



November 20, 2013

Dr. Glenn Paulson
Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Dear Dr. Paulson,

Environmental Defense Fund (EDF) welcomed the recent release of the Environmental Protection Agency (EPA)'s updated guidance for the [Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents](#). Efforts to increase transparency of this process and reduce the potential for conflict-of-interest concerns to arise during panel formation, through both greater public participation and internal Agency review, are critical to ensure the integrity and credibility of peer review.

Nevertheless, upon further examination, we have identified serious shortcomings in the implementation of EPA's new guidance and related procedures regarding contractor-managed peer reviews. We strongly believe that these deficiencies, detailed below, jeopardize the ability to form panels that are free of actual or potential conflicts of interest and the appearance of a lack of impartiality, as mandated by [EPA's Peer Review Handbook, 3rd Edition](#), (page 62). These concerns are not merely theoretical; we have identified several recent instances in which contractor-selected peer review panel candidates have had actual or potential conflicts of interest or an appearance of a lack of impartiality.

In order to ensure the integrity of, and public confidence in, peer review of Agency science, we urge that your office promptly make the following improvements in the procedures used to implement and ensure adherence to existing policies and the recently updated guidance:

- 1) Strengthen conflict of interest disclosure procedures for panel candidates;
- 2) Require contractors to conduct a thorough, certified assessment of appearance of a lack of impartiality of panel candidates; and

- 3) Ensure contractors routinely search for and examine information sources needed for a comprehensive screening of conflict of interest and lack of impartiality.
- 4) Provide transparency in contractor/Agency response to public comments

Strengthen conflict of interest disclosure procedures for peer review candidates

As described in the updated guidance document, contractors are directed to select panel members based, among other considerations, on “adherence to the conflict of interest requirements in the contract.” An associated footnote indicates that such requirements include to:

evaluate and update specific conflict of interest-related financial and professional information related to peer review candidates and their spouses (e.g., assets, liabilities, funding sources for research, employment information, compensated consulting and expert witness activities, and previous public statements related to the chemical or matter under review)...[and] certify that the contractor has evaluated each candidate, and that there is not significant evidence to support a finding or an actual or potential conflict of interest (page 2, paragraph 6, footnote 3).

Contractors are to obtain the information necessary for assessing actual or potential conflict of interest of candidate peer reviewers in three primary ways: review of candidate resumes, evaluation of candidate conflict-of-interest disclosure forms, and examination of relevant information obtained through additional searches.

According to [EPA's Peer Review Handbook, 3rd Edition](#) (page 78), conflict-of-interest disclosure forms for each panel are to be developed by the EPA peer review manager and the contracting officer (CO). While the handbook provides examples of key questions that the “contractor may be advised to consider,” the precise nature of the disclosure form may vary between panels, based on the judgment of the aforementioned individuals. We are concerned that the lack of sufficiently detailed guidance for this process may result in the development of conflict-of-interest disclosure forms that are insufficient to assure contractors have access to the information necessary to carry out the robust screenings mandated by current policies and the updated guidance.

As examples, we have attached to this letter the conflict-of-interest disclosure forms used to select candidates for two recent contractor-managed peer reviews of Agency documents relating to: (1) the Office of Pollution Prevention and Toxics’ (OPPT) draft risk assessments for methylene chloride (DCM) and N-methylpyrrolidone (NMP), and (2) the National

Center for Environmental Assessment's (NCEA) draft report "Advancing the Next Generation of Risk Assessment." These forms, each developed, we presume, by the relevant EPA peer review manager and CO, contain nine yes/no questions intended to assist the contractor in a conflict-of-interest analysis. However, instead of requiring full disclosure of potentially relevant information and then allowing the contractor to make an informed judgment about actual or potential conflict, the form gives the candidates themselves the authority and responsibility to make such judgments. Only if the candidate decides to answer affirmatively to one of the nine questions is he or she required to elaborate and provide more detail. A process that places this critical judgment in the hands of the candidates themselves, and does not provide contractors with the information needed to verify the candidates' answers, is deeply flawed.

That these overly simple yes/no questionnaire forms were developed, approved, and utilized for a conflict-of-interest screenings even under the new guidance highlights shortcomings in the implementation of current policies and the requirements of the new guidance. Other contractor-managed peer reviews across the Agency may be similarly at risk for inadequate screenings.

To strengthen these essential conflict-of-interest assessments and ensure compliance with existing Agency policies and guidance, full upfront disclosure to contractors (with access by relevant EPA staff) of pertinent information by each peer review candidate is necessary. The list of recommended questions and issues on page 78 of EPA's Peer Review Handbook – together with the candidates' information required to answer them – can and should serve as the foundation for this evaluation; the Agency need only provide additional direction on the format of the final forms.

We suggest as a model the [Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees \(EPA Form 3110-48\)](#), which requires documentation of candidates' answers to key questions in anticipation of the requisite evaluation of actual or potential conflicts. While we fully recognize that contractor-selected peer reviewers are not considered special government employees (SGEs) and that there may be reasons to distinguish between persons anticipated to be designated SGEs versus those that are not, both serve on panels that are subject to government standards requiring demonstration of the absence of actual or potential conflicts of interest for the selected members. Thus, we believe that a similar format, or analogous questions, should be used for non-government employees proposed as candidates for peer review panels.

Improving the existing disclosure forms will provide contractors with access to information pertinent to identifying potential or actual conflicts of interest, which is

necessary for adherence to contract requirements and Agency policies regarding the screening process. Use of such forms will appropriately place the responsibility of making the critical judgments on the contractors, instead of the candidates themselves, and thereby better ensure the credibility of contractor-managed conflict-of-interest evaluations.

Require contractors to conduct a thorough, certified assessment of appearance of a lack of impartiality of peer review candidates

Another crucial component in the selection of panel members is supposed to be an evaluation of any appearance of a lack of impartiality. As indicated in the Agency's updated policy, contractors must "follow guidance articulated in EPA's current Peer Review Handbook and related documents (currently the 2006 Science Policy Council Peer Review Handbook, 3rd Edition, and the 2009 Addendum to the Peer Review Handbook) that address identification and resolution of *appearances of a loss of impartiality*" (page 2, paragraph 6, footnote 3; emphasis added). In turn, the contractor must "certify that the contractor has evaluated each candidate, and that there is no significant evidence to support a finding of...an *appearance of a lack of impartiality*" (page 2, paragraph 6, footnote 3, emphasis added).

Based on our understanding of current practices, however, this guidance has not been adequately implemented. While, as discussed earlier, candidates are required to complete conflict-of-interest forms to the contractor during the selection process, there is no analogous form addressing the potential for the appearance of a lack of impartiality. Furthermore, conversations with EPA staff indicate that contractors do not routinely submit formal certifications of such assessments. These deficiencies are not only serious flaws in the screening process, they may also indicate a disregard for or lack of enforcement of Agency policy.

