



TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT

Address: 2300 Montana Avenue, Suite 409, Cincinnati, Ohio 45211

Tel : (513) 542.7475

Fax : (513) 542-7487

Email : tera@tera.org

www.tera.org



The cover features a background of dandelions against a light blue sky. A large, dark green geometric shape, resembling a stylized letter 'E' or a series of overlapping triangles, is positioned in the lower half. The text is overlaid on this shape and the sky.

TERA
TOXICOLOGY EXCELLENCE FOR
RISK ASSESSMENT

 **PROTECTING PUBLIC HEALTH**

**2012
ANNUAL
REPORT**



INDEPENDENT

NONPROFIT

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SCIENCE

EXPANDING OUR IMPACT



2012 was a year of growth for TERA. With an increased international focus, continued investment in partnership building, and new initiatives to improve our risk communication, TERA's public health impact has never been greater.

We invite you to browse through this report and explore the many ways TERA has grown over the last 18 years into a global force for science, the environment, and public health. Of course, we can't capture the entirety of the year, so we have highlighted a few projects, tools, and initiatives we are excited to share.

Mission/ Vision / Core Values

Mission

Toxicology Excellence for Risk Assessment (TERA) is a non-profit and tax-exempt organization organized for scientific and educational purposes. Our mission is to support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues.

Vision

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, and communicating these results widely.



Core Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations - from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

- + Honesty and Integrity
- + Independence
- + Transparency
- + Collaboration

Public Health PROTECTION



**“ IT IS TRULY
REMARKABLE THAT
SUCH A SMALL
ORGANIZATION HAS
HAD SUCH AN IMPACT
ON THE SCIENCE OF
RISK ASSESSMENT
NATIONALLY AND
INTERNATIONALLY... ”**

Letter from the Chairman

Dear Colleagues:

As Chair of TERA's Board of Directors, I am pleased to report that 2012 was a banner year for TERA. It has received a number of grants and contracts from government, industry, and private sources to support its mission to improve the public's awareness of the risk of chemical exposure in the home, the workplace, and the environment. In addition, its very productive staff of scientists have garnered several awards for the excellence of their research (see examples throughout the Annual Report),

and they have published several significant reports and manuscripts in the scientific literature.

It is truly remarkable that such a small organization has had such an impact on the science of risk assessment nationally and internationally. The quality of TERA's science is considered to be impeccable and their publications have received much acclaim from their peers. It is very clear that the key word is quality and not quantity.

I feel much honored to be associated with such a fine organization and to have been selected as Chair of the Board of Directors. I am very certain that TERA's future is very bright and that we can expect more outstanding work and research to come from its staff.

Best wishes,



Daniel Acosta, Jr., PhD
Chair, Board of Directors

Carl Chair of Pharmacy
University of Cincinnati

BOARD OF DIRECTORS

DATE INDICATES ENDING YEAR OF CURRENT TERM

CHAIR

Daniel Acosta, Jr. (2013)
Chair, Board of Directors
STET Chair of Pharmacy
University of Cincinnati

Gail Charnley Elliott (2012)
HealthRisk Strategies

Michael Dourson (perpetual)
President
Toxicology Excellence for Risk
Assessment

Mike Fremont (2014)
Restoration Foundation

FINANCE COMMITTEE CHAIR
Gregory S. Romshe (2015)
Sr. Accountant
The Procter & Gamble
Company

VICE CHAIR
Chad B. Sandusky (2013)
Retired - Physicians
Committee for Responsible
Medicine

Jon L. Seymour (2014)
Director
Oxbow Inc.

Philip E. Tobin (2013)
Mercer University

James D. Wilson (2013)
Emeritus
Resources for the Future

AUDIT COMMITTEE CHAIR
Chase D. Wright (2013)
Deloitte

A busy year...



