Example of Collaborative Work in Environmental Risk Assessment by Toxicology Excellence for Risk Assessment (TERA)

TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion. Of the work performed by TERA, 1/3 has been for industries; 2/3 has been for government groups. The projects below are examples of this transparent and/or collaborative work.

CPSC: Draft Final Rule [1]

Toxicology Excellence for Risk Assessment (TERA) is a contractor to the Consumer Products Safety Commission (CPSC). Below is a recent public exchange regarding work performed by TERA that might be of interest.

Public Comment 16: A commenter states that the contractor (TERA) engaged by the CPSC to study phthalate use and investigate the presence of phthalates in four specified plastics may have a conflict of interest (COI). The commenter notes TERA's past litigation support for regulated industries. The commenter asserts TERA's potential conflict of interest is exemplified in a 2016 paper sponsored by a chemical manufacturers' trade group.

The commenter adds that TERA is a founding member of the Alliance for Risk Assessment (*ARA*). The *ARA*'s Standing Panel includes the TERA founder, two industry consultants, employees of Dow Chemical and ExxonMobil, and two government employees. The commenter alleges that, in light of TERA's relationship with ExxonMobil, TERA's conclusions should be viewed with caution.

CPSC Response 16: We consider TERA to be an independent organization that focuses on advancing the science of toxicology and risk assessment. We do not agree that work by TERA or individual TERA staff in scientific projects, workshops, or publications concerning industrial chemicals or products or that include chemical firms, industry employees, or trade organizations necessarily indicates unreliable performance or improper influence in CPSC contract work.

As standard procedure, CPSC reviews potential conflicts of interest before awarding a contract or task order. We did not identify any conflicts for TERA related to the investigation of the production and use of phthalates or the production of the specified plastics. We do not agree that the membership in ARA is evidence of a potential conflict of interest. Rather, we consider ARA to be a transparent, multi-stakeholder scientific collaboration to develop risk assessment information to advance public health activities.

[1] Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics, 8-26-17.

Furthermore, the commenter does not specify any projects by the ARA that suggest that the contracted TERA work is affected by potential conflicts of interest.

Alachlor and Acetochlor [2]

Claim: Dourson sought to undermine drinking water standards for the breakdown products of alachlor and acetochlor, two herbicides manufactured by Dow and Monsanto.

Reality:

1. TERA was approached by DowAgro Sciences and Monsanto to develop Reference Doses (RfDs) for degradates (break down products) of these pesticides.
2. Michael Dourson talked with senior US EPA leaders to determine their interest.
3. EPA stated that they had developed RfDs for the parent chemicals and did not consider the degradates to be more toxic.
4. Michael Dourson suggested that DowAgro Sciences and Monsanto petition the *ARA* for their review.
5. The *ARA* Steering Committee endorsed a collaborative approach.
6. TERA formed a team of risk assessment scientists from 3 states and the EPA to develop these RfDs. COIs statements were developed and reviewed at the meeting.
7. The meeting was open to the public.
8. The results were described in a report available to the public and in a publication.

1-Bromopropane [3]

Claim: TERA proposed a weaker standard for 1-bromopropane, a solvent used in degreasers, aerosol solvents, spray adhesives and dry cleaning.

Reality:

1. In 2004, occupation limits for 1-bromopropane differed by 16-fold between several organizations' risk values.
2. TERA critically evaluated the underlying information and recommended an occupational exposure limit (OEL) of 20 ppm based on effects in newborns.
3. TERA's value was lower than EPA's.

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[2] Source:

- http://www.tera.org/ART/Degradates/index.html;
- Gadagbui, B; Maier, *M; Dourson*, M; Parker, A; Willis, A; Christopher, JP; Hicks, L; Ramasany, S; Roberts, SM. 2010. Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation. Regulatory Toxicology and Pharmacology 57:220-234.

[3] http://www.tera.org/Publications/TERA%20Analysis%20of%20OELs%20for%201-Bromopropane.pdf.

4. An NTP study was conducted after the TERA assessment showing cancer findings.
5. New evaluations based on the cancer study (new data) suggest lower limits could be considered.
6. In light of the new data, TERA would be available to work with federal agencies to develop a scientifically defensible position on this chemical under the Lautenberg Chemical Safety Act (LCSA).

Chlorpyrifos [4]

Claim: Michael Dourson argued that chlorpyrifos was safe, despite three major studies showing that mothers and children who consume it are more at risk of giving birth to kids with ADHD and other neurological problems.

