

January 25th, 2010 (due date)

Comments on the List of Candidates for the
EPA Science Advisory Board
IRIS Trichloroethylene (TCE) Review Panel

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The following comments are being submitted on behalf of the Natural Resources Defense Council (NRDC) and the following public interest and public health organizations and individuals.

List of Supporters:

Documentation:

Information on the IRIS assessment of TCE is available here:
<http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsRequestsforCommentsBOARD/773DC7E8C5C1332D852574F200699A89?OpenDocument&TableRow=2.1#2>

Biosketches of panel shortlist is contained in the EPA Invitation for Public Comment on the List of Candidates for the EPA Science Advisory Board IRIS Trichloroethylene (TCE) Review Panel (January 5, 2010), available here:
[http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsRequestsforCommentsBOARD/773DC7E8C5C1332D852574F200699A89/\\$File/Candidate+Biosketches+for+IRIS+TCE+Rev+Panel+01-05-2010.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsRequestsforCommentsBOARD/773DC7E8C5C1332D852574F200699A89/$File/Candidate+Biosketches+for+IRIS+TCE+Rev+Panel+01-05-2010.pdf)

Scientists with financial conflicts and lack of impartiality should be excluded

The recommendations of this SAB are likely to impact federal clean-up standards, and may have further impacts on occupational and public health protections in the U.S. and internationally. NRDC respectfully reminds SAB staff of its professional and legal duty to select board members who adequately represent the protection of public health and the environment, consistent with the mission of EPA. The Agency cannot accomplish this vital mission if its regulatory priorities and health concerns are dictated by people who have a financial stake in encouraging EPA to do as little as possible to regulate their products.

In its invitation to comment, EPA identified specific criteria to be used in evaluating a candidate including the absence of financial conflicts of interest and the absence of appearance of a lack of impartiality. On the whole, industry-employed scientists and scientists working for industry-supported research institutions tend to

downplay the adverse health effects or environmental impacts of toxic chemicals, and committees must be composed in a manner that ensures that this perspective does not unduly influence panel decisions. Thus, nominees affiliated with industries and industry-supported research institutions are unfit to provide EPA with robust independent scientific advice.

By law, EPA committees must be composed in order to ensure that industry bias is publicly disclosed, minimized, and eliminated if possible. The Federal Advisory Committee Act (FACA) imposes requirements on agencies when they establish or utilize any advisory committee, defined as a group of individuals, including at least one non-federal employee, which provides collective advice or recommendations to the agency. 5 U.S.C. App. II, § 3(2). When an agency seeks to obtain such advice or recommendations, it must ensure the advisory committee is "in the public interest," id. App. II, § 9(2), is "fairly balanced in terms of points of view represented and the function to be performed," id. § 5(b)(2), and does not contain members with inappropriate special interests. Id. § 5(b)(3).

Committee membership should exclude financially conflicted members, so that committees are composed of scientists who are able to provide a fair and complete review of all relevant data or issues. If industry representatives have specific knowledge or expertise of value to the deliberations of a committee, then invitations to address the committee during public meetings are appropriate. However, individuals with financial conflicts should not be serving as members of the SAB.

We object to the following individuals

The following individuals cannot be considered impartial, and should not serve on this federal advisory committee as independent experts, for the reasons provided here.

- Alexander, Dominik
- Anderson, Mel
- Bogen, Ken
- Borghoff, Susan
- Bruckner, James
- Clewell, Harvey
- Everitt, Jeffrey
- Fenner-Crisp, Penelope
- Kelsh, Michael
- Klaunig, James
- Lash, Lawrence

Lockheed Martin consultants should not be selected: *Bruckner, Clewell, Kelsh, and Lash*

These four individuals are all retained by Lockheed Martin as paid consultants (documentation available upon request). Their work for Lockheed is in conjunction with

a current lawsuit on behalf of residents of Redlands, California for the contamination of their groundwater with TCE and perchlorate. This case, *Acklin v. Lockheed Martin*, has been ongoing for over a decade, resulting in significant financial gains for these paid experts to provide testimony on behalf of Lockheed about the lack of harm caused by TCE. Their opinion on TCE must be viewed as serving the interests of their corporate client to diminish or deny the hazards of TCE. A reduced risk estimate for TCE would significantly reduce the clean up costs and liabilities for Lockheed Martin.

Scientists affiliated with Hamner Institute, formerly CIIT, should not be selected: Anderson, Borghoff, Clewell, Everitt

The Hamner Institute, formerly CIIT, formerly the Chemical Industry Institute of Toxicology was created in the 1970s, by the leaders of 11 major chemical companies including Union Carbide, Dow Chemical, Exxon Chemical, Shell Chemical, DuPont, and Monsanto.¹ As such, the Insitute has long represented a clear industry orientation toward the link between chemical exposure and disease. A significant portion of the Institute's funding still comes from industry, and is generally focused on developing data or models to support lack of relevance of animal data to humans, or threshold models as opposed to linear models for carcinogens. CIIT scientists' work on TCE is no exception.

