Integrated Environmental Assessment and Management — Volume 12, Number 1—pp. 96–108

Decision Analysis

Applying Comprehensive Environmental Assessment to Research Planning for Multiwalled Carbon Nanotubes: Refinements to Inform Future Stakeholder Engagement

Christina M Powers,† Khara Grieger,‡ Connie A Meacham,† Meredith Lassiter Gooding,† Jeffrey S Gift,† Geniece M Lehmann,† Christine O Hendren,§ J Michael Davis,|| and Lyle Burgoon†*

†National Center for Environmental Assessment, Office of Research and Development, US Environmental Protection Agency, Research Triangle Park, North Carolina

‡RTI International, Research Triangle Park, North Carolina, USA

§Center for the Environmental Implications of NanoTechnology (CEINT) Duke University, Durham, North Carolina, USA

||USEPA National Center for Environmental Assessment (Retired), Pittsboro, North Carolina, USA

(Submitted 28 July 2014; Returned for Revision 28 October 2014; Accepted 5 May 2015)

ABSTRACT

Risk assessments and risk management efforts to protect human health and the environment can benefit from early, coordinated research planning by researchers, risk assessors, and risk managers. However, approaches for engaging these and other stakeholders in research planning have not received much attention in the environmental scientific literature. The Comprehensive Environmental Assessment (CEA) approach under development by the United States Environmental Protection Agency (USEPA) is a means to manage complex information and input from diverse stakeholder perspectives on research planning that will ultimately support environmental and human health decision making. The objectives of this article are to 1) describe the outcomes of applying lessons learned from previous CEA applications to planning research on engineered nanomaterial, multiwalled carbon nanotubes (MWCNTs) and 2) discuss new insights and refinements for future efforts to engage stakeholders in research planning for risk assessment and risk management of environmental issues. Although framed in terms of MWCNTs, this discussion is intended to enhance research planning to support assessments for other environmental issues as well. Key insights for research planning include the potential benefits of 1) ensuring that participants have research, risk assessment, and risk management expertise in addition to diverse disciplinary backgrounds; 2) including an early scoping step before rounds of formal ratings; 3) using a familiar numeric scale (e.g., US dollars) versus ordinal rating scales of "importance"; 4) applying virtual communication tools to supplement face-to-face interaction between participants; and 5) refining criteria to guide development of specific, actionable research questions. *Integr Environ Assess Manag* 2016;12:96–108. © 2015 SETAC

Keywords: Comprehensive environmental assessment Research planning Risk assessment Risk management Nanomaterials

INTRODUCTION

Chemical risk assessments and subsequent risk management plans to protect human health and the environment can benefit from early, coordinated research planning by researchers, risk assessors, and risk managers. The benefits of strategic research planning and the particular importance of engaging stakeholders (e.g., researchers, risk assessors, risk managers, community members) early in the process are well recognized (USEPA 2000; NRC 2009; US GAO 2013); however, the underlying processes and procedures that go into such planning and engagement have received relatively little attention in the scientific literature on environmental issues. We address this dearth in literature by discussing a recent application of the United States Environmental Protection Agency's (USEPA) Comprehensive Environmental Assessment (CEA) approach, which is one way to manage complex information and input from diverse stakeholder perspectives on research planning that will ultimately support human and environmental health decision-making processes (features of the CEA approach are highlighted in the Supplemental Data and in other articles [e.g., Powers et al. 2012; Davis 2013]).

This article includes online-only Supplemental Data.
* Address correspondence to davis.jmichael@mindspring.com
Published online 23 May 2015 in Wiley Online Library (wileyonlinelibrary.com).
DOI: 10.1002/ieam.1663

Organizations across the scientific community (e.g., academia, governmental institutions, research organizations) might structure input in research planning through a variety of approaches (e.g., multicriteria decision analysis [Belton and Stewart 2001], structured expert elicitation [USEPA 2009]). Several approaches are possible for public participation and stakeholder engagement, some of which have been applied to emerging topics such as nanotechnology-related applications (Wynne 2007; Grieger et al. 2012; Powers, Grieger et al. 2014). Yet few examples exist of applying these methods to research planning targeted to inform future risk assessment and risk management of environmental contaminants (e.g., Kandlikar et al. 2007; Linkov et al. 2011; Zimmer et al. 2012). Indeed, less structured approaches (e.g., committees or workgroups using informal open group discussion) are commonly employed to develop research strategies in governmental or academic institutions and organizations (OECD 2003; NNI 2011; Sá and Tamtik 2012).

In contrast to less-structured approaches, structured stakeholder engagement can help ensure that individuals with different viewpoints or interest areas have relatively equal input in an outcome. The breadth of technical disciplines included in environmental risk assessment and management suggests an inherent benefit from using structured methods to engage stakeholders with diverse perspectives in research planning for future risk assessment and risk management of many environmental issues. In addition, structured stakeholder engagement is perhaps of paramount importance for emerging technologies characterized by a lack of information to guide researchers in generating new data to fill key knowledge gaps (Linkov et al. 2013). As noted by a recent National Research Council (NRC) review of data on one emerging class of materials, engineered nanomaterials (ENMs), data that result from less structured and nonintegrated approaches to research planning can be disconnected from and relatively uninformative for subsequent risk assessments and risk management decisions (NRC 2012; Linkov et al. 2013).

With diminishing resources available to conduct research, a growing need has arisen to transparently plan research that balances competing priorities (e.g., social, political, economic) and maximizes the cost-effectiveness of research (e.g., new data to support economic development, public health protection) for emerging materials such as ENMs (OECD 2003; NRC 2012). A variety of methods may engage stakeholder groups with diverse organizational and technical backgrounds, and several of these methods have been applied to ENM-related topics, including public participation activities (e.g., Delgado et al. 2011), structured decision analytical approaches (Seager and Linkov 2008; Linkov et al. 2011), and risk governance approaches (IRGC 2009).

The CEA approach adds several key features to the toolbox of available methods to engage stakeholders in research-planning processes that inform future risk assessments and risk management of environmental contaminants. First, CEA uses an extensive framework (Figure 1) to organize information and stakeholder thinking on a substance, material, or group of materials (e.g., nanoscale Ag, biofuels, polychlorinated