EPA has developed guidance for conducting an evaluation of an appearance of a lack of impartiality: It is provided in the [Addendum to the Peer Review Handbook, 3rd Edition: Appearance of a Lack of Impartiality in External Peer Reviews](#), which as noted above is among the guidance documents to which contractors must adhere. This addendum states that "an appearance of a lack of impartiality can occur when an expert participating in a particular matter involving specific parties may cause a reasonable person with knowledge of the relevant facts to question the expert's ability to carry out official duties without bias or influence"(page 5).

In addition to providing this definition, the addendum describes several interests and activities that may create an appearance of lack of impartiality. Though not exhaustive, this list includes:

- financial relationships
- organizational relationships
- contributions to the materials that will be peer reviewed
- public statements about the materials that will be peer reviewed or closely related matters
- testimony related to the materials that will be peer reviewed or closely related matters

Guidance is also provided on key criteria that should be used to evaluate whether there may be an appearance of a lack of impartiality, including:

- the nature of the relationship involved
- the effect that the resolution of the matter would have upon the financial interests of the person involved in the relationship
- the nature and importance of the expert's role in the matter, including the extent to which the expert is called upon to exercise discretion in the matter
- the sensitivity of the matter
- the difficulty of finding other experts with similar expertise and perspective to participate in the review
- adjustments that may be made in the expert's review duties that would reduce or eliminate the likelihood that a reasonable person would question the expert's impartiality

This guidance, however, lacks the necessary level of detail for actual implementation; nor have any accompanying candidate-directed questionnaires been developed to inform and guide contractors in conducting adequate evaluations. Therefore, we recommend – as elaborated below – that the Agency: (1) provide additional clarification to existing definitions and guidelines, and (2) develop formal screening questions to be used by contractors to assess the appearance of a lack of impartiality. Such improvements will promote adherence to Agency guidance, compliance with which is essential to ensure comprehensive and credible screening of panel candidates.

(1) Additional clarification to existing definitions and guidelines is needed

While the information in the Addendum (listed above) serves as a useful foundation, additional details are necessary to clarify the definition and scope of what would constitute an appearance of a lack of impartiality under current policy. For example:

- What time frame should be considered when evaluating relevant interests and activities?
- What is meant by and intended to be encompassed under the term “financial or organizational relationships”?
- What is the policy regarding interests and activities of family members?
- How should the contractors determine whether “sensitivity of the matter” or “the effect that the resolution of the matter would have upon ... financial interests” are significant enough to merit concern?

These questions, and others, should be addressed by EPA to ensure that contractors managing peer reviews across the Agency are applying consistent standards during the screenings, that these standards are aligned with the articulated guidance, and that the decision-making process and criteria are fully transparent to the public.

(2) Formal screening questions for an assessment of the appearance of a lack of impartiality are needed

In conjunction with a further elucidation of scope, formal questions should be developed to assist contractors in complying with existing policies regarding the impartiality screening process. Some suggestions for screening questions, drawn from EPA's *Peer Review Handbook*, 3rd Edition, or that EDF proposes based on existing Agency criteria, include:

- Do you believe there is any reason that would impede your ability to provide impartial advice on the matter to come before the panel?
- Do you believe there is any reason that your impartiality in the matter might be reasonably questioned?
- Have you had any previous involvement with the development of review document(s) under consideration? If so, please identify and describe that involvement.
- Have you served on previous advisory panels, committees, or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- Have you made any public statements (written or oral) on the issue or related issues? If so, please identify those statements.
- Have you made any public statements that would indicate to an observer that you have taken a position on issues relevant to the topic under discussion? If so, please identify those statements.
- Have you given expert witness testimony on the issue under consideration or related issues?

- Do you have relationships with organizations that may have a strong interest, financial or otherwise, in the issues under discussion in this panel or on related issues?
- Do any of your immediate family members (spouse, partner, parents, children) have relationships with organizations that may have a strong interest, financial or otherwise, in the issues under discussion in this panel or related issues?
- Do any of the organizations that you have relationships with receive funding from individuals or organizations that may have a strong interest, financial or otherwise, in the issues under discussion in this panel or related issues?
- To the best of your knowledge and belief, is there any other information that might reasonably raise a question about an actual or potential lack of impartiality?

The development of specific questions aimed at screening for any appearance of a lack of impartiality should serve as the basis for an official disclosure form, analogous to existing conflict-of-interest disclosure forms. Such a mechanism, wholly absent from the current process, is essential to ensure that the Agency's policy regarding the selection of panel candidates is actually implemented in a consistent, accountable and transparent manner.

Finally, as specified in the recently updated guidance document, contractors must be required to certify to EPA that the appropriate screening for an appearance of lack of impartiality has been conducted. Accordingly, EPA must ensure that such language is included in each contract for externally-managed peer reviews and that contractors adhere to these requirements.

Ensure contractors routinely search for and examine information sources needed for a comprehensive screening of conflict of interest and lack of impartiality

While disclosure forms serve as the foundation for candidate screening, contractors must also be required and enabled to search for and examine additional information about the candidate and chemical under review. As detailed below, relevant information can and should be obtained through: (1) accessing existing EPA databases and other authoritative state, federal, or multinational data sources, and (2) targeted internet searches to identify information potentially relevant to the conflict-of-interest and lack-of-impartiality screenings.

(1) Examination of EPA databases and other authoritative state, federal, or multinational data

In order to conduct comprehensive conflict-of-interest and lack-of-impartiality screenings, contractors must have access to the identities of companies that manufacture, import,

process and use the chemicals or groups of chemicals that are the subject of a particular review. Without access to the names of such companies, contractors may be unable to identify relationships such as employment or investments that may signal the existence of a potential conflict, financial or otherwise, for a particular candidate. Providing contractors with access to this information, therefore, is directly in keeping with current Agency policies governing the screening process.

EPA routinely collects and accesses chemical information that is relevant to identifying companies and sites engaged in production, import, processing, use and release of specific chemical substances. For example (by no means an exhaustive list):

- Under the Agency's Chemical Data Reporting (CDR) requirements established pursuant to section 8 of the Toxic Substances Control Act (TSCA), EPA collects information from manufacturers and in some cases, processors, of thousands of chemicals produced in or imported into the United States. Information obtained through the CDR process includes:
 - Parent company name and location
 - Chemical production or import site location
 - Employment at chemical site
 - Company activity (production or import)
 - Volume manufactured (production or import)
 - Chemical processing, function and use information
- The Toxics Release Inventory (TRI), an EPA database of annual facility chemical releases, can also provide insight into chemical production, processing and use by specific companies.

Numerous other sources of similar information exist, including information on specific types of chemicals (e.g., pesticides, antibiotics, etc.) and information collected by different offices within EPA, by other Federal agencies (e.g., FDA, OSHA, CPSC), by State agencies (e.g., toxics use information collected by Massachusetts and New Jersey), and by multinational entities (e.g., OECD).