Occupational Risk Assessment

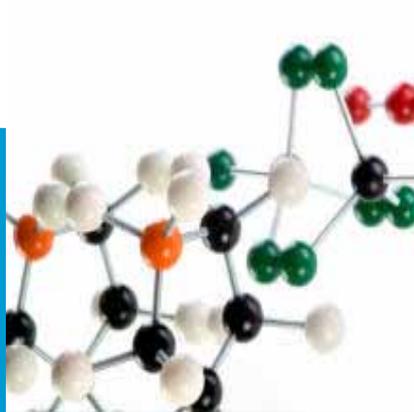
The Board of the American Industrial Hygiene Association (AIHA) approved a proposal to house the Workplace Environmental Exposure Levels (WEEL) development activities within TERA under the recently formed Occupational Alliance for Risk Science (OARS). TERA will be working with AIHA and the WEEL Committee on a smooth transition of the WEELs to OARS. www.tera.org/OARS



Beyond Science & Decisions: From Problem Formulation to Dose-Response

Over 55 organizations came together under the Alliance for Risk Assessment to review case studies illustrating the latest advances in risk assessment and dose-response assessment methods.

www.allianceforrisk.org/ARA_Dose-Response.htm



TOXIDROMES: A Decision making tool for chemical emergencies

On behalf of the Department of Homeland Security, TERA convened a team of expert first responders to develop sets of symptoms to help emergency personnel quickly determine appropriate medical treatment in a chemical emergency.

Ms. Jaqueline Patterson Receives SRA Presidential Recognition Award

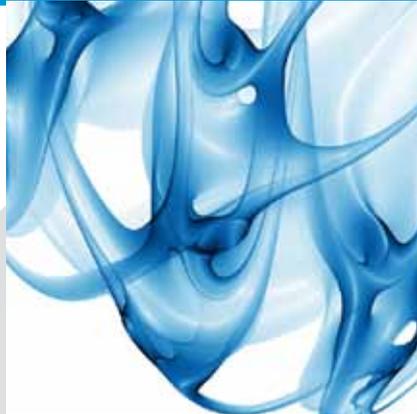
Ms. Patterson was given the Society for Risk Analysis (SRA) Presidential Recognition Award at the 2012 Annual Meeting held in San Francisco, California. The award was for her outstanding contributions to the Conferences & Workshops Committee.



Lessons Learned, Challenges, and Opportunities: The US Endocrine Disruptor Screening Program

This open workshop was designed to focus on the science and experiences of organizations and scientists working on various aspects of EDSP to date.

www.tera.org/peer/edsp/



CHEMM: Chemical Hazards Emergency Medical Management

For the National Library of Medicine, TERA helped develop content for a website to enable first responders, first receivers, other healthcare providers, and planners to plan for, respond to, recover from, and mitigate the effects of mass-casualty incidents involving chemicals.

www.chemm.nlm.nih.gov/



Working Locally: TERA helps Local Tri-State Family

Dead farm animals and sick children drove this tri-state family to TERA for help discerning what was ailing them. TERA's assessment was a local news headline when elevated levels of hydrogen sulfide were discovered in the home septic system.



Dose Response Boot Camp:

Boot Camp travelled across the globe to New Zealand to train a new crop of risk scientists.

www.tera.org/Global/Bootcamp/index.html

NEW HOME OF WHEEL DEVELOPMENT





OARS

OCCUPATIONAL ALLIANCE FOR RISK SCIENCES

The Occupational Alliance for Risk Science (OARS) is an initiative to facilitate sharing of information with workers and occupational health and safety professionals. OARS provides a forum for information exchange about exposure guidance for chemical stressors, methods for improving occupational risk assessments, and training opportunities.

The OARS serves as the home of exposure guide values, and related guideline documents, for chemical stressors. These guide values and supporting documentation related to worker and community exposure levels for chemical and physical agents and stressors are published by the OARS. OARS is managed by Toxicology Excellence for Risk Assessment (TERA).

Workplace Environmental Exposure Limits (WEELs) are now developed by a collaboration of experts managed by TERA.

