2008 Annual Report

Toxicology Excellence for Risk Assessment (TERA)

Cincinnati, Ohio

March 30, 2009
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**TERA: Providing Public Service through Excellence in Risk Assessment**

In 1995, Dr. Michael Dourson organized TERA as a non-profit and independent corporation with a mission to support the protection of public health and a vision of toxicology excellence for risk assessment. TERA focuses on high quality science and on developing partnerships among all members of the risk assessment community. TERA supports the protection of public health by developing and communicating risk assessment information, sponsoring peer reviews and consultations, improving risk methods through research, and educating interested parties on risk assessment issues. TERA donates a percentage of staff time to serve the risk assessment community, professional societies, and the public.

Today, our mission and our vision remain unchanged, but are carried out by a dedicated staff of 20 diverse individuals. See highlights that follow and visit www.tera.org to see more of what TERA has accomplished.

**Development of Novel Risk and Dose-Response Methods**

TERA has a number of active projects focusing on biomarkers of effect, including characterization of toxicity processes and research on how to quantitatively include biomarkers in dose-response assessment. Ultimately, our aim is for these projects to work toward the vision outlined in the NAS report “Toxicity Testing in the 21st Century.” We are collaborating with Gradient in work for the USEPA on characterizing the pathophysiological progression (including biomarkers) for endpoints such as pulmonary fibrosis, using phosgene as a case study, and neurotoxic effects of acrylamide. In work for NIOSH, we have applied novel approaches to quantitatively use biomarker precursor data to inform dose-response evaluations for benzene (based on a Bayesian causality network model) and TiO₂ (based on an approach for maximizing the likelihood for linked dose-response functions). In other work for NIOSH, we have developed and applied updated methods related to acute inhalation effects for IDLH development and for assessing dermal contact hazards. We have also published a new approach for informing mode of action (MOA) analysis for cancer risk assessment of mutagenic chemicals with multiple plausible MOAs, based on the use of transgenic animals to directly evaluate mutations in the tumor target tissue in the same rodent strain. We can work with your group to develop MOA evaluations, including support of research program design using the most current molecular toxicology methods. Contact: Lynne Haber (Haber@tera.org, 513 542-7475 ext 17).
Application of Cutting Edge Science for Human Health Assessment

TERA has a number of projects in which we are developing and applying cutting-edge approaches in the development of human health risk assessment documents. We have conducted an extensive mode of action (MOA) analysis of tumors induced by acrylamide in rats, including the thyroid ([Dourson et al., 2008. Reg Toxicol Pharm 52:264-289]), tunica vaginalis mesotheliomas ([Haber et al., 2009. Reg Toxicol Pharm 53:134-149]), and mammary gland ([Maier et al. submitted]), including detailed evaluation in light of EPA’s modified Hill criteria, and guidance for evaluating human relevance, as well as EPA’s draft guidance for evaluating mutagenicity as a MOA. We have also evaluated acute exposure to two sensory irritants (chloropicrin and MITC), using several modeling approaches, including benchmark concentration, categorical regression, and the ten Berge (2007) approach to modeling responses when both exposure duration and exposure concentration are varied. We have provided support for occupational exposure limit development for food, chemical, and pharmaceutical products, including an analysis of the butter flavor – diacetyl. We are developing and reviewing robust summaries and other documentation for several organizations under the HPV and REACH programs. Contact: Andrew Maier (Maier@tera.org; 513 542-7475 ext 16).

Involving Expert Peers in Risk Assessment

Expert review of draft assessments and methods is critical to high-quality risk assessment. TERA works with private and public partners to design an approach that is most effective for the type of work product, stage of development, and purpose for engaging experts. Peer input, peer consultation, and peer review are three approaches we use, all of which follow the principles that are the cornerstone of our program – selection of appropriate expertise, scientific robustness, and transparency. A fourth principle, independence, is essential for all peer reviews and an important consideration for peer input and consultation efforts. These principles were described in a recent TERA publication (Meek et. al., 2007. Engaging Experts Peers in the Development of Risk Assessment, Risk Analysis 27:1609-1621).

