



Annual Report

2009

Prepared: March 2010

Introduction

Toxicology Excellence for Risk Assessment (*TERA*) was founded in 1995 as a non-profit 501 (c) (3) corporation organized for scientific and educational purposes. The mission of *TERA* is to support the protection of public health by developing, reviewing and communicating risk assessment values and analyses, improving risk assessment through research, and educating risk assessors and managers and the public on risk assessment issues. *TERA* is an independent non-profit, conducting work for diverse partners from government, industry and non-governmental organizations (NGOs) under contracts and grants. *TERA* provides sponsors and the public with independent and objective scientific opinions and conclusions. *TERA* strives to effectively address important risk assessment issues using a collaborative approach that uses the best science input from all parties.

Assessment and Risk Technology

Risk Methods Development—The field of risk assessment is changing rapidly as the “omics” revolution and the burgeoning field of molecular toxicology provide a wealth of data that were not available with classical toxicology. *TERA*’s research enhances the use of data on mode of action (MOA) to inform qualitative and quantitative aspects of risk assessment. Recent work has developed methods to incorporate biomarker data to extend the dose-response curve and design targeted studies to address key MOA questions. See <http://www.tera.org/ART/Methods.html>.

Hazard and Dose-Response Assessments—*TERA* scientists combine a practitioner’s knowledge of the issues in developing human health risk assessments, together with cutting-edge toxicology, dose-response modeling, and PBPK modeling expertise, to develop state-of-the-science assessments. These strengths form the basis for our development of independent and science-driven analyses for a range of risk assessment products such as screening-level assessments, dossiers for HPV and REACH, occupational assessments, and in-depth evaluations (e.g., RfD development and cancer risk assessments). See <http://www.tera.org/ART/Assessments.html>

For more information contact Dr. Andy Maier at maier ATtera.org

Peer Review and Consultation

Engaging outside experts to review risk assessments and methods can help insure high quality and scientifically-defensible work products and results. Government agencies, non-governmental organizations (NGOs) and industry recognize the value added by expert peer review and *TERA* is a world leader in providing independent expert review for all types of risk assessment documents and activities. *TERA* provides a variety of opportunities and services to

engage expert peers, including in-person panel meetings, webcasts and webinars; letter reviews; workshops to develop risk values or methods; and in-house technical reviews. Results of reviews are posted at www.tera.org/peer. Peer-reviewed risk values are made available on *TERA*'s free Internet databases.

For more information contact Ms. Jacqueline Patterson at Patterson.A@tera.org

Global Risk Resources and Training

To assist risk and decision-makers world-wide, *TERA* provides a number of free Internet database resources. The International Toxicity Estimates for Risk Assessment (*ITER*) is a free Internet database of human health risk values and cancer classifications for over 670 chemicals of environmental concern from multiple organizations worldwide. *ITER* is the only database that presents risk data in a tabular format for easy comparison, along with a synopsis explaining differences in data and a link to each organization for more information. Available via *TERA*'s website (www.tera.org/ITER) and as part of the National Library of Medicine's TOXNET compilation of databases (<http://toxnet.nlm.nih.gov>). Risk Information Exchange (RiskIE) is a companion to *ITER* and is a database of notifications of over 5000 ongoing and recently completed human health assessment projects from over a dozen countries. Explore RiskIE at <http://www.allianceforrisk.org/RiskIE>. *TERA* also offers risk assessment support to State agencies through the State Hazard Evaluation Lending Program (StateHELP), providing up to 10 hours annually of free technical support from *TERA* scientists.

TERA conducts training courses for a variety of audiences and skill levels. These range from our flagship 5-day "Dose Response Boot Camp" (an intensive hands-on training in hazard characterization and dose-response) to customized on-site courses on topics such as occupational exposure limit (OEL) development, dosimetric adjustments, benchmark dose, or hazard characterization. See www.tera.org/global/training.

For more information contact Ms. Andrea Wullenweber at Wullenweber@tera.org

Collaboration and Science Initiatives

In solving health risk assessment problems for a diverse array of government and private sponsors, we apply a collaborative philosophy that emphasizes partnership building, allowing us to expand our pool of expertise, build on multiple perspectives, and ensure the best use of all available scientific information. In particular, through our participation in the Alliance for Risk Assessment (www.allianceforrisk.org) and *TERA*'s Peer Review and Consultation Program, we help environmental, industry and government groups find common ground through the application of good science to risk assessment. In fostering successful partnerships, improvements in the science and practice of risk assessment will follow.