KEY FIGURES FOR 2012



Investing in the
Science

\$2.38 Million

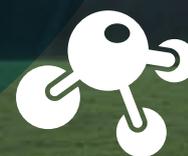
ANNUAL REVENUE

\$2.35 Million

EXPENSES

\$27,000

2012 NET GAIN



Investing in
Chemical Safety

2012

18

NEW TERA PUBLICATIONS



2012 PROPORTION OF WORK BY PROJECT SPONSOR

40% **>**
FOR PROFIT
PROJECT SPONSORS

< **7%**
EDUCATION
PROJECTS

22%
COLLABORATIONS
COALITION OF PROJECT SPONSORS

60%
GOVERNMENT /
NON-PROFIT
PROJECT SPONSORS



TERA FOCUS AREAS

Informing the protection of public health is

accomplished through efforts of all parts of society and takes lots of different forms. TERA focuses on careful and comprehensive evaluation of toxicity, utilizing all available data to determine potential human health effects and risks. We accomplish this through scientific assessment and evaluations on chemicals and mixtures, independent peer review of technical assessments and documents, and collection and broad dissemination of risk values and other health risk information.

Assessments & Risk Technology

TERA scientists combine a practitioner's knowledge of the issues and pitfalls involved in the development of human health risk assessments, together with cutting-edge toxicology expertise, to develop state-of-the-science assessments. Our research, aimed at improving risk assessment methods particularly in the areas of dose-response and mode of action, further enhances our analyses. In solving risk 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 use of the best science. These strengths form the basis for our development of independent and science-driven analyses for a range of risk assessment needs.

- + Screening-level assessments and hazard and risk ranking
- + Dossiers and Risk Assessments for HPV and REACH
- + Occupational risk assessments, including OEL development
- + Comprehensive in-depth evaluations for non-cancer and cancer risk
- + Risk methods and framework development in dose-response modeling, mixtures risk issues, mode of action evaluation techniques, and special issues such as children's risk.

Recent examples at: www.tera.org/ART/



OCCUPATIONAL SAFETY

TERA works to support Worker Safety by developing occupational exposure levels (OEL), and organizing independent peer reviews of values developed by others.



Independent Peer Review and Consultation

TERA's Peer Review and Consultation program provides government, industry and others with high quality expert review and discussion on chemical risk assessments, research plans, and methods. TERA is uniquely qualified to organize peer review meetings and technical workshops, bringing our extensive corporate experience and practitioner's knowledge of risk methods and issues to identify the key scientific issues and engage a diverse group of experts needed to tackle complex risk issues. TERA and the sponsor work together to clearly identify the goals and purpose for engaging experts and to design an approach that meets those needs efficiently and effectively. Options for peer involvement include panel meetings, written reviews, and workshops.

Recent panel meetings and workshops have addressed issues related to specific chemicals or classes of chemicals. In addition, TERA conducts "letter" peer reviews of chemical assessments for agencies such as Health Canada, the Consumer Product Safety Commission (CPSC) and the Texas Commission on Environmental Quality (TCEQ), as well as companies and trade groups.

Project examples at TERA.ORG/PEER/

GLOBAL IMPACT



GENOTOX IMPURITIES TRAINING

Canadian Association of Professional Regulatory Affairs
CANADA

TOXIDROME WORKSHOP

US Department of
Homeland Security
UNITED STATES

TERA Scientists

HAVE TRAVELLED

THE WORLD TO SPREAD THE SCIENCE

18 YEARS OF PUBLIC HEALTH

HISTORY

Toxicology Excellence for Risk Assessment (TERA) is a non-profit corporation dedicated to the best use of toxicity data for risk assessment. TERA was founded in 1995 by Dr. Michael Dourson, a board-certified toxicologist with 15 years experience working for the U.S. Environmental Protection Agency (EPA). TERA helps 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.



RISK TRAINING
 Turkish Society of Toxicology
 TURKEY

GLOBAL HOST
 TERA hosted
 Dr. Sri Noegrohati,
 Gadjah Mada University
 INDONESIA

RISK ASSESSMENT TRAINING
 NIGERIA & GHANA

WORLD CONGRESS
 Society for Risk Analysis
 AUSTRALIA & NEW ZEALAND

TEAM

1

TERA STAFF
 has grown substantially in
 size and impact

17

1995

2012

TOTAL PUBLICATIONS

3

TERA PUBLICATIONS
 have been prolific over the
 years- nearly 200
 publications since 1995!