EDF recommends that:

- all relevant data in the Agency's possession (including the CDR and TRI data) be routinely provided to contractors for their use during the candidate screening process; and
- a list of sources of similar information collected by other authoritative federal, State or multinational (e.g., OECD) entities be developed and provided to contractors, accompanied by a requirement that they routinely search these sources for information relevant to the review being conducted.

While much of this information is publicly available, some companies claim certain identifying data they submit as “confidential business information” (CBI). In such cases, contractors may need to receive the appropriate clearance to access this information, or other mechanisms need to be employed to ensure relationships between candidates and companies manufacturing, processing or using chemicals that are the subject of assessments undergoing peer review are identified. Again, without these details, robust screenings for conflict of interest and lack of impartiality cannot be conducted.

(2) Targeted internet searches

In addition to reviewing the sources noted above, contractors should be required to conduct targeted internet searches to look for information potentially relevant to the screening process. Guidance is already generally articulated in the Agency’s updated policy, which directs the contractor to “supplement the information obtained from the candidates by internet searches or other appropriate methods” (page 2, paragraph 3). However, we have found that this guidance does not contain sufficient detail to ensure adequate and consistent implementation.

EDF recommends that contractors be directed to routinely conduct, at minimum, the following structured searches using combined search terms to acquire additional information that may identify potential conflicts of interest or appearances of a lack of impartiality in particular candidates:

- “Chemical name” and “candidate name”
- “Chemical name” and “candidate’s employer name”
- Name of each company identified through CDR and TRI databases and “candidate name”
- Name of each company identified through CDR and TRI databases and “candidate’s employer name”

The information obtained through these searches may bring to light connections between a candidate or his/her employer and a chemical that may not have been identified through other means. The contractors can then further examine these results for potential financial linkages.

A thorough review of information obtained from relevant databases and targeted internet searches serves as an additional, essential part of the conflict-of-interest and lack-of-impartiality screenings and is consistent with current Agency policies governing these processes.

Consequences of existing procedures and practices

Our suggestions to improve the implementation of current policies and guidance governing screening for conflict of interest and lack of impartiality are not based on theoretical concerns. EDF has reviewed the lists of proposed panel members for several recent OPPT work plan chemical risk assessment peer review panels and found that existing procedures have resulted in flawed decisions by contractors. We have attached three submissions to EPA that detail our serious concerns about specific candidates selected by contractors for these reviews and demonstrate a lack of adherence to Agency policy requiring the selection of panel members free of actual or potential conflict of interest or an appearance of lack of impartiality.

Particularly problematic is that, in more than one instance, we identified candidates who are directly employed by companies that are major users of the specific chemicals under review. These examples serve to illustrate that without strengthened screenings for conflict of interest and lack of impartiality and assured contractor access to relevant information about the chemical under review, contractors may well continue to make inappropriate selections regarding panel membership.

Provide transparency in contractor/Agency response to public comments

A welcome and essential element of the recently updated guidance is the opportunity for public comment on the proposed peer review panel members. EDF has appreciated the chance to voice our concerns about actual or potential conflict of interest or lack of impartiality with respect to individual candidates.

The new guidance also specifically directs contractors to select a proposed final panel “after considering information about the candidates received from the public” (page 2, paragraph 6), among other criteria. For some of the OPPT work plan chemical risk assessment peer review panels on which EDF has commented, changes are apparent between the initially proposed and final panel members. It is not possible, however, for us or others submitting public comments to know that those comments were in fact considered, what if any impact they had on panel selection, and why or why not. This is because no information or explanation has been provided that would allow the public to understand the basis for final decisions regarding candidates about which public comments were submitted.

Transparency, a core theme in the Agency’s updated guidance, needs to be extended to this part of the panel vetting process. Specifically, EDF recommends that contractors or EPA

officials provide and make public written responses to public comments received that include an explanation and justification for their final decisions regarding each candidate that was a subject of those public comments. This documentation will ensure that the decision-making process is clear to the public and will help to hold contractors accountable as to how they have taken into account any concerns raised in the public comment process.

Conclusion

EDF strongly supports the Agency's recent efforts to increase transparency and improve the conflict of interest screening process for contractor-managed peer review panels. Such work is essential to maintain the credibility of panel conclusions and the integrity of Agency science.

There is significant room for improvement, however, and we appreciate the opportunity to provide recommendations to strengthen the implementation of the existing policies. We look forward to discussing this matter further with you, and we would be pleased to address any questions or concerns and to provide additional clarification or assistance if needed.

Respectfully submitted,



Richard A. Denison, Ph.D.
Senior Scientist



Rachel Shaffer
Research Assistant

cc: Kenneth Olden, Director, National Center for Environmental Assessment
Vincent Cogliano, Acting Director, Integrated Risk Information System
Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Wendy Cleland-Hamnett, Director, Office of Pollution Prevention and Toxics
Jeff Morris, Deputy Director for Programs, Office of Pollution Prevention and Toxics
Stanley Barone, Chief, Science Support Branch, Risk Assessment Division, Office of Pollution Prevention and Toxics

**U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics (OPPT) Program
CONFLICT OF INTEREST DISCLOSURE FORM**

External Peer Review:

Draft Risk Assessment for Methylene Chloride (DCM) and N-Methylpyrrolidone (NMP)
Paint Stripping Use

Reviewer Certification

Please sign below to certify that: (1) you have fully and to the best of your ability completed this disclosure form; (2) you will update your disclosure form promptly by contacting The Scientific Consulting Group, Inc.—the OPPT peer review contractor—if relevant circumstances change; (3) you are not currently arranging new professional relationships with, or obtaining new financial holdings in, an entity (related to the subject chemical) that is not yet reported; and (4) the certification below, based on information you have provided, and your CV may be made public for review and comment.

Reviewer's Signature _____

Date _____

(Print name) _____

The Scientific Consulting Group, Inc. (SCG) Certification

SCG has reviewed the information provided on the Conflict of Interest Disclosure form for _____ and certifies that to the best of SCG's knowledge and belief, there are no relevant facts or circumstances that could give rise to a conflict of interest, as defined in FAR subpart 9.5, and that SCG has disclosed all such relevant information.