ASSESSMENT AND RISK TECHNOLOGY (ART) PROGRAM



TERA's Assessment and Risk Technology (ART) Program focuses on technology leadership - developing and using state-of-the-science approaches and novel collaborative processes in developing non-cancer and cancer risk values for use in human health risk assessments. The program is diverse with regard to both the nature of the assessment problems addressed as well as the spectrum of organizations and industrial sectors where we applied our expertise.

Highlighted projects initiated or completed in 2009 are noted below and additional details and study reports are available on our website. Nearly all of these projects have been presented at scientific meetings and are expected to be produced as peer review publications.

TERA has been very active in developing assessments and methodologies to improve dose-response assessments using toxicological mode of action data. We also have initiated projects to address issues surrounding biological variability and uncertainty in dose-response assessment.

- We continue to partner with the Food and Drug Administration's (FDA) National Center for Toxicological Research and industry partners to develop case studies for assessing dose-response approaches for *in vivo* mutagenicity data – a project intended to greatly develop the current understanding of low-dose behavior for DNA reactive chemicals.
- In a project with the National Institute for Occupational Safety and Health (NIOSH) we used linked dose-response functions for a series of biological key events to integrate early biological effects with traditional toxicological endpoints to inform the shape of the dose response curve for lung tumors from inhaled titanium dioxide.
- We initiated a project with the Environmental Protection Agency (EPA) to develop statistical approaches to better model the toxicological interactions of mixtures of chemicals using data sets for mixed exposures to carbamate pesticides.
- TERA was tapped to support EPA in evaluating and developing physiologically-based pharmacokinetic models in support of their Integrated Risk Information System. These models improve dose-response assessments by allowing for estimation of internal target tissue doses.
- TERA is working with NIOSH on improving models for evaluating the disposition of nanoparticles in rats and in the human lung. Adjustable parameters from existing models were calibrated for each data set using maximum likelihood methods. Bayesian population analysis using Markov Chain Monte Carlo (MCMC) simulation is being used to calibrate the models and generate improved assessments of parameter variability and uncertainty.

TERA initiated or completed many innovative health risk assessments for government and industry sponsors in 2009. Our efforts led to the development and implementation of systematic approaches for hazard characterization and safe dose/concentration estimation for

acute and longer term exposure scenarios as well as exposures relevant to the general public and workplace environments.

- *TERA* continued to support the development and application of systematic methods for occupational risk assessment in projects for NIOSH. We developed a refined methodology and completed new assessment documents for over 40 chemicals as part of the NIOSH Immediately Dangerous to Life or Health (IDLH) values project. We also completed a project that significantly enhanced the utility of the skin notation concept – with completion of skin notation dossiers for 112 chemicals.
- In a project for The Soap and Detergent Association – *TERA* developed an approach for evaluating epidemiology studies using an adaption of the Klimisch score method and developed a systematic weight of evidence process for integrating epidemiology and toxicology studies. This effort was developed to assess the potential for cleaning products to contribute to asthma responses.
- *TERA*, in a project funded by a coalition of companies in the Food Production sector, developed an occupational exposure limit analysis for the butter flavor – diacetyl – which has been implicated as a cause of “popcorn worker’s lung”. The work included outreach and discussion of our findings with researchers and stakeholders.
- *TERA* was asked to work with EPA and industries associated with the production and use of Methyl Isothiocyanate (MITC), a chemical used for fumigation on a variety of crops, in order to develop a safe air concentration after short-term exposures. *TERA* accomplished this by integrating available human clinical and epidemiology data and experimental animal information into existing frameworks for assessing Mode of Action (MOA) and Chemical Specific Adjustment Factors (CSAFs).

PEER REVIEW AND CONSULTATION PROGRAM

During 2009 *TERA* organized independent peer consultations and reviews for state and federal governments, private companies, and consulting firms. For each project *TERA* designed an approach to provide expert independent scientific evaluation to best meet the needs of the risk assessment effort. Approaches included expert panel meetings, collaborative workshops, written reviews, and teleconferences. Results of these reviews are summarized in reports that are made available at www.tera.org/peer.



