs as "Important" and "Not Confident" generally decreased, possibly due to the effect of participants reviewing the results from one round and then incorporating the opinions of others into their thought processes prior to the next round.

Fifteen of the most agreed upon prioritized E-RRFs from Round 3 mainly fell within the areas of human health and largely focused on aspects related to 1) release rate of MWCNT (in product manufacturing, use, disposal/recycling, and material processing), 2) persistence (in air, wastewater, sediments), 3) mobility (in wastewater, air), and 4) behavior in the human body (inhalation, absorption, metabolism, excretion). The rationales behind the prioritization of these 15 E-RRFs largely related to a lack of data or insufficient analytical methods for quantifying MWCNT; the importance of the prioritized E-RRFs for assessing various exposures to MWCNT for workers, consumers, and the environment; or the importance of determining other risk parameters related to various aspects of exposures and impacts (e.g., degradation, persistency, release, distribution).

Four breakout groups then developed specific, detailed research questions for these 15 prioritized E-RRFs and illuminated the connections between the priority research, the types of assessments this research would support, and ultimately, the risk management decisions those assessments would inform. The four breakout groups generated a total of 45 specific, detailed research questions that were framed within a given risk scenario for each of these E-RRFs. Across all 15 prioritized E-RRFs, the generated research questions largely focused on 1) understanding impacts to human health from inhalation of MWCNT; 2) understanding the release of MWCNT;

3) understanding the material properties of MWCNT that related to exposure; 4) developing analytical methods of detection, characterization, and quantification of MWCNT in the environment and within the body; and 5) understanding the fate and behavior of MWCNT in various environmental matrices. Additional information pertaining to the research-to-risk management continuum was also developed for each of the detailed research questions generated by the breakout groups. It should be noted that the final research priorities identified in this process will be incorporated into the revised draft case study document (U.S. EPA, 2012b) to support research planning.

In addition to the specific prioritization results for MWCNT, this application of the CEA process had other results relating to the overall goals of the CEA approach for prioritizing risk trade-offs and developing risk management plans. Specifically, this application of CEA has produced the following:

- 1. *Establishing a strategic linkage between research planning, risk assessment, and risk management.* Through the developed prioritization process, prioritized research areas (i.e., E-RRFs) were identified and then used by the breakout groups during the face-to-face workshop to develop specific and framed information regarding these prioritized research areas, linking specific research questions to aspects of risk management and related decisions.
- 2. *Systematically integrating and structuring complex information.* The prioritization process used in this application of CEA integrated multiple assessment types and analytical approaches across the entire life cycle of MWCNT. In addition, the prioritization process provided a structured methodology for diverse stakeholders to rate the various life cycle aspects of MWCNT in terms of aspects related to its potential for health and environmental risks.
- 3. *Engaging diverse perspectives to inform near- or long-term risk management efforts.* The developed prioritization process involved a wide range of stakeholder groups in diverse sectors and areas of expertise in order to identify prioritized research areas and then develop detailed, actionable research questions for these prioritized research areas.
- 4. Supporting holistic, sustainable risk assessment and subsequent risk management efforts. Through the conduct and completion of the prioritization process, a range of stakeholder groups were involved in rating various areas of the CEA Framework according to its importance to risk assessment efforts and confidence in the current availability and utility of data to support risk management decisions. This inclusion of diverse stakeholders who rated research areas over the life cycle of MWCNT based on the CEA Framework was well aligned with efforts to ensure a more holistic and sustainable risk assessment and risk management efforts.

In addition to the positive outcomes of this prioritization process, as highlighted above, there were also a number of challenges. One of these has been obtaining active participants to be involved in the entire prioritization process, despite a number of offered incentives¹⁹ to participate. This is most likely due to the time- and energy-intensive nature of this CEA application, which involved, among other aspects, reviewing extensive background literature and

¹⁹ It should be noted that the incentives were provided by RTI, while EPA provided overall project funding.

information on the material and related aspects for its potential for health and environmental risks, learning how to use the prioritization spreadsheet tool, and attending a face-to-face workshop. It is acknowledged that this challenge is not unique to this application, as it is well known that involving the public or various stakeholder groups is indeed a challenging endeavor in and of itself (e.g., Grieger et al., 2012). Investigating the drivers and barriers for obtaining expert participation in future applications of CEA may, therefore, be a topic for further research. In addition, future applications of this CEA approach may also consider the proposal of other/alternative incentives to involve a larger number of participants if required. An additional challenge in the process was the "user friendliness" of the developed CEA MWCNT Prioritization Tool, as several participants indicated that they did not find it particularly user friendly through participant evaluations as well as oral feedback during the workshop (see Appendices B and F). Therefore, future applications of this CEA approach may wish to consider revising this tool to improve its user friendliness. Participant feedback regarding the prioritization process reflected that many participants found the instructional materials, particularly the webinar, to be particularly useful. In addition, many participants reflected upon the utility of the NGT (Round Robin) session, and provided positive feedback regarding the size of the workshop as well as the benefits of discussing and engaging with other participants during the workshop.

Future applications of this process may benefit significantly through the development of online, web-enabled collective judgment tools. This would allow a large number of diverse stakeholders to participate in the prioritization process, potentially eliminate many costs and impacts of travel, and offer the ability to more easily incorporate a range of international participants if desired. Such web-enabled collective judgment tools are starting to emerge as a path forward to incorporate a wide range of stakeholders, including international participants, and it will be interesting to view their development in the coming years. In addition to these ideas for future directions, it would also be interesting to monitor the progress of the prioritized research areas identified in this process within the coming years. This would provide an important and critical reflection on how well the prioritized research areas identified in this process compare with future funding of research areas focused on better understanding of the potential health and environmental risks of MWCNT.

