



Toxicology Excellence for Risk Assessment

2021
ANNUAL REPORT

INDEPENDENT • NON-PROFIT • SCIENCE
protecting public health

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BOARD OF DIRECTORS



TERA Board of Directors

-  Board Chairperson Finance Committee Chair
Gregery S. Romshe, CMA
The Procter & Gamble Company
-  Audit Committee Chair
Chase D. Wright. CPA
-  TERA President
Patricia McGinnis Ph.D., DABT
Toxicology Excellence for Risk
Assessment (TERA)

A CHANGE IN LEADERSHIP

Our President, Dr. Patricia McGinnis retired mid-year in 2021.



TERA staff and Board of Directors are grateful for Dr. McGinnis's leadership and guidance during her tenure.

We are also happy to have her as one of our cherished fellows and hope that the relationship continues well into the future.

Please join us in wishing Patricia a heartfelt "Happy Retirement!"

Dr. Michael Dourson resumed his role as President of TERA upon Dr. McGinnis's retirement.

We are all pleased to have Michael back at the helm! Dr. Dourson founded Toxicology Excellence for Risk Assessment in 1995 after working for the U.S. Environmental Protection Agency (EPA) for 15 years. TERA continues to help environmental, industry, and government groups find common ground through the application of good science to risk assessment.

ABOUT US



Toxicology Excellence for Risk Assessment (TERA) is a 501(c)(3) non-profit corporation dedicated to the best use of toxicity data for risk assessment.

TERA was organized as a non-profit corporation to facilitate successful partnerships between environmental, industry and government groups. Through these partnerships, TERA helps environmental, industry, and government groups find common ground through the application of robust and cutting-edge science to risk assessment. Improvements in the science and practice of risk assessment are developed.

MISSION

Toxicology Excellence for Risk Assessment Mission



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.



Independence from all parties and groups is essential for our science and results to be credible by all parties.

TERA has instituted policies and procedures and maintains a corporate environment that ensures that all our work efforts are conducted in a manner that maintains our independence.

We perform all our work in a scientifically objective fashion with our results reflecting our best critical analysis and objective evaluation of the scientific information. We are continuously vigilant to make sure that we remain open to new ideas, but we are not swayed or influenced by our funding sponsors, or any other party, in reaching our conclusions or communicating our results.



CORE PRINCIPLES AND VALUES



TERA Core Principles and Values

Honesty and Integrity

We operate at the highest level of ethical and scientific standards, fully communicating issues and uncertainties.

Independence

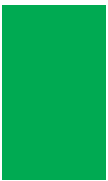
We approach our work with an open mind and objectivity, without regard to sponsor or stakeholder interests.

Transparency

We share our work broadly to maximize benefit to public health.

Collaboration

We use collaboration as a fundamental and preferred approach to technical problem resolution.



These core principles guide day-to-day TERA operations from consideration of new projects and sponsors, to our scientific evaluations and communication of results. Numerous measures ensure our work is based upon our principles.

TERA Core Principles and Values

We recognize the importance of independent and scientific objectivity and continually monitor projects and personal work efforts to ensure we maintain our high ethical and scientific standards.

We are transparent about how we do our work and the methods and approaches we use, so that others can evaluate and judge the strength and scientific validity of our conclusions.

We strive to fully characterize and communicate scientific uncertainties and limitations in our work.

We are transparent about who our funders are and what role they had, if any, in commenting on the TERA scientific opinions or results. We make it clear to all funders and sponsors of our work that TERA is an independent scientific organization and as such we will provide them our independent scientific evaluation and conclusions. We discuss (prior to starting work) the level and types of involvement of the sponsors and other outside parties.

We offer our independent scientific services to a broad range of sponsors, including government agencies, industry, non-governmental organizations, and consultants. By collaborating with many types of organizations, TERA gains an appreciation and understanding of the scientific perspectives of these various parties. We utilize this understanding and the resulting relationships to identify and encourage collaboration among a range of parties to improve risk assessment and protection of public health.

We seek to have a balance of work among public and private sector. In recent years, about 2/3 of our work has been for training, non-profit companies, Internal Research and Development (IR&D) and government agencies, and the other 1/3 for industry. See: <http://www.tera.org/about/FundingSources.html> for a breakdown by year.