A risk assessment prepared by LyondellBasell Industries on **tertiary-butyl acetate** (TBAC) was reviewed by an expert peer consultation panel organized by *TERA*. The risk assessment was prepared under a voluntary agreement between Lyondell and the U.S. Environmental Protection Agency (EPA) as part of a Lyondell petition to EPA to exempt TBAC from regulation as a volatile organic compound (VOC). EPA requested Lyondell conduct additional testing, assessment, and review of TBAC and subject the results to a third party review. Lyondell and EPA worked cooperatively to assure that the assessment adequately addressed potential public health concerns. Lyondell contracted with *TERA* to provide the independent peer review panel under the voluntary agreement. The January meeting was open to the public to observe in person or via an Internet WebCast.

For the State of Texas, *TERA* conducted peer reviews of the toxicological support documents that are the basis for derivation of Effects Screening Levels for **nickel and for arsenic** (acute and noncancer toxicity). These independent peer reviews were conducted as letter reviews, with a diverse group of expert scientists providing written comments on each assessment. *TERA* reviewed the individual comments and identified outstanding issues and questions that were then the subject of a teleconference of panel members with the TCEQ scientific staff. These teleconference meetings were open to the public and results were summarized and made available on *TERA's* peer page.

Four reference doses (RfDs) were derived for **acetanilide degradates** in a peer consultation workshop organized by *TERA* in May. *TERA* has used this model of developing risk values by committee several times in the past to facilitate quick and efficient development of needed risk values. Prior to the workshop, *TERA* compiled toxicology and other relevant data and provided a data package to the panel a month prior to the workshop. The package included charge questions, issue descriptions, data summary tables from relevant studies, key findings on the selection of potential critical effects, and benchmark dose modeling results. Care was taken to not provide the panel with recommended values, rather a range of potential point of departure options and considerations related to uncertainty factor selection were provided for deliberation and selection by the panel in deriving final risk value estimates. This process facilitates the work of the panel but maintains a process so that the panel will reach conclusions

using their independent scientific judgment. Full study reports and all data used in developing the data package were made available to the panel members. Funding for this project was provided by Dow AgroSciences and Monsanto. The results were summarized in a report and a manuscript, which has been accepted for publication in *Regulatory Toxicology and Pharmacology*.

A community-wide **human health risk assessment (HHRA)** for the communities of Flin Flon, Manitoba, and Creighton, Saskatchewan was the subject of an independent expert review panel meeting organized by *TERA*. The Hudson Bay Mining and Smelting Company (HBMS) operates a base metal smelting complex in Flin Flon, which produces copper, cadmium, and zinc metals. An HHRA was prepared by Intrinsik Environmental Sciences Inc. for HBMS to address the potential human health risks associated with exposure to smelter-related metals in soils and other environmental media in the Flin Flon and Creighton area. *TERA* independently selected a panel of eight scientists with extensive experience in metals, mining and smelting risk assessment to review the HHRA in June. The panel discussed key issues and scientific support for conclusions regarding chemicals of concern, exposure pathways and concentrations, toxicity values, and risk characterization. A summary of the panel deliberations and conclusions will be part of the final HHRA to be released to the public in 2010.

TERA convened a science advisory panel to provide guidance on the design and conduct of a series of studies investigating the **mode of action by which hexavalent chromium is carcinogenic** in rats and mice following drinking water exposure. The National Toxicology Program recently completed a two-year cancer bioassay for sodium dichromate dehydrate in drinking water (NTP, 2007) that reported intestinal tumors in mice and oral mucosal tumors in rats following lifetime exposure to hexavalent chromium. The subject of the review was a research proposal that described a program to investigate the mode(s) of action underlying these tumorigenic responses in rodents in order to determine the shape of the dose response curve and the human relevance of these responses prior to the development of an oral slope factor for hexavalent chromium. The research project was organized by ToxStrategies and the research proposal was prepared by The Hamner Institute. ToxStrategies engaged *TERA* to independently organize and conduct the review to provide peer consultation on study design as well as on the interpretation of the study findings. The SAB reviewed the research proposal to ensure that the appropriate studies are conducted and to ensure that the studies are of high quality and useful for risk assessment purposes. Funding for the project was provided by the Aerospace Industry Association through its membership.

