

U.S. Environmental Protection Agency
Nanomaterial Case Studies:
Nanoscale Titanium Dioxide
in Water Treatment and in Topical Sunscreen
(External Review Draft)

Charge to Workshop Participants

NOTE: IT IS IMPORTANT TO READ THIS ENTIRE CHARGE AND THE ACCOMPANYING INSTRUCTIONS BEFORE STARTING YOUR REVIEW

Introduction and Objectives

The document you are being asked to review is one step in the development of a research strategy for the comprehensive environmental assessment of nanomaterials such as nanoscale titanium dioxide (nano-TiO₂). It is a starting point for the Nanomaterial Case Studies Workshop that will be held on September 29-30, 2009. Prior to the workshop (by September 10) you should submit your review comments and ranking of Questions (research/information needs), as explained below. The preliminary ranking results will be provided at the workshop. New questions submitted by September 10 will be distributed to workshop participants approximately one week in advance of the meeting.

The document attempts to take a holistic view of selected uses of nano-TiO₂ and the potential ecological and health implications of such products across their life cycle. Although much information is presented in the document, many questions remain to be answered. Several of these questions, which can also be thought of as information or research needs, are listed throughout the document. As you review the document, please consider this overarching question:

“What research or information is most needed in order to conduct a comprehensive environmental assessment of nano-TiO₂?”

- You are asked to read the entire document, not just your own areas of expertise or interest. We want reviewers to take a “big picture” view and not focus exclusively on a particular chapter or section.
- The document is meant to stimulate your thinking about potential release scenarios and implications, both direct and indirect. It is a starting point for your thinking, not an end in itself.
- A key aspect of your review is to **identify and rank the research or information that is most needed in order to conduct a comprehensive environmental assessment of nano-TiO₂**. Separate instructions for the ranking process are provided below and should be read before reviewing the document.

- If you have **comments** on specific text in the document:
 - 1) Please “triage” your comments for us by noting your 5 most important substantive comments.
 - 2) Please indicate the specific document page and line number. For Questions that are listed at the ends of chapters or sections, please indicate the Question number (e.g., 1-1, 2.1-1).
 - 3) Email your review comments to Audrey Turley (aturley@icfi.com) by September 10, 2009.

In your review comments, please indicate:

- 1) Is the information presented in the document accurate, objective, and logical? Are statements properly supported by references? Note that we have by necessity had to rely on gray literature and personal communications at times. If you have better sources to cite for such information, please provide them.
 - 2) Is information clearly and concisely presented? If not, please suggest alternative wording.
 - 3) Is the information complete? Have any important points been omitted? Do you know of other information that bears directly or indirectly on the case studies? Can you provide a source (e.g., a document, Web site, person) for additional information?
- Please submit a brief **biosketch** of up to 200 words through the Web form by September 10. This information will be shared with the other workshop participants and will facilitate introductions and interactions.

Instructions are provided below for accessing the case studies document and submitting your input prior to the workshop. A checklist is provided at the end of this Charge to assist you.

Thank you for your thoughtful review and participation in this endeavor.

Instructions for Accessing the Draft Case Studies Document

You can download an Adobe PDF version of the document at the following Web URL:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=210206>

If you expressed a preference for a hardcopy version when you registered, ICF will send it to you by FedEx within three days.

Instructions for Submitting Pre-Workshop Input

The following instructions describe how to prepare and submit (a) your ranking of questions, (b) new/modified questions, and (c) your biosketch via the Web form. You will also find instructions on how to access the Web form. If you have difficulty accessing or using the Web form, please contact Audrey Turley (aturley@icfi.com) for assistance. **Your rankings, any new or modified questions, and your biosketch must be completed and submitted on-line by September 10, 2009.**

Ranking the Questions

A key task related to your review of the document is to identify and rank the most important questions that need to be addressed in order to conduct a comprehensive environmental assessment of nano-TiO₂. These research/information needs are posed as Questions at the end of chapters and certain sections in the document.