Reality:

1. TERA was funded by DowAgro Sciences to review the Reference Dose (RfD) developed by the EPA and others; results were published in 2005 and 2006.
2. The science for chlorpyrifos has progressed since the time of these publications a decade ago.
3. One recent epidemiology study shows associations of neurological effects at exposures lower than the current RfD; other studies do not show this association.
4. Based on how chlorpyrifos works in the body, this association is not expected.
5. The raw data from this epidemiology study are not available for review.
6. In light of new data, TERA would be available to work with investigators of this study to obtain these raw data, and work with epidemiologists within EPA and other organizations to incorporate new information so that public health is protected.

Diacetyl [5]

Claim: TERA sought to weaken standards for diacetyl, a chemical added to food and other products for flavor and aroma.

[4] Source:

- Zhao, Q., B. Gadagbui and M. Dourson. 2005. Lower birth weight as a critical effect of Chlorpyrifos: A comparison of human and animal data. Reg. Toxicol. Pharmacol. 42:55-63.
- Zhao, Q., M. Dourson and B. Gadagbui. 2006. A Review of the Reference Dose (RfD) for Chlorpyrifos. Reg. Toxicol. Pharmacol. 44:111-124.

[5] Maier, AM; Kohrman-Vincent, M; Parker, A; Haber, LT. (2010) Evaluation of concentration-response options for diacetyl in support of occupational risk assessment. Reg. Toxicol. and Pharmacol. 58(2): 285-296.

Reality:

1. At the time of TERA's work no standards existed for worker protection.
2. TERA's standard published in 2010 (i.e., range from 70 to 200 ppb) was based on the best science at the time, through careful consideration of toxicology, epidemiology, and background exposures.
3. Subsequent analyses published by various organizations include standards of 5 to 20 ppb based on different emphasis on toxicology and epidemiology data.
4. TERA is continuing its ongoing relationship with National Institute for Occupational Safety and Health (NIOSH) since 2010 through an Interagency Personnel Agreement Fellowship.
5. This ongoing close relationship with TERA-NIOSH suggests that it finds TERA's work scientifically credible.

1,4-Dioxane [6]

Claim: TERA sought to dramatically weaken the safety standard for 1,4-dioxane, an industrial chemical used in chemical processing.

Reality:

1. Dioxane occurs naturally in foods (up to 15 ppb in dairy products).
2. Dioxane causes cancer at high doses, but EPA's Integrated Risk Information System (IRIS) peer review panel thought that a nonlinear assessment might be appropriate.
3. Kentucky petitioned the *ARA* to work collaboratively; 4 other states joined a request to the government of Japan, US National Toxicology Program (NTP) had previously helped.
4. Two publications resulted and support the EPA IRIS panel's threshold suggestion.
5. All of this information has been publicly available.
6. Health Canada is using TERA's collaborative work in their evaluation of dioxane.
7. In light of these data, TERA would be available to work with EPA offices to incorporate new information so that public health is protected.

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[6] Source:

- Nishimura et al., 2004. Study of 1,4-dioxane intake in the total diet using the market-basket method. Journal of Health Science 50:101-107.
- Dourson, M; Reichard, J; Nance, P; Burleigh-Flayer, H; Parker, A; Vincent, M; McConnell, EE; (2014). Mode of Action Analysis for Liver Tumors from Oral 1,4-Dioxane Exposures and Evidence-Based Dose Response Assessment. Reg. Toxicol. Pharmacol. Volume 68, Issue 3, April 2014, Pages 387–401
- Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard. 2017. Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane. Regulatory Toxicology and Pharmacology 88:45-55.
- Website is currently in transfer mode. For current version see: http://med.uc.edu/eh/centers/rsc/risk-resources/ara.

Flame Retardants [7]

Claim: Dourson served on Science Advisory Council of the North American Flame Retardant Alliance (NAFRA) and co-wrote an article about the flame retardant chemical tetrabromobisphenol A, or TBBPA, casting doubt on whether the flame retardant has reproductive, neurological or development effects.

Reality:

1. Flame retardants save lives and property in innumerable situations. Countless examples exist of damage to property and lives lost when flame retardants are not available.
2. The Science Advisory Council of the NAFRA recommended publishing toxicology studies on several flame retardant chemicals so that the information was more publicly available, since current studies had been submitted to EPA in a confidential manner.
3. The publication on TBBPA showed no human relevant effects even at the highest dose used. This information can be used along with other toxicology studies to determine EPA's Reference Dose (RfD) for this chemical, which will then allow its regulation.
4. Michael Dourson worked with NAFRA so that this study, and all of its raw data, could be sent to the US National Institute of Environmental Health Sciences (NIEHS) for their deliberation on whether to conduct a replicate study, thus potentially saving the US government approximately a million dollars.