197

1995

2012



BUILDING

PARTNERSHIPS

As part of the Beyond Science & Decisions Workshop Series, over 55 organizations, representing state and federal governments, industry, academia, consulting firms and non-profit interests, have come together to advance the science of risk assessment. The Workshop series has now reviewed over 30 innovative risk methods.

The methods and their various applications can be viewed at CHEMICALRISKASSESSMENT.ORG

**SHARING COSTS, INFORMATION,
AND HUMAN RESOURCES AMONG
MULTIPLE STAKEHOLDERS TO
INCREASE RISK ASSESSMENT
CAPACITY AND QUALITY**



ALLIANCEFORRISK.ORG

ALLIANCEFORRISK 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 address chemical risk assessment issues that individual organizations cannot resolve on their own.

Working Together to protect public health and improve risk assessment.

RISK TOOLS

ITER

INTERNATIONAL TOXICITY ESTIMATES FOR RISK

ITER is a free Internet database of human health risk values and cancer classifications for over 730 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.

Original ITER:

TERA.ORG/ITER/

On National Library of Medicine's TOXNET:

[HTTP://TOXNET.NLM.NIH.GOV/](http://TOXNET.NLM.NIH.GOV/)

ITER now includes information from:

- Agency for Toxic Substances and Disease Registry (ATSDR)
- Health Canada
- International Agency for Research on Cancer (IARC)
- International Programme for Chemical Safety (IPCS)
- NSF International
- National Institute of Public Health and the Environment (RIVM), The Netherlands
- Texas Commission on Environmental Quality (TCEQ)
- U.S. Environmental Protection Agency (EPA)
- Independent parties whose risk values have undergone peer review

RISKIE

RISK INFORMATION EXCHANGE

RiskIE contains over 4700 in-progress human health risk assessment projects from 35 organizations in 13 countries around the world. RiskIE offers a view into the risk science work of other organizations, in an effort to bridge communication gaps among risk assessors of government, industry, academic, and environmental organizations.

ALLIANCEFORRISK.ORG/RISKIE.HTM



UP 27% ITER WEB TRAFFIC

driven by increased use outside of the U.S.

SEARCH

STATE ENVIRONMENTAL AGENCY RISK
COLLABORATION FOR HARMONIZATION

SEARCH is a free online interactive tool designed to help create a collaborative network among state agencies to aid in efficiently sharing information and resources, and to work toward the harmonization of risk values used by state agencies.

ALLIANCEFORRISK.ORG/SEARCH/INDEX.HTML

FRAMEWORK

DOSE RESPONSE FRAMEWORK

The Dose Response Framework is a tool for selecting a dose response technique based on a risk assessment problem formulation, data availability, and regulatory context. Methods are systematically organized into three categories; qualitative decision, quantitative screening decision, and in-depth assessment.

CHEMICALRISKASSESSMENT.ORG/METHODS

TERA'S STRATEGY TO IMPROVE RISK ASSESSMENT

SHARE
INFORMATION



TERA's risk databases are designed to help get the data into the hands of the people who need it.

ENCOURAGE
COLLABORATION



Public health is a public concern. More perspectives, more expertise, better decisions.

IMPROVE
EFFICIENCY



A little communication and cooperation will help reduce duplication of effort and improve efficiency.

A young girl with blonde hair is swimming underwater in a pool. She is wearing a purple and yellow patterned swimsuit and is smiling at the camera. The water is clear and blue, and the background shows the tiled bottom of the pool.

SCIENTIFIC OUTREACH

**BALANCED, SCIENTIFICALLY
ACCURATE CHEMICAL HEALTH
INFORMATION.**

KIDSCHEMICALSAFETY.ORG

KIDS + CHEMICAL SAFETY

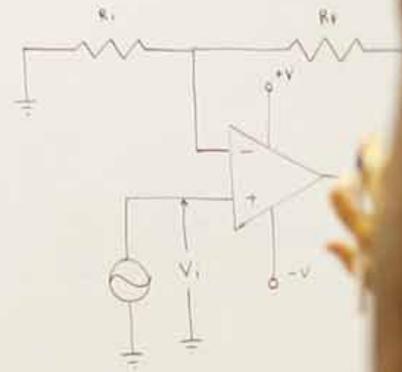
TERA proudly introduced a new website for scientific outreach to parents this year. Kids + Chemical Safety strives to provide up-to-date health information on chemical hazards and safe use of chemicals around children. The site features articles on hazards around the house, in food, and in consumer products, and offers readers the opportunity to submit their own chemical safety questions.