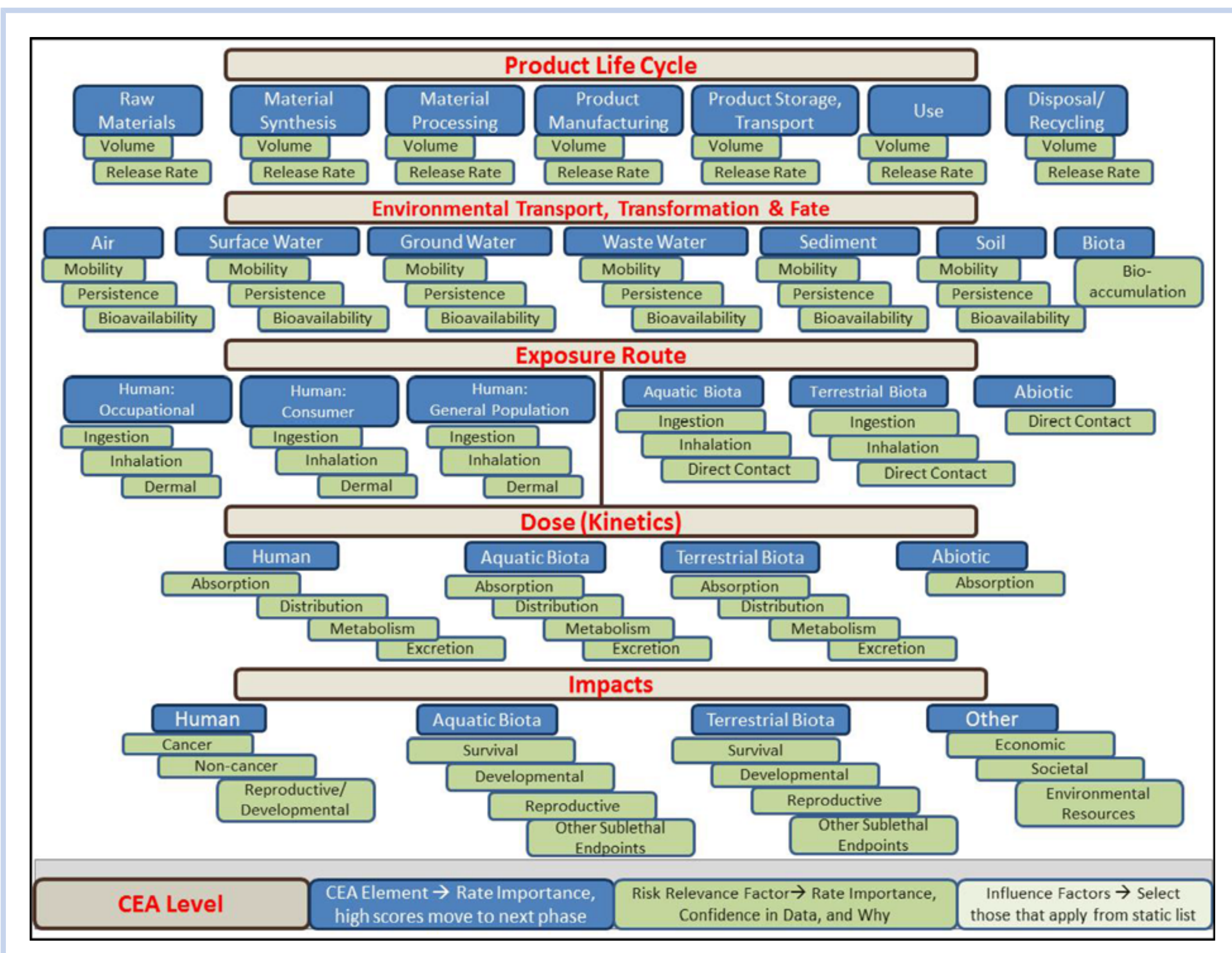

Figure 1. Detailed CEA framework used for MWCNT Workshop Process. The structure used to organize potential research areas for MWCNT. Gray bars with red text represent broad areas that the previously existing CEA framework can encompass (Powers et al. 2012). Blue boxes, elements, denote more specific subareas or pathways within each area. Green boxes, risk relevance factors, denote parameters that risk assessors or risk managers might consider related to each element. Pairing an element with a risk relevance factor (i.e., an element-risk relevance factor pair, termed research areas in this article) allows expert stakeholders to provide increasing amounts of detail in areas they determine are priorities for future research on a particular substance (e.g., MWCNTs). Note that risk relevance factors are not listed in a particular order for any element; rather, the potential importance of any risk relevance factor is determined by participants in the CEA process. The vertical bar connecting exposure and dose denotes the interconnected nature of these 2 areas (i.e., external exposures leading to internal dose).

biphenyls) (Davis 2007; Powers et al. 2012). Second, CEA incorporates a structured collective judgment process to engage stakeholders with diverse technical expertise and organizational perspectives in prioritizing research gaps. Collective judgment processes include a variety of formal methods to ensure that individuals have equal opportunities for input in a decision (e.g., nominal group technique, multicriteria decision analysis, and Delphi); entities using the CEA approach may select a specific method based on factors such as the resources and scope of the research planning effort (for more discussion, see Powers et al. 2012; Davis 2013). The use of the CEA framework and collective judgment process in research planning facilitates consideration of a diverse array of information and perspectives in prioritizing research gaps. Third, the outcome of a CEA collective judgment process for research planning is a prioritized list of research topics to inform future risk assessment and risk management efforts for a particular material or substance. The focus on prioritization is intended to increase the efficiency of generating data for risk assessments by helping to ensure that resources (e.g., time, funding, personnel) are devoted first to the research that would most inform future assessments. Data generated from these research efforts can then subsequently increase the scientific robustness of assessments and potentially decrease uncertainty in risk management decisions. The rationale for and advantages of the CEA approach are discussed in more depth in Davis (2007), Powers et al. (2012), and Davis (2013).

The USEPA has thus far applied CEA to identifying research priorities in several case studies involving ENMs: 1) nanoscale titanium dioxide (nano-TiO_2) in water treatment and sunscreen (USEPA 2010b), 2) nanoscale silver (nano-Ag) in a disinfectant (USEPA 2012b), and most recently, 3) multi-walled carbon nanotubes (MWCNTs) in flame-retardant coatings applied to upholstery textiles (USEPA 2013). As part of the development of each CEA case study, a group of stakeholders participated in a workshop process that used collective judgment methods to identify research priorities for each ENM (USEPA 2010a; ICF 2011; RTI International 2012).

We have previously described our collective judgment methods to engage expert stakeholders in the CEA workshop process applied to nano-TiO_2 and nano-Ag research planning (USEPA 2010a; ICF 2011; Powers, Hendron et al. 2014). We identified several lessons learned in engaging stakeholders to identify clear research priorities for ENMs, including identifying broad information priorities (e.g., human occupational exposures) before discussing more detailed research questions, and rating rather than ranking research priorities. This paper builds on our previous work by outlining the application of these lessons learned in our most recent work with MWCNTs (Powers, Hendron et al. 2014). The objectives of this article are to 1) describe the outcomes of applying these earlier lessons to the collective judgment process for MWCNTs and 2) discuss new insights and possible refinements for future efforts to engage stakeholders in research planning to support risk assessment and risk management of environmental issues. In addition to informing research planning for ENMs, this discussion may also enhance research planning to develop data for assessments of other emerging technologies and even more well-known chemicals with remaining, critical knowledge gaps. Regardless of how applied, the focus of this paper is on the process or methodology rather than the resulting research priorities for MWCNTs. Additional discussion on the specific priorities identified through the CEA collective judgment process is available in other articles and reports (RTI International 2012; USEPA 2013; Powers et al. 2015; Powers, Gift et al. 2014).

METHODS

Workshop Objectives

The objective of the recent CEA for research planning on MWCNTs in flame-retardant coatings applied to upholstery textiles was to transparently produce a list of prioritized, actionable research questions directly relevant to future risk assessments and subsequent risk management decisions for MWCNTs. To achieve this overarching objective, USEPA developed, and RTI International applied, a collective judgment approach with 2 key components. (Note: The workshop process for MWCNTs was funded by the USEPA and independently conducted by RTI International.) The components consisted of 1) iterative incorporation of the collective knowledge of a diverse and balanced group of expert stakeholders representing a variety of organizational perspectives (e.g., industry, academia, government) and technical expertise areas (e.g., analytical chemistry, ecology, human health effects) (for more details on the selection of CEA participants, please see Supplemental Data Section 2 and Supplemental Data Figure 3); and 2) stakeholders independently identifying broad areas of information (e.g., human occupational exposure) as important for future MWCNT risk assessments before identifying more specific research gaps (e.g., human occupational inhalation exposure) (RTI International 2012). These components were not intended to reach a group consensus, and thus no attempt was made to have the participants interact in a manner to seek or agree on a consensus view of the research priorities; rather, research gaps that individual stakeholders identified were collated such that the research priorities were those that stakeholders collectively identified as a high priority for future risk assessments but lacking information for use in risk management decisions. Specific research questions were then developed for the 15 research gaps that participants most commonly identified as highly important and as lacking information to support risk management decisions.