Kids Chemical Safety website [8]

Claim: Michael Dourson's TERA was given money by industry to create a misleading website on chemical safety for children.

Reality:

1. Stories on this website are written by identified experts for parents in an easier to understand way, since government websites are data-dense and hard for parents to decipher; activist websites appear designed for fundraising.
2. Experts are from Cincinnati Children's Drug & Poison Information Center, Harvard Superfund Research Program, National Sanitation Foundation (NSF) International, and Toxicology Excellence for Risk Assessment (TERA).
3. TERA received cash gifts from the *ARA*, American Chemistry Council (ACC), Combined Federal Campaign (CFC) of the US Federal Government, and the

[7] Cope, Rhian B., Sam Kacew, Michael Dourson. 2015. A reproductive, developmental and neurobehavioral study following oral exposure of tetrabromobisphenol A on Sprague-Dawley rats. Toxicology 329 (2015) 49–59.

[8] Source: http://web.archive.org/web/20161031132803/http://kidschemicalsafety.org/health/about/

public.
4. Another nonprofit organization is reviewing this website for adoption.

MCHM-West Virginia [9]

Claim: Michael Dourson did not disclose a conflict of interest prior to chairing this panel meeting.

Reality:
1. As for all of TERA's peer review meetings a COI disclosure was conducted prior to the meeting and commented on by all panel members.
2. This disclosure was part of the panel report.
3. West Virginia requested a closed review meeting, so such disclosures were not publicly available until the time of the press release the day after the meeting.
4. The Dourson-lead panel recommended the level of MCHM (4-methyl-1-cyclohexanemethanol) to be 8-fold lower (or more protective).
5. All of this information has been publicly available.

Peer Review [10]

Claim: Over 50% of TERA's peer reviews are for industry. TERA whitewashes industry risk assessment values and places them on websites with other government information.

Reality:
1. Over 50% of TERA public peer review panel meetings were for governments.
2. Over 99% of TERA letter peer reviews were for governments.
3. All members of TERA's peer review panels were vetted for COI and balance was maintained among scientific disciplines and sector representation.
4. The panels decide whether information is sufficiently credible to load on the website.
5. The EPA Inspector General (IG, 2009) commented favorably on TERA's peer review process, including its COI disclosures, COI updates at the meeting, and its documentation of COI in panel reports.
6. TERA is the only group to document COI decisions in its reports out of 6 groups reviewed by the EPA IG, including EPA's IRIS and the National Academy of

[9] Report of Expert Panel Review of Screening Levels for Exposure to Chemicals from the January 2014 Elk River Spill. West Virginia Testing Assessment Project, May 5, 2014.

[10] Source:
- http://www.tera.org/Peer/MeetingReports/index.html
- U.S. Environmental Protection Agency. 2009. Office Of Inspector General. EPA Can Improve Its Process For Establishing Peer Review Panels. Report No. 09-P-0147. April 29.

Sciences (NAS).

Perchlorate [11]

Claim: Michael Dourson's TERA was supported and paid to bless a high level of the rocket fuel perchlorate found at numerous sites around the country.

Reality:

1. In 1995, Perchlorate Study Group (PSG) hired TERA to develop a safe dose, after EPA rejected PSG's proposed level.
2. TERA developed a safe dose that was 100-fold lower (more protective) than the original value PSG proposed to EPA, and recommended peer review.
3. The peer review recommended additional studies, which probably cost over 10 million dollars.
4. Afterwards, EPA and the Department of Defense (DOD) disagreed on the safe dose.
5. After reviewing new studies, TERA independently made its safe dose 5-fold lower (more protective) than that developed previously (under #2 above) and published it.
6. The NAS also developed a safe dose, which was 25 times higher than EPA's, 12-fold lower than DOD's, but within 3-fold of TERA's value.
7. In light of new data, TERA would be available to work with EPA offices to incorporate new information so that public health is protected.

Petcoke-Chicago [12]

Claim: Michael Dourson's TERA was supported by Koch industries to bless a petcoke storage facility in Chicago.

Reality:

1. The citizens of Chicago can make any risk management decision they desire regarding exposures to chemicals from any industry in their city.
2. TERA lead a team of scientists to determine exposures to petcoke in appropriate neighborhoods in Chicago.
3. Modeled exposures were compared to EPA's PM_{10} National Ambient Air Quality Standards (NAAQS).

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[11] Source: Strawson, J., Q. Zhao and M. Dourson. 2004. Reference dose for perchlorate based on thyroid hormone change in pregnant women as the critical effect. Reg. Tox. Pharm. 39: 44-65.