Kids + Chemical Safety is a collaborative effort of TERA, NSF, Harvard Superfund Research Group, American Chemistry Council, the Alliance for Risk Assessment, and the Cincinnati Drug & Poison Information Center.

TRAINING

SCIENTISTS

$$\cos \theta = pf$$



DOSE-RESPONSE BOOT CAMP

This course is a 5-day intensive hands-on training 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. Course lectures are supplemented with daily hands-on application exercises.



DOSE RESPONSE BOOT CAMP

5-DAY INTENSIVE HANDS-ON TRAINING IN HAZARD CHARACTERIZATION AND DOSE-RESPONSE ASSESSMENT

41

BOOT CAMP GRADS IN 2012

Dose Response Boot Camp is TERA's initiative to train risk scientists around the world, offering an intensive crash course on the state-of-the-science.

TERA PUBLICATIONS

2012

Allen, B., A. Maier, A. Willis, L.T. Haber. (2012) Use of early effect biomarker data to enhance dose-response models of lung tumors in rats exposed to titanium dioxide. Submitted.

Dourson, M.L., B. Gadagbui, S. Griffin, D.H. Garabrant, L. Haws, C. Kirman, C. Tohyama. The Importance of Problem Formulation in Risk Assessment, A Case Study Involving Dioxin-Contaminated Soil. Submitted

Dourson, M., R. Becker, L. Haber, P. Fenner-Crisp, L. Pottenger, T. Bredfeldt. 2012. Advancing Human Health Risk Assessment: Charting a Course Through Committee Recommendations. In preparation.

Effio, D., O. Kroner, A. Maier, B. Hayes, A. Willis, J. Strawson. (2012) A Look at State Risk Assessment: Making Decisions in the Absence of Federal Risk Values. Risk Analysis, May 2012.

Gadagbui, B., J. Patterson, A. Rak, R.S. Kutzman, G. Reddy, and M. S. Johnson. (2012) Development of a Relative Source Contribution Factor for Drinking Water Criteria: The case of Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). Human and Ecol. Risk Assess. 18:2, 338-354.

Haber, L.T., A. Parker, J. Haney, D.A. Kaden, L.M. Sweeney, A. Maier. A Tiered Methods Framework for Evaluating Alternative Temporal Patterns of Exposure for Risk Characterization. Submitted.

Hasegawa, R., M. Hirata-Koizumi, M.L. Dourson, A. Parker, A. Ono, A. Hirose. Safety assessment of boron by application of new uncertainty factors and their subdivision. Regulatory Toxicology and Pharmacology. In press.

Hertzberg, R.C., Y. Pan, R. Li, L.T. Haber, R.H. Lyles, D.W. Herr, V.C. Moser, J. E. Simmons. A four step approach to evaluate mixtures for consistency with dose addition. In press. doi:pii: S0300-483X(12)00368-X. 10.1016/j.tox.2012.10.016 [epub ahead of print]

Laufersweiler, M.C., B. Gadagbui, I.M. Baskerville-Abraham, A. Maier, A. Willis, A.R. Scialli, G. Carr, S.P. Felter, K. Blackburn, and G. Daston. (2012) Correlation of chemical structure with reproductive and developmental toxicity as it relates to the use of the threshold of toxicological concern. Regulatory Toxicology and Pharmacology, 62:160-182.

[Named #6 on SciVerse ScienceDirect's Top 25 Hottest Articles List for the Regulatory Toxicology & Pharmacology Journal for first quarter 2012. The quarterly list is the most read articles, counted by article downloads on SciVerse ScienceDirect]

Maier, A., M. Kohrman-Vincent, E. Hack, P. Nance, W. Ball. OEL for Inorganic Borates Using a Weight of Evidence Approach. Submitted

Maier, A., M. Kohrman, R. Hertzberg, M. Dourson, L.T. Haber, B. Allen. (2012) Critical review of dose-response options for F344 rat mammary tumors for acrylamide - Additional insights based on mode of action. Food and Chemical Toxicology. 50:1763-75.