Recent Peer Reviews or Peer Consultation meetings organized by TERA addressed topics including HPV submissions, screening assessments, tertiary-butyl acetate, statistical relationships to describe toxicity of petroleum substances, carcinogenicity of 1,3-butadiene, adult-to-child toxicokinetic differences, community-wide ecological and human health risk for Sudbury, Ontario, a methodology for developing Effect Screening Levels, QSAR for genotoxicity and carcinogenicity, and a harmonized trichloroethylene PBPK Model. Contact: Jacqueline Patterson (Patterson@tera.org, 513-521-7426).
Dose-Response Assessment Boot Camp

TERA’s Dose-Response Assessment Boot Camp is an intensive hands-on training course in hazard characterization and dose-response assessment. Beginners through expert toxicological risk assessors will learn advanced methods, as well as enhance their understanding and skills in the basics. Upon completing the course, participants will be able to derive and evaluate risk values and supporting documentation for both non-cancer and cancer risk assessments. Five Certification Management (CM) points are available from the American Board of Industrial Hygienists (ABIH), and the camp is endorsed by both the Society of Toxicology and the Society of Risk Analysis. The next Boot Camp course will be held September 21-25, 2009 in Cincinnati, OH. See www.tera.org/education/Bootcamp/Bootcamp.htm for more information. Contact: Patricia Nance (Nance@tera.org, 513 542-7475 ext 25).

Global Risk Resources

TERA provides multiple global risk assessment resources to ensure that existing risk information is readily available and to help risk assessors collaborate during the risk assessment process.


**Risk Information Exchange (RiskIE)** - A free Internet database that contains notifications about a variety of human health risk assessment projects that are underway or recently completed. RiskIE contains over 5600 projects from 31 organizations in 13 countries and the European Union. Available at http://www.allianceforrisk.org/ARA_tools.htm and will soon join ITER on TOXNET.

**Alliance for Risk Assessment (ARA)** - A collaboration of organizations dedicated to supporting public health protection by working together on projects to improve the process, efficiency, and quality of risk assessment. See www.allianceforrisk.org.

**State Hazard Evaluation Lending Program (StateHELP)** - ARA provides up to 10 hours of free technical support to each state and tribe annually. States and tribes may unite to combine their StateHELP hours for large projects. Contact: Andrea Wullenweber Wullenweber@tera.org, 512-863-5441) or Oliver Kroner (Kroner@tera.org, 513-542-7475, ext.19).
Introducing the New and Enhanced TERA.ORG!

As TERA grows, we want to ensure that you continue to find the highest quality risk science you have come to expect. We have restructured our site and enhanced search ability to put TERA’s wealth of risk and toxicity data at your finger tips. You’ll find old favorites such as our ITER database and Peer Review Program, as well as fresh new content, such as TERA’s recent REACH work and the latest in risk methods development. Come explore www.tera.org!
Program Updates

Global Risk Resources:
International Toxicity Estimates for Risk (ITER) and Risk Information Exchange (RiskIE) Databases

The purpose of the Global Risk Resources program is to compile, distribute, and maintain a comprehensive database of peer reviewed risk assessment values and a database of in progress human health risk assessment work, both of which provide risk assessors tools to access current risk information, encourage data sharing and collaboration among organizations, and ultimately help protect public health through the use of the best toxicity information.

We have provided the ITER database to the risk assessment community since 1996, having developed and expanded ITER during this time to add more organizations and to offer a more searchable version of ITER to users via the National Library of Medicine’s (NLM) TOXNET compilation of databases. In 2007, we created the RiskIE in 2007 to provide risk assessors with notifications about a variety of human health risk assessment projects that are underway. As of the end of 2008, RiskIE tracks over 5600 in progress or recently completed risk assessment projects conducted by 31 different organizations representing 13 different countries and the European Union. We anticipate that RiskIE will join ITER on TOXNET during 2009.