Overview of CEA collective judgment applied to MWCNTs

The steps of applying CEA to MWCNTs are briefly described here and detailed in the Supplemental Data. Before the collective judgment workshop process, information on MWCNTs used in flame-retardant coatings applied to upholstery textiles was compiled in a draft case study document (USEPA 2012a). The collective judgment workshop process then proceeded in the following steps (Figure 2) (RTI International 2012):

1. Expert stakeholders representing diverse perspectives in terms of technical expertise areas and organizational sectors were asked to participate in the CEA workshop process for MWCNTs (hereafter “CEA participants”).
2. CEA participants accessed a secure website to review background materials (e.g., webinar on prioritization process, draft case study document [USEPA 2012a], spreadsheet rating tool).

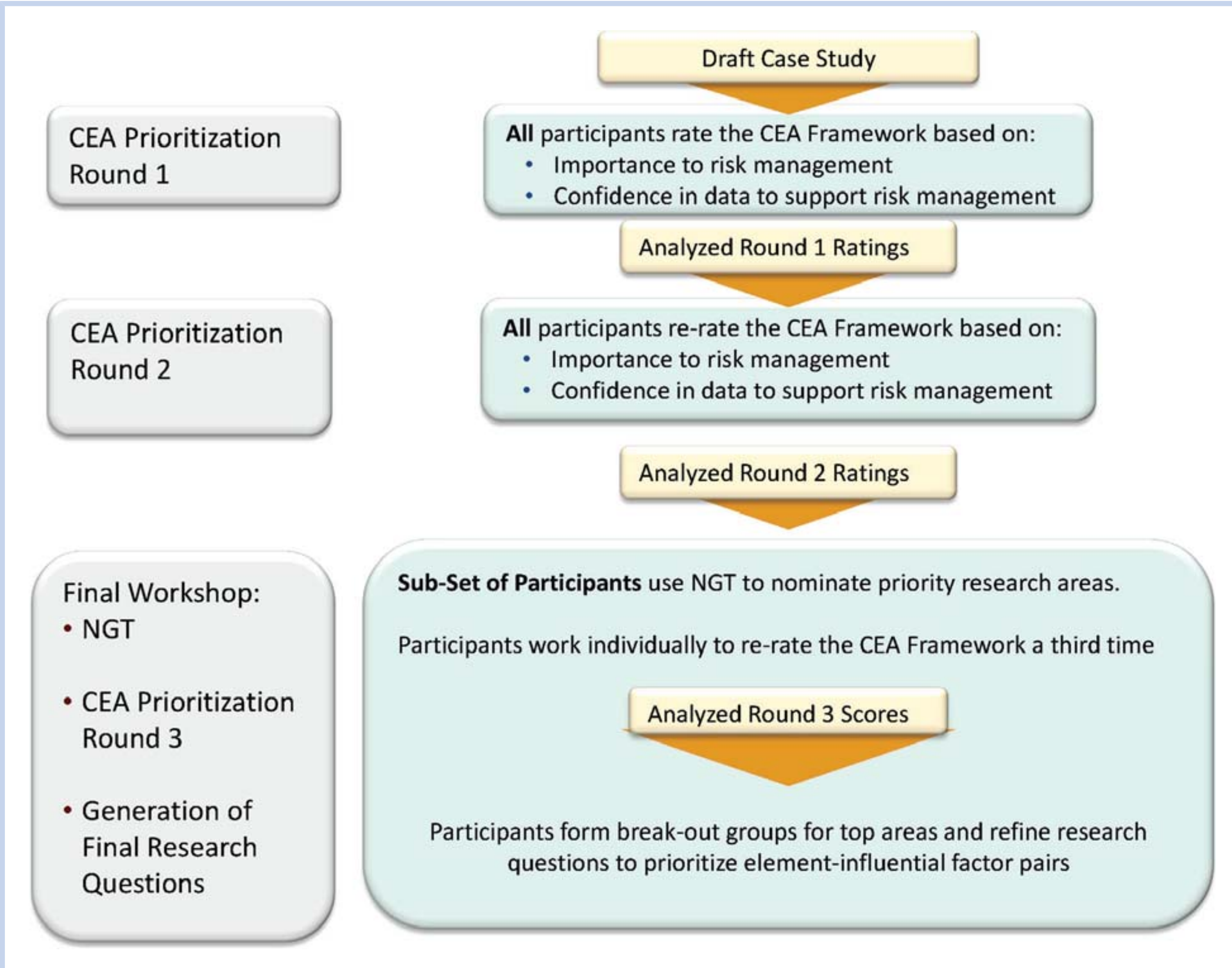

Figure 2. Schematic overview of CEA MWCNT Workshop Process. Stakeholders with diverse technical expertise and organizational perspectives identified research priorities for future MWCNT risk assessment and risk management through 3 rounds of rating. In each round, stakeholders rated potential research areas based on relative importance for future risk assessment and current state-of-the-science. Stakeholder completed rounds 1 and 2 virtually (without interacting face-to-face). A subset of stakeholders then participated in a structured face-to-face workshop to finalize research priorities. Between each prioritization round, rating results from all stakeholders were collated and shared with participants in the form of bar graphs and tables.

3. CEA participants identified research priorities for future MWCNT risk assessment and risk management by completing 3 rounds of prioritization:

   a. Round 1: CEA participants independently identified MWCNT research priorities using a computer spreadsheet. Research priorities were identified by rating individual information areas (e.g., Human Occupational Inhalation Exposure) (Figure 1). Each information area was identified as an element-risk relevance factor pair for CEA participants but will be referred to simply as "research area" for the purposes of this article. The CEA participants rated each research area based on 1) importance to consider in future risk assessment of MWCNTs and 2) confidence in the availability and utility of current data to support risk management decisions for MWCNTs (Figure 3). After rating all areas, CEA participants submitted their completed spreadsheet via email.
   b. Round 2: CEA participants were asked to review the results submitted by all participants from round 1. Bar charts and tables of round 1 results, which included compiled, anonymous rationales for the selection of ratings from participants, were available on the secure website so that CEA participants could compare the research priorities they identified individually with the priorities the group collectively identified. This comparison of individual versus group results took place without face-to-face interaction between participants. After reviewing input from the group, CEA participants could revise their initial list of research priorities by completing a second copy of the spreadsheet used in round 1. They then submitted the second spreadsheet via email.
   c. Round 3: A subset of CEA participants with technical expertise in areas identified as potential research priorities in round 2 were asked to attend a face-to-face workshop; selection of participants was carried out to ensure that those attending the workshop provided a distribution of organizational perspectives. The subset of CEA participants met face-to-face in a structured workshop setting to discuss and debate research priorities before completing the spreadsheet individually for a final time. They then met in breakout groups at the workshop to develop detailed research questions for the 15 priorities most agreed on as being of high importance for future MWCNT risk assessment yet lacking sufficient data for current risk management. A set of criteria was adapted from Sutherland et al. (2011) and provided to

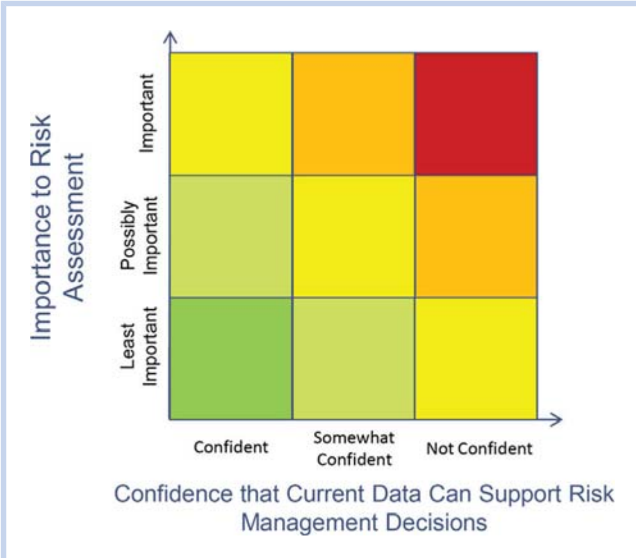

Figure 3. CEA Prioritization Matrix. The structure used to directly link the identification of research priorities for MWCNTs to future risk assessment and risk management. Potential research areas were rated on 1) importance to consider in future risk assessments (*y*-axis), and 2) confidence in data availability and utility to support risk management (*x*-axis). Combinations of importance (important, possibly important, less important) and confidence (not confident, somewhat confident, confident) provided a prioritization for future research. Areas rated of highest importance and lowest confidence were considered research priorities for MWCNTs. Colors correspond to priority levels, with red denoting the highest priority, followed by orange, yellow, and green.

guide participants in developing specific research questions (Table 1). Efforts were made to align breakout group participants areas of expertise with the priority research areas that breakout group was charged with developing research question for (e.g., assigning an inhalation toxicologist to a breakout group charged with developing specific question for the research area of occupational inhalation exposures).