[12] Dourson, Michael, Chinkin, Lyle, MacIntosh, D.L., Finn, Jennifer, Brown, Kathleen, Reid, Stephen, Martinez, Jeanelle. 2016. A Case Study of Potential Human Health Impacts from Petroleum Coke Transfer Facilities. Journal of the Air & Waste Management Association May. DOI: 10.1080/10962247.2016.1180328

4. The work was published, allowing citizens of Chicago to consider these results in their risk management decision.

PFOA-Dupont [13]

Claim: Michael Dourson's TERA was hand picked by Dupont and paid to bless a high level of perfluorooctanoic acid (PFOA) in water in West Virginia.

Reality:

1. In 2002, 4 governments and one industry recommended TERA as the independent and neutral party to assist in a PFOA evaluation. A West Virginia judge agreed.
2. TERA, unaware of this agreement, was hired by the State of West Virginia.
3. Dr. Deanne Statts of West Virginia Department of Environmental Protection (DEP) chaired a 10-member scientific panel.
4. Five panelists were government employees; 3 were from EPA.
5. The panel made a unanimous determination of a safe water level of 150 ppb.
6. All of this information has been publicly available.
7. The science of PFOA has progressed since 2002.
8. In light of new data, TERA would work with EPA offices to incorporate new information so that public health is protected.

Regulatory Toxicology and Pharmacology Journal [14]

Claim: Michael Dourson publishes extensively in this journal, a mouthpiece of industry.

Reality:

1. This journal is unique in that it publishes papers that integrate toxicology and pharmacology findings into risk assessment and regulatory positions.
2. Because of this, many scientists from around the world publish in it.
3. The two most cited papers by Dr. Dourson were in this journal.
4. Dr. Dourson wrote these two papers while an US EPA employee (1980-1994).

Tobacco [15]

Claim: Michael Dourson is a schill for the tobacco industry.

[13] Source: FINAL CATT REPORT WITH ATTACHMENTS, AUGUST 2002

[14] https://scholar.google.com/citations?user=N3DABAQAAAAJ&hl=en

[15] Response to Questions from U.S. House Committee on Science, Space, and Technology on EPA's 2015 Ozone Standard: Concerns Over Science and Implementation, Thursday, November 5, 2015.

Reality:

1. TERA's work in tobacco has been previously described in a 2015 hearing of the U.S. House Committee on Science, Space, and Technology.
2. The total tobacco money received by TERA in 21 years was ~$12,635.
3. Approximately $6,000 was for a study on distribution of environmental tobacco smoke (ETS)-related chemicals for nonsmoking workers.
4. Approximately $6,000 of this was for seminars on EPA's chemical mixtures risk assessment guidelines.
5. $550 was for the development of a benchmark dose (BMD) for an ETS. constituent, since the industry did not know how to use this new EPA method.
6. $85 was for copying papers on work related to EPA's IRIS nickel document.

Trichloroethylene (TCE) [16]

Some are claiming that Michael Dourson's TERA was hand-picked by American Chemical Council (ACC) and paid to bless a high level of TCE at superfund sites around the country. Such a high TCE value might have implications for Camp Lejeune risk evaluations.

In reality, Michael Dourson's TERA has never worked on issues associated with Camp Lejeune. Rather, he worked with the *ARA* to improve the understanding of current EPA risk assessment values. The resulting range of values includes EPA's current Reference Concentrations (RfCs).

The way this came about was the following:

- *ARA* was petitioned by the Alliance for Site Closures, a small company in Indiana composed of retired state government scientists, to develop a collaboration of interested groups to review EPA's noncancer toxicity of TCE.
- The Steering Committee of the *ARA*, composed almost exclusively of government officials, asked that the collaboration focus instead on building a range in EPA's risk values, based on EPA methods.
- The collaboration team included scientists from US Agency for Toxic Substances and Disease Registry (ATSDR).
- The team had 6 conference calls, 3 webinars, one of which included over 400 folks, including scores of government scientists.

[16] Source:

- Michael Dourson, Bernard Gadagbui, Rod Thompson, Edward Pfau, and John Lowe. 2016. Managing Risks of Noncancer Health Effects at Hazardous Waste Sites: A Case Study Using the Reference Concentration (RfC) of Trichloroethylene (TCE). Regulatory Toxicology and Pharmacology 80:125-133.
- http://web.archive.org/web/20161031132803/http://kidschemicalsafety.org/health/about/

- The team gave 8 presentations to a variety of audiences, including US government groups.
- The team developed a method that was independently vetted by a team of risk assessment experts, including EPA scientists, and wrote one manuscript that was published in a peer review journal.
- The team has conducted a training sessions on this method with the scientists from the States of Indiana and Missouri.
- All of this information has been publicly available through the *ARA* website.