Our ITER web statistics for 2008 (based on usage of original ITER) show that we had an average of 509 users per day; the average for 2007 was 692 daily users. The 2007 launch of RiskIE may have contributed to the large increase in ITER users in that year (it doubled from 2006 to 2007). Additional web statistics are listed in the table for multiple years. This data only reflects users of the original ITER database. The data from NLM shows that there is an average of 1990 queries per month to ITER on the TOXNET system.
ITER WEBSTATS – AVERAGES
(Original ITER)

<table>
<thead>
<tr>
<th>Year</th>
<th>Avg. Daily Hits</th>
<th>Avg. Daily Users</th>
<th>Avg. Length in Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>2975</td>
<td>509</td>
<td>43</td>
</tr>
<tr>
<td>2007</td>
<td>2934</td>
<td>692</td>
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<td>2404</td>
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<td>1812</td>
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<td>10</td>
</tr>
<tr>
<td>2001</td>
<td>1318</td>
<td>97</td>
<td>8</td>
</tr>
</tbody>
</table>

ITER WEBSTATS COMPARED WITH EPA’s IRIS WEBSTATS
(ITER and IRIS on TOXNET\(^1\))

<table>
<thead>
<tr>
<th>Year</th>
<th>EPA’s IRIS Average Monthly Queries</th>
<th>ITER Average Monthly Queries</th>
<th>ITER’s % of IRIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>4261</td>
<td>1990</td>
<td>47%</td>
</tr>
<tr>
<td>2007</td>
<td>4018</td>
<td>2031</td>
<td>51%</td>
</tr>
<tr>
<td>2006</td>
<td>4153</td>
<td>1743</td>
<td>42%</td>
</tr>
</tbody>
</table>

\(^1\) Note that both ITER and IRIS are also available at other “original” sites.
We continued to coordinate with Noblis, Concurrent Technologies Corporation (CTC), States, and other parties to further the concept of the Alliance for Risk Assessment and to further the development of RiskIE. We presented posters and made presentations at several scientific meetings, such as the Toxicology and Risk Assessment Conference (TRAC), an ancillary meeting on Aggregate Databases at the Society of Toxicology (SOT) Annual meeting, the 2008 Society for Risk Analysis (SRA) Annual Meeting, as well as the SRA World Congress meeting in Guadalajara, Mexico.


We continued to update and expand ITER with additional data from existing organizations (ATSDR, EPA, NSF International, RIVM, and IARC). We are also making improvements in format of RiskIE to balance ease of use and ease of data entry. As of the end of 2008, RiskIE tracks over 5600 in progress or recently completed risk assessment projects conducted by 31 different organizations representing 13 different countries and the European Union.
Peer Consultation and Review Program

This program was organized to provide scientists and others with the opportunity for expert independent peer consultation and peer review of risk assessment related documentation through panel meetings or other venues.

We have provided this service to the risk assessment community since 1996, having organized and conducted over 50 panel reviews and numerous paper reviews. Meetings are conducted in a transparent fashion and are usually open to the public. TERA manages all aspects of the peer consultation or review including: the selection of the panel, identification of conflict of interest and bias, development of issues to focus panel discussions, conducting meeting, all logistical and facility arrangements, and preparation of a meeting report.

Our peer consultation and review program continues to provide expert review for both public and private parties for the 13th year. During 2008 we assisted a variety of government and industry sponsors with independent peer reviews and technical in-house reviews. We have provided these services to organizations such as the Texas Commission on Environmental Quality (TCEQ, Health Canada), Concurrent Technologies Corporation (CTC), LyondellBasell, Inc., Health Canada, the U.S. EPA, the American Chemistry Council, and the Ontario Ministry of the Environment. TERA also provided expert technical review of REACH-related documentation that has been prepared for private clients.