Finally, as emerging technologies and materials continue to develop at an ever-increasing pace, including the use of ENMs in a wide range of products and applications, it is becoming increasingly important to develop meaningful ways to engage a wide range of stakeholders to help identify priority research areas that, if funded, would help inform risk management decisions in both the near and long terms. This application of CEA, which focused on the use of MWCNT in flame-retardant coatings applied to upholstery textiles, is one such application of a collective judgment approach that applied a structured prioritization process in order to elicit specific, detailed research questions from a diverse group of experts. Future applications of CEA to other emerging materials such as ENMs may benefit from a reflection on some of the successful results generated from this application as well as other "lessons learned" from some of the main challenges described herein.

5. References

Aspinall, W. (2010). A route to more tractable expert advice. Nature 463: 2. http://dx.doi.org/10.1038/463294a

- Cooke, RM; Probst, KN. (2006). Highlights of the expert judgment policy symposium and technical workshop. Resources for the Future: Expert Judgment Policy Symposium and Technical Workshop, March 13-14, 2006, Washington, DC.
- Davis, JM. (2007). How to assess the risks of nanotechnology: Learning from past experience [Review]. J Nanosci Nanotechnol 7: 402-409.
- <u>Grieger, KD; Hasen, SF; Baun, A.</u> (2009). The known unknowns of nanomaterials: Describing and characterizing uncertainty within environmental, health and safety risks. Nanotoxicology in press: in press. <u>http://dx.doi.org/10.1080/17435390902944069</u>
- <u>Grieger, KD; Baun, A; Owen, R.</u> (2010). Redefining risk research priorities for nanomaterials. J Nanopart Res In press: In press. <u>http://dx.doi.org/10.1007/s11051-009-9829-1</u>
- <u>Grieger, KD; Fern, W; Andersen, HB; Renn, O.</u> (2012). Improving risk governance of emerging technologies through public engagement: The neglected case of nano-remediation? The International Journal of Emerging Technologies and Society 10: 61-78.
- Hansen, SF; Maynard, A; Baun, A; Tickner, JA. (2008). Late lessons from early warnings for nanotechnology. Nat Nanotechnol 3: 444-447. http://dx.doi.org/10.1038/nnano.2008.198
- ICF (ICF International). (2011). Nanomaterial case study workshop: Developing a comprehensive environmental assessment research strategy for nanoscale silver Workshop report [EPA Report]. Research Triangle Park, NC: U.S. Environmental Protection Agency.
- Page, SE. (2007). The difference: How the power of diversity creates better groups, firms, schools, and societies. Princeton, NJ: Princeton University Press.
- Powers, CM; Dana, G; Gillespie, P; Gwinn, MR; Hendren, CO; Long, TC; Wang, A; Davis, JM. (2012). Comprehensive environmental assessment: a meta-assessment approach. Environ Sci Technol 46: 9202-9208. <u>http://dx.doi.org/10.1021/es3023072</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2009). Expert elicitation task force white paper (external review draft) [EPA Report]. Washington, DC. <u>http://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/F4ACE05D0975F8C68</u> <u>525719200598BC7/\$File/Expert_Elicitation_White_Paper-January_06_2009.pdf</u>
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2010a). Nanomaterial case studies workshop: Developing a comprehensive environmental assessment research strategy for nanoscale titanium dioxide [EPA Report]. (EPA/600/R-10/042). Research Triangle Park, NC.
- U.S. EPA (U.S. Environmental Protection Agency). (2010b). Nanomaterial case studies: Nanoscale titanium dioxide in water treatment and in topical sunscreen (final) [EPA Report]. (EPA/600/R-09/057F). Research Triangle Park, NC. <u>http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=230972</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2011). ICF: Nanomaterial case study workshop: Developing a comprehensive environmental assessment research strategy for nanoscale silver Workshop report [EPA Report]. Research Triangle Park, NC: U.S. Environmental Protection Agency.
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2012a). Comprehensive environmental assessment: A metaassessment approach to increase effectiveness of risk management and research planning [Fact Sheet]. Research Triangle Park, NC: <u>http://www.epa.gov/nanoscience/files/CEAPrecis.pdf</u>. U.S. Environmental Protection Agency. <u>http://www.epa.gov/nanoscience/files/CEAPrecis.pdf</u>
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2012b). Nanomaterial case study: a comparison of multiwalled carbon nanotube and decabromodiphenyl ether flame-retardant coatings applied to upholstery textiles (draft) [EPA Report]. (EPA/600/R-12/043A). RTP, NC.

- U.S. EPA (U.S. Environmental Protection Agency). (2012c). Nanomaterial case study: Nanoscale silver in disinfectant spray (final report) [EPA Report]. (EPA/600/R-10/081F). Washington, DC.
- Van de Ven, AH; Delbecq, AL. (1972). The nominal group as a research instrument for exploratory health studies. Am J Public Health 62: 337-342. <u>http://dx.doi.org/10.2105/AJPH.62.3.337</u>
- Walker, KD. (2004). Memo: Appropriate Number of Experts for the PM EJ Project. Memo to Jim Neumann, Henry Roman, and Tyra Gettleman. Available online