Workshop outcome analysis

The extent to which the CEA workshop process for MWCNTs met its objectives and used the related components (described previously) was evaluated in several ways. A key component of the workshop was engaging stakeholders with a spectrum of diverse technical expertise areas and organizational perspectives. The fulfillment of this component was evaluated by reviewing the number of areas of the CEA framework that participants represented, along with the number of organizational perspectives represented, in each prioritization round. This review was based on information that participants provided before agreeing to participate in the process.

The number of research priorities that CEA participants identified in the process was reviewed by checking the number of priority research areas (i.e., research areas in top right, red cell of Figure 3) after round 3. The number of specific research questions that participants generated was also evaluated. The extent that CEA participants changed their ratings from

Table 1. Criteria provided to CEA participants for developing specific, actionable research questions[a]

	Criteria provided to participants	Characteristics of research questions fully meeting each criterion
1	Be answerable through a realistic research design	Includes a general description of what to measure or detect and in what context; or describes what analytical methods to develop and for what purpose
2	Have a factual answer that does not depend on value judgments	States what is measured or developed; does not include subjective terms (e.g., "adequate," "better")
3	Address a highly prioritized research area for future risk assessment and risk management of MWCNTs (i.e., an E-RRF, associated influential factors [IFs], and reasoning)	Specifies an E-RRF pair and IFs (or other parameters to include in experimental design such as dose level or characterization metrics)
4	Be of a spatial and temporal scope that could be reasonably addressed by a research team	Describes research generally undertaken by 1 research team (e.g., 2-y rodent bioassay); or defines temporal and spatial scales to the extent that work is reasonable for 1 research team to complete
5	Not be answerable with "it depends"	States what is measured or developed as a result of research; defines experimental design such that outcomes do not depend on which procedures are selected (e.g., which control technique is in place to protect worker health)
6	Should not be answerable by "yes" or "no"	Not stated as a "yes" or "no" question
7	If related to impact(s) and intervention(s), contains a subject, an intervention, and a measurable outcome.	States what impact is being measured, how measurement occurs, and experimental design to test whether impact is mitigated

[a]Criteria (left-hand column) were provided to participants as a guide for developing research questions in Research Priority Areas. For the purposes of this article, the characteristics listed in the right-hand column were used 1) to qualitatively evaluate the extent to which each question met each criterion, and 2) to identify which criteria would benefit from revision in future research planning efforts.

rounds 1 to 3 was analyzed throughout the process by calculating the percentage change in priority research areas between rounds. Attention was also paid to which areas had the largest percentage changes between rounds 1 and 3. This information was used to inform observations on the potential influence of using online tools versus face-to-face interaction in stakeholder engagement by comparing changes between rounds 1 and 2 with changes between rounds 2 and 3.

After the workshop, we analyzed the effectiveness of the criteria that we had provided to CEA participants for generating specific, actionable research questions (Table 1). Each research question was independently scored by 2 authors (CP and GL) of this article for how well it met each criterion shown in Table 1. A score of 0 was assigned to research questions that did not meet the criterion, 0.5 to those that partially met the criterion, and 1 to those that completely met the criterion (see Supplemental Data Table 1). The 2 independent authors responsible for scoring the research questions then met to discuss discrepancies in scores and to come to agreement on each score. For each breakout group, percentage scores to represent the effectiveness of each criterion were calculated by adding together the scores for each criterion across research questions, dividing by the number of research questions generated by that breakout group, and multiplying by 100.

Finally, we completed a qualitative evaluation of the potential benefits and limitations of the workshop process based on participant responses to questions on the process (see Supplemental Data Section 8). Each participant response was scored according to 1 of 3 categories: "No Changes Suggested," "Needs refinement," or "Did not work" (see Supplemental Data Table 2). Scores for participant responses were reached in a manner similar to the scoring process for research questions described. For each question, the number of responses in each category was presented as the percentage of the total number of participants.

RESULTS AND DISCUSSION

We developed and applied several refinements to the CEA workshop process in the application of this approach to MWCNTs based on previous CEA applications to identify research priorities for other ENMs (USEPA 2010a; ICF 2011; Powers, Hendron et al. 2014). We now report the results and discuss the extent to which these refinements facilitated meeting the objectives and fulfilling the key design components of the workshop process discussed previously. We then identify additional lessons learned to inform future efforts to engage stakeholders in research planning for environmental issues.

Systematically engaging diverse perspectives

We initially set a target number of 80 participants for the first 2 prioritization rounds, using online tools. Our primary objective in selecting a participant group was to ensure that it included the broad range of technical expertise and organizational perspectives required for collective judgment in CEA (USEPA 2010a; ICF 2011; Powers et al. 2012). Our target participant number was based on several factors, including 1) a larger participant group compared with previous CEA applications (i.e., 23 or 49 [USEPA 2010a; ICF, 2011]) in initial prioritization rounds, which could provide greater diversity in perspectives within represented areas (e.g., 3 individuals representing material characterization rather than 1), and 2) possible statistical evaluations of how different technical or organizational perspectives rated each area of the CEA framework. However, because of participant attrition between prioritization rounds, these statistical analyses were not performed, although changes in research priorities between prioritization results are noted later.

Although RTI International generated a list of potential participants that exceeded 200 experts, and invited more than 95 individuals to participate, only 32 participants completed round 1 of prioritization. Nevertheless, in each prioritization round at least 1 participant represented the technical disciplines contained in the CEA framework (i.e., product life cycle; environmental transport, transformation, fate; exposure, dose; and impacts) (Supplemental Data Figure 3). In addition, experts in material characterization, policy, and risk assessment participated in the process, although policy experts were not available to participate in round 3. In all 3 prioritization rounds, participants represented 5 different organizational areas (i.e., academia, government, independent consultants, industry, and nongovernmental organizations). Although the limited number of participants precluded some of the initial goals we set (e.g., including multiple perspectives from the same field), the number of experts seemed sufficient to achieve our primary objective of having a range of perspectives to prioritize research gaps.

Identifying research priorities

The CEA participants identified a total of 26 research priorities (i.e., research areas in top-right graph of round 3 results in Figure 4). These research priorities span the CEA framework (Figure 1). The 15 most agreed-on research priorities (i.e., research areas that CEA participants most frequently rated as of highest importance and lowest confidence) generally related to 1) MWCNT release from several stages of the product life cycle (e.g., material processing, disposal); 2) environmental behavior in air, waste water, and sediment; 3) human exposure (occupational populations and consumers) and dose; and 4) human health impacts. For the 15 most agreed-on priority research areas, experts developed 45 research questions that contained more detailed indications of which data would be beneficial to develop in each priority area (RTI International 2012) (Supplemental Data Table 1).

The CEA participants thus identified a smaller number of high-priority research areas ($n = 26$) compared with specific research questions ($n = 45$). This suggests that the prioritization process facilitated participants in developing more detail in those areas that may benefit from research in the near term, whereas less detail is provided for areas that might be pursued after new data are gathered in priority areas (e.g., after completing hazard identification for noncancer human health effects, researchers could determine what additional studies would improve confidence in dose–response assessments for cancer effects). Moreover, by asking CEA participants to focus on developing specific questions for only a subset of areas, we avoided the potential inclination that participants might have to develop questions only for areas they are most familiar with, rather than those that are considered the highest priorities by the group.