Disclosure (if applicable):

SCG Peer Review Coordinator's Signature _____

Date _____

The Scientific Consulting Group, Inc. [INSERT NAME OF SIGNER]

Conflict of Interest Analysis and Certification Questions and Supporting Information

If you answered YES to any of the nine questions below, please elaborate: (*Attach additional pages if necessary.*)

1. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your and/or your spouse's compensated or non-compensated employment, including government service, during the past 24 months? Yes__ No __
2. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your and/or your spouse's research support and project funding, including from any government, during the past 24 months? Yes__ No __
3. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any consulting work by you and/or your spouse, during the past 24 months? Yes__ No __
4. To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any expert witness activity by you and/or your spouse, during the past 24 months? Yes__ No __
5. To the best of your knowledge and belief, have you, your spouse, or dependent child, held in the past 24 months, any financial holdings (excluding well-diversified mutual funds and holdings, with a value less than \$15,000) with any connection to the subject chemical or topic? Yes__ No__
6. Have you made any public statements or taken positions on the subject chemical under review (or closely related to the subject chemical)? Yes__ No __
7. Have you had previous involvement with the development of the document (or review materials) you have been asked to review (citation of a paper you authored does not count as previous involvement)? Yes__ No __
8. To the best of your knowledge and belief, is there any other information that might reasonably raise a question about an actual or potential personal conflict of interest or bias? Yes__ No __
9. To the best of your knowledge and belief, is there any financial benefit that might be gained by you or your spouse as a result of the outcome of this review? Yes__ No __

For elaboration:

Compensated and non-compensated employment (for panel member and spouse): list sources of compensated and non-compensated employment, including government service, for the preceding 2 years, including a brief description of work.

Research Funding (for panel member): list sources of research support and project funding, including from any government, for the preceding 2 years for which the panel member served as

the Principal Investigator, Significant Collaborator, Project Manager or Director. For panel member's spouse, provide a general description of the research and project activities in the preceding 2 years.

Consulting (for panel member): compensated consulting activities during the preceding 2 years, including names of clients if compensation provided 15 percent or more of your annual compensation. For panel member's spouse, provide a general description of consulting activities for the preceding 2 years.

Expert witness activities (for panel member): list sources of compensated expert witness activities and a brief description of each issue and testimony. For panel member's spouse, provide a general description of expert testimony provided in the preceding 2 years.

Assets: Stocks, Bonds, Real Estate, Business, Patents, Trademarks, and Royalties (for panel member, spouse and dependent children): specific financial holdings that collectively had a fair market value greater than \$15,000 at any time during the preceding 2-year period (excluding well-diversified mutual funds, money market funds, treasury bonds and personal residence).

Liabilities (for panel member, spouse and dependent children): liabilities over \$10,000 owed at any time in the preceding 12 months (excluding a mortgage on a personal residence, home equity loans, automobile and consumer loans).

Public Statements: A brief description of public statements and/or positions on the subject chemical under review by the panel member (or closely related to the subject chemical).

Involvement with the document under review: A brief description of any previous involvement of the panel member in the development of the document (or review materials) the individual has been asked to review.

Other potentially relevant information: A brief description of any other information that might reasonably raise a question about actual or potential personal conflict of interest or bias.

This written certification has been prepared for EPA. By signing this letter, EPA acknowledges that the contractor has certified that no conflict of interest exists or an appearance of a lack of impartiality, and that all conflicts of interest have been reported. A copy of this letter will appear in the EPA Peer Review Record.

Date _____
(EPA COR Signature)

Date _____
(Print COR Name)

(EPA Peer Review Leader Signature)

(Print Peer Review Leader Name) Stanley Barone Jr., Ph.D.

CONFLICT OF INTEREST ANALYSIS AND CERTIFICATION

Task Order 20
Contract EP-C-12-029

External Peer Review of EPA’s draft document, “*Advancing the Next Generation of Risk Assessment*”

Please be aware that if any of the following situations apply to you, you will be perceived as having a conflict of interest or be deemed to have a lack of impartiality in accordance with the peer review contract:

- Author or co-author of report
- Contributor to report
- Ex-EPA employee, with less than 5 years from last date of EPA employment
- Married to a current EPA employee or a current EPA contractor

If none of the above apply, please continue to fill out this form, answering all questions, sign and date, and return to the attention of peerreview@erg.com, Subject line: TO 20 Nex Gen RA

Email: peerreview@erg.com

Fax: 781-674-2906

Mail: ERG, 110 Hartwell Avenue, Lexington, MA 02421

Name: _____
(Please Print)

Signature: _____ Date: _____
(Required)

Conflict of Interest Analysis and Certification: Questions and Supporting Information		
	YES	NO
A. Employment: To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your, and/or your spouse’s, compensated or uncompensated employment, including government service, during the past 24 months? If Yes, please explain:		
B. Research: To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any of your, and/or your spouse’s, research support and project funding, including from any government, during the past 24 months? If Yes, please explain:		
C. Consulting: To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any consulting by you and/or your spouse, during the past 24 months? If Yes, please explain:		

	YES	NO
D. Expert Witness Activities: To the best of your knowledge and belief, is there any connection between the subject chemical or topic and any expert witness activity by you and/or your spouse, during the past 24 months? If Yes, please list sources of compensated expert witness activities and a brief description of each issue and testimony:		
E. Financial Holdings: To the best of your knowledge and belief, have you, your spouse, or dependent child, held in the past 24 months any financial holdings (excluding well-diversified mutual funds, and holdings with a value of less than \$15,000) with any connection to the subject chemical or topic? If Yes, please explain:		
F. Public Statements: Have you made any public statements or taken positions on or closely related to the subject chemical or topic under review? If Yes, please explain:		
G. Review Materials: Have you had previous involvement with the development of the document (or review materials) you have been asked to review? If Yes, please explain:		
H. Other: To the best of your knowledge and belief, is there any other information that might reasonably raise a question about an actual or potential personal conflict of interest or bias (i.e., a connection with any stakeholder/advocacy group connected to the peer review topic)? If Yes, please explain:		

	YES	NO
I. Personal Benefit: To the best of your knowledge and belief, is there any financial benefit that might be gained by your or your spouse as a result of the outcome of this review? If Yes, please explain:		



**Environmental Defense Fund Comments on
Meetings: Proposed Peer Review Panel Members: Trichloroethylene; Toxic Substances
Control Act Chemical Risk Assessment**

EPA-HQ-OPPT-2012-0723-0023

78 Federal Register 34377 - 34379 (Friday, June 7, 2013)

Submitted Friday June 28, 2013

Environmental Defense Fund (EDF) appreciates the opportunity to comment on the proposed list of candidates for the Environmental Protection Agency's peer review panel for "TSCA Workplan Chemical Risk Assessment for Trichloroethylene (TCE): Degreaser and Arts/Crafts Uses." This panel will be responsible for reviewing the scientific and technical validity of the draft TCE risk assessment, the first in a series of TSCA work plan risk assessments.

According to the Federal Advisory Committee Act (FACA), this peer review panel must be both balanced and free from conflict of interest. EDF has reviewed the list of peer review experts and is concerned about the potential for conflict of interest and/or lack of balance with respect to two of the candidates, based primarily on their associations with the Dow Chemical Company. Dow is one of the world's largest producers of TCE, and in 2005 was one of only two companies producing TCE in the United States¹. In light of the financial ties of these two candidates to a company with a significant interest in the market for this chemical, it is likely that these individuals have financial conflicts of interest, or will not – or will not be perceived to – be able to provide impartial guidance in this important review process.