For Health Canada *TERA* continues to organize letter reviews of screening assessments being developed by Health Canada under the Chemical Management Plan Challenge. We completed reviews for fifteen Challenge assessments from Batches 6, 7, and 8 during 2009. For each Batch, we arranged for letter reviews by 3-4 scientists for 5 screening assessments per batch. These reviews provided HC with expert opinions on the exposure and toxicity information used as the basis for decisions. In addition to the Challenge assessments, letter reviews were also organized for Health Canada State of the Science Reports on ethylene glycol and perfluorooctanoic acid (PFOA).



GLOBAL RISK RESOURCES AND TRAINING PROGRAM

TERA continues to develop risk assessment resources and make them widely available. *TERA*'s *ITER* database is accessed by about 400 users per day and now contains chronic human health risk assessment data for over 670 chemicals. Entries are updated with new and revised information from six organizations from around the world, as well as independent groups. *TERA* plans to continue to expand and enhance the database with revised data and new organizations. *TERA*'s companion database, the Risk Information Exchange (RiskIE), tracks over 4700 in progress or recently completed risk assessment projects conducted by 35 different organizations representing 13 different countries and the European Union.

TERA conducted multiple training courses on risk assessment methods during 2009. Thirty-three scientists were trained in the September 2009 Dose Response Assessment Bootcamp. Since 2007, a total of 150 of people have "survived" *TERA*'s intense training course on hazard characterization and dose response. Additional private training was provided to risk assessors from the State of Wyoming Department of Environmental Quality and the U.S. Department of Agriculture (including microbial methods), and on children's risk for Texas environmental regulators.

TERA volunteered approximately \$10,000 of staff time, via the Alliance for Risk Assessment, to provide risk assessment support to state and local governments and organizations. For the State of Maine, we collected references reviewing the proteins from transgenic (Bt) corn. For the State of Minnesota, *TERA* helped to develop a white paper describing various methods that could be used to estimate probabilities of adverse effects, i.e., risks, from pollutant concentrations that exceed their RfDs or RfCs, or when hazard indexes approach or exceed a hazard index of one for multiple pollutants with the same target organ and exposure route. *TERA* also helped Tennessee regulators evaluate the use of the Mann-Kendall method in a plume analysis.

ALLIANCE FOR RISK ASSESSMENT

The Alliance for Risk Assessment (ARA) is a collaboration of diverse organizations representing government, academic, industry, environmental and consulting perspectives teaming up to protect public health. Working together, the ARA pools resources, information, and expertise to take on chemical risk assessment issues that individual organizations cannot. The Alliance has a web site that is used to house the RISKie database and disseminate results of ARA projects. See www.allianceforrisk.org.

Guiding Principles of the Alliance for Risk Assessment

- Promote science-based decision making to protect human health

- Enhance harmonization and consistency in risk assessments through an open, transparent, multi-stakeholder approach
- Maintain access to groups of risk assessment experts that are normally not available within a single organization, agency or state
- Share costs, information, and human resources among multiple stakeholders to increase the capacity and quality of risk values

2009 Steering Committee

The ARA is guided by a Steering Committee comprised of individuals with governmental, academic, industry, and environmental backgrounds. All projects conducted by the ARA are vetted by the Steering Committee, which includes:

- Anita Meyer, United States Army Corps of Engineers
- Barbara Harper, Confederated Tribes of the Umatilla Indian Reservation
- Bette Meek, University of Ottawa
- Edward Ohanian, United States Environmental Protection Agency
- Michael Dourson, Toxicology Excellence for Risk Assessment (TERA)
- Michael Honeycutt, Texas Commission on Environmental Quality
- Phil Wexler, National Library of Medicine (NLM)
- Ruthann Rudel, Silent Spring
- William Hayes, State of Indiana

Projects

Peer Workshop on Toxicological Assessment and Development of RfDs for Acetanilide Degradates

Under the auspices of the Alliance for Risk Assessment (ARA), TERA convened a 2-day independent expert peer workshop to develop Reference Doses (RfDs) for the degradates: alachlor t-ESA, alachlor t-OXA, acetochlor t-ESA, and acetochlor t-OXA. The meeting, supported by Monsanto and Dow AgroSciences, was held on Monday and Tuesday, May 11 and 12, 2009 at the Northern Kentucky University METS Center located near the Greater Cincinnati International Airport. The public was invited to attend and to provide written and/or oral comments. The meeting also was available in real time to registered off-site observers via a webcast.