The prioritization process we employed in this CEA application was based in part on indications in our previous work and that of others that including confidence in current data is equally informative to research planning as the

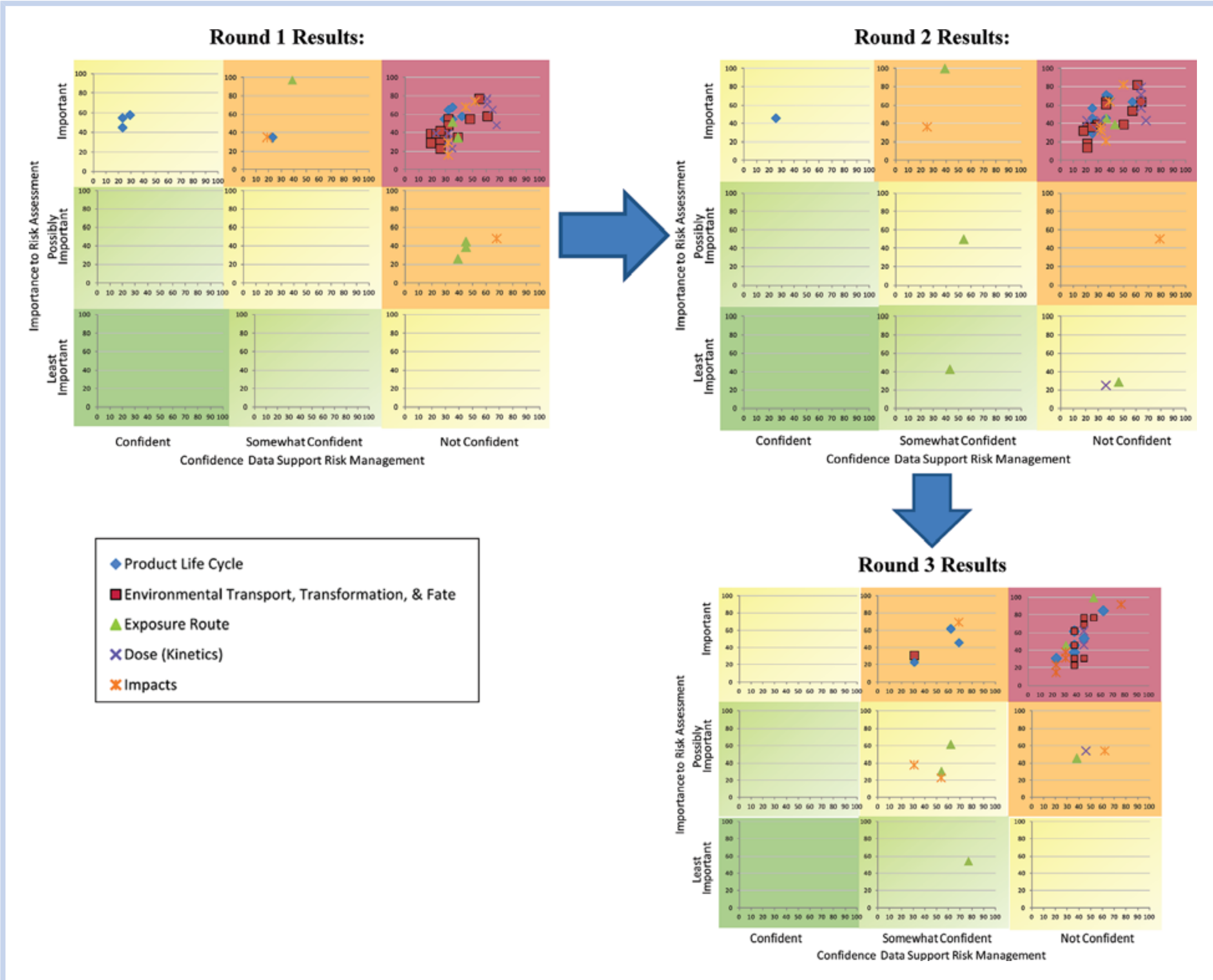

Figure 4. Changes in research priorities during the workshop process. Collated rating of each potential research area in each round of prioritization. Rating results are displayed on the CEA prioritization matrix (Figure 3) to show the change in the number of potential priorities assigned to each category as the process progressed from round 1 (upper left panel) to round 3 (lower right panel). Results are displayed as the percentage of participants rating an area as a combination of importance and confidence (e.g., 98% of participants rated an area important, and 30% of participants rated an area somewhat confident). Details on the rating process and collation of results from individual participants are in Supplemental Data.

identification of important areas to consider in future risk assessment of a material (USEPA 2010a; ICF 2011; Zimmer et al. 2012). Specifically, CEA participants were asked to prioritize research areas based on their relationship to future MWCNT risk assessment and risk management (Figure 3). This approach allows for the identification of 1) research priorities in the context of future risk assessment, and 2) areas for which experts were confident enough in available data to move forward with risk management decisions (i.e., top left cell of Figure 3).

Although experts did not identify any areas in the high confidence category for MWCNTs, they did identify 5 areas (e.g., human occupational inhalation exposure) in which they had greater levels of confidence and that were also important for future risk assessments ("Important/Somewhat Confident" graph in round 3 results of Figure 4). This suggests that relatively few additional data in these areas would support moving forward with risk management plans for MWCNTs in these circumstances (e.g., utilizing the National Institute of Occupational Safety and Health recommended occupational exposure limit to develop Occupational Safety and Health Administration guidelines for occupational inhalation limits). In future applications of CEA on chemicals with larger available datasets, experts may identify areas in which they are confident enough in the data to move forward with developing risk management options. In these CEA applications, experts may focus on identifying tradeoffs related to risk management options for those areas (e.g., economic costs of 2 risk mitigation approaches vs. estimated decreases in human exposure of each approach).

Focusing research

We asked CEA participants to rate the same potential research areas in each round of prioritization. After the first round of prioritization, participants could evaluate how the group rated each area in comparison with their own rating, and subsequently decide whether to reexamine their own rating. For example, 1 participant described their evaluation of the group data in the following way: "I felt the collated responses were helpful in the second round of prioritization, as it led me to specific areas of the document [draft case study] that I wanted to consider in further detail to see if I had potentially missed something that others found important." Including the second round of remote rating thus allowed CEA participants to benefit from the insight of other experts while avoiding the issue of undue influence from a subset of experts with strong opinions or influential personalities.

Data show that the number of research priorities (i.e., research areas in top-right, red graphs of Figure 4) decreased overall from prioritization round 1 to 3 (34 to 26, Table 2). Most of the decrease in identified research priorities occurred in the following CEA areas: 1) environmental transport, transformation and fate (13 to 8 research areas), and 2) dose (kinetics) (8 to 3). In addition, while in prioritization round 1 CEA participants did not identify any areas as of lesser importance to consider in future risk assessments (i.e., research areas in lower row of cells of Figure 4), in prioritization round 3 they identified 1 area as of lesser importance (dermal occupational exposures). This change aligns with a general shift in the distribution of potential research areas in the matrix (Figure 3) from the top row (i.e., all important) to the 4 upper-right categories (i.e., important and possibly important with confidence levels of "not" or "somewhat") (Figure 4). Through the iterative rating process, CEA participants may have recognized that if everything is considered "important," then effectively allocating resources for research becomes difficult for those managing research organizations or funding sources.

Thus, CEA participants ultimately focused on a relatively small percentage of all possible priority areas (26 research areas [Figure 4] out of the 76 possible [Figure 1]). Notably, areas that participants rated as of lower Importance or had greater confidence in available data may still be interesting to pursue, and may become important to research later; however, in this application of CEA we emphasized the importance of focusing resources on the highest priority research for future risk assessment and risk management, given limited budgets and time with which to pursue the multitude of possible research questions on MWCNTs.