We have provided additional details below and urge EPA's contractor, the Scientific Consulting Group (SCG), to consider this information as the panel is finalized.

Michael Jayjock

Michael Jayjock is the founder and sole proprietor of Jayjock Associates, LLC, a for-profit consultancy working on human health chemical risk assessments. Jayjock also works as a subcontractor for both The LifeLine Group and LINEA, Inc., which provide similar consultancy services. These firms are often hired by chemical companies and materials manufacturers to develop risk assessments or conduct scientific studies.

¹Lacson, J., CEH Marketing Research Report: C2 Chlorinated Solvents, SRI Consulting, Report 632.3000A; 2005, pages 5-6.

The Dow Chemical Company is listed as a client on Dr. Jayjock's webpage², indicating that he has provided services for payment to them during his work at one or more of the three consulting firms noted above. While no specific details are provided on timing of the contracts, these recent and potentially ongoing relationships could represent a financial conflict of interest or influence the ability of Dr. Jayjock to provide objective input. For example, comments he may offer in the peer review could be, or could be perceived to be, offered with the incentive of preserving current or future business opportunities.

Jeffrey Driver

Jeffrey Driver is a principal and co-founder of risksciences.net, LLC, a consulting firm that primarily conducts risk analyses. He is also a co-founder and manager of infoscientific.com, Inc., which conducts chemical exposure and risk assessments for a variety of clients.

Over the years, Dr. Driver has frequently collaborated with Dow Chemical or its affiliate, Dow Agrosciences. For example, in 2007 and 2008, he was a co-author, along with Dow employees, on two papers.^{3,4} Both of these papers indicate that the work was funded by a group of several industry "exposure task forces;" Dow is in turn a member of each of these task forces. Dr. Driver also collaborated with a Dow employee to publish a 2008 paper on the volatilization of chemicals.⁵ While no funding source is explicitly noted in this last publication, co-authorship indicates a clear affiliation.

It should also be noted that this affiliation between Dr. Driver and Dow extends well into the past. He was an editor of *Residential Exposure Assessment: A Sourcebook*,⁶ which was produced in 2001 with financial support from several organizations of which Dow is a member, including the American Chemistry Council, the American Crop Protection Association (now "CropLife"), and the Chemical Specialties Manufacturers Association (now "Consumer Products Specialty Association"). These relationships, built and sustained through the years, may inhibit Dr. Driver's ability to provide objective comments.

The comments above are not intended to challenge the scientific and technical expertise or impugn the integrity of Dr. Jayjock or Dr. Driver. However, we are concerned that these candidates may have financial conflicts of interest or otherwise not be able to provide the necessary impartial guidance for this specific peer review panel, given to their close connection to a company that is a leading producer of TCE.

² <http://www.jayjock-associates.com/clients/>

³ Driver J, Ross J, Mihlan G, Lunchick C, Landenberger B. "Derivation of single layer clothing penetration factors from the pesticide handlers exposure database." *Regulatory Toxicology and Pharmacology*: 2007 Nov, 49 (2): 125-137.

⁴ Ross J, Chester G, Driver J, Lunchick C, Holden L, Rosenheck L, Barnekow D. "Comparative evaluation of absorbed dose estimates derived from passive dosimetry measurements to those derived from biological monitoring: validation of exposure monitoring methodologies." *Journal of Exposure Science and Environmental Epidemiology*: 2008 Mar, 18(2): 211-230.

⁵ Van Wesenbeeck I, Driver J, Ross J. "Relationship between the evaporation rate and vapor pressure of moderately and highly volatile chemicals." *Bulletin of Environmental Contamination and Toxicology*: 2008 April, 80 (4): 315-318.

⁶ *Residential Exposure Assessment: A Sourcebook*. Baker SR, Driver J, McCallum DB. Springer 2001.

Please let us know if you have questions about this information or wish to discuss it further. We appreciate the opportunity to comment, and look forward to the timely finalization of EPA's first work plan chemical risk assessment.

Environmental Defense Fund

Comments on

Meetings: Proposed Peer Review Panel Members: Dichloromethane (CAS No. 75-09-2) and N-Methylpyrrolidone (CAS No. 872-50-4) Toxic Substances Control Act

EPA-HQ-OPPT-2012-0725-0038
Federal Register Number: 2013-20748

Submitted: Friday, September 13

Environmental Defense Fund (EDF) appreciates the opportunity to comment on the proposed list of candidates for the Environmental Protection Agency's peer review panel for the "TSCA Workplan Chemical Risk Assessment for Dichloromethane and N-methylpyrrolidone." This panel will be responsible for reviewing the scientific and technical validity of this draft risk assessment, the second in a series of TSCA work plan risk assessments.

According to EPA's [Peer Review Handbook](#) and EPA's [Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents](#), peer review panels must be balanced and its members free from both actual or potential conflicts of interest and an appearance of a lack of impartiality. EDF has reviewed the list of peer review experts and is concerned about conflict of interest and lack of impartiality with respect to one of the candidates, Dr. Annette Guiseppi-Elie. EDF wishes to emphasize that our comments are not intended in any way to challenge the scientific and technical expertise or impugn the integrity of Dr. Guiseppi-Elie.

Dr. Guiseppi-Elie is Principal Consultant on Exposure and Risk Assessment issues for Dupont Chemical Company. Dupont utilizes both of the chemicals that are the subject of the risk assessment for which this peer review panel is being established. Specifically, DCM and NMP are used as ingredients or solvents for several key products manufactured and sold by Dupont. These include the following:

- Dichloromethane (DCM) is listed as one of three ingredients in Dupont's chemical intermediate NPR 5470, and as one of two ingredients in its chemical intermediate NPR 6985^{1,2}.

¹ NPR 5470; MSDS Ref. 150000002498 [Online]; Dupont, July 9, 2008.
http://msds.dupont.com/msds/pdfs/EN/PEN_09004a35803d164e.pdf (accessed August 29, 2013)

² NPR 6985; MSDS Ref. 150000002499 [Online]; Dupont, July 9, 2008.
http://msds.dupont.com/msds/pdfs/EN/PEN_09004a35803d164f.pdf (accessed August 29, 2013)

- Two of the company's trademark herbicides, Assure ® II and Perimeter™ II, contain N-methylpyrrolidone (NMP) as an ingredient^{3,4}.
- NMP is used as an essential solvent in the patented production process of Dupont's highly profitable aramid, Kevlar ®^{5,6,7}, which is used in at least 24 of the company's products⁸.