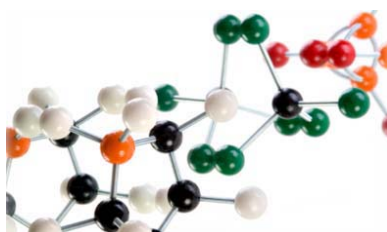
Mercury Exposure from Broken Compact Fluorescent Bulbs

The New Zealand Ministry of Health asked the Alliance for Risk Assessment to evaluate risk of mercury exposure from broken compact fluorescent light bulbs (CFLs). This screening level assessment included discussion on the type(s) of mercury in compact fluorescent light bulbs and all available information on the variation of mercury levels in CFL among manufacturers. A review of the latest dose response assessment values (e.g., RfC, for the type of mercury in CFLs) will be done. After this analysis a calculation of risk to children and adults, based on typical exposure parameters and

assumptions and use of standard risk characterization techniques such as Hazard Index, was completed.

StateHELP: Minnesota – Risk Above the Reference Concentration

The Minnesota Pollution Control Agency asked the ARA to help develop a white paper describing various methods that could be used to estimate probabilities of adverse effects, i.e., risks, from pollutant concentrations that exceed their RfDs or RfCs, or when hazard indexes approach or exceed a hazard index of one for multiple pollutants with the same target organ and exposure route. The paper assumes that there has been some refinement of exposure and toxicity information; for concentrations in air - the estimated emission rates are correct, refined dispersion modeling has been done, and the result incorporates fairly up-to-date toxicity information. The paper includes a description of how human benchmark dose information can be used, using examples such as methyl-mercury or other methods to demonstrate the risk estimation methodology.



Beyond Science and Decisions: From Issue Identification to Dose-Response Assessment

A multi-party collaboration to continue the discussion set forth by the National Academy of Science's Science and Decisions: Advancement of Risk Assessment (2008), toward a unified approach to dose response assessment. To be conducted under the aegis of the Alliance for Risk Assessment (ARA), a series of three meetings is envisioned over the course of a year, with the ultimate goal of reaching consensus among the participants on a guidance document highlighting key considerations for applying dose-response techniques for common risk assessment applications. The workshops will be lead by an Expert Panel, and will focus on biological and statistical issues that relate to dose response assessment.

TERA PUBLIC SERVICE ACTIVITIES



TERA staff continued to dedicate significant effort providing support to local communities and governments, as well as, supporting scientific development through *pro bono* activities and our TERA Corporate Development funds. The total value of TERA staff *pro bono* activities in 2009 was approximately \$89,000. Highlights of the *pro bono* efforts of the staff for 2009 are provided below.

Professional Societies. TERA staff are members of many professional societies, including the Society for Toxicology (SOT), the Society of Risk Analysis (SRA), and the American Industrial Hygienist Association (AIHA). Many hold office or leadership positions within these professional societies. During 2009, TERA scientists held numerous positions, including an officer for the Mixtures Specialty Section of the Society of Toxicology (SOT), Chair of the AIHA Workplace Environmental Exposure Levels Committee, member of the Science Symposium Committee, member of a special AIHA Task Force on Guideline Values, co-chair of the subcommittee that organizes continuing education workshops at the Society for Risk Analysis (SRA) Annual Meeting, and an Executive Committee member of SOT's Special Interest Group - Toxicologists of African Origin (TAO).