Outcomes of online and face-to-face workshop approach to applying CEA

Financial and environmental costs combined with diminishing returns on productivity as group size increases provide reasons against bringing large groups of experts together for face-to-face interactions (Lowry et al. 2006). Engaging stakeholders using online tools would decrease financial and environmental costs while allowing the inclusion of more experts. We were able to make some initial observations on whether reviewing input from other participants without any interaction (i.e., using online tools) was comparable to interacting face-to-face for research prioritization by including the second round of prioritization, during which participants only had input from other CEA participants in the form of aggregated tables, graphs, and written rationales that were not attributed to any individual participant.

We observed that, compared with providing input using online tools, structured face-to-face discussion resulted in greater changes in research priorities in this CEA application. For example, a larger change occurred in the number of areas rated as important/not confident after the face-to-face interactions in prioritization round 3 compared with prioritization rounds 1 and 2, in which participants identified research priorities with no direct interaction with other participants (Table 2). We focused our attention on changes in research areas rated as "important/not confident" for 2 reasons: First, in each prioritization round, most of the potential research areas within the matrix (Figure 3) are located in this category (i.e., top right, red graph). Thus, this category provides the largest sample to evaluate. Second, because this category represents the highest priorities, participants likely focused more attention on discrepancies between their ratings and the CEA group's ratings for this category. After participants reviewed input from round 1 in the form of bar charts and tables, the number of research areas in this category increased by 1 (i.e., 34 to 35 between rounds 1 and 2). In contrast, after participants discussed research priorities face-to-face (i.e., structured workshop discussion using nominal group technique [see Supplemental Data Section 9]), the number of research areas in this category decreased by nine (i.e., 35 to 26 between rounds 2 and 3). The greatest changes in prioritization between rounds 1 and 2 compared with rounds 2 and 3 occurred in a) environmental transport, transformation and fate and b) dose (kinetics) (see Table 2 for details).

The larger change in prioritization results between rounds 2 and 3 compared with that between rounds 1 and 2 could be attributable to a number of factors (e.g., repetition of the rating process, time between ratings). Nevertheless, our observations suggest 2 important considerations for future efforts to engage experts via online tools. First, some structured face-to-face interaction may be necessary to finalize key decisions about research priorities. This may be particularly true for research areas for which public concern or other factors drive an

Table 2. Changes in research priorities from round 1 to round 3 of the MWCNT CEA Workshop Process[a]

CEA level	E-RRF pairs (*n*)	Round 1 *n* (%)	Round 2 *n* (%)	Round 3 *n* (%)	1–2 *n* (%)	2–3 *n* (%)
Product life cycle	14	6 (43)	9 (64)	7 (50)	+3 (21)	–2 (14)
Environmental transport, transformation & fate	19	13 (68)	12 (63)	8 (42)	–1 (5)	–4 (21)
Exposure route	16	2 (13)	2 (13)	2 (13)	0	0
Dose (kinetics)	13	8 (62)	7 (54)	3 (23)	–1 (8)	–4 (31)
Impacts	14	5 (36)	5 (36)	6 (43)	0	+1 (7)
Total	**76**	**34**	**35**	**26**	**1**	**–9**

[a]Data are the collated ratings of potential research areas (i.e., E-RRF pairs) that participants identified as "Important/ Not Confident" in each round of prioritization. For each round of rating, results are shown as the number and percentage of the total number of possible E-RRFs included in each level of the CEA framework (Figure 1). The final 2 columns show the change between rounds 1 to 2 and rounds 2 to 3, respectively, in research areas identified as "Important/ Not Confident". A graphical display of these data is included in Figure 4 with details on the rating process available in the Supplemental Data.

increased scrutiny of how to best allocate resources because verbal rationales from each participant may help to clarify different perspectives (see Supplemental Data Section 9). Second, incorporating virtual face-to-face interactions (e.g., virtual meetings, social media tools that enable video or text-based conversations) could improve future efforts to engage stakeholders using online tools (Bohannon 2011).

In our applications of CEA, we have consistently included a mechanism to structure how participants interacted, regardless of whether this interaction occurred with or without face-to-face interaction (e.g., nominal group technique, or review of graphs and tables) (USEPA 2010a; ICF 2011; RTI International 2012). As discussed below, certain aspects of these mechanisms may benefit from improvement in future applications, but fundamentally they ensured that each CEA participant had equal input into the results of each prioritization round (RTI International 2012). Future efforts to engage stakeholders using online tools, face-to-face interaction, or a combination, may benefit from structured techniques similar to what we applied here to avoid pitfalls such as "groupthink" or domination of the discussion by 1 or more strongly outspoken individuals.

Specific Research Questions

The CEA participants generated 45 research questions that pertained to the 15 research areas most commonly agreed on as "important/not confident" for risk assessment and risk management of MWCNTs (RTI International 2012) (Supplemental Data Table 1). A qualitative review of these questions shows that they vary in specificity but are consistently more detailed than the broader research priorities to which they relate, the breadth of which aligns closely with the detail level of existing recommended lists of research priorities for ENMS (e.g., NNI 2011; NRC 2012; OECD 2012). This indicates that the progression from prioritizing relatively broad potential research areas (e.g., human occupational exposure) to developing more specific research questions, combined with focusing on a specific ENM (i.e., MWCNTs), effectively advanced the conversation by adding to existing research priorities to provide greater granularity (NNI 2011; NRC 2012; OECD 2012). Additional discussion of these research questions, their potential use in research planning across the scientific community, and their comparison with previously identified research gaps is the topic of other papers (Powers, Gift et al. 2014; Powers, Hendron et al. 2014).

Based on previous work and that of others (Sutherland et al. 2011), we provided participants with a set of criteria for developing specific, actionable research questions (Table 1). Our review of the research questions that CEA participants developed against the provided criteria suggests that some criteria were easier for participants to meet (e.g., have a factual answer that does not depend on value judgments [#2]) than others (e.g., not answerable by "it depends" [#5]; Figure 5). One criterion that was more difficult to meet (#7 in Table 1: If related to impact[s] and intervention[s], contains a subject, an intervention, and a measurable outcome) was specific to questions that related to impacts, and thus had less applicability to questions that addressed the development of methods or other endpoints (e.g., exposure).

Our qualitative review suggests that the extent to which participants met each criterion for the research questions they developed varied across breakout groups. For all criteria, 1 breakout group (group 1) more consistently met criteria compared with the other groups (Figure 5; Supplemental Data