TERA evaluates each new project to ensure that it is mission-related, will benefit public health, and that TERA's participation does not pose a conflict of interest, and will make a quality contribution to the effort. We decline projects that do not meet these criteria.

We strive to publish our work in the peer-reviewed literature or on our website to make the work available to a broad audience.

The background of the page is a photograph of a forest floor. It is covered in a thick layer of green moss. Scattered throughout the moss are several small, white, star-shaped flowers with green leaves. The lighting is soft, creating a natural and serene atmosphere.

TERA

In addition to paid work, TERA provides *pro bono* support to local and state governments, non-government organizations, and others to provide training and to help them address important human health and risk issues.

VISITING SCIENTISTS AND FELLOWS

TERA has developed both the Visiting Scientist and Fellow Programs to encourage collaboration with others and to improve risk assessment practices.

TERA Fellows

are senior scientists associated with TERA on a longer-term basis with ongoing scientific interactions.

Fellows and Visiting Scientists are not employees of TERA, but rather scientists who share TERA's mission and values and seek to improve the practice of risk assessment. TERA collaborates with Visiting Scientists and/or TERA Fellows on projects of mutual interest.

In the past, scientists have worked with TERA and coauthored manuscripts or reports on a variety of topics, including methods for evaluating persistent and bioaccumulative chemicals, exposure assessment methods, dose-response modeling, mixtures assessment, and investigating the magnitude of adult-to-child toxicokinetic differences in inhalation dosimetry of gases.

Visiting Scientists

are those engaged with TERA for a fixed period of time or on a defined project. Project work may or may not be onsite at TERA's Cincinnati office. While visiting scientists are often senior scientists, positions can also be considered for scientists who are beyond internship level, but for whom a period at TERA would be of mutual benefit.

2021 Dr. Virunya Bhat, Visiting Scientist

TERA has the good fortune to include Dr. Virunya Bhat as a visiting scientist to our group of outside experts.

We've known Virunya for years as one of the senior risk scientists at NSF international. One of her favorite projects is international collaboration and coordination, such as when she assisted World Health Organization from 2015-2019. Her contributions varied widely from drafting technical memos, reports, guidance documents or manuscripts, to being the focal point coordinating small (<10 members) and large (20+) working groups, to coordinating and conducting risk assessment training.

Dr. Bhat will be assisting in TERA's Beyond Science and Decisions Workshop XII and other TERA projects that benefit from her talents.



INVITED PRESENTATIONS



“Comparing human observational studies with clinical findings: the half-life of perfluorooctanoate (PFOA)”



Cleanup Symposium, Emerging Contaminants. **CRC CARE, GlobalCARE Alliance, Virtual**, March 24-25, 2021.

Ratin Mathur, Industry Training Manager of CRC CARE commented:

Thank you for your presentation and support during the CleanUp Emerging Contaminants Virtual Symposium 2021 held on 24 and 25 March 2021.

The symposium was a huge success and we have got excellent feedback from the delegates about the symposium and you as a presenter.



“**The Future of Uncertainty Factors with In Vitro Studies Using Human Cells**”

For the Question: Uncertainty Factors Will Be Needed in In Vitro Studies Using Human Cells. **Society of Toxicology**. Virtual, March 18th, 2021.



“**The Role of Toxicology and Toxicologists in Combating the COVID-19 Pandemic**”

Understanding the Spread and Toxicological, Environmental, and Public Health Impact of the COVID-19 Pandemic on the African Continent. **Society of Toxicology**, Virtual, March 15th, 2021.



TERA PUBLICATIONS

RISK ASSESSMENT PUBLICATIONS

Krishan, Mansi, Lisa Navarro, Barbara Beck, Ricardo Carvajal, *Michael Dourson*. 2021. A regulatory relic: After 60 years of research on Cancer risk, the Delaney Clause continues to keep us in the past, *Toxicology and Applied Pharmacology* (2021), <https://doi.org/10.1016/j.taap.2021.115779>

Dourson, M.L and B.K Gadagbui. 2021. The Dilemma of Perfluorooctanoate (PFOA) Human Half-life. Accepted for publication in *Regulatory Toxicology and Pharmacology*. 126 (2021) 105025.