Publications. TERA staff routinely volunteer their time to review scientific papers for peer-reviewed journals. TERA staff have also authored and co-authored a number of journal articles and book chapters in 2009. Some examples of these publications include a leading industrial hygiene textbook, *The Occupational Environment: It's Evaluation, Control, and Management*, a chapter on Introduction to Human Health Risk Assessment in *Application of Toxicogenomics in Safety Evaluation and Risk Assessment*; a chapter on Quantitative modeling in noncancer risk assessment in *Quantitative Modeling in Toxicology*; a chapter on Assessing Risks to Human Health in *Comprehensive Toxicology*, 2nd Ed; and a chapter on Linear Low-Dose Extrapolation in *Cancer Risk Assessment*. TERA scientists presented over 30 papers, posters and workshops in 2009 at meetings of SOT, SRA, AIHA, Toxicology and Risk Assessment Conference, and the Midwest States Risk Assessment Symposium. A full list of TERA's publications can be found on our website at <http://www.tera.org/Publications/Publications.html>.

Community Service & Other Activities. TERA prides itself on being involved with our local communities. We have given guest-lectures at the University of Cincinnati on toxicology, risk assessment, and systematic approaches for evaluating the quality of epidemiological and clinical studies. One staff member serves as an Adjunct Associate Professor in the University of Cincinnati's Department of Environmental Health, providing lectures to graduate students and serving as a member of the Advisory Committee for the Biological Monitoring Core. One staff member was an invited presenter at the 7th Congress of Toxicology in Developing Countries at Sun City, South Africa. TERA is also a member of the Cincinnati Alliance for Chemical Safety

(ACS), and has given lectures at their monthly meetings. *TERA* staff won the annual ACS risk communication award for developing the Hamilton County Air Toxics Report. Another staff member served as a panel member in the U.S. EPA's IRIS Peer Review for Ethyl Tert-Butyl Ether (ETBE).

TERA also enjoys being involved with local activities, such as Earth Day. *TERA* staffed a booth at Cincinnati's Earth Day Celebration that focused on educating the public on toxicology and risk assessment and how it relates to their daily lives. Children's activities were also provided.

RECENT TERA PUBLICATIONS

Journal Articles

Allen, B.C., Maier, A., Willis, A., Haber, L.T. 2010. **Use of Early Effect Biomarker Data to Enhance Dose-Response Models of Lung Tumors in Rats Exposed to Titanium Dioxide.** In preparation; submitted to NIOSH.



Dotson, S.G., Chen, C-P., Gadagbui, B., Maier, A., Ahlers, H.W., Lentz, T.J. 2009. **The evolution of skin notations for occupational risk assessment: a new NIOSH strategy.** Submitted to Int Archives Occup Environ Health.

Gadagbui, B., Maier, A., Dourson, M., Parker, A. Willis, A., Christopher, J.P., Hicks, L., Ramasamy, S., Roberts, S.M. 2010. **Derived reference doses (RfDs) for the environmental degradates of the herbicides alachlor and acetochlor: Results of an independent expert panel deliberation.** Accepted for publication to Regul Toxicol Pharmacol.

Gadagbui, B., Patterson, J., Kueberuwa, S.S., Rak, A., Kutzman, R.S., Reddy, G., Johnson, M.S. 2010. **Development of a Relative Source Contribution Factor for Drinking Water Criteria: The case of Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX).** In preparation; submitted to DoD.

Haber, L.T., Maier, A., Kroner, O.L., Kohrman, M.J. 2009. **Assessment of Human Relevance and Mode of Action for Tunica Vaginalis Mesotheliomas Resulting from Oral Exposure to Acrylamide.** Regul Toxicol Pharmacol 53(2):134-49.

Hack, C.E., Haber, L.T., Maier, A., Schulte, P., Fowler, B., Lotz, W.G., Savage, R.E. 2010. **A method for biomarker validation and biomarker-based dose response: A case study with benzene and a Bayesian network.** Risk Analysis. Accepted for publication.

Maier, A., Kohrman-Vincent, M., Haber, L., Parker, A. 2010. **Evaluation of concentration-response options for diacetyl in support of occupational risk assessment.** Submitted to Regul Toxicol Pharmacol.

Maier, A., Kohrman-Vincent, M., Hertzberg, R., Allen, B., Haber, L.T., Dourson, M.L. 2010. **Re-evaluation of Dose-Response Options for F344 Rat Mammary Tumors for Acrylamide – Additional Insights Based on Mode of Action.** Submitted to Food Chem Toxicol.