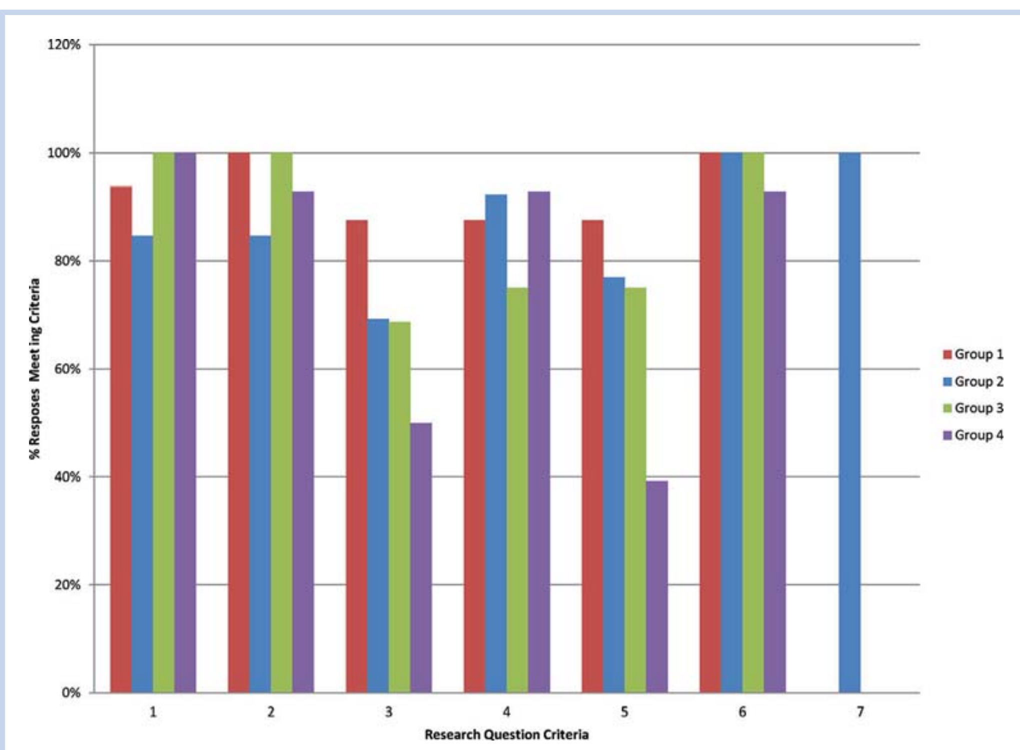

Figure 5. Effectiveness of research question criteria. Results of qualitative review of research questions that CEA participants developed compared with criteria provided. Research criteria are displayed across the *x*-axis (see Table 1 for description of each criterion) with the percentage of questions meeting each criterion displayed on the *y*-axis. Results are displayed by breakout group (see legend) for comparison across groups of experts (see Supplemental Data Table 1 for details).

Table 1). Variation in group dynamics, alignment of expertise areas with the research area they focused on, and experience with developing specific research questions (e.g., writing grants, doing research) are possible explanations for the differences across groups but are outside the scope of this paper. As will be discussed, future efforts may modify some of the criteria or include additional criteria to minimize such factors when participants develop specific, actionable research questions. Nevertheless, the generally high rate of participants meeting these criteria suggests that the active pursuit of these questions by the research community can provide valuable support for future risk assessments and risk management efforts for MWCNTs.

Participant feedback

The CEA participants provided feedback on the workshop process by responding to specific questions (listed in Supplemental Data Section 8). Our categorization of participant responses to questions about the process suggests a variety of potential ways to continue refining the approach (Figure 6, Supplemental Data Table 2). For instance, some CEA participants suggested reducing the number of potential research areas to rate, although most participants did not suggest any changes to the potential research areas (Figure 6; no changes suggested: 54%). We discuss below how future efforts could facilitate participants rating fewer areas while maintaining the benefit of pairing potential research areas with factors that risk assessors may consider in conducting an assessment.

The CEA participant responses were split on whether the use of terms to add more detail to potential research areas (i.e., influential factors; see Supplemental Data Section 3.1) needed improvement (Figure 6). Suggestions for improvement included reducing the number of terms and facilitating the selection of multiple terms at once. We addressed some of the concerns related to selecting detailed terms in a recent pilot study that developed and applied a website version of the spreadsheet tool used in MWCNT workshop process (Powers, Grieger et al. 2014).

Most CEA participants responded that data could be more clearly presented to inform the rating of potential research areas in subsequent rounds (Figure 6; Process could work but needs refinement: 50%). Future efforts could also improve how data are presented to participants to help ensure that they better understand how their views may differ from others. For instance, several CEA participants suggested that a verbal or extended text description of results could help them better interpret the group results or the rationales of other participants (Supplemental Data Table 2). Most participant responses also indicated specific suggestions for improving the process (Figure 6; Process could work but needs refinement: 59%). We discuss ways to improve structured stakeholder engagement in research planning for emerging materials based on participant feedback and our own observations from applying CEA to MWCNTs.

Lessons learned

Although we actively applied lessons learned from previous applications of CEA in this work with MWCNTs, we identified additional ways to improve the workshop process in this current application. Below, we focus on specific suggestions for the 5 main aspects of the process discussed: 1) selecting participants, 2) identifying research priorities, 3) focusing research through multiple rating rounds, 4) using online tools

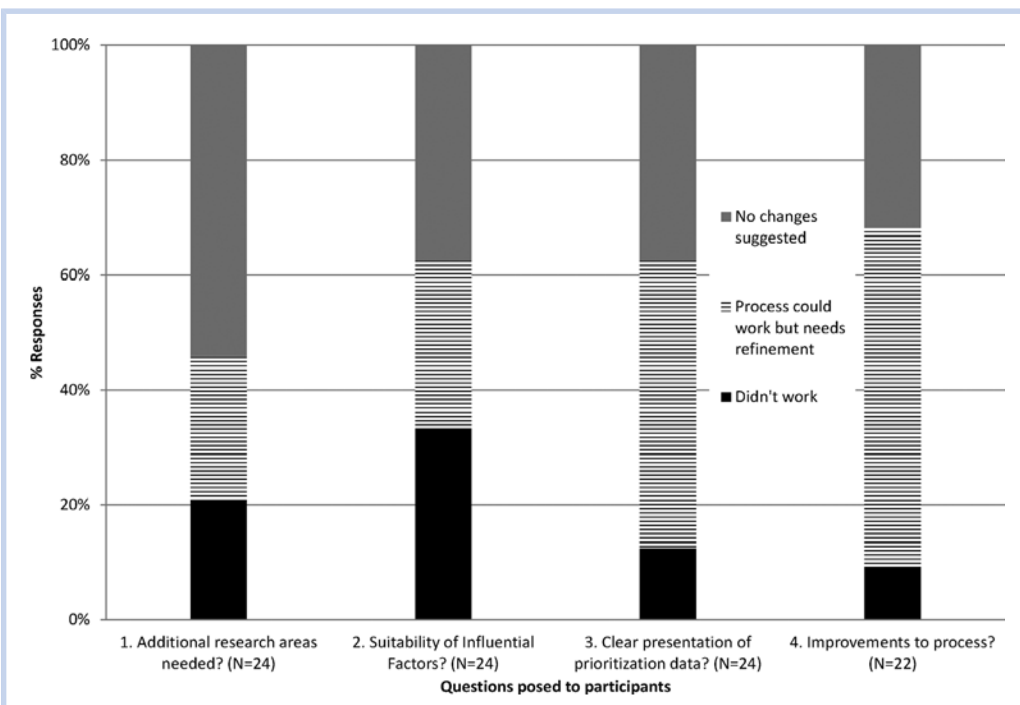

Figure 6. Participant responses to questions on the workshop process. Results of qualitative evaluation of participant feedback on the workshop process. Questions posed to participants were developed by the USEPA and shared with participants by RTI International. Authors binned participant responses into 3 categories (no changes suggested, process could work but needs refinement, and did not work). Questions posed to participants are listed across the *x*-axis and with the percentage of participant responses meeting each response category displayed on the *y*-axis. See Supplemental Data Table 2 for details on response categorization.

and face-to-face interactions, and 5) developing specific research questions.

Participant selection: Include individuals from across the information chain (i.e., research design, risk assessment, risk management). As already discussed, we engaged a group of experts with diverse technical and organizational perspectives; however, future efforts may benefit from placing more emphasis on incorporating expertise specific to 3 areas: designing applied research (i.e., targeted to inform risk assessment or risk management), conducting risk assessments, and developing risk management plans. Although these expertise areas may overlap to some extent with those included in this application of CEA (e.g., an expert in ecology may also have expertise in applied research design), without a specific focus on including individuals from each of these 3 areas this aspect of the participant group may be easy to overlook (e.g., preference for including more technical experts regardless of whether they are familiar with risk assessment). Although participants with knowledge in these 3 areas would likely be informative throughout the process of prioritizing research gaps, they would be particularly important to include once participants are focused on generating specific, actionable research questions. Dialogue between experts involved in each stage of the flow of information from research to risk assessment to risk management is critical to help ensure that the specifics of identified research priorities (i.e., detailed research questions) align with the needs of risk assessors and risk managers who will use the resulting data. In addition, the inclusion of individuals from across the information chain may develop more support for pursuing the identified priorities, and thus help to ensure that they are addressed through research plans across the scientific community.