Through the ARA program and in other efforts TERA has been encouraging the use of peer consultation by state and local governments to help resolve scientific issues and move past impasses on issues or the lack of resolution on risk values.

Research Program

The purpose of the Research Program is to move the science of risk assessment forward globally by improving the application of current methods, developing and defining new methods, and obtaining the data to support such applications and to educate the scientific community and the general public about advances in risk assessment research. To accomplish this, the research program works closely with the VERA program in identifying and addressing key issues related to risk assessment methods. While many of the research projects have traditionally been on the border between methods development and application to risk assessment, we have been also been working to build qualifications and our work portfolio in fundamental risk assessment methods issues.
During 2008, TERA began developing a manuscript on the toxicology of diacetyl, a respiratory tract toxicant found in butter flavoring. Also, for a private sponsor, TERA analyzed the mode of action for the tumors induced by acrylamide in rats – thyroid, tunica vaginalis of the testis, and mammary gland. In collaboration with biomathematicians at Emory University, TERA supported EPA on evaluation of mixtures data. In an ongoing project for NIOSH, TERA conducted a case study on titanium dioxide, including nano-sized particles, mathematically linking precursor biomarker data to the lung tumor response, in order to quantitatively use the biomarker data in the dose-response analysis.

TERA is working with another consulting company (Gradient) on providing support to EPA for developing an approach for categorizing biomarkers and other endpoints along a pathophysiological progression. An analysis for lung fibrosis (using phosgene as a case study) was completed and presented at the SOT annual meeting.

**Verifiable Estimates for Risk Assessment (VERA) Program**

The purpose of the VERA Program is to provide high quality risk assessment service by developing unbiased and science-based risk assessments for all sponsors, including government agencies, industry groups, and environmental groups, as well as to educate the scientific community and the general public about methods for conducting hazard identification and dose-response assessments.

The VERA program continues to be a significant contributor to the overall scientific effort of TERA. TERA staff worked on almost 20 significant projects during 2008, as well as a variety of other small projects. The program has maintained a diverse portfolio of work. Significant TERA projects in 2008 were sponsored (directly or through intermediary contractors) by EPA (5), local governments (1), international governments (2), NIOSH (2), industry (6), and miscellaneous sponsors (primarily boot camp, which is funded by individual registrations).

TERA is viewed as a source of high quality technical expertise as evidenced by ongoing projects, requests for new work by existing and former sponsors, recent referrals, and requests for training. Specific project highlights demonstrating these points are presented below.

TERA staff continued to be active in support of EPA. For the Office of Water, as part of the review of the toxicity of chemicals that occurs every 6 years for prioritization for future analysis, TERA reviewed the basis of assessments by EPA and other agencies for noncancer and cancer endpoints, as well as considered the availability of new studies, to determine whether there are new
data that could affect the assessments. TERA also conducted screening-level evaluations of RfDs for developmental and reproductive toxicity endpoints. In other work for EPA, TERA completed work on the revisions to the soluble nickel IRIS document, and reviewed summaries prepared as part of the Office of Water’s Criteria Contaminant list 3 (CCL3) process.

In a project conducted for the Army, in consultation with the Office of Water, analyzed the data available to derive the percentage contribution of RDX (Royal Demolition Explosive or Research Department Explosive) exposure from drinking water when compared to the total RDX exposure, including other oral sources such as food, and dermal and inhalation exposure. This work will lead to development of the relative source contribution (RSC) of RDX.

Risk assessment development projects for NIOSH continued to grow. TERA continued to support a program for assigning skin notations. Building on success in prior work, TERA continued to provide support for the development of Immediately Dangerous to Life or Health (IDLH) values for NIOSH, as well as supporting NIOSH in developing documentation for an updated IDLH methodology. IDLH poster presentations received awards at two professional society meetings.