Nance, P., Patterson, J., Willis, A., Foronda, N., Dourson, M. 2010. **Screening Level Risk Characterization for Mercury Exposure from Compact Fluorescent Lamps.** Prepared by Toxicology Excellence for Risk Assessment (TERA) for New Zealand Ministry of Health. Manuscript in preparation.

Sweeney, L.M., Kirman, C.R., Albertini, R.J. Tan, Y.-M., Clewell, H.J., III, Filser, J.G., Csanády, G., Pottenger, L.H., Banton, M.I., Graham, C.J., Andrews, L.S., Papciak, R.J., Gargas, M.L. 2009.

Derivation of inhalation toxicity reference values for propylene oxide using mode of action analysis: example of a threshold carcinogen. Crit Rev Toxicol. 39:462-486.

Sweeney, L.M., Kirman, C.R., Gannon, S.A., Thrall, K.D., Gargas, M.L., Kinzell, J.H. 2009.

Development of a physiologically based pharmacokinetic (PBPK) model for methyl iodide in rats, rabbits and humans. Inh. Toxicol 21:552-82.

Sweeney, L.M., Kirman, C.R., Gargas, M.L., Carson, M.L., Tardiff, R.G. 2010. **Development of a physiologically-based toxicokinetic model of acrylamide and glycidamide in rats and humans.** Food Chem Toxicol. 48:668-85.

Sweeney, L.M., Kirman, C.R., Gargas, M.L., Dugard, P.H. 2009. **Contribution of trichloroacetic acid to liver tumors observed in perchloroethylene (perc)-exposed mice.** Toxicology 260:77-83.

Book Chapters

Baskerville-Abraham, I., Willis, A., Gadagbui, B., Haber, L.T. 2010. **Introduction to Human Health Risk Assessment.** In: *Application of Toxicogenomics in Safety Evaluation and Risk Assessment.* John Wiley and Sons Inc., D.R. Boverhof and B. B. Gollapudi, ed. In press.

Nance, P., Kroner, O., Haber, L., Dourson, M. 2010. **Assessing Risks to Human Health.** In. *Comprehensive Toxicology*, 2nd Ed., Charlene A. McQueen, ed. In press.

Nelson, D., Bratt, G., Maier, A., Mirer, F., Anderson, D., **Occupational and Environmental Health Risk Assessment.** In. *The Occupational Environment: Its Evaluation, Control, and Management.* 3rd Ed., AIHA Press, D. Anna, ed. In press.

Zhao, Q.J, Haber, L., Kohrman-Vincent, M., Nance, P., Dourson, M. 2010. **Quantitative modeling in noncancer risk assessment.** In: *Quantitative Modeling in Toxicology*, John Wiley, K. Krishnan and M.E. Andersen, ed. In press.

Financial Statement

TERA's 2009 income was \$2,356,812 and actual expenses totaled \$2,315,789. This resulted in net gain of \$41,023.

As an independent non-profit corporation focused on providing science to support public health protection, *TERA* strives to balance our work among diverse sponsors. We provide leading science efforts on projects funded by both public and private organizations in a roughly equal amount. In 2009 *TERA* conducted a larger percentage of work for government agencies and other non-profits (65%), than for private sector sponsors (35%). The table below shows the percentage of work for these types of sponsors for each year since our inception. This balance of sponsors varies from year-to-year, reflecting the needs of sponsors and our goal of providing scientifically credible and neutral guidance.

Year/Source	Government and other Nonprofit	Industry and Industry Related
1995	67%	33%
1996	37%	63%
1997	55%	45%
1998	63%	37%
1999	66%	34%
2000	59%	41%
2001	48%	52%
2002	72%	28%
2003	66%	34%
2004	82%	18%
2005	82%	18%
2006	79%	21%
2007	71%	29%
2008	67%	33%
2009	65%	35%

TERA BOARD OF DIRECTORS AND OFFICERS- 2009

BOARD OF DIRECTORS

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Sam Kacew (2011)

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Philip Tobin (2010)

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OFFICERS

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Jacqueline Patterson, Vice President, Corporate Secretary

Andrew Maier, Treasurer

¹ Trustee serves 3 year term; date indicates ending year of current term,