In 2004 Clewell and M. Anderson (also named on this provisional list and discussed elsewhere in these comments), both employed by CIIT, developed a model for TCE that predicted that it was not as potent a carcinogen as determined by either EPA or CalEPA, arguing that humans were less sensitive than the animal studies used by these agencies in their risk assessments. The paper by Clewell and Anderson went so far as to argue that exposures 50-times higher than the current drinking water Maximum Contaminant Level (MCL) of 5 µg/L were unlikely to lead to cancers in humans.² The model and its conclusions were subsequently debunked by EPA expert scientists in a published response.³ It thus seems clear that Clewell or Anderson, or any other CIIT-sponsored scientist (such as Borghoff or Everitt), should not be seen as having an independent position from their corporate client's interests.

Scientists affiliated with Exponent Inc. should not be selected: Alexander, Bogen, Kelsh

Alexander, Bogen, and Kelsh are all employed by Exponent, a large corporate science-for-hire consulting firm. As one of the largest of such firms, Exponent earned a

¹ <http://www.thehamner.org/institutes/ciit/ciit-history.html>

² Clewell, H.J. and M.E. Andersen. 2004. Applying mode-of-action and pharmacokinetic considerations in contemporary cancer risk assessments: An example with trichloroethylene. *Crit. Rev. Toxicol.* 34(5): 385-445. For a summary see: http://gc.energy.gov/NEPA/nepa_documents/ea/ea1527/Appendix_A_2.pdf

³ Caldwell J. C., Evans M. V., Marcus A. H., Siegel Scott S., Chiu W. A., Okino M. S., Preuss P. W. Comments on article "Applying Mode-of-Action and Pharmacokinetic Considerations in Contemporary Cancer Risk Assessments: An Example with Trichloroethylene" by Clewell and Andersen. *Crit. Rev. Toxicol.* 2006; 34(5)385-445, 2004

lengthy place in the book titled Doubt is Their Product: How Industry's Assault on Science Threatens Your Health (2008) by David Michaels, now Director of the Occupational Safety and Health Administration (OSHA). Dr. Michaels writes, "While some may exist, I have yet to see an Exponent study that does not support the conclusion needed by the corporation or trade association that is paying their bill."⁴ The author then spends the next one-and-one-half pages summarizing some of the most egregious efforts by Exponent to bend science in the favor of its corporate clients. Included in the list is Exponent's work for Lockheed Martin to defend it from having to clean up the groundwater sites that it contaminated with perchlorate. This is the same litigation case discussed above, where TCE is a co-contaminant with perchlorate. The opinion of these Exponent scientists on TCE must be viewed as serving the interests of Exponent's corporate client to diminish or deny the hazards of TCE. A reduced risk estimate for TCE would significantly reduce the clean up costs and liabilities for Lockheed Martin.

Kelsh, in his biography on the Exponent website, identifies support from Lockheed for research conducted from 2000-2005, for which he was co-principal investigator.⁵ Although this research is likely on perchlorate (because it is a thyroid study) and not TCE, the fact that he works for Lockheed as a litigation expert, and has his research sponsored by Lockheed, certainly suggests that his "expert opinion" on TCE is very likely to favor the interests of his corporate client. And, the fact that this litigation is ongoing certainly suggests that his opinion is likely to continue to be tied to his client's interests.

Scientists affiliated with ILSI should not be selected: *Fenner-Crisp*

Fenner-Crisp was Executive Director of the Risk Science Institute of the International Life Sciences Institute (ILSI) from 2000-2004 and has since worked as a private consultant. ILSI represents several hundred corporations in the chemical, processed food, agro-chemical and pharmaceutical industries and received at least \$2.1 million in EPA grants in 2005.⁶ Members of ILSI include companies such as DuPont, 3M, Syngenta, Eli Lilly, ExxonMobil Biomedical Sciences, and Dow Chemical.⁷ ILSI-sponsored scientists should not be seen as having an independent position with regards to TCE or other industrial chemicals. Before Dr. Fenner-Crisp is considered for any government advisory committee, her clients should be disclosed. If she mainly serves industry clients, then this would indicate that her services continue to be of most value to the industry, and she should not be seen as having an independent position from her client's interests.