In addition to the specific products listed above, there may well be numerous others. Dupont's "Product Safety Summary Sheet" for NMP indicates that this chemical is also used generally in the "manufacture of bulk, large scale chemicals (including petroleum products) and...fine chemicals."⁹

While sales data are not disclosed, Dupont's reporting of total on- and off-site disposal and other releases of DCM and NMP from multiple Dupont facilities under the Toxics Release Inventory (TRI) provides further evidence that these chemicals are widely used by the company in significant amounts. Data from 2011 and preliminary data from 2012 are listed below: :

- DCM
 - 2011¹⁰
 - Dupont La Porte Plant: 54,947 lbs.
 - Dupont Washington Works: 33,519 lbs.
 - Dupont Fayetteville Plant: 10,284 lbs.
 - Dupont Sabine River Works: 101 lbs.
 - 2012¹¹
 - Dupont Washington Works: 28,091 lbs.
 - Dupont La Porte Plant: 22,405 lbs.
 - Dupont Fayetteville Plant: 9,074 lbs.
 - Dupont Sabine River Works: 137 lbs.

³ Assure ® II Herbicide; MSDS Ref. 130000023960 [Online]; Dupont, January 9, 2013. Accessed August 29, 2013. http://msds.dupont.com/msds/pdfs/EN/PEN_09004a35805d3dfa.pdf

⁴ Perimeter™ II Herbicide; MSDS GPA02012 [Online]; Dupont, May 2, 2012. Accessed August 29, 2013. http://www2.dupont.com/Crop_Protection/en_CA/assets/downloads/20120502_Perimeter_II_MSDS_English.pdf

⁵ Chanda M and Roy Salil K. *Industrial Polymers, Specialty Polymers, and Their Applications, Plastics Engineering Series*. CRC Press 2008. Retrieved from: http://books.google.com/books?id=yTP_38Ex5mYC&dq=dupont+kevlar+n-methyl+pyrrolidone&source=gbs_navlinks_s

⁶ E.I. Du Pont De Nemours and Company. "High Strength polyamide fibers and films." US Patent 3869429 A. 04 Mar 1975.

⁷ E.I. Du Pont De Nemours and Company. "Dry jet wet spinning process." US Patent 3767756 A. 23 Oct 1973

⁸ Dupont. "Product Finder: Kevlar." 2013. Accessed September 12, 2013. http://duponttools.force.com/ppf/ppfSearch?lang=EN_US&country=USA&str=Kevlar

⁹ Product Safety Summary Sheet; Dupont N-methyl-pyrrolidone [Online]; Dupont, November 1, 2012. Accessed September 12, 2013. <http://www.dupont.com/content/dam/assets/corporate-functions/our-approach/sustainability/commitments/product-stewardship-regulator/articles/product-stewardship/documents/N-Methyl-Pyrrolidone%20Product%20Safety%20Summary.pdf>

¹⁰ Environmental Protection Agency. "TRI Explorer: Facility Report: Dichloromethane, US 2011." September 2013. Accessed September 12, 2013. http://iaspub.epa.gov/triexplorer/release_fac?P_VIEW=USFA&trilib=TRIO1&TAB_RPT=1&sort=VIEW&Fedcode=&FLD=RELLBY&FLD=TSFDSP&sort_fmt=1&industry=ALL&STATE=All+states&COUNTY=All+counties&chemical=000075092&YEAR=2011&TopN=ALL

¹¹ Environmental Protection Agency. "TRI Explorer: Facility Report: Dichloromethane, US 2012." September 2013. Accessed September 12, 2013. http://iaspub.epa.gov/triexplorer/release_fac?p_view=USFA&trilib=TRIO1&TAB_RPT=1&Fedcode=&LINESPP=&sort=VIEW&industry=ALL&FLD=RELLBY&FLD=TSFDSP&sort_fmt=1&TopN=ALL&STATE=All+states&COUNTY=All+counties&chemical=000075092&year=2012&report=&BGCOLOR=%23D0E0FF&FOREGCOLOR=black&FONT_FACE=arial&FONT_SIZE=10+pt&FONT_WIDTH=normal&FONT_STYLE=roman&FONT_WEIGHT=bold

- NMP
 - 2011¹²
 - Dupont Spruance Plant: 59,893 lbs.
 - Dupont Pontchartrain Works: 18,720.
 - Dupont Parlin Plant: 1,707 lbs.
 - Dupont EKC Technology: 112 lbs.
 - Dupont Performance Elastomers LLC Pontchartrain Site: 23 lbs.
 - Dupont Towanda Plant: 70 lbs.
 - 2012¹³
 - Dupont Spruance Plant: 54,177 lbs.
 - Dupont Pontchartrain Works: 14,156 lbs.
 - Dupont Parlin Plant: 571 lbs.
 - Dupont Valdosta Manufacturing: 250 lbs.
 - Dupont EKC Technology: 92 lbs.
 - Dupont Towanda Plant: 20 lbs.

While we have not conducted a comprehensive search, these examples of key products and facility releases related to both DCM and NMP identified from readily available public information serve to demonstrate the importance of these compounds to the business interests of Dupont, Dr. Guiseppi-Elie's employer.

Based on the value of the chemicals under review to her employer, EDF is very concerned that this candidate has financial conflicts of interest that could impede, and would certainly cause a reasonable person to question, her ability able to provide the necessary impartial guidance for this specific peer review panel.

Even though the evidence we have provided does not indicate that Dupont utilizes these compounds for paint-stripping purposes, which is the subject of this particular work plan chemical risk assessment, the company would undoubtedly benefit from any finding that the hazards or risks posed by such chemicals are minimal, given that such conclusions made in one context will certainly have an impact in others.

¹² Environmental Protection Agency. "TRI Explorer: Facility Report: N-Methyl-2-Pyrrolidone, US 2011. September 2013. Accessed September 12, 2013.
http://iaspub.epa.gov/triexplorer/release_fac?p_view=USFA&trilib=TRIQ1&TAB_RPT=1&Fedcode=&LINESPP=&sort=VIEW_&industry=ALL&FLD=RELLBY&FLD=TSFDSP&sort_fmt=1&TopN=ALL&STATE=All+states&COUNTY=All+counties&chemical=00872504&year=2011&report=&BGCOLOR=%23DoEoFF&FOREGCOLOR=black&FONT_FACE=arial&FONT_SIZE=10+pt&FONT_WIDTH=normal&FONT_STYLE=roman&FONT_WEIGHT=bold

¹³ Environmental Protection Agency. "TRI Explorer: Facility Report: N-Methyl-2-Pyrrolidone, US 2012. September 2013. Accessed September 12, 2013.
http://iaspub.epa.gov/triexplorer/release_fac?p_view=USFA&trilib=TRIQ1&TAB_RPT=1&Fedcode=&LINESPP=&sort=VIEW_&industry=ALL&FLD=RELLBY&FLD=TSFDSP+&sort_fmt=1&TopN=ALL&STATE=All+states&COUNTY=All+counties&chemical=00872504&year=2012&report=&BGCOLOR=%23DoEoFF&FOREGCOLOR=black&FONT_FACE=arial&FONT_SIZE=10+pt&FONT_WIDTH=normal&FONT_STYLE=roman&FONT_WEIGHT=bold

We urge EPA and its peer review contractor, Scientific Consulting Group (SCG), to take this information into account as it finalizes this panel, as we believe it strongly indicates an actual or potential conflict of interest, as well as an appearance of a lack of impartiality, for Dr. Guiseppi-Elie.