Research priority identification: Include an initial structured discussion to identify focus areas before formal rating rounds. The inclusion of 76 potential research areas in the CEA workshop process for MWCNTs helped ensure that the participants comprehensively evaluated potential research priorities for these materials. Nevertheless, participant feedback suggests that reducing the number of potential research areas could decrease the amount of time necessary to complete the rating process. A smaller number of areas could be identified in an initial round of structured discussion and streamlined rating that precedes the rounds of rating used in this CEA application (i.e., an early scoping step). Specifically, participants could engage in a structured discussion about what potential research areas are most important for the material or chemical of focus (e.g., human exposures, terrestrial biota impacts). Participants could then independently identify the areas they view as important, using a spreadsheet or other online tool. A potential drawback of this initial round of prioritization is that by design it will narrow the scope of subsequent rounds of consideration, such that an individual participant may find that their highest priority area is not under consideration as the CEA process progresses through the various steps. However, this aspect of the collective process, though it may appear biased away from a single individual's priorities, would indeed represent the majority opinion of the group in a way that allows for streamlined focus on the topics deemed most important to the collective. This further highlights the importance of adequate stakeholder representation as noted in Supplemental Data Section 3.7.1. Ultimately, the stakeholder feedback that the process could be prohibitively onerous leads us to recommend this new round of engagement. This new, initial round of rating would not include adding any detail to areas (i.e., participants would not identify important risk relevance factors [Figure 1]). Rather, participants could add detail to areas in subsequent prioritization rounds. The research areas that participants added detail to in subsequent rounds would be based on the areas that participants most commonly rated as of highest importance for research in the initial round. For example, some parameters that may influence risk and therefore need to be included in designing research could be identified in this process. This new initial round of engagement may help to balance the benefits of being as inclusive as possible when considering potential research gaps or future risks with the amount of time that such comprehensive evaluations can take.

Multiple rating rounds to focus research: Use a familiar numeric rating scale. Participants in this process identified top priority areas through an iterative rating process focused on placing research areas in ordinal qualitative bins to represent relative priority levels. Although this iterative process narrowed the list of top priority research gaps between rounds 1 and 3, some research suggests it might be improved by asking participants to rate each area on a more familiar numerical scale (e.g., the amount of money they would allocate for an area) (Evans 2012). This change could help more clearly define how participants view an area (Hubbard and Evans 2010). Furthermore, using such a numeric rating scale would allow the data to be presented on a continuous scale with means and ranges, which could potentially inform participants more about the distribution of participant viewpoints on each area of the CEA framework. Though rating systems can be concluded to be better suited than ranking systems for considering options as numerous as the research areas considered in this exercise (Munson and McIntyre 1979), a drawback of rating systems is that they often cannot ensure the scale is used consistently, either between or within respondents. Although a rating system is clearly better than a ranking system for assessing the distance between values for a single respondent, ratings using arbitrarily defined categories such as those applied in this version of the CEA may not be able to completely ensure that within-respondent ratings are consistent (Ovadia 2004).

Therefore, we suggest that tying ratings to a more widely familiar and understood metric (e.g., US dollars) could impart additional consistency to adjust for this weakness. Nevertheless, the potential benefits of using such a numeric scale would need to be balanced against potential challenges and limitations, such as requiring more training to help participants understand a rating scale before initiating the prioritization process.

Use of online tools and face-to-face interactions: Supplement face-to-face interactions with virtual communication tools. The results of the workshop process described here suggest that remote stakeholder engagement tools can supplement but not fully replace face-to-face discussions. We have carried out initial work to facilitate online engagement through a web-based version of the spreadsheet tool employed in workshop process we described, but future efforts might benefit from using virtual communication tools (e.g., web-based meetings, web chat features) to encourage more communication between participants before face-to-face discussions. This could help address some participant concerns that having a verbal summary of results or more description of other participants' rationales for particular rating selections would be useful (Supplemental Data Table 2). The virtual communication tools that are used should help ensure that interactions between participants are structured in a manner similar to face-to-face discussions.

Specific research question development: Provide refined criteria and interim breakout reports. Two factors contributed to participants' developing specific research questions in this workshop process: 1) the progression from prioritizing relatively broad areas of research to developing more specific research questions, and 2) a set of guidance criteria for each question (Table 1). Future efforts might modify the criteria that were used here to help ensure that participants understand the criteria and appropriately use them in developing their research questions. For instance, participants frequently struggled to fully meet criteria #3 and #5 (see Supplemental Data Table 1), suggesting that these guidelines would benefit from revision or further explanation. In particular, to fully meet criterion #3, breakout groups were expected to specify particular parameters that would be important to include in experimental research design and to provide sufficient detail to support their reasoning. For criterion #5, research questions were required to define the experimental design such that the outcomes would not be dependent on unspecified parameters. These criteria were meant to reinforce the precept that research questions should be both specific and actionable. In general, research questions that did not fully meet 1 or both of these criteria were those that did not provide important experimental design details. Future efforts might facilitate the development of questions meeting these criteria by 1) rewording the criteria to better emphasize the importance of providing details; 2) including examples of sufficiently detailed research questions; and 3) incorporating a structured interim report out from breakout groups to allow for feedback on how well draft research questions meet the provided criteria.

CONCLUSIONS

The CEA workshop process for MWCNTs engaged a group of stakeholders representing diverse perspectives to identify a clear list of research priorities that can inform research managers in organizations across the scientific community. This process builds on previous CEA applications in several ways, including 1) using additional online tools in stakeholder engagement; 2) prioritizing research in broad areas before developing specific research questions; and 3) providing criteria for specific, actionable research questions. Based on the outcomes of the process and participant feedback, these refinements generally worked well to fulfill the objective of identifying research priorities for future risk assessment and risk management of MWCNTs. The identified research priorities can inform research managers in developing strategic plans, whereas data resulting from the strategic research plans can strengthen the foundation for risk assessments of MWCNTs. In addition, we identified several new lessons learned that can enhance future efforts to derive research priorities not only for ENMs and emerging technologies but for environmental issues generally. These insights relate to 1) the importance of including participants with research, risk assessment, and risk management expertise in addition to diverse disciplinary backgrounds; 2) the potential value of adding an early scoping step before formal rating efforts; 3) the benefits of a using a familiar metric such as dollars versus an ordinal qualitative rating scale to represent the importance of a research question; 4) the potential utility of virtual communication tools to supplement face-to-face interaction between participants; and 5) enhancements in the guidance for developing specific research questions.

Acknowledgment—The authors are grateful to Kristen Smith, Matt Scruggs, and Timothy Albrecht (RTI International) for their assistance in developing tools and logistical plans for the workshop process. In addition, we appreciate insightful feedback from Nora Savage, George Woodall, Reeder Sams, and John Vandenberg (EPA) to improve previous drafts of the manuscript.

Disclaimer—Views expressed in this article are those of the authors and do not necessarily represent the views or policies of the US Environmental Protection Agency. The authors declare no competing interests.

SUPPLEMENTAL DATA

Supplemental Data: Highlights of CEA features, more details on methods

Table 1. Scoring of research questions based on criteria.

Table 2. Categorization of participant feedback on rating process.

Figure 1. CEA framework.

Figure 2. CEA process.

Figure 3. CEA Participant Expertise & Organizational Affiliations.

Figure 4. Example of spreadsheet rating tool used in the MWCNT workshop process.

Figure 5. Schematic of Rating Process Used in Each Round of Prioritization for CEA Applied to MWCNTs (RTI International, 2012).

Figure 6. Example bar graph used to share prioritization results with CEA participants.

Figure 7. Outcomes from the NGT process during the face-to-face workshop, shown graphically on the detailed CEA framework.

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