⁴ Michaels, David. *Doubt Is Their Product: How industry's assault on science threatens your health*. Oxford University Press (2008): p. 47-49

⁵ http://www.exponent.com/files/Attorney/37e71bad-8eea-4dc6-bab6-4e46435748a0/Presentation/ceExpertCVUpload/kelsh,m_full.pdf

⁶ The ILSI IRS Form 990 for 2005 lists \$2.5 million in government contributions. The EPA Grants Awards Database reports over \$2 million in awards to the ILSI Risk Science Institute. In a January, 2007 response to a FOIA request from NRDC, the EPA provided a list of the ILSI projects that EPA participates in. FOIA Request HQ-RIN-0029-07 to Jennifer Sass, NRDC.

⁷ See the ILSI website for a full list of its membership: <http://www.ils.org/AboutILSI/>.

Scientists with industry-biased positions on key issues should not be selected:

Klaunig, Fenner-Crisp

EPA authors published a research paper in *Environmental Health Perspectives* (2006) that presented a cogent scientific argument to support the conclusion that the human relevance of observed TCE-induced effects in animals should not be dismissed;⁸ the same position that is posited in the TCE toxicologic review that is the subject of this SAB. A joint response was published in 2007 by Klaunig, Fenner-Crisp, and industry affiliated colleagues from Pfizer Inc., K&D Scientific Consulting Inc., Merck Research Laboratories, ExxonMobil Biomedical Sciences, Inc., and AstraZeneca.⁹ The industry authors and consultants disclosed that their clients or employers have a financial interest in PPAR (peroxisome proliferator-activated receptor). The industry letter argued that EPA's position lacked sufficient scientific support, referencing as evidence an earlier article of theirs that questions the human relevance of rodent tumors induced by exposure to PPARalpha agonist chemicals like TCE (Klaunig et al, 2003).¹⁰ Fenner-Crisp is the corresponding author on this 2003 article. Although neither Klaunig nor Fenner-Crisp disclose any conflicts in either the 2003 or 2007 articles, the fact that almost all their co-authors disclose a direct financial interest in PPAR, it seems reasonable that the opinions of Klaunig and Fenner-Crisp are consistent with the interests of the industries that they share authorship with.

The special case of ILSI

ILSI routinely hosts workshops (often co-funded by EPA) where industry specialists, academics and agency officials come together to discuss science and policy. There often is little or no effort made to inform the public or the public interest community about these meetings, and as a result the public health and environmental voice is frequently entirely absent, marginalized, or ignored when final decisions are made. As a result, EPA policy decisions that emerge from this kind of process are flawed, and those decisions are being overturned. For example, in 2003, EPA issued a proposed guidance (based on a proposed policy that was drafted by a sub-group of ILSI) on how to assess a class of chemicals that includes perfluorochemicals used by DuPont to make Teflon. The ILSI-EPA proposed policy claimed that while these chemicals caused cancer in laboratory animals, they were not carcinogenic to humans. An independent scientific panel rejected the ILSI-EPA draft policy because it was not supported by data.¹¹ Later, in December of 2005, DuPont paid more than \$16 million to

⁸ Key issues in the role of peroxisome proliferator-activated receptor agonism and cell signaling in trichloroethylene toxicity. Keshava N, Caldwell JC. *Environ Health Perspect.* 2006 Sep;114(9):1464-70.

⁹ Klaunig JE, Babich MA, Cook JC, David RM, DeLuca JG, McKee RH, Peters JM, Roberts RA, Fenner-Crisp PA. PPARalpha and effects of TCE. *Environ Health Perspect.* 2007 Jan;115(1):A14-5; author reply A15-6.

¹⁰ Klaunig JE, Babich MA, Baetcke KP, Cook JC, Corton JC, David RM, et al. PPARalpha agonist-induced rodent tumors: modes of action and human relevance. *Crit Rev Toxicol.* 2003;33:655-780

¹¹ See EPA Advisors Split Over Use of Animal Studies In Human Risk Reviews, Inside EPA (Dec. 10, 2003).

settle charges that it hid information for more than two decades showing that its Teflon chemicals are a significant threat to human health.¹² In 2007 a local newspaper reported on a government study showing elevated cancer rates in the people living around the DuPont plant that manufactured these chemicals.¹³

In response to a request under FOIA, NRDC has received a list of projects that EPA has undertaken with ILSI that add up to well over \$1 million, from agreements signed by the Office of Pesticide Programs and ORD.¹⁴

Even now ILSI is convening a peer consultation panel to review the biodegradation testing of certain fluorotelomer-based chemicals under an agreement between DuPont Company and EPA (September, 2010).¹⁵ The undersigned organizations strongly recommend that EPA discontinue its reliance on ILSI because of the organization's extensive support by industry for science that feeds directly or indirectly into the regulatory process.