Please let us know if you have any questions or wish to discuss this matter further. We appreciate the opportunity to comment and look forward to the timely finalization of these EPA work plan chemical risk assessments.

Respectfully submitted,

Richard A. Denison, PhD.
Senior Scientist

Rachel Shaffer
Research Assistant



Environmental Defense Fund

Comments on Meetings: Antimony Trioxide TSCA Chemical Risk Assessment

**EPA-HQ-OPPT-2012-0724-0017
Federal Register Number: 2013-23634**

Submitted: October 10, 2013

Environmental Defense Fund (EDF) appreciates the opportunity to comment on the list of candidates for the Environmental Protection Agency (EPA)'s peer review panel for the "TSCA Workplan Chemical Risk Assessment for Antimony Trioxide." This panel will be responsible for reviewing the scientific and technical validity of this draft risk assessment, the fourth in a series of TSCA work plan risk assessments.

According to EPA's [Peer Review Handbook](#) and EPA's [Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents](#), peer review panels must be balanced and their members free from both actual or potential conflicts of interest and any appearance of a lack of impartiality. EDF has reviewed the list of candidates for this peer review panel and is concerned about actual or potential conflicts of interest and an appearance of a lack of impartiality with respect to four of the candidates: Dr. Vincent Rudigar Battersby, Dr. James Deyo, Dr. Erik Smolders, and Dr. Anne Fairbrother, the proposed chair. Our concerns are detailed below. EDF wishes to emphasize that our comments are not intended in any way to challenge the scientific and technical expertise or impugn the integrity of any of these proposed panel members.

Dr. Vincent Rudigar Battersby

Dr. Vincent Rudigar Battersby is Managing Director and Principal Coordinating Toxicologist at EBRC Consulting GmbH, a consulting firm based in Germany. Dr. Battersby has been hired by the antimony industry to conduct extensive work, including to undertake and provide guidance on risk assessment-related activities. The company website indicates that EBRC has provided

“support to the...Antimony industry in their EU ESR risk assessments,”¹ and Dr. Battersby worked specifically as the Principal Industry Coordinator in the context of the European Union Existing Substances Program’s assessment of antimony trioxide from 1998-2006.² The European Union Risk Assessment Report for Diantimony Trioxide (2008) cites ten publications prepared by EBRC on behalf of the International Antimony Oxide Industry Association.³ (Note that diantimony trioxide is a synonym for antimony trioxide.)

Dr. Battersby was also contracted by several metals industry associations, including the European Association of Metals and the International Council of Mining and Metals, as the principal author for a human health risk assessment guidance document for metals, which included substantial sections on antimony.⁴

Not only has Dr. Battersby regularly undertaken paid work on behalf of the antimony industry, his company has also provided support on matters that are directly related to the scope of the work plan chemical risk assessment under review, namely the use of antimony trioxide as a synergist for flame retardants. EBRC has “actively provided consulting activities for...the antimony industry in their EU RAR procedure for diantimony trioxide (ATO), a FR [flame retardant] synergist.”⁵

While we recognize Dr. Battersby’s expertise in issues related to antimony trioxide, we believe he has a clear conflict of interest because of the significant funding that he and his consulting firm have received from the antimony and closely related industries to work specifically on issues directly related to the chemical substance and the specific use of the substance under review by this peer review panel. Moreover, there is clear basis to conclude his selection would present to a reasonable observer an appearance of a lack of impartiality.

Dr. James Deyo

Dr. James Deyo is Senior Associate and Senior Toxicologist in the Product Safety & Health Division at Eastman Chemical Company. According to data collected from EPA’s Chemical Data Reporting (CDR) requirements in 2011, Eastman Chemical Company is a significant importer of antimony trioxide. While the company has claimed the quantity of the chemical imported as

¹ EBRC. “Industrial Chemicals – REACH; Recent projects and references: Experience gained in previous risk assessment of Existing Chemicals.” Accessed October 2, 2013. <http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/experience-gained-in-previous-risk-assessment-of-existing-chemicals.php>

² Environmental Protection Agency, personal communication, September 26, 2013. Europass Curriculum Vitae: Dr. Vincent Rudigar Battersby.

³ European Union Risk Assessment Report: Diantimony Trioxide Risk Assessment. 2008. http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/datreport415.pdf

⁴ EBRC. “Industrial Chemicals – REACH; Recent projects and references: HERAG.” Accessed October 2, 2013. <http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/herag.php>

⁵ EBRC. “Industrial Chemicals – REACH; Recent projects and references: Experience gained in previous risk assessment of Existing Chemicals.” Accessed October 2, 2013. <http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/experience-gained-in-previous-risk-assessment-of-existing-chemicals.php>

“confidential business information” (CBI), it can be assumed to have been at least 25,000 pounds per year per site of import, the threshold level above which reporting is required.⁶

Information reported by Eastman Chemical Company on its total on-and off-site disposal and other releases under the Toxic Release Inventory (TRI) provides additional evidence of the use of this and closely related chemicals by Eastman. Data from 2011 and preliminary data from 2012 indicate that the company’s Tennessee Operations site released 15,700 pounds and 7,067 pounds of antimony compounds, respectively.^{7,8} Together, the CDR and TRI data clearly demonstrate the use of the chemical under review by the company that employs Dr. Deyo.

Further confirmation can be found on the website of a leading fiberglass production company, Perry Fiberglass Products, Inc.⁹ That company currently advertises two Eastman Chemical resins, with flame retardant capabilities, that contain antimony trioxide.¹⁰ Our searches, though certainly not exhaustive, indicate that Eastman Chemical Company produces the chemical under review for the specific use discussed in EPA’s draft work plan chemical risk assessment.

Not only does Eastman Chemical Company have direct financial and business interests in antimony trioxide, but Dr. Deyo or his company has also received industry funding to work on risk issues associated with this specific chemical. For example, he was a co-author on a recent publication funded by the International Antimony Oxide Industry Association and the Antimony Trioxide Stakeholders, which, though now dissolved, was an organization of manufacturers and downstream users of antimony trioxide.^{11,12} This study is actually discussed and cited in EPA’s draft work plan chemical risk assessment.¹³

Based on this information, EDF is concerned that this candidate has financial conflicts of interest, and that his employment and activities would certainly cause a reasonable person to

⁶ Environmental Protection Agency. “Chemical Data Access Tool (CDAT).” Search term: 1309-64-4. 2012. Accessed October 2, 2013. http://java.epa.gov/oppt_chemical_search/