Using a Web form, you will be asked to:

1. **Rank the top 10 needs:** Identify and rank the top 10 priorities by assigning a score of 10 to the question you believe is most important of all identified, a score of 9 to the question you think is the second most important, a score of 8 for the third most important, and so on.
2. **Identify the top 25 needs:** Your top 10 priorities will automatically be included in this group. Select an additional 15 questions you believe are among your 25 most important. In the Web form, select “High (not ranked)” for these 15 questions.
3. **Identify the 10 lowest or “zero” priority needs:** Identify up to 10 questions that you believe are not important or are the lowest priority of all of the questions listed in the document. In the Web form, mark these questions as “Low.”

NOTE: We recommend using the separate list of questions excerpted from the document to make notes about your rankings before entering them into the Web form.

Adding New and Modified Questions

You also may submit new questions and revisions of existing questions. Any new research/information needs should be significantly and directly relevant to a comprehensive environmental assessment of nano-TiO₂. (Many interesting questions could be asked, for example, about uses of nanomaterials or about policies or regulations that could be applied to them; but these types of questions are outside the intended purview of this exercise.)

Please add only questions that you would consider among your top ranked issues. The Web form is not capable of including new questions in the pre-workshop rankings, but all new questions will be distributed in advance to the workshop participants, and participants will have an opportunity to discuss their highest priority issues during the workshop. A primary objective

of the workshop is to derive a ranking of priorities after the participants have considered the pre-workshop rankings along with new questions.

You will need to type (or copy and paste) any new questions in the spaces provided. You should identify the case studies chapter to which each question belongs:

- Chapter 1: Introduction
- Chapter 2: Life Cycle Stages
- Chapter 3: Fate and Transport
- Chapter 4: Exposure-Dose Characterization
- Chapter 5: Characterization of Effects
- “Multiple”: Cross-cutting issues

If you are modifying an existing question, please indicate the number of the original question and enter the revised wording. Please limit modifications to questions that are among your top 25. You should rank the original question if it is among your top 10.

The Web form can accommodate submittal of up to 10 questions, each with a maximum of 250 characters. If you have more than 10 new questions, please email your entire list to Audrey Turley (aturley@icfi.com).

Submitting Your Biosketch

Please submit a biosketch of up to 200 words through the Web form.

Accessing the Web Form

Log into the Workshop Web site using the link and log in credentials provided in the email accompanying this charge. Under the “Participant Info” menu, click on the link “Submit Pre-Workshop Input” to access the Web form for submitting the rankings, new/modified questions, and your biosketch.

Check List

By September 10:

- Rank the questions (research/information needs) on Web form
 - Top 10 rank-order needs
 - Top 25 needs
 - Lowest 10 priority needs
- (Optional) Add new or modified questions
 - If 10 or fewer new questions, submit them on the Web form
 - If 11 or more new questions, email all of them to Audrey Turley, ICF
- Email review comments on draft document to Audrey Turley, ICF
- Submit a 200-word biosketch through the Web form

Charge Questions for Letter Review of Nano-TiO₂ Case Studies

The EPA *Nanotechnology White Paper*¹, under the heading of Risk Assessment (section 6.2.7), recommended developing case studies of engineered nanomaterials and conducting workshops to identify data gaps and research needs related to assessment efforts. Subsequently, the National Center for Environmental Assessment (NCEA) prepared the draft document *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and Topical Sunscreen*² and held the “Nanomaterial Case Studies Workshop: Developing a Comprehensive Environmental Assessment Research Strategy for Nanoscale Titanium Dioxide” on September 29-30, 2009. The goal in preparing that document and holding the workshop was to identify and prioritize research needed to support a comprehensive environmental assessment of nanoscale titanium dioxide (nano-TiO₂) as a first step in refining a strategic approach for nanomaterials risk assessment research, consistent with objectives described in the EPA *Nanomaterial Research Strategy*³.

The case studies were constructed with a comprehensive environmental assessment (CEA) framework, which is a holistic approach that incorporates a life-cycle perspective in the risk assessment paradigm.⁴ However, the case studies were not intended to be actual or even preliminary assessments, nor were they meant to provide an immediate basis for risk management, regulatory, or policy decisions. Instead, the intent was to organize information on nanomaterials in a manner that would facilitate thinking about information gaps that would need to be filled to support future assessment efforts.