Gadagbui, Bernard K., Raymond G. York, *Michael L. Dourson*, Patricia M. McGinnis, Rhian B. Cope. 2021. Analysis for Data-derived Extrapolation Factors for Procymidone, *Regulatory Toxicology and Pharmacology*, 104972, ISSN 0273-2300, <https://doi.org/10.1016/j.yrtph.2021.104972>.



APPOINTMENTS OR ELECTIONS

Appointments or Elections for Dr. Michael Dourson (Selected)

- 2021 to... **Executive Director**
Toxicology Education Foundation
- 2018 to... **Affiliate Professor**
Cincinnati's Drug and Poison Information Center
- 2018 to... **Member, Board of Scientific Advisors**
American Council on Science and Health
- 2009 to... **Fellow**
Society for Risk Analysis
- 2007 to... **Advisor**
African Society of Toxicological Sciences
- 2007 to... **Fellow**
Academy of Toxicological Sciences
- 1995 to... **Member**
Editorial Board of the Journal *Regulatory Toxicology and Pharmacology*

ARA

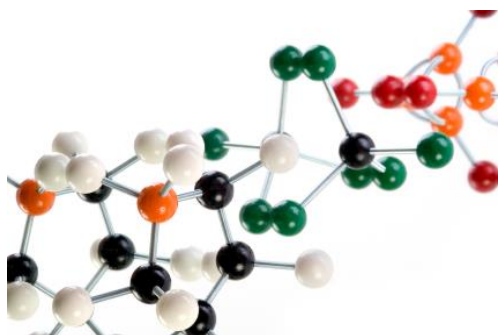


ARA

ALLIANCE FOR RISK ASSESSMENT



Workshop XII - Beyond Science and Decisions: From Problem Formulation to Comprehensive Risk Assessment



Purpose:

To advance the recommendations in the NAS (2009) report concerning issue identification (problem formulation) and all aspects of risk assessment and management, through selection of illustrative research case studies for further development.

a Virtual Event

Workshop Co-Chairs	Workshop Coordinators	Workshop Rapporteur
James Bus, Exponent Mark S. Johnson, US Army	Christen Williams, TERA Bethany Hansen, TERA	Bernard Gadagbui, TERA

presented on February 24 and 25, 2021

TERA'S DOSE-RESPONSE ASSESSMENT BOOT CAMP[®] COURSE

Dose-Response Assessment Boot Camp[®]

19

650+

10+

Global attendees represent 19 countries	Over 650 people have completed this course	TERA has presented this course in >10 countries
Argentina · Australia · Brazil Canada · Chile · China Egypt · India · Indonesia Jamaica · Japan · New Zealand Nigeria · Saudi Arabia · S. Africa S. Korea · Switzerland Taiwan · United States	From the fields of Industry · Education Military · Research Private Sector and Government, both US and foreign	Onsite trainings presented in Africa (Nigeria, South Africa, Egypt) · Australia · Brazil China · India · Indonesia New Zealand & numerous presentations in Canada and the United States

RISK ASSESSMENT FROM 0 TO 95% CONFIDENCE IN 5 DAYS!

This course is a 5-day intensive, hands-on training in hazard characterization and dose-response assessment. Both beginners and expert toxicological risk assessors learn advanced methods and enhance their understanding and skills in the basics. Course lectures are supplemented with daily hands-on application exercises. The course is held Monday through Friday from 9:00am to 5:00pm. Lunches are included.

COURSE TOPICS:

- Non-Cancer and Cancer Risk Assessment Methods
- Critically analyze effect data
- Apply frameworks for evaluating mode of action (MOA) & human relevance
- Understand & apply toxicokinetic data in evaluating MOA & developing risk values
- Synthesize data for hazard characterization and critical effect identification
- Learn latest technologies in risk assessment


Upon completion of the course:

Participants will be able to derive and evaluate risk values and supporting documentation for both non-cancer and cancer risk assessments. And attendees receive a Certification of Course Completion.