Meek, M.E., M. Bolger, J. Bus, J. Christopher, R. Conolly, R. Lewis, G. Paoli, R. Schoeny, L. Haber, A. Rosenstein, M. Dourson. (2012) A Framework for Fit-for-Purpose Dose Response Assessment. Submitted.

Moser, V.C., S. Padilla, J.E. Simmons, L.T. Haber, and R.C. Hertzberg. Impact of Chemical Proportions on the Acute Neurotoxicity of a Mixture of Seven Carbamates in Preweanling and Adult Rats. Toxicological Sciences. 129(1):126-34. doi: 10.1093/toxsci/kfs190

Mwanza, J.C., D.F. Lyke, R.C. Hertzberg; L. Haber, M. Kohrman-Vincent, R. Li, Y. Pan, R.H. Lyles, J.E. Simmons, J.K. MacMillan, R.D. Zehr, A.E. Swank, D.W. Herr,. (2012) Cholinesterase inhibition and depression of the photic after discharge of flash evoked potentials following acute or repeated exposures to a mixture of carbaryl and propoxur neurotoxicology. Neurotoxicology. 33(3):332-46.

Nance, P., J. Patterson, A. Willis, N. Foronda, M. Dourson. (2012) Human health risks from mercury exposure from broken compact fluorescent lamps (CFLs). Regulatory Toxicology and Pharmacology, 62, 542-552.

[Named #23 on SciVerse ScienceDirect's Top 25 Hottest Articles List for the Regulatory Toxicology & Pharmacology Journal for first quarter 2012.]



Patterson, J., A. Maier, M. Kohrman-Vincent, M.L. Dourson. (2012). Peer Consultation on Relationship between PAC Profile and Toxicity of Petroleum Substances. *Regul Toxicol Pharmacol.* doi:pii: S0273-2300(12)00224-3. 10.1016/j.yrtph.2012.11.005. [Epub ahead of print]

Sweeney L., A. Parker, L.T. Haber, C.L. Tran, E. D. Kuempel. 2013. Application of Markov Chain Monte Carlo Analysis to Biomathematical Modeling of Respirable Dust in US and UK Coal Miners. *Regul Toxicol Pharmacol.* Jun;66(1):47-58. doi: 10.1016/j.yrtph.2013.02.003

Williams, P.R., G.S. Dotson, A. Maier. (2012) Cumulative Risk Assessment (CRA): Transforming the Way We Assess Health Risks. *Environ Sci Technol.* Oct 16;46(20):10868-74. doi: 10.1021/es3025353. Epub 2012 Sep 11.

Book Chapters

- Doepker, C.L., A. Maier, A. Willis, S.J. Hermansky. (2012) Toxicology of Flavors in the Food Industry. In: *Patty's Toxicology, 6th Edition, Volume 5.* John Wiley and Sons Inc., E. Bingham and B. Cofrssen, eds.
- Wexler, P., F. Berman, P. Nance, A. Parker, and J. Patterson. "The Information Infrastructure of Toxicology." In: *Principles and Methods of Toxicology, 6th ed.* A.W. Hayes, ed. In press.
- L.T. Haber; J.E. Strawson, A. Maier, I.M. Baskerville-Abraham. A. Parker; M.L. Dourson. "Noncancer Risk Assessment: Principles and Practice in Environmental and Occupational Settings" in *Patty's Toxicology, 6th ed.*
- York, R.G., R.M. Parker, L.T. Haber. (2013) Test Methods for Assessing Female Reproductive and Developmental Toxicology. IN: *Principles and Methods of Toxicology, Sixth Edition.* A.W. Hayes, ed. In Preparation.
- Haber, L., A. Willis, P. Nance. (2012) 630. Mode of Action. In: *Encyclopedia of Toxicology.* M. Abdollahi, ed. Submitted for Review.