TERA continues to demonstrate technical leadership in risk assessment development through risk assessment training development:

- The demand for TERA’s Dose-Response Assessment Boot Camp and presentation in various venues continues to grow. The course received excellent evaluations and positive feedback.
- TERA scientists also continued to build work of interest to industry partners. We conducted an in-depth assessment of health effects associated with exposure to Teflon® fumes. TERA conducted two assessments on exposures to vapors from irritant pesticides. We also conducted an update to our work on chlorpyrifos in response to comments from EPA’s Science Advisory Panel (SAP), and made a presentation (on behalf of TERA) to the SAP. Other industry projects in the VERA program focused on product safety support, including developing and applying hazard screening approaches for product ingredients and preparing material safety data sheets (MSDS), developing health-protective screening-level Occupational Exposure Levels (OELs), and evaluation of the risk from exposure to a chemical contaminant that develops from an active ingredient in an eyedrop solution.
- TERA continued to look for opportunities to pursue collaborations outside of North America.
The Alliance for Risk Assessment (ARA) has continued to progress steadily in 2008. ARA provides a collaborative multiple-stakeholder approach for solving public health risk assessment issues and sharing resources to increase the output of technical risk assessment products. 2008 Milestones included:

- **New Zealand Compact Fluorescent Lights (CFLs).** The ARA was approached by the New Zealand Ministry of Health to assess the risk of mercury exposure following breakage of a CFL light bulb.

- **ARA Steering Committee welcomes Anita Meyer, D.A.B.T.** Ms. Meyer, of the U.S. Army Corps of Engineers, brings a new perspective to our Committee, with extensive experience in the risk assessment of emerging contaminants.

- **Growth of the Risk Information Exchange (RiskIE).** RiskIE is a web-based system for coordinating work on chemical risk value and methodology documents that are under development or revision. Since its launch in 2007, RiskIE has grown to include over 5,500 projects being conducted by over 30 organizations representing 13 countries. RiskIE is scheduled to join ITER and NLM’s TOXNET in 2009.

- **Presentation at World Congress on Risk.** The Alliance and its risk database resources were presented at the World Congress on Risk, in Guadalajara, Mexico.

- **StateHELP (State Hazard Evaluation and Lending Program).** TERA’s pro bono StateHELP was very busy in 2008. Projects included
  - **California Green Chemistry Initiative: Scientific Advisory Panel for the (California Department of Toxic Substance Control)**
    Michael Dourson sat on the Green Chemistry Initiative’s Science Advisory Panel, which completed its report on advancing green chemistry in California.
  - **Area Land Trust (SALT).**
    Joan Strawson helped write a cooperative agreement with the Army at Fort Bragg to purchase and preserve 13,000 acres of red cockaded woodpecker habitat.
  - **Arsenic in Soil (Hawaii Department of Health and Texas Commission on Environmental Quality)**
    Compiled information related to arsenic toxicity in the range of dietary exposure for the Hawaii Department of Health and Texas Commission for Environmental Quality.
  - **Ohio Wellhead Protection**
    The ARA is working with a group of citizens in Athens, Ohio, concerned with a golf course scheduled for development atop the town well. ARA is reviewing the pesticides and fertilizers to be used.

**TERA Public Service Activities**

TERA staff continued to dedicate significant effort supporting scientific development through *pro bono* activities and our TERA Corporate Development
funds. Highlights of the pro bono efforts of the staff for 2008 are provided below.