Continuing Education Credits Available:

- 5 (CM) points are available from the American Board of Industrial Hygienists (ABIH)
- 4 (CEU) are available from the National Environmental Health Association (NEHA)

2021 saw another successful Boot Camp!



RISK ASSESSMENT from 0 to 95% Confidence in 5 days!

HQ
Risk Characteristic
RID
Toxicity profiles
Uncertainty factor
RFC
BMR
Mode of action
critical
$$-y = (1-p) \left[\frac{1}{f(\sigma)} \int_0^{\sigma} f(x) dx \right]$$

Dose-Response Assessment Bootcamp Course

The accelerated, intensive hands-on training in **HAZARD CHARACTERIZATION** and **DOSE-RESPONSE ASSESSMENT** for which TERA is known worldwide.



This course was held at the Graduate hotel in Cincinnati, Ohio.



Dr. Dourson and Dr. Gadagbui reviewing course materials over a break.

Our Boot Camp course, known for its excellent content, has evolved beyond training. Attendees arrive as strangers, establish relationships with instructors, and naturally form bonds within their groups and with other participants. In over 10 years, every class has exchanged contact information and stayed connected, often meeting at work or industry events like SOT and SRA.

AWARDS AND HONORS

Toxicology Excellence for Risk Assessment (TERA) has earned, and maintains the Independent Charities Seal of Excellence.

This award is given to the members of Independent Charities of America and Local Independent Charities of America that have, upon rigorous independent review, been able to certify, document, and demonstrate on an annual basis that they meet the highest standards of public accountability, program effectiveness, and cost effectiveness.

These standards include those required by the US Government for inclusion in the Combined Federal Campaign, probably the most exclusive fund drive in the world. Of the 1,000,000 charities operating in the United States today, it is estimated that fewer than 50,000, or 5 percent, meet or exceed these standards, and, of those, fewer than 2,000 have been awarded this seal.



SOT AND SRA 2021 ANNUAL MEETINGS

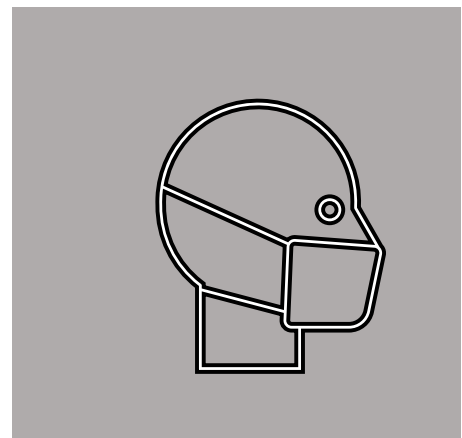
Due to the Covid-19 virus, both SOT and SRA Annual Meetings were held virtually this year.



SRA 2021 ANNUAL MEETING

SUN. 5 DECEMBER 2021 – THU. 9 DECEMBER 2021
ONLINE

As a result, TERA was unable to hold our annual onsite Ice Cream Social for both of these meetings. However, we are very much looking forward to resuming these important events next year.



THE NUMBERS



2021 Project Time by Sponsor

Non-profit 60% *Profit* 40%



-ARA: Beyond Science and Decisions, XII
 -ARA: Beyond Science and Decisions, XIII
 -ARA: PFOA Half Life International
 -Collaboration Australian Government: Procymidone assessment
 -Internal R&D: PFOA Half Life paper
 -Internal R&D: PFOA RfD Paper
 -International Toxicity Estimates for Risk (ITER)
 -TERA: Dose Response Assessment Boot Camp
 -Workplace Environmental Exposure Levels (WEELs)

-Becton Dickinson: ethylene oxide review
 -Private concern: PFAS review
 -Private concern: Site review
 -Cobalt Inst.: Inhalation paper series

NOTES:

- 1) Internal Research & Development refers to TERA's internal funds used for the benefit of scientific research and development.
- 2) Training includes courses, lectures, and workshops provided to scientists and other professionals from all business sectors, both profit and non-profit.
- 3) The sponsors listed above are sponsors that each comprise 2% or more of our work.



Toxicology Excellence for Risk Assessment (TERA)

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