Process for developing the list of candidates for SAB should be re-considered

It reflects poorly on the SAB staff to publicly announce nominees for the provisional list that are clearly ineligible for service on the committee. Additionally, it distresses the public, including members of impacted communities, to see a list of potential committee members that are so allied with the interests of polluting industries. And, it is unnecessary and unreasonable to expect the public to develop informative and researched comments on forty-five provisional panel members when in fact only 10 or 15 will be selected to serve on the final committee.

Before names are moved forward to the provisional list of nominees that the public will comment on, SAB staff should screen the nominees, and omit any with ethical and financial conflicts according to its procedures and FACA requirements. Scientists that are consulting for any industry that could benefit from the deliberations of the committee should not be included in the provisional list. Similarly, scientists that are employed, contracted, or supported by any consulting firm whose clients could benefit from the deliberations of the committee should not be included in the provisional list.

In addition to eliminating the nominees with known ethical or financial conflicts prior to announcing a candidate list, EPA should provide the names of the remaining

¹² See DuPont fined more than \$10M over Teflon, Randall Chase, Associated Press (December 14th, 2005); Consent Agreement, December 14, 2005. (available at: www.epa.gov/compliance/resources/cases/civil/tzca/eabmemodupontpfoasettlement121405.pdf).

¹³ Cancer rates high in C8 areas. Residents in the communities where water is polluted with the toxic chemical C8 have elevated levels of several cancers, according to a previously confidential state government analysis. Charleston Gazette, West Virginia. Ken Ward Jr. March 14, 2007 <http://wvgazette.com/section/News/2007031320>

¹⁴ Freedom of Information Request HQ-RIN-0606-07 to Jennifer Sass, NRDC.

¹⁵ Project is described here: <http://www.ilsil.org/ResearchFoundation/Pages/SEPPanel.aspx>

candidates with information on any competing interests identified in their biosketch for public scrutiny.

Recommendations for a stricter conflict standard and an improved vetting process:

According to the 2004 Implementation Plan for the new Structural Organization of the EPA Science Advisory Board¹⁶, all new appointees must complete the “*Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the US Environmental Protection Agency*” (EPA Form 3310-48).¹⁷ However, while this form collects a broad range of information, we are concerned that the SAB staff only considers a candidate to have a financial conflict if he or she received compensation for work directly related to the chemical or topic under consideration by the committee. This is too permissive, and should be stricter so that, for example, someone who consults with Lockheed on perchlorate should not appear to be clean for this review of TCE. The standard should eliminate nominees when they, their employers, their clients, or their employers’ clients have received compensation from a commercial entity that has an interest in the chemical or topic under consideration by the committee.

We recommend that the SAB adopt the process used by the International Agency for Research on Cancer (IARC) to select working group participants for its Monograph meetings. IARC is the premiere chemical evaluation program of the World Health Organization. Its Monograph program has provided rigorous extensive evaluations of over 900 chemicals since 1971 to meet its goal of identifying environmental factors that can increase the risk of human cancer.¹⁸ The Agency accomplishes this arduous task through the use of interdisciplinary working groups of expert scientists that are carefully selected by the IARC staff and invited to working meetings that often last well over a week to review the weight of evidence. It is a process with many relevant similarities to the SAB process.

However, IARC does not share with the public its list of invited workgroup members until each expert has been vetted for conflicts and competing interests by IARC staff. The IARC process for selecting members of the working groups for Monographs meetings is as follows:¹⁹ a Declaration of Interests form is included in the first e-mail IARC staff send to prospective experts at Monograph meetings. If an expert is interested, s/he must complete and submit a Declaration before the process goes any further. An expert will not get an invitation until the IARC Monograph staff verify that there is no conflict or only a minimal conflict. IARC staff post the names of vetted, accepted experts on their website for public scrutiny only after they have been vetted internally.

¹⁶ EPA report. EPA-SAB-04-002. November, 2003. Available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ImplementReorgSAB/\\$File/sab04002.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ImplementReorgSAB/$File/sab04002.pdf)

¹⁷ EPA financial disclosure form available at <http://www.epa.gov/scipoly/SAP/pubs/form3110-48.pdf>

¹⁸ IARC Monographs web page. Available at <http://monographs.iarc.fr/index.php>

¹⁹ Preamble to the IARC Monographs. A. General principles and procedures. (5) Meeting participants. Available at <http://monographs.iarc.fr/ENG/Preamble/currenta5participants0706.php>

Any public comments IARC receives on potential committee members are subsequent to the staff's determinations, and therefore provide an additional check on the efficiency of the vetting. By this method, the credibility and public-trust of IARC and its staff is not unfairly compromised or questioned by suggestions that obviously conflicted nominees are being considered to serve on committees.

Thank you for your consideration of these comments.

Respectfully,

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