- Served as peer reviewer of submitted manuscripts for the journal, Critical Reviews in Toxicology.
- Multiple presentations (several of which won science awards) occurred at national and international meetings: the Society for Risk Analysis, the SRA World Congress, Society of Toxicology Annual Meeting, the Toxicology and Risk Assessment Conference, and the American Industrial Hygiene Conference.
- TERA staff members are officers in professional societies: the Society for Risk Analysis Ohio Chapter (Secretary - Gadagbui), the American Industrial Hygiene Association WEEL Committee (Vice-Chair - Maier).
- Served on committees for professional societies and scientific non-profit organizations, for example, African Society of Toxicological Sciences (Dourson), SRA World Congress Finance Committee (Nance and Dourson), Conference and Workshop Committee for SRA (Patterson), Awards Review Committee for SOT Risk Assessment Specialty Section (Haber), formation of Toxicologists of African Origin - Special Interest Group President (TAO-SIG) for SOT (Gadagbui); NSF International peer review panel (Dourson), Underwriters Lab peer review panel (Haber).
- Provided courses or lectures to Universities or Professional Societies: risk assessment lectures for several graduate courses at the University of Cincinnati (Dourson and Maier), Miami University of Ohio (Patterson), and as continuing education courses at the SOT annual meeting (Maier and Haber), the Toxicology and Risk Assessment Conference (Haber), George Washington University (Haber) and the SRA World Congress (Haber).
- Participated in local environmental group efforts: participated in local group events hosted by the Alliance for Chemical Safety (Nance, Dourson and Haber), served as member of the board for Oxbow Inc. and editor of Wetland Matters, Oxbow’s newsletter (Poehlmann), and newsletter and webpage editor for EchoBats Inc. (Nance).
- Provided comments on Health Canada’s uncertainty factor documentation (Dourson and Nance), comments on California EPA text on uncertainty factors (Dourson and Kohrman), and comments on methylmercury and fish to the Virginia DEQ (Dourson and Nance).
- Served on EPA’s Board of Scientific Counselors (BOSC) review of EPA’s Land Research Program mid-cycle review (Haber).
• Participated in the City of Cincinnati Climate Protection Initiative (Patterson). Citizen Task Teams will work to develop proposals for a regional Climate Action Plan for reducing green house gas emissions (GHG).
• Registered 300 new recyclers as part of the Mayor Mallory’s Cincinnati Community Recycling Challenge (Kroner).
• Coordinated 85 neighborhood volunteers for the Great American Cleanup (Kroner).

**TERA 2008 Publications**


TERA’s 2008 income was $1,800,948 and actual expenses totaled $1,983,724. This resulted in net loss of $182,776.

As a neutral, non-profit corporation, TERA strives for work on both public and private projects in a roughly equal amount. In 2008 TERA conducted a larger percentage of work for government agencies and other non-profits (67%), while 33% of work was for private sector sponsors. The table below shows the percentage of government and private work 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.

<table>
<thead>
<tr>
<th>Year/Source</th>
<th>Government and other Nonprofit</th>
<th>Industry and Industry Related</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>67%</td>
<td>33%</td>
</tr>
<tr>
<td>1996</td>
<td>37%</td>
<td>63%</td>
</tr>
<tr>
<td>1997</td>
<td>55%</td>
<td>45%</td>
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<tr>
<td>1998</td>
<td>63%</td>
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<td>2006</td>
<td>79%</td>
<td>21%</td>
</tr>
<tr>
<td>2007</td>
<td>71%</td>
<td>29%</td>
</tr>
<tr>
<td>2008</td>
<td>67%</td>
<td>33%</td>
</tr>
</tbody>
</table>
TERA’S Board of Trustees

TERA’s Board of Trustees consists of up to 10 members who serve 3-year rotating terms. Listed below are TERA’s Board members for 2008. The date in parenthesis indicates the year each member’s term on TERA’s Board of Trustees concludes.

TERA’s Board of Trustees plays an important role in the organization. We seek nominations for a diverse membership. We have members who are involved with government agencies, universities, industry and nonprofit organizations. By having a diverse membership, our board is better able to advise TERA on issues and growth in the field of toxicology and risk assessment.

**Board of Trustees - 2008**

**Michael Dourson** (perpetual)

**Daniel Acosta** (2009)

**Gail Charnley Elliott** (2009)

**Michael Fremont** (2008)

**Sam Kacew** (2008)

**Randall Manning** (2008)

**Gregery Romshe** (2009)

**Sue Ross** (2008)

**Chad B. Sandusky** (2010) FINANCE COMMITTEE CHAIR

**James D. Wilson** (2010) CHAIR