The external review draft of the case studies² has been revised based on comments received from workshop participants and the public. NCEA is requesting a letter review of this draft by individuals with expertise in one or more topic areas related to life cycle and risk assessment of nanomaterials. Charge questions to guide the review are listed below. Reviewers should address all questions either as a specialist in an area or as a general reader; however, if a question requires expertise outside a reviewer’s area, the reviewer may so indicate.

Following the review, NCEA staff will revise the case studies to consider comments from the peer reviewers. The final document is planned for release in June 2010.

Charge to the Peer Reviewers

1. Chapter 1 provides introductory material regarding the approach used in these case studies, definitions of conventional and nanoscale TiO₂, the use of nano-TiO₂ in drinking

¹ U.S. Environmental Protection Agency (2007) *Nanotechnology White Paper*. Science Policy Council, Washington, DC. EPA 100/B-07/001, February. Available at: http://www.epa.gov/nanoscience/files/epa_nano_wp_2007.pdf

² U.S. Environmental Protection Agency (2009) *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and Topical Sunscreen* (External Review Draft). ORD, NCEA, Washington, DC. EPA/600/R-09/057, July. Available at: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=210206>

³ U.S. Environmental Protection Agency (2009) *Nanomaterial Research Strategy*. Washington, DC. EPA 620/K-09/011, June. Available at: http://www.epa.gov/nanoscience/files/nanotech_research_strategy_final.pdf

⁴ **Error! Main Document Only.** Davis, J. M. (2007) How to assess the risks of nanotechnology: learning from past experience. *J. Nanoscience and Nanotechnology*, 7: 402-409

water treatment and sunscreens, and analytical methods for characterizing nano-TiO₂. Is this information accurately and clearly presented? Please comment on the utility of the chapter in providing background and support for the remainder of the document. How might this chapter be improved?

2. Chapter 2 presents information on the lifecycle of nano-TiO₂, including potential releases to the environment. To what extent does this chapter accurately and sufficiently characterize what is known and what is unknown with regard to the various stages of the lifecycle of nano-TiO₂ as used for arsenic removal in water treatment systems? To what extent does this chapter accurately and sufficiently characterize what is known and what is unknown with regard to the various stages of the lifecycle of nano-TiO₂ as used in sunscreens? To what extent is the material effectively organized and sufficiently informative to support planning for future research? How might this chapter be improved?
3. Information on the fate and transport of nano-TiO₂ in air, water, and soil is discussed in Chapter 3. Please comment on the extent to which this chapter accurately and sufficiently characterizes the state of understanding regarding the known and anticipated behavior of nano-TiO₂ in the environment. To what extent is this information presented in a manner that would inform consideration of likely exposure routes relevant to biota and human health? To what extent is the material effectively organized and sufficiently informative to support planning for future research? How might this chapter be improved?
4. Chapter 4 provides information on exposure, dose, and translocation of nano-TiO₂ in biota and humans. Please comment on the extent to which this chapter accurately and sufficiently characterizes this information and forms a basis for considering the health and ecological effects of nano-TiO₂. To what extent is the material effectively organized and sufficiently informative to support planning for future research? How might this chapter be improved?
5. Chapter 5 characterizes factors that influence ecological and health effects of nano-TiO₂ and discusses the currently available scientific evidence regarding these effects. Please comment on the extent to which this chapter accurately and sufficiently characterizes the state of the science. To what extent is the material effectively organized and sufficiently informative to support planning for future research? How might this chapter be improved?
6. Chapter 6 summarizes the information and research questions presented in the nano-TiO₂ water treatment and sunscreen case studies, as well as discussing the role of case studies in the refinement of research strategies and potential future assessment efforts. We would appreciate comment from the peer reviewers on the integration of evidence in this chapter and its usefulness in supporting future development of research strategies and assessments. How might this chapter be improved?

7. The case studies follow the comprehensive environmental assessment (CEA) approach, which combines a product life-cycle framework with the risk assessment paradigm. Please comment on aspects of this approach that can be improved in future case studies. We would appreciate comment on the overall structure and scope of the case studies and the extent to which the case studies support the development and refinement of research directions for future CEAs of nano-TiO₂ in particular and nanomaterials in general.