⁷ Environmental Protection Agency. “TRI Explorer: Facility Report: Antimony Compounds, US 2011.” September 2013. Accessed October 2, 2013 http://iaspub.epa.gov/triexplorer/release_fac?P_VIEW=USFA&trilib=TRIQ1&TAB_RPT=1&sort=VIEW&Fedcode=&FLD=REL_LBY&FLD=TSFDSP&sort_fmt=1&industry=ALL&STATE=All+states&COUNTY=All+counties&chemical=No10&YEAR=2011&TopN=all

⁸ Environmental Protection Agency. “TRI Explorer: Facility Report: Antimony Compounds, US 2012.” September 2013. Accessed October 2, 2013 http://iaspub.epa.gov/triexplorer/release_fac?P_VIEW=USFA&trilib=TRIQ1&TAB_RPT=1&sort=VIEW&Fedcode=&FLD=REL_LBY&FLD=TSFDSP&sort_fmt=1&industry=ALL&STATE=All+states&COUNTY=All+counties&chemical=No10&YEAR=2012&TopN=all

⁹ Perry Fiberglass Products, Inc. “Download Area.” Accessed October 10, 2013. http://www.perryfiberglass.com/plastic_duct/download.htm

¹⁰ Perry Fiberglass Products, Inc. “Industrial & Commercial Specification Sheet.” Accessed October 10, 2013. http://www.perryfiberglass.com/plastic_duct/PDF/screen/3_specsheet_screen.pdf

¹¹ Kirkland D, Whitwell J, Deyo J, Serex T. Failure of antimony trioxide to induce micronuclei or chromosomal aberrations in rat bone-marrow after sub-chronic oral dosing. *Mutation Research*. 2007; 627: 119-128. Available at: <http://www.sciencedirect.com/science/article/pii/S1383571806003998>

¹² International Antimony Association. “ATOS.” 2012. Accessed October 9, 2013. <http://www.antimony.com/en/atos.aspx>

¹³ Environmental Protection Agency. TSCA Workplan Chemical Risk Assessment: Antimony Trioxide; External Review Draft. December 2012. Pages 52, 61. http://www.scgcorp.com/atO2013/pdfs/ATO%20TSCA_Workplan_Chemical_Risk_Assessment.pdf

question his ability to provide the requisite impartial review of EPA's risk assessment that is the intended purpose of this specific peer review panel.

Dr. Erik Smolders

Dr. Erik Smolders is a Professor in the Division of Soil and Water Management at the Katholieke Universiteit Leuven in Belgium. While his expertise in metals risk assessments is relevant for the panel, Dr. Smolders has received funding from the International Antimony Association (formerly the International Antimony Oxide Industry Association) to support his recent publications on antimony and antimony trioxide, which indicates that Dr. Smolders appears to have a conflict of interest for this review.^{14,15}

Dr. Anne Fairbrother

Dr. Anne Fairbrother, the proposed chair of this peer review panel, is Principal Scientist in Exponent's EcoSciences division and Office Director of Exponent's office in Bellevue, Washington. While we do not have any indication as to whether Dr. Fairbrother specifically works on antimony trioxide, EDF is concerned that Exponent's work on closely related issues may inhibit her ability to provide an impartial review. The EPA Peer Review Handbook states that a conflict of interest can arise not only in regard to a candidate's personal financial interests, but also when "he/she, his/her associates or other individuals whose interests are imputed...would derive benefit from incorporation of their point of view in an Agency product, and/or when their professional standing and status or the significance of their principal area of work might be affected by the outcome of the peer review."¹⁶

Given her high rank in the company as both a Principal and an Office Director, Dr. Fairbrother may have financial interests in Exponent beyond her personal compensation as an employee. Even if Dr. Fairbrother is not deemed to have a potential or actual conflict of interest, we urge further inquiry into her potential lack of impartiality on this panel.

An appearance of impartiality is important for all panel members but particularly crucial for the chairperson.

According to its website, Exponent provides companies with a range of services related to flame retardants, the primary use for antimony trioxide in the United States. Among these services are quantitative exposure assessments, human health risk assessments, and environmental and ecological risk assessments. Several staff members based in the office of Exponent that Dr.

¹⁴ Oorts K, Smolders E, Degryse F, et al. Solubility and Toxicity of Antimony Trioxide (Sb₂O₃) in Soil. *Environ. Sci. Technol.* 2008; 42: 4378-4383. Available at: <http://pubs.acs.org/doi/abs/10.1021/es703061t?journalCode=esthag>

¹⁵ Oorts K and Smolders E. Ecological threshold concentrations for antimony in water and soil. *Environ. Chem.* 2009; 6: 116-121. doi:10.1071/EN08109

¹⁶ Environmental Protection Agency. Peer Review Handbook, 3rd Edition. 2012. Page 64. http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf

Fairbrother directs (Bellevue, WA), and hence has direct responsibility for, are listed as relevant “Related Professionals” specifically for such projects.¹⁷

Exponent’s work on flame retardants is just one aspect of services offered through its large “TSCA Existing Chemicals Management & Regulatory HPV Support” program.¹⁸ In a news item on the company’s website dated June 2012, the company advertised its varied expertise and ability to assist clients with a range of issues related specifically to EPA’s work plan chemical risk assessment initiative.¹⁹

While the information provided above does not necessarily indicate a direct financial conflict of interest for the proposed candidate, EDF believes that her inclusion in the panel would at the least suggest to a reasonable person the appearance of a lack of impartiality. As Principal Scientist and Office Director, Dr. Fairbrother would certainly have or be perceived as having an interest in conclusions of an EPA assessment that would be favorable to her employer’s clients and hence profitable for her company and team. We are especially concerned about such an appearance of a lack of impartiality given her proposed position of authority as panel chair, and we urge EPA to at least consider an alternate chairperson in order to maintain the credibility and integrity of this peer review.

EDF wishes to reiterate that the comments above are not intended in any way to challenge to scientific expertise or personal integrity of any of the proposed panel members. We are, however, very concerned about the apparent lack of adherence to Agency policy requiring the selection of panel members who are free of actual or potential conflicts of interest and appearances of lack of impartiality.

Please let us know if you have any questions or wish to discuss this matter further. We appreciate the opportunity to comment and look forward to the timely finalization of these EPA work plan chemical risk assessments.

Respectfully submitted,

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Senior Scientist

Rachel Shaffer
Research Assistant

¹⁷ Exponent. “Flame Retardant Risk Assessment.” March 30, 2013. Accessed October 2, 2013. <http://www.exponent.com/Flame-Retardant-Risk-Assessment-03-30-2013/>

¹⁸ Exponent. “TSCA Existing Chemicals Management & Regulatory HPV Support.” 2010. Accessed October 2, 2013. http://www.exponent.com/tsc_a_high_production_volume_support/#tab_overview

¹⁹ Exponent. “EPA Adds Chemicals to Work Plan Initiative For Review Under TSCA.” June 6, 2012. Accessed October 2, 2013. <http://www.exponent.com/EPA-Adds-Chemicals-to-Work-Plan-Initiative-For-Review-Under-TSCA